

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

DATED: OCTOBER 15, 2009

PACIRA PHARMACEUTICALS, INC.

and

EKR THERAPEUTICS, INC.

**AMENDED AND RESTATED
STRATEGIC LICENSING, DISTRIBUTION AND MARKETING AGREEMENT**

THIS AMENDED AND RESTATED STRATEGIC LICENSING, DISTRIBUTION AND MARKETING AGREEMENT (the “**Agreement**”) is made on October 15, 2009 (the “**Agreement Date**”) and is effective as of the Effective Date (as defined below), between:

PACIRA PHARMACEUTICALS, INC. (F/K/A SKYEPHARMA, INC.) a company incorporated in the state of California whose principal place of business is 10450 Sciences Center Drive, San Diego, California 92121 USA (“**PPI**”); and

EKR THERAPEUTICS, INC., a company incorporated in the state of Delaware whose principal place of business is 1545 Route 206 South, Third Floor, Bedminster, New Jersey 07921 (“**EKR**”).

Recitals

PPI owns and has all right title and interest in or has acquired exclusive rights to the PPI IP (as defined below), the Trademark (as defined below) and the Product (as defined below).

EKR has, among other things, specialized knowledge and expertise in relation to the marketing and sale of pharmaceutical products.

Pursuant to that certain Strategic Licensing, Distribution and Marketing Agreement between EKR and PPI dated as of August 10, 2007 (the “**Original Agreement**”), PPI granted and EKR acquired the exclusive right and license to sell, offer to sell, distribute and market the Product in the Territory (as defined below) in the Field (as defined below).

EKR and PPI desire to amend and restate the Original Agreement in its entirety as set forth herein in order to provide for: (i) certain changes to the financial terms set forth in the Original Agreement, (ii) the transfer of Marketing Authorizations (as defined below) from PPI to

EKR, and EKR's assumption of obligations thereunder, (iii) the transfer of title to certain manufacturing equipment from PPI to EKR and the lease of such equipment back from EKR to PPI and (iv) certain other changes as are set forth herein; all of the foregoing subject to and in accordance with the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the following mutual agreements and covenants set forth herein and intending to be legally bound hereby, PPI and EKR (each, a "**Party**" and collectively, the "**Parties**") acknowledge and agree that this Agreement shall amend and supersede in its entirety the Original Agreement and hereby agree as follows:

Operative Provisions

1. **Definitions**

1.1 As used in this Agreement, the following words and expressions have the following meanings:

"Affiliate"	With respect to any Party to this Agreement shall mean any company, corporation, firm, individual or other entity which Controls, is Controlled by or is under common Control with such Party to this Agreement for only so long as such Control exists;
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“Applicable Laws”	Shall mean all laws, rules and regulations regarding the manufacture, packaging, labeling, import, export, storage, distribution, representation, promotion, marketing and sale of the Products including but not limited to the Federal Food, Drug and Cosmetic Act of 1938, as amended (“ FD&C Act ”) and the Controlled Substances Act, as amended (21 U.S.C. §801 et seq.), or as defined in attendant regulations promulgated under authorities granted by the FD&C Act, together with any equivalent laws, rules, regulations, codes or guidelines having effect in any jurisdiction in the Territory;
“Calendar Year”	Shall mean the period of twelve months commencing on 1st January in any year, and each consecutive period of twelve months thereafter during the Term;
“cGMP”	Means Current Good Manufacturing Practices pursuant to 21 CFR Parts 210 and 211, as may be amended from time to time;
“Commercial Launch”	Shall mean the date of the first arm’s length sale by EKR to an unaffiliated Third Party customer for commercial use of Product in a country within the Territory following the grant of Marketing Authorization and any necessary pricing approval in that country;
“Commercialization Committee”	Shall mean the committee to be set up under the terms of Article 5 ;

“Competing Product”	Means any [**] ([**] hours) [**] preparation (other than the Product) available in a country in the Territory which competes or would compete directly with the Product. For the avoidance of doubt, the definition of “Competing Product” does not include Depobupivacaine or any improvement thereto;
“Confidential Information”	<p>Means all confidential information, data and materials in whatever form disclosed by or on behalf of one Party or its Affiliates to the other Party or its Affiliates including, without limitation, the terms of this Agreement, data, formulae, unpublished patent disclosures, processes, protocols, marketing studies, sales information, specifications and know-how, (and, in the case of EKR’s Confidential Information, EKR’s marketing plans and EKR’s sales forecasts), but excluding information which either Party can establish by written documentation:</p> <ul style="list-style-type: none"> (i) at the time of disclosure, is in the public domain or is public knowledge; (ii) after disclosure, becomes part of the public domain by publication, except by breach of any obligation of confidentiality by a Party hereto or an Affiliate of such Party; (iii) was already in its possession at the time of its receipt and was not acquired directly or indirectly from the other Party or its Affiliates; or (iv) received from Third Parties who were lawfully entitled to disclose such information;

“Control”	Means in relation to any Party or an Affiliate the possession directly or indirectly, of the power to direct or cause the direction of the management and policies of such firm, person or entity, by contract or otherwise, or the ownership either directly or indirectly of 50% or more of the voting securities of such Party;
“Copyrights”	Means (i) the copyright registrations and applications for registration identified on <u>Schedule III</u> , (ii) works of authorship whether or not copyrightable and (iii) any other copyrights and works, together with all common law rights, used or held for use by PPI or any of its Affiliates in connection with the Products in the Territory (including, but not limited to, any license or other rights of PPI or any of its Affiliates, whether as a licensor, licensee or otherwise relation to any of the foregoing);
“Current Base Price”	Means the Product’s current (as of the Effective Date) net average selling price of \$[**] ([**] mg) and \$[**] ([**] mg);
“DEA”	Shall mean the United States Drug Enforcement Administration and any successor thereto performing similar functions;
“Distribution Rights”	Shall have the meaning set forth in <u>Section 2.1</u> hereof;
“Domain Name”	Shall mean Depodur.com and any other domain names owned or licensed by PPI related to the Product set forth on <u>Schedule IV</u> hereto;

“EKR Improvement”	Means any Improvement generated, conceived, reduced to practice or other created during the Term by EKR or any of its Affiliates.
Endo/PPI Unit Sales	Shall have the meaning set forth in <u>Section 3.19</u> hereof;
Endo Product	Means: (i) DepoDur Injectable Liposomal Epidural 10 mg/ml NDC # [**]; and (ii) DepoDur Injectable Liposomal Epidural 15 mg/1.5 ml NDC # [**];
“Effective Date”	Means August 10, 2007;
“FDA”	Means the United States Food and Drug Administration or any successor thereto performing similar functions;
“Field”	Means the management of post-operative pain following major orthopedic, abdominal or pelvic surgery;

“Force Majeure”	Means in relation to either Party, any cause affecting the performance of this Agreement or the Supply Agreement arising from or attributable to any acts, events, non-happenings, omissions or accidents beyond the reasonable control of the Party to perform and in particular but without limiting the generality thereof shall include strikes and labor disturbances, lock-outs, industrial action, civil commotion, riot, invasion, war, threat of or preparation for war, terrorist activity, fire, explosion, storm, flood, earthquake, subsidence, epidemic or other natural physical disaster, impossibility of the use of railways, shipping, aircraft, motor transport, or other means of public or private transport, failure or suspension of utilities, unavailability, shortage or interruption in the supply of raw material, and political interference with the normal operation of either Party;
“Improvements”	Means any discovery, development, improvement, know-how or patent relating to the Product generated, conceived, reduced to practice or otherwise created during the Term by PPI or EKR (or any Affiliate of PPI or EKR);
“Joint Improvements”	Means any Improvements generated, conceived, reduced to practice or other created jointly by EKR and PPI or their Affiliates.
“Known In-Channel Product Units”	Shall have the meaning set forth in <u>Section 3.19</u> hereof;

“Marketing Authorization”	Means the new drug application (“ NDA ”) and all other necessary regulatory and governmental approvals by a Regulatory Authority or other governmental body required to market and sell the Product in any country of the Territory, including, but not limited to, those set forth on <u>Schedule V</u> hereto;
“Marketing Plan”	Means the plan for the marketing, distribution and sale of the Product in the Territory submitted to the Commercialization Committee in accordance with <u>Section 5.4</u> ;

“Net Sales”

Means total gross sales of Product invoiced by EKR, its Affiliates and sub-distributors in arms length sales to Third Parties, less the following amounts actually incurred, deducted, accrued or allowed:

- (i) transport, freight and insurance costs which are separately stated;
- (ii) sales and excise taxes and duties;
- (iii) normal and customary trade, quantity and cash discounts, rebates and chargebacks;
- (iv) amounts repaid or credited for properly rejected, returned or recalled goods or resulting from retroactive price adjustments related to the Product;
- (v) amounts incurred or resulting from government (or an agency thereof) mandated or managed care or other rebate programs now existing or implemented hereafter;
- (vi) any other identifiable amounts included in gross sales of the Product that were or ultimately will be credited and that are substantially similar to those listed hereinabove; and
- (vii) any other deductions allowed by GAAP which effectively reduce the net selling price of Product;

“PPI Improvement”

Means any Improvement generated, conceived, reduced to practice or otherwise created during the Term by PPI or any of its Affiliates;

“PPI IP”	Means the Copyrights, PPI Know-How, PPI Patents and PPI Improvements; and PPI’s interest in Joint Improvements;
“PPI Know-How”	Means all information, procedures, instructions, techniques, data, technical information, knowledge and experience (including, without limitation, toxicological, pharmaceutical, clinical, non-clinical and medical data, health registration data and marketing data), designs, dossiers (including, without limitation, manufacturing assay and quality control dossiers) manufacturing formulae, processing specifications, sales and marketing materials and technology relating to the Product;
“PPI Patents”	Means those patents set out in <u>Schedule I</u> which cover the Products and such other patents as PPI may include from time to time, including additions, divisions, confirmations, continuations-in-part, substitutions, re-issues, re-examinations, extensions, registrations, patent terms extensions, supplementary protection certificates and renewals of any of the above or any other patents owned or licensed by PPI subsequent to the Effective Date which cover the Products or any Improvements;

“Product(s)”	Means: (i) DepoDur Injectable Liposomal Epidural [**] mg/ml [**]; (ii) DepoDur Injectable Liposomal Epidural [**] mg/[**] ml [**]; (iii) such other presentations and dosages which hereafter receive Marketing Authorization in any country of the Territory; in each case for epidural administration presented in Vials or other approved vessels, appropriately packaged and labeled for sale to end users and (iv) any and all Improvements of the items listed in clauses (i) through (iii).
“Promotional Materials”	Means promotional, sales, marketing, educational and training materials which are necessary to support the marketing of the Products;
“Quarter”	Means a three month period ending on the last day of March, June, September or December in any Calendar Year;
“Regulatory Authority”	Means any competent regulatory authority or other governmental body (for example, but not by way of limitation the FDA and DEA) responsible for granting a Marketing Authorization in the Territory;
“Royalty Cap”	Shall have the meaning set forth in <u>Section 6.4</u> ;
“Supply Agreement”	Means: (i) with respect to periods between the Effective Date and the Agreement Date, that certain Supply Agreement entered into by the Parties on the Effective Date and (ii) with respect to periods on or after the Agreement Date, that certain Amended and Restated Supply Agreement entered into by the Parties on the Agreement Date (as may be amended from time to time);

“Term”	Means the term of this Agreement as set out in Section 15;
“Territory”	Means each of the countries and territories listed in <u>Schedule VII</u> ;
“Third Party”	Means any company, corporation, firm, individual or other entity but excluding a Party to this Agreement or an Affiliate;
“Trademarks”	Means those Trademarks registered or applied for set out in <u>Schedule II</u> ;
“Transition Services and Inventory Agreement”	Means that certain Transition Services and Inventory Agreement entered into between the Parties on the Effective Date;
“Vial”	Means a vial containing the Product supplied to EKR in presentations and dosages and other relevant terms set out in the Supply Agreement;
“Year”	Means the period of twelve months commencing on the first Commercial Launch of the Product in the Territory, and each consecutive period of twelve months thereafter during the Term.

1.2 In this Agreement, unless the context requires otherwise:

- (a) the headings are included for convenience only and shall not affect the construction of this Agreement;
- (b) references to “persons” includes individuals, bodies corporate (wherever incorporated), unincorporated associations and partnerships;
- (c) words denoting the singular shall include the plural and vice versa;
- (d) words denoting one gender shall include each gender and all genders; and

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- (e) any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re-enacted.
- 1.3 The Schedules comprise part of and shall be construed in accordance with the terms of this Agreement. In the event of any inconsistency between the Schedules and the terms of this Agreement, the terms of this Agreement shall prevail.
2. **Grant of Rights**
- 2.1 **Retention of EKR.** Subject to the terms of this Agreement, PPI hereby appoints EKR and EKR agrees to be retained as the exclusive distributor, and Authorized Distributor of Record, of the Products in the Field in the Territory during the Term to market, distribute, warehouse and sell the Products. EKR shall have the right to appoint sub-distributors hereunder in each country of the Territory.
- 2.2 **Grant of License and Distribution Rights.** PPI hereby grants EKR the exclusive right and license (with the right to sublicense) to use, market, promote, sell, distribute and warehouse the Products (the “**Distribution Rights**”) in the Field in the Territory during the Term, as well as to make or have made the Products anywhere in the world for import or sale in the Field in the Territory in each case, under the PPI IP provided that PPI retains all rights necessary to manufacture and supply the Products to EKR in accordance with this Agreement and the Supply Agreement. Such grant by PPI shall include the right of EKR to market the Product in the Territory during the Term as an EKR product using in addition to the Trademarks, EKR’s own trademarks, trade dress, trade names and other proprietary designations in combination with the Trademarks.
- 2.3 **Grant of Trademark Rights.** PPI hereby grants to EKR a royalty free and exclusive license (with the right to sublicense) to use the Trademarks in the Territory solely in connection with the exercise of the Distribution Rights in the Territory during the Term (and thereafter as set forth in Section 17.4) and EKR shall market and sell the Products under the Trademarks. For the avoidance of doubt, the term “exclusive” for the

purposes of Sections 2.1, 2.2 and 2.3 means to the exclusion of all others, including PPI and its Affiliates, except to the extent necessary to enable PPI to perform its specific obligations under this Agreement and the Supply Agreement. Notwithstanding the foregoing, nothing contained herein shall prohibit PPI from utilizing the Trademarks in the Territory in connection with its business for the sole purpose of signifying that PPI is the manufacturer of the Products for EKR.

- 2.4 Transfer of Domain Names. On the Effective Date, PPI has transferred the Domain Names to EKR for use in connection with the exercise of the Distribution Rights. PPI has provided EKR with reasonable assistance as was necessary to effectuate the transfer of the Domain Names. Upon any termination or expiration of this Agreement, EKR shall promptly transfer the Domain Names back to PPI.
- 2.5 Condition of Appointment. The acceptance of forecasts and orders for the Products (as provided in the Supply Agreement), and PPI's obligation to supply the Product to EKR shall at all times be conditioned by the Marketing Authorization for the Product being in force in the country of Territory to which such acceptance and order relates.
3. Undertakings of PPI
- 3.1 Manufacturing Activities. Subject to Section 17.5, PPI shall manufacture and supply, or procure the manufacture and supply of, the Product in accordance with the terms and conditions of the Supply Agreement.
- 3.2 Transfer of Transferred NDA. Effective as of the Agreement Date, PPI hereby sells, transfers, conveys and assigns to EKR all right, title and interest in and to [**] (the "**Transferred NDA**"). Each Party shall, within five (5) business days after the Agreement Date, file with the FDA a notice letter, substantially in the form attached as Schedule XI(A) or Schedule XI(B) (as applicable), regarding the transfer to EKR of the Transferred NDA. PPI represents, warrants and covenants that: (i) prior to the Agreement Date, it has provided EKR with complete, up-to-date copies of the Transferred NDA and all material correspondence with Regulatory Authorities in the

Territory in connection with the Transferred NDA (including, but not limited to, any periodic and annual report submissions, and all adverse event reports and data) and (ii) on the Agreement Date, EKR shall receive sole ownership of, and good and valid title to, the Transferred NDA, free and clear of any liens and encumbrances. For the avoidance of doubt, nothing in this Agreement regarding the appointment of EKR as PPI's distributor of the Products shall be construed to diminish any rights of EKR as holder of the Transferred NDA. Upon termination of this Agreement for any reason except by EKR pursuant to Section 16.1(a), EKR shall promptly transfer the Transferred NDA and related regulatory documentation to PPI in accordance with Section 17.1(e).

3.3 Maintenance of Transferred NDA. The Parties acknowledge that prior to the Agreement Date, PPI was responsible at its own cost and expense for maintaining and updating the Transferred NDA, and agree that PPI shall retain all liabilities with respect to the foregoing obligations to the extent relating to periods prior to the Agreement Date. Commencing as of the Agreement Date, EKR shall, at its own cost and expense, maintain and update the Transferred NDA and be responsible for all liabilities with respect to the foregoing obligations to the extent relating to periods after the Agreement Date.

3.4 Assistance. PPI shall, at EKR's cost and expense, provide EKR with all assistance, information and guidance, including where appropriate direct access to employees of and consultants to PPI and its Affiliates and shall use reasonable efforts to obtain such assistance and access from any sub-contractors of PPI and its Affiliates (including for the avoidance of doubt any manufacturers of the Product) which is reasonably necessary in relation to the conduct of any post-marketing or Phase IV studies to be conducted by EKR in the Territory or otherwise in connection with the discharge of EKR's obligations under the terms of this Agreement (including, but not limited to, the maintenance of the Transferred NDA); provided, however, that any such post-marketing or Phase IV studies to be conducted by EKR shall be at EKR's sole cost and expense. Any labor

costs of PPI employees related to this assistance shall be reimbursed by EKR at a rate of [**] dollars (\$[**]) per hour. PPI represents and warrants that as of the Agreement Date, except for the studies set forth on Schedule X attached hereto (the “**Required Studies**”), no post-marketing or Phase IV studies are required by any applicable Regulatory Authority to be conducted with respect to the Product. EKR shall be responsible for the conduct of the Required Studies after the Agreement Date, at its own expense, in accordance with the requirements of the applicable Regulatory Authorities. PPI shall be responsible for all costs and liabilities incurred prior to the Agreement Date with respect to the Required Studies, and shall indemnify and hold harmless EKR from such costs and liabilities. Promptly after the Agreement Date, PPI shall provide EKR with copies of all agreements relating to the Required Studies and shall assign such agreements to EKR if and to the extent (i) such agreements are assignable in accordance with their terms and (ii) requested by EKR.

- 3.5 Adverse Events. PPI shall at its own cost and expense promptly provide EKR with all information in its possession or otherwise coming to its attention relating to the occurrence of a serious adverse event or an adverse event (in any jurisdiction throughout the world) in connection with the Product. PPI shall be responsible, to the extent required by Applicable Laws, to report all charges, complaints or claims reportable to the FDA relating to the Product, to the extent such charges, complaints or claims are made prior to the Agreement Date. EKR shall be responsible, to the extent required by Applicable Laws, to report all charges, complaints or claims reportable to the FDA relating to the Product, to the extent such charges, complaints or claims are made after the Agreement Date.
- 3.6 Reserved.
- 3.7 Delivery of Materials. The Parties acknowledge that prior to the Agreement Date, PPI has delivered to EKR (i) all existing PPI produced Promotional Materials (if any) and (ii) any existing market research in its possession related to the Product.

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- 3.8 Customer Orders. PPI shall at its own cost and expense during the Term, promptly forward to EKR any customer orders or inquiries for the Product within the Territory received after the Effective Date and shall inform any customers ordering the Product that EKR is now distributing the Product and provide such customers with EKR's address and telephone number.
- 3.9 Payment of Third Party Royalties. During the Term, PPI shall be solely responsible for and pay any royalties or other amounts due to Third Parties related to the Product and shall indemnify and hold EKR harmless from any claims arising from or related thereto.
- 3.10 Customer Returns. PPI shall at its own cost and expense be responsible for all customer returns of Product sold prior to the Effective Date.
- 3.11 Governmental Rebates. PPI shall at its own cost and expense be responsible for all discounts, rebates, or promotional allowances/incentive programs deemed to be "discount[s] or other reduction[s] in price" for purposes of 42 U.S.C. Section 1320a-7b(b)(3)(A) and may be subject to the reporting requirements under state and federal Medicaid and Medicare laws for sales of Product prior to the Effective Date. PPI represents that it is aware of its obligations to report discounts resulting from this Agreement to the appropriate reimbursing agencies and authorities (including Medicaid and Medicare). PPI is responsible for complying with and agrees to comply with all applicable requirements, if any, in respect of providing information on such discounts to reimbursing agencies (including Medicaid and Medicare) and other entities in accordance with Applicable Laws and regulations for sales of Product prior to the Effective Date and for sales of any PPI labeled product subsequent the Effective Date.
- 3.12 Chargebacks. PPI shall at its own cost and expense be responsible for all chargebacks for sales of Product prior to the Effective Date.
- 3.13 Exclusivity. During the Term, PPI and its Affiliates shall not: (i) file for Marketing Authorization with respect to any Competing Product in any country in the Territory, (ii) manufacture or have manufactured any Competing Product in any country in the Territory, (iii) market or have marketed any Competing Product in any country in the Territory or (iv) license any Third Party to do any of the foregoing.

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- 3.14 Product Development. PPI shall at its own cost and expense cooperate fully and assist EKR with the preparation of any necessary submissions to any of the Regulatory Authorities in the Territory for the development and approval or supplemental approval(s) of the Products, including, but not limited to, by providing access to all PPI Know-How, the drug master file and any other information necessary for approval or supplemental approval of the Product in any country of the Territory. In addition, PPI shall cooperate fully in participating in interactions with the appropriate Regulatory Authorities including FDA related to such product development so as to enable EKR to fully exploit the Distribution Rights granted hereunder. For purpose of this Section, the contact person for each of the parties is set forth below.

EKR – Graham May, MD - CMO

PPI – Gary Patou, MD - CMO

- 3.15 Reserved.
- 3.16 Recalls and PostMarket Notifications. All costs of safety alerts and all other forms of notifications regarding safety risks associated with the Products in the United States shall be borne by PPI to the extent arising prior to the Agreement Date and by EKR to the extent arising after the Agreement Date.
- 3.17 Compliance. During the Term PPI shall at its own cost and expense take all actions necessary to comply with all Applicable Laws and obtain and maintain all necessary license, permits, records and authorizations PPI is required to obtain and maintain hereunder so as to enable PPI to perform its obligations hereunder and under the Supply Agreement so as to enable EKR to fully exercise the Distribution Rights.
- 3.18 Assignment of ICS Agreement. The Parties acknowledge that effective upon the termination or expiration of the Transition Services and Inventory Agreement, PPI has

assigned to EKR all of PPI's right, title and interest under that certain Commercial Outsourcing Services Agreement between PPI (f/k/a SkyePharma, Inc.) and Integrated Commercialization Solutions, Inc. ("ICS") dated April 3, 2007 (the "**ICS Agreement**"), and EKR has assumed all obligations and liabilities under the ICS Agreement arising after the Effective Date. The Parties further acknowledge that as of the Effective Date, the Parties have entered into an Assignment and Assumption Agreement to further evidence the foregoing assignment and assumption of the ICS Agreement.

- 3.19 Product in Channel. All sales of Product conducted by PPI and its distributors and wholesalers (and, to the knowledge of PPI, by Endo Pharmaceuticals and its distributors and wholesalers) during the six month period prior to the Effective Date have been conducted in the ordinary course upon standard payment terms. PPI has provided EKR: (i) all information regarding sales by Endo Pharmaceuticals during the six month period prior to the Effective Date and (ii) all information regarding the number of units of Product and Endo Product that were in the possession or control of PPI or Endo Pharmaceuticals (and their respective distributors or wholesalers) as of the Effective Date (the "**Known In-Channel Product Units**"). Within 10 days of the end of each month following the Effective Date, PPI shall provide EKR with copies of: (i) any reports provided by Endo Pharmaceuticals of the number of units of Endo Product sold to hospitals or other customers during the preceding month by Endo, and (ii) information possessed by PPI of such sales by PPI or any of their respective distributors or wholesalers (the "**Endo/PPI Unit Sales**").
- 3.20 Sale and Leaseback of Transferred Equipment.
- (a) In consideration of and subject to EKR's payment of the Equipment Purchase Price (as defined below), effective as of the Agreement Date, PPI hereby sells, transfers, conveys and assigns to EKR all right, title and interest in and to the equipment described on Schedule XII (the "**Transferred Equipment**"). The

Parties shall share equally the responsibility for any and all sales, transfer and conveyance taxes occasioned by the sale of the Transferred Equipment by PPI to EKR. PPI represents and warrants that: (i) on the Agreement Date, EKR shall receive sole ownership of, and good and valid title to, the Transferred Equipment, free and clear of any liens and encumbrances, (ii) the Transferred Equipment as of the Agreement Date is in good operating condition, normal wear and tear excepted and (iii) the Transferred Equipment constitutes all specialized equipment that is used in the manufacture of Product by PPI as of the Agreement Date. For purposes of clarity, the Transferred Equipment does not include any standard, non-specialized equipment generally found in manufacturing facilities or available to manufacturers of products similar to the Product (e.g., refrigerators, freezers, safes, incubators, stability chambers, clean utilities, supportive utilities, temperature control units and other supportive equipment). On the Agreement Date, PPI shall execute and deliver to EKR a Bill of Sale with respect to the Transferred Equipment substantially in the form attached hereto as Exhibit 3.20(a).

- (b) EKR will pay PPI [**] Dollars (\$[**]) for the Transferred Equipment (the “**Equipment Purchase Price**”) as follows:
- (i) within five (5) days after the Agreement Date, EKR will pay PPI [**] Dollars (\$[**]) of the Equipment Purchase Price in cash; and
 - (ii) concurrently with the execution of this Agreement, EKR will issue to PPI a promissory note in principal amount of [**] Dollars (\$[**]), such note to be substantially in the form attached hereto as **Exhibit 3.20(b)** (the “**Promissory Note**”).
- (c) Commencing as of the Agreement Date, EKR agrees to lease the Transferred Equipment to PPI through the end of the then-current calendar quarter and, subject to renewal as provided below, on a calendar quarter-to-calendar quarter

basis thereafter (the “**Lease Term**”), for use solely in connection with the (i) performance of PPI’s obligations under the Supply Agreement, (ii) the supply of Products to PPI’s other licensees and collaborators and (iii) the supply of placebo for PPI’s Exparel product to PPI’s other licensees and collaborators. The Lease Term shall automatically renew at the end of each calendar quarter of the Lease Term. The Lease Term will automatically terminate immediately upon (i) any termination or expiration of this Agreement and/or the Supply Agreement or (ii) any exercise by EKR of the Step-in Right described in Section 17.5 below.

- (d) At any time between the Agreement Date and July 1, 2015, EKR shall have the right, exercisable upon sixty (60) days prior written notice to PPI, to terminate the Lease Term and sell the Transferred Equipment back to PPI, subject to payment by PPI to EKR within five (5) days of such notice of \$[**] in cash, which if exercised shall result in (i) an offset against the unpaid balance of principal and interest under the Promissory Note pursuant to Section 3.20(f) below; and (ii) the termination of the Step-in Right described in Section 17.5.
- (e) At any time after July 1, 2015, PPI shall have the right, exercisable upon sixty (60) days prior written notice to EKR, to terminate the Lease Term and repurchase the Transferred Equipment from EKR, subject to payment by PPI to EKR within five (5) days of such notice of any principal paid by EKR under the Promissory Note, which if exercised shall result in the termination of the Step-in Right set forth in Section 17.5.
- (f) If, upon the expiration or earlier termination of the Lease Term (except as provided in Section 3.20(e) above), the aggregate amount of repayments and Royalty Offsets (as defined below) earned by EKR pursuant to Section 6.3 below have not equaled or exceeded the Advanced Royalty Payment (as defined below), then EKR shall have the right, at its option, to offset against the unpaid balance of principal and interest under the Promissory Note, by an amount equal to the

then-current balance of the Advanced Royalty Payment that has not yet been recouped by EKR through repayments and Royalty Offsets pursuant to Section 6.3 below (the “**Remaining Balance**”), in which event PPI’s obligations under Section 6.3 below with respect to repayment of the Advanced Royalty Payment shall be deemed to have been paid in full.

- (g) In consideration of the foregoing lease, PPI shall pay EKR [**] lease payments in the amount of \$[**]per calendar quarter, with the first lease payment due on the Agreement Date and each subsequent lease payment due during the Lease Term on the first day of each calendar quarter thereafter.
- (h) PPI shall not, without the prior, written consent of EKR, remove any of the Transferred Equipment from the locations within the Approved Facilities (as defined in the Supply Agreement) where such Transferred Equipment is installed as of the Agreement Date.
- (i) During the Lease Term, PPI shall: (i) assume the risk of loss or damage to the Transferred Equipment; (ii) maintain the Transferred Equipment in good operating condition and appearance, ordinary wear and tear excepted; (iii) comply with all requirements necessary to enforce any warranty rights and to maintain eligibility for any manufacturer maintenance program; (iv) promptly repair any repairable damage to the Transferred Equipment and (v) maintain property damage and liability insurance and insurance against loss or damage to the Transferred Equipment as part of PPI’s general liability insurance.
- (j) If any of the Transferred Equipment is lost, stolen, destroyed, damaged beyond repair or in the event of any condemnation, confiscation, seizure or expropriation of any Transferred Equipment (“**Casualty Transferred Equipment**”), PPI shall promptly (i) notify EKR of the same, and (ii) pay to EKR an amount equal to the estimated in-place, fair market value of the Casualty Transferred Equipment as of the date of the loss, as determined by a mutually agreed nationally recognized

appraiser; provided that (i) in the event there are any amounts owed to PPI under the Promissory Note as of the date of such loss, PPI shall have the right, at its option, to offset against the unpaid balance of principal and interest under the Promissory Note, the amounts owed to EKR pursuant to this Section 3.20(k), and (ii) in no event shall PPI be required to pay EKR an amount that exceeds [**] Dollars (\$[**]) plus the amounts paid by EKR pursuant to the Promissory Note.

- (k) Subject to Sections 3.20(d) and (e) and Section 6.3(d) and PPI's right to repurchase the Transferred Equipment thereunder, upon the expiration or earlier termination of the Lease Term, EKR shall remove the Transferred Equipment from PPI's premises (unless EKR at its option elects to retain the Transferred Equipment at PPI's premises in connection with EKR's exercise of step-in rights under Section 17.5). PPI agrees to cooperate with EKR in the removal of the Transferred Equipment, including providing the necessary access to the Transferred Equipment and the facilities where it is located at times mutually agreed by the Parties, such agreement not to be unreasonably withheld or delayed by either Party.
- (l) Upon termination of the Lease Term, unless PPI has repurchased the Transferred Equipment, EKR will, at PPI's request, use commercially reasonable efforts to (i) supply the Product and (ii) supply placebo for [**], to PPI's other licensees and collaborators outside the Territory, excluding PPI and any of its Affiliates (the "**Other PPI Customers**"), in each case in accordance with the commercially reasonable requirements of any existing agreements between PPI and such Other PPI Customers, subject to EKR's receipt of payment required under such agreements for supplying such Products and/or other products. PPI will use commercially reasonable efforts to cooperate with EKR so as to enable EKR to supply Product and, if applicable, other products, to such Other PPI Customers.

4. **Undertakings of EKR.**

- 4.1 **Marketing Authorizations.** EKR shall, as determined in its sole discretion to be commercially reasonable, prepare studies of the markets and sales potential of the Products for countries in the Territory other than the United States and present such studies to the Committee. EKR shall at its own cost and expense use commercially reasonable efforts to take those steps reasonably necessary in order to obtain and thereafter maintain Marketing Authorizations (including pricing and reimbursement approvals) for the Product in those countries of the Territory other than the United States which the Committee determines to present commercially viable opportunities for the Product. EKR shall provide PPI with a copy of any original certificates of approval/registration in each country in the Territory other than the United States. EKR shall provide PPI with a copy of any other registration matters received from the appropriate Regulatory Authorities concerning maintenance, renewal or variations to the original certificates of approval/registration in each country in the Territory. Except as provided in Section 3.17, EKR shall be solely responsible for, and shall bear all costs associated with, all regulatory activities related to the development and approval of the Product in the countries of the Territory (including, after the Agreement Date, the United States) and shall own the Marketing Authorizations for the Product in each other country of the Territory. EKR will comply with all conditions and requirements attaching to such Marketing Authorizations.
- 4.2 **Liaison with Regulatory Authorities.** Pursuant to Section 4.1 above, EKR shall at its own cost and expense liaise with the relevant Regulatory Authorities in respect of each Marketing Authorization and notify PPI of all material communications relating thereto. The cost of submitting any data generated by any Phase IV studies conducted by EKR which is required to be filed with the FDA shall be borne by EKR and the cost of submitting any other data (including data submitted to support the use of the Product for additional indications) shall also be borne by EKR;

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- 4.3 Submission of Promotional Materials. Pursuant to Section 4.1 above, EKR shall at its own cost and expense submit and obtain the approvals of Regulatory Authorities in the Territory of Promotional Materials as required by Applicable Laws;
- 4.4 Pre-Launch and Post Launch Activities. Pursuant to Section 4.1 above, EKR shall at its own cost and expense carry out reasonable pre-launch market development and conduct such post-marketing clinical trials (as determined solely by EKR in its reasonable business judgment) in accordance with the Marketing Plan. Any data resulting from such trials shall be owned by EKR but shall be provided on a royalty-free license to PPI for use outside of the Territory. PPI shall cooperate with EKR in connection with such pre-launch and post launch activities as provided in sections 3.3 and 3.14 hereof;
- 4.5 Launch of Products. Pursuant to Section 4.1 above, EKR shall at its own cost and expense launch and achieve Commercial Launch of the Products in accordance with the Marketing Plan but no later than 18 months following receipt of Marketing Authorization in each country in the Territory provided however that EKR shall not be obligated to launch such Product in such country of the Territory where the approved pricing in such country provides EKR a gross margin of less than [**]% (after payment of Royalties, Additional Royalties and Cost of Goods) or where the launch of the Product in such country of the Territory as determined by EKR is not commercially reasonable.
- 4.6 Marketing Activities. EKR shall at its own cost and expense, during the term of this Agreement, promote, market, sell and distribute the Products to customers within the Territory and provided that PPI has supplied EKR with necessary quantities of Product, satisfy the demand for the Product throughout the Territory. EKR shall be solely responsible for, and shall bear all costs associated with, all marketing and selling activities related to the Products in the Territory;
- 4.7 SubDistributors. EKR shall at its own cost and expense maintain, or use reasonable commercial efforts to ensure that sub-distributors maintain, adequate sales and, where

appropriate, warehouse facilities and employ, or use reasonable commercial efforts to procure that sub-distributors employ, a sufficient number of experienced, trained and qualified personnel to promote the sale of the Product in the Territory and perform, or procure the performance of the activities set forth in the Marketing Plan;

- 4.8 Inventory and Promotional Materials. EKR shall maintain a sufficient inventory of Product and support material to reasonably fulfill the requirements of its customers in the Territory provided that, subject to Section 17.5, PPI shall comply with the Supply Agreement;
- 4.9 Records. EKR shall maintain adequate records concerning the sale of the Product as required by any applicable Regulatory Authority in the Territory;
- 4.10 Promotional Materials. EKR shall provide PPI with copies of the Promotional Materials proposed to be used in connection with the sale of the Products in the United States for approval, solely with respect to Trademark usage, (such approval not to be unreasonably withheld, conditioned or delayed) to the extent such Promotional Materials include any Trademark. EKR shall submit such Promotional Materials to PPI at least five (5) business days in advance of its intended use of the same and such Promotional Material shall be deemed to have received PPI's approval unless PPI Provides EKR with written notice of rejection within said five (5) business day period and EKR shall be authorized to finalize and use same. For the avoidance of doubt, any Trademark usage set forth on any Promotional Materials in use as of or prior to the Agreement Date are hereby deemed to be approved by PPI.
- 4.11 Adverse Events. Each Party shall promptly provide the other Party with all information in its possession or otherwise coming to its attention relating to the occurrence of a serious adverse event or an adverse event (in any jurisdiction throughout the world) in connection with the Product, and promptly forward to such other Party information concerning any and all charges, complaints or claims reportable to any Regulatory Authority relating to the Product that may come to the first Party's attention, and

otherwise comply in all respects with the adverse drug event reporting and recall procedures set out or referred to in the Supply Agreement from time to time. EKR shall be responsible, to the extent required by Applicable Law, to report all charges, complaints or claims reportable to any Regulatory Authority outside of the United States relating to the Product, as well as any such charges, complaints or claims reportable to any Regulatory Authority inside the United States to the extent such charges, complaints or claims are made after the Agreement Date.

- 4.12 Permits. EKR shall obtain and maintain all necessary licenses, permits, records and authorizations required by Applicable Laws as holder of the Transferred NDA after the Agreement Date and in order to exercise the Distribution Rights and observe and comply with all Applicable Laws, ordinances, rules and regulations including, but not limited to those of the applicable Regulatory Authorities in the exercise of the Distribution Rights save insofar as PPI is required to obtain the same as holder of the Marketing Authorizations prior to the Agreement Date, or under the terms of this Agreement;
- 4.13 Compliance. EKR shall conduct the promotion and marketing and sale of the Products in accordance with Applicable Laws and with all due care and diligence.
- 4.14 Sales and Promotional Activities. In connection with the promotion, marketing and sale of the Product, EKR shall, without limitation:
- (a) observe and comply with such storage, stock control and operational practices and procedures as may be legally required in the Territory and as reasonably specified in writing by PPI from time to time;
 - (b) from time to time consult with PPI's representatives for the purpose of assessing the state of the market in each country of the Territory and permit representatives of PPI, on reasonable prior notice, to inspect any premises or documents used in connection with the marketing, distribution and sale of the Products;

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- (c) provide PPI on reasonable prior notice but not more than once in any Calendar Year, copies of its up-to-date price list for the Product together with full details of standard discounts and any special pricing arrangements entered into or proposed to be entered into;
 - (d) market the Product throughout the Territory under the Trademarks and any EKR trademarks and ensure that all marketing materials for the Product shall display the Trademarks; and
 - (e) comply with all applicable regulatory and statutory requirements imposed in relation to the Product, including, without limitation, those imposed by the US Drug Enforcement Agency (“**DEA**”) and other equivalent agencies in the Territory.
- 4.15 Prohibition on Sales Outside the Territory. EKR shall not directly or indirectly market distribute and/or sell the Product outside the Territory, or sell the product to any Third Party that EKR knows intends to sell or distribute the Product outside the Territory. In addition, the Parties acknowledge that since the Product is a controlled substance, the DEA and other law enforcement agencies will not permit any sale outside the Territory without relevant clearances and approvals.
- 4.16 Non-Compete. EKR shall not, during [**], market, distribute or sell a Competing Product in the Territory unless during such time an A/B rated generic product of the Product(s) is launched in such country of the Territory or in the event this Agreement is terminated or EKR exercises its rights under Section 17.4 hereof.
- 4.17 PPI as Exclusive Provider. During the Term, except if PPI is unable to supply Products (including, but not limited to, in connection with EKR’s exercise of its rights under Section 17.5 below) or as provided in the Supply Agreement, EKR shall purchase all of its requirements for the Product from PPI.
- 4.18 Packaging. During the Term, EKR shall not use in relation to the Product any packaging, labeling and Product inserts, nor any advertising literature that has not been

approved by PPI in writing with respect to Trademark usage (such approval not to be unreasonably withheld, conditioned or delayed) or deemed approved pursuant to Section 4.10, to the extent such materials include any Trademark. EKR shall be responsible for insuring that any packaging, labeling and Product inserts, and advertising literature complies with Applicable Laws.

- 4.19 Customer Orders. If EKR receives a request from a customer located outside the Territory for supply of the Product outside of the Territory, EKR shall promptly forward such request to PPI.
- 4.20 Governmental Rebates. Any discounts, rebates, or promotional allowances/incentive programs provided are “discount[s] or other reduction[s] in price” for purposes of 42 U.S.C. Section 1320a-7b(b)(3)(A) and may be subject to the reporting requirements under state and federal Medicaid and Medicare laws. EKR represents that it is aware of its obligations to report discounts resulting from this Agreement to the appropriate reimbursing agencies and authorities (including Medicaid and Medicare). EKR is responsible for complying with and agrees to comply with all applicable requirements, if any, in respect of providing information on such discounts to reimbursing agencies (including Medicaid and Medicare) and other entities in accordance with Applicable Laws and regulations.
- 4.21 Resale Pricing. In exercising the Distribution Rights, EKR shall determine resale pricing of the Products in its sole discretion.
5. Commercialization Committee.
- 5.1 Establishment of Committee. The Parties have established a Commercialization Committee (“**Committee**”) consisting of 4 individuals (“**Committee Members**”); 2 of whom were nominated by PPI; and 2 of whom were nominated by EKR. The Committee Members may be replaced by notice to the other Party and shall be appropriately qualified and experienced in order to make a meaningful contribution to Committee meetings.

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- 5.2 Purpose. The purpose of the Committee is to provide a forum for the Parties to share information and knowledge on the on-going Commercialization of the Product including, but not limited to, monitoring progress on clinical studies, reviewing clinical trial programs, discussing the appropriate regulatory strategy for the Products in the Territory, considering proposed marketing and promotional plans, reviewing competitor activity and discussing any regulatory, technical, quality assurance or safety issues in relation to the Product. The Committee shall conduct its discussions in good faith with a view to operating to the mutual benefit of the Parties and in furtherance of the successful development and marketing of the Products.
- 5.3 Meetings. The Committee shall meet as often as the Committee Members may determine, but in any event not less than 2 times per Calendar Year. The Committee may invite individuals with special skills to attend such meetings where considered to be relevant and appropriate. The quorum for Committee meetings shall be 2 Committee Members, comprising 1 Committee Member from each Party.
- 5.4 Marketing Plan. The Parties acknowledge that EKR has provided the Committee with its Marketing Plans for Calendar Years 2008 and 2009 pursuant to the Original Agreement. EKR shall on or before October 15th 2009 and October 15th of each Calendar Year thereafter provide the Committee with its Marketing Plan for the coming Calendar Year. Each Marketing Plan shall include, without limitation, Net Sales targets and projections with respect to sales force staffing levels, market research, physician education, marketing expenditure, post-approval clinical trials and advertising. With regard to pre-marketing clinical trials, the design and conduct shall be subject to the written approval of PPI, such approval not to be unreasonably withheld or delayed.
- 5.5 Decision Making. Decisions of the Committee shall be made as follows:
- (a) The Committee may make decisions with respect to any subject matter that is subject to the Committee's decision-making authority. Except as expressly provided in this Agreement, all decisions of the Committee

shall be made by unanimous vote or written consent, with EKR and PPI each having, collectively, one vote in all decisions. The Committee shall use commercially reasonable efforts to resolve the matters within its roles and functions or otherwise referred to it.

- (b) If, with respect to a matter that is subject to the Committee's decision-making authority, the Committee cannot reach consensus within 15 days after it has met and attempted to reach such consensus or the Parties cannot reach consensus on whether the Committee has decision-making authority regarding a matter within 15 days after such matter was first raised by either Party, the dispute in question shall be referred to the Chief Executive Officer of PPI, on behalf of PPI, or such other person holding a similar position designated by PPI from time to time, and the Chief Executive Officer of EKR, or such other person holding a similar position designated by the EKR from time to time (such officers collectively, the "**Executive Officers**"), for resolution. The Executive Officers shall use reasonable efforts to resolve the matter referred to them.
- (c) If the Executive Officers cannot resolve the matter in accordance with Section 5.5(b) within 30 days of the reference of the matter to them, then EKR shall have the final decision-making authority if the matter relates to the sale or marketing of the Product in any country of the Territory and PPI shall have the final decision-making authority if the matter relates to the development, manufacture or Trademarks of the Product.

6. **Fees, Milestones and Royalties.**

- 6.1 **Up-Front Payment.** In consideration for work previously undertaken by PPI in respect of the Product, the Parties acknowledge that EKR has paid a non-refundable, non-creditable up front payment of \$[**] to PPI pursuant to the Original Agreement.
- 6.2 **Deferred Milestone Payments.** As further consideration for the work previously undertaken by PPI and in consideration for the license and grant of the Distribution Rights to EKR under this Agreement, EKR shall pay to PPI the following milestone payments (the “**Deferred Milestone Payments**”) on the date when due:

Deferred Milestone

\$[**] (the “First Deferred Milestone”)

\$[**] (the “Second Deferred Milestone”)

Due Date

The Parties acknowledge that EKR has paid the First Deferred Milestone to PPI prior to the Agreement Date.

Within three (3) days of the Agreement Date, EKR shall pay the Second Deferred Milestone.

6.3 **Advanced Royalty Payment to PPI.**

- (a) Within three (3) days of the Agreement Date, EKR shall make an advanced Royalty payment to PPI of \$[**] (the “**Advanced Royalty Payment**”), which will be offset against EKR’s payment obligations or otherwise repaid to EKR as set forth below in this Section 6.3.
- (b) Offsets and/or repayment of the Advanced Royalty Payment shall commence on [**] and shall continue, unless sooner paid, through [**] (the “**Royalty Offset Period**”) and such offsets will be taken by EKR (and such repayment will be made by PPI) as follows:
- (i) by a reduction in Royalties due under Section 6.4 of this Agreement of \$[**] for each [**] mg vial of Product sold during the Royalty Offset Period and \$[**] for each [**] mg Vial of Product sold during the Royalty Offset Period (collectively the “**Royalty Offset**”) which amounts shall be deducted by EKR from any Royalty payments due PPI and reflected in the quarterly and annual reports required in Section 6.5 of this Agreement;

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- (ii) by payment to EKR of [**] percent ([**]%) of any purchase price payments, license fees, other access fees or royalties received by PPI or any of its Affiliates after the Agreement Date in connection with the license (to the extent permitted hereunder) or transfer of any rights to the Product (and/or any underlying intellectual property rights) in the Field in the Territory to a Third Party (other than pursuant to any transaction described in Section 6.3 (b)(iii) below), which payment shall be made by PPI to EKR within ten (10) days of PPI's receipt of such payments; and
 - (iii) upon any Change of Control (as defined in Section 20.4) of PPI, by repayment to EKR in full of the balance of the Advanced Royalty Payment not previously used for offsets, which payment shall be made to EKR by PPI within ten (10) days after the closing date (without any conditions) of any such Change of Control.

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- (c) Notwithstanding Section 6.3(b), effective July 1, 2013, the balance of the Advanced Royalty Payment that is available for subsequent offsets and/or repayments under Section 6.3(b) above shall be reduced to the lesser of (x) \$[**] or (y) the actual amount of such balance as calculated based upon any payments and offsets deducted to date from the beginning Advanced Royalty Payment balance of \$[**], as outlined in clauses (i) and (ii) of Section 6.3(b) above. As of [**] the balance of the Advanced Royalty Payment shall have been deemed repaid in full by PPI and no additional offsets to or repayments of the Royalties shall thereafter be applied for any reason.
- (d) Notwithstanding anything to the contrary, in the event EKR exercises its right of termination pursuant to Section 16.3(b) of this Agreement or PPI terminates this Agreement pursuant to Section 16.1(a): (i) EKR will sell the Transferred Equipment back to PPI, subject to payment by PPI to EKR (within five (5) days of the date of termination) of \$[**] in cash and cancellation of any remaining obligation of EKR under the Promissory Note, (ii) the Advanced Royalty Payment shall be deemed to have been repaid in full, and EKR shall not have the right to the Royalty Offset between the date of notice of such termination and the termination date of the Agreement and (iii) EKR shall promptly transfer the Marketing Authorizations to PPI or its nominee in accordance with Section 17.1(e) below.

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- (e) Notwithstanding anything to the contrary, during the Royalty Offset Period, or until such time that the Advanced Royalty Payment balance has been fully repaid, the combined Royalty and Supply Price (as defined in the Supply Agreement) shall not exceed [**] percent ([**]%) of the net average selling price of the Product.
 - (f) For the avoidance of doubt, the Royalty Offset described in clause (i) of Section 6.3(b) shall not be applied against any Additional Royalty due PPI pursuant to Section 6.4.

6.4 Royalties. As further consideration for the license and grant of Distribution Rights and other rights under this Agreement, EKR shall pay to PPI a royalty (“**Royalty**”) equal to (a) \$[**] for each [**] mg Vial of Product sold during the Term and \$[**] for each [**] mg Vial of Product sold during the Term (the “**Minimum Royalty**”) plus (b) an additional [**]% of any post Effective Date incremental price increase implemented by EKR over the Current Base Price of \$[**] for the [**] mg Vial and \$[**] for the [**] mg Vial (the “**Additional Royalty**”); provided, however, that Additional Royalty shall not be payable to the extent that the sum of (i) the Minimum Royalty and Additional Royalty payable hereunder and (ii) the Supply Price (as defined in the Supply Agreement) shall at any time during the Term exceed [**] percent ([**]%) of the net average selling price of the Product (the “**Royalty Cap**”); provided, however, that the Royalty Cap shall be [**] percent ([**]%) of the net average selling price of the Product during certain periods as described in Section 6.3(e) above. EKR shall be entitled to offset certain amounts from Royalties payable hereunder as set forth in Section 6.3(b) above. Royalties on other presentations and dosages which hereafter receive Marketing Authorization in any country of the Territory shall be negotiated in good faith by the parties in a manner consistent with the Royalty currently being paid by EKR as of the date of the receipt of Marketing Authorization for such new presentations and dosages.

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- 6.5 Quarterly Reports and Annual Reports. Within 30 days of the end of each Quarter and within sixty (60) days of the end of each Calendar Year during the Term of this Agreement EKR shall send to PPI a statement setting out in respect of each country in the Territory in which Product is sold, details of Product sold during the previous Quarter or Calendar Year, as applicable, itemized by presentation form, quantity, total gross receipts, itemized deductions which are applied to achieve the Net Sales figure, and Net Sales of Product. The statement shall (where appropriate) show:
- (a) the total Net Sales for each country expressed both in local currency and in Dollars and the conversion rate used;
 - (b) the total number of Vials sold in each country (less properly rejected, returned or recalled Vials) for each of the [**] mg Product and the [**] mg Product (the “Unit Sales”);
 - (c) the applicable Royalty rate multiplied by the Unit Sales for each of the [**]mg and [**] mg Products in that Quarter (“Prepayment”) (or in that Calendar Year, as applicable);
 - (d) any Additional Royalties due in that Quarter (or for such Calendar Year);
 - (e) the total Royalties payable on those Unit Sales (subject to the Royalty Cap) in accordance with Section 6.4, and any deductions taken pursuant to Section 6.3.
- 6.6 Payment. EKR shall pay to PPI, any Minimum Royalties and Additional Royalties due within forty-five (45) days of the end of each Quarter as the case may be subject to reconciliation at the end of each Calendar Year as set forth in Section 6.9.
- 6.7 Reserved.
- 6.8 Reserved.
- 6.9 Reconciliation. Within forty-five (45) days of the end of each Contract Year, there shall be a reconciliation between the sums paid under Section 6.6 and the Royalties payable under Section 6.4, and any payment due (or in the event of an overpayment by EKR to PPI) such amounts shall be paid by one Party to the other within thirty (30) days of the resolution of such reconciliation.

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- 6.10 **Withholdings.** In the event that a Party is required under the laws of a country or other political subdivision of competent jurisdiction to withhold any tax to the tax or revenue authorities in such jurisdiction in connection with any payment to the other Party, such amount shall be deducted from the payment to be made by such withholding Party; provided that the withholding Party shall take reasonable and lawful actions to avoid and minimize such withholding and promptly notify the other Party so that the other Party may take lawful actions to avoid and minimize such withholding. The withholding Party shall promptly furnish the other Party with copies of any tax certificate or other documentation evidencing such withholding as necessary to satisfy the requirements of the appropriate regulatory authority related to any application by such other Party for foreign tax credit for such payment. Each Party agrees to reasonably cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect.
7. **Payment, Accounting, Audit Rights.**
- 7.1 **Currency.** Unless otherwise agreed between the Parties, all payments to be made hereunder shall be made in US Dollars. Net Sales shall be determined in the currency in which the Product was sold and shall, if necessary, be converted into US Dollars using the noon buying rate as published in the Wall Street Journal for the last day of the Quarter for which such payment is being determined.
- 7.2 **Maintenance of Records.** EKR shall maintain and shall procure the maintenance of accurate and up to date records and books of account showing the quantity, description and value of the Products supplied in each country of the Territory during the previous six (6) Calendar Years.
- 7.3 **Inspection.** EKR shall during business hours, on no less than 14 day's notice from PPI and not more than once in any Calendar Year, make available for inspection the records

and books referred to in Section 7.2. Such inspection shall be undertaken by an independent auditor appointed by PPI and reasonably acceptable to EKR for the purpose of verifying the accuracy of any statement or report given by EKR to PPI and/or the amount of Royalties due. Upon completion of such inspection, PPI shall not be entitled to inspect nor shall EKR be required to make available the records and books for any Calendar Year for which such inspection was previously undertaken.

- 7.4 Confidentiality. PPI shall procure that any independent auditor appointed under Section 7.4 shall maintain all information and materials received, directly or indirectly, by it from EKR in strict confidence and shall not use or disclose the same to any Third Party nor to PPI save for the sole purpose of conducting the audit pursuant to this Section.
- 7.5 Audit. In the event that an auditor appointed pursuant to this Section concludes that there has been an underpayment or overpayment, PPI shall deliver to EKR a copy of such auditor's report. Any deficit payable by EKR or any excess refundable by PPI shall be payable within 30 days of EKR's receipt of such report. The fees charged by such auditor shall be payable by PPI, provided that if the audit reveals that payments due to PPI for any Calendar Year have been understated by more than [**]%, the fees charged by such auditor shall be payable by EKR.
- 7.6 Interest. Should any amount not be paid by either Party on or before the due date for payment interest on such unpaid amount at the rate of [**]% above the prime lending rate of Citibank, N.A. (or its successor in interest) in effect from time to time and such interest shall be calculated and payable in respect of the period from the date such amount is due until the date payment in full is received in cleared funds.
8. Intellectual Property and Trademarks.
- 8.1 Limitation of License. Except as set out in this Agreement, all right, title and interest in the PPI IP or Trademarks shall belong to PPI and EKR shall not have any right, title or interest in the PPI IP or Trademarks.

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- 8.2 Trademark Standards. EKR shall use the Trademarks in a manner which conforms to the reasonable directions and standards notified to it by PPI from time to time and not do anything which could, in the PPI's reasonable opinion, bring the Trademarks or PPI into disrepute or otherwise damage the goodwill attaching to the Trademarks.
- 8.3 Maintenance of Trademarks. PPI shall, at its own cost, take all steps required to maintain those registrations for the Trademarks subsisting at the Effective Date, and prosecute any applications subsisting at the Effective Date for registration of the Trademarks through to grant (including oppositions thereto) in each country of the Territory.
- 8.4 Additional Trademark Registrations. EKR may request that PPI use reasonable efforts to obtain Trademark registrations in respect of the Trademarks, in classifications which cover the Product, in any countries in the Territory. PPI shall promptly notify EKR if it does not intend to make or pursue any such Trademark registration in any of the countries in the Territory and EKR shall thereafter be entitled to make applications for such Trademark registrations in its own name.
- 8.5 Domain Names. EKR shall have the right during the Term to register domain names in its own name specific to the countries comprised in the Territory that incorporate the Trademark.
- 8.6 Improvements. PPI Improvements shall be owned by PPI and be licensed to EKR hereunder. EKR Improvements shall be owned by EKR and upon termination of this Agreement by PPI pursuant to Section, shall be deemed be licensed to PPI on a worldwide, non-exclusive, irrevocable basis, at a royalty or for such other consideration as may be mutually agreed upon by the parties in writing. Joint Improvements shall be owned jointly by the Parties, and PPI's interest therein shall be licensed to EKR hereunder.

9. **Representations and Warranties.**

9.1 **Representations and Warranties of Both Parties.** Each Party represents and warrants to the other Party as of the Effective Date, that:

- (a) **Organization.** Such Party is duly organized and validly existing and in good standing of the laws of the jurisdiction of its incorporation and it has full power and authority and legal right to enter into this Agreement and perform the obligations under it;
- (b) **Authorization.** Such Party has taken all corporate action such that the execution and delivery of this Agreement and the consummation of the transaction contemplated hereby has been duly authorized by all necessary actions;
- (c) **Valid Obligation.** This Agreement is a legal and valid obligation of such Party, binding on each of the Parties and enforceable in accordance with its terms;
- (d) **Execution and Delivery.** The execution and entry into and exercise of the respective rights and obligations under this Agreement including the granting of rights to the other Party pursuant to this Agreement do not, and will not conflict with, or violate any provision of any agreement or other instrument or document to which it is Party or affect or be in conflict with or result in the breach of or constitute a default under any such agreement, instrument or document or conflict with any rights granted by such Party to any Third Party or breach any obligation that such Party has to any Third Party; and
- (e) **Debarment.** It is not currently debarred, suspended or otherwise excluded by the United States, under any Federal law, including, without limitation, the Generic Drug Enforcement Act of 1992, or by any other country in the Territory under any analogous law, rule or regulation, and does not and will not use in any capacity the services of any person debarred under applicable law, rule or regulation, in the Territory in the performance of its obligations under this Agreement.

9.2 Representations and Warranties of PPI. PPI hereby represents and warrants to EKR as of the Effective Date that:

- (a) Ownership; Validity. It is the owner of, or has exclusive rights to, all of the PPI IP and Trademarks in existence on the Effective Date, and has the exclusive right to grant the Distribution Rights and other rights granted under this Agreement. All of the PPI Patents in existence on the Effective Date are valid, enforceable, in full force and effect and have been maintained to date and are not the subject to any interference or opposition procedures. All of the PPI Patents listed in the Orange Book are properly filed in accordance with Applicable Laws;
- (b) Third Party Interests. There are no Third Party interests or rights in the PPI IP or Trademarks that may prevent, encumber or restrict the exercise by EKR of the Distribution Rights or other rights granted under this Agreement.
- (c) Third Party Infringement. No Third Party is infringing or has infringed the intellectual property rights of PPI in any of the PPI IP or Trademarks;
- (d) Distribution Rights and other Rights. That neither the Products, the exercise of EKR's Distribution Rights and other rights granted under this Agreement or the manufacture of the Products as contemplated by this Agreement or the Supply Agreement do not and will not infringe or conflict with any Third Party intellectual property rights and EKR will not incur any obligation to any Third Party by the exercise of the rights granted hereunder;
- (e) Renewal and Maintenance Fees. All renewal and maintenance fees and all steps necessary for the filing, prosecution and maintenance of the PPI

Patents and Trademarks due and payable as of the Effective Date have been paid or taken and there are no actions due within 180 days of the Effective Date;

- (f) Trademarks. The Trademarks are the only trademarks, trade dress or service marks related to the Product that are owned by PPI or licensed by PPI (with the right to sublicense);
- (g) Adverse Events. To its knowledge and belief all information, data and Third Party notices in relation to adverse events serious adverse events or recalls with respect to the Product and of which PPI is aware have been disclosed by PPI to EKR;
- (h) Access to Documents. PPI has provided EKR or given EKR access to true, complete and unredacted copies of all (i) regulatory documentation or (ii) material agreements between PPI and any Third Party including all effective amendments to any such agreements which in any event (A) affects or may affect EKR's rights under this Agreement or (B) relates to the Product;
- (i) No Brokers. Neither PPI nor any office, director or agent of PPI has employed any broker, finder or agent with respect to this Agreement or the transactions contemplated hereby;
- (j) Right to License. PPI has the right to use and license PPI IP and Trademarks free and clear of any material liens, security, interests, licenses, obligations, transfer agreements, enforceable claims or encumbrances;
- (k) Litigation. There is no litigation, arbitration, proceeding, governmental investigation, action or claim of any Third Party or to the knowledge of PPI threatened by or against PPI relating specifically to the PPI IP, or the Trademarks which would impede, impair, restrict or interfere with the rights granted EKR hereunder or the ability of PPI to perform its obligations hereunder; and

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- (l) Customer Lists. PPI has or prior to the Effective Date will have provided EKR with complete and accurate lists of the names and addresses of all material customers and suppliers of the Products.
 - (m) Permits. PPI has and shall maintain at all times during the Term all necessary license, permits, records and authorizations required by Applicable Laws necessary to perform its obligations hereunder and shall observe and comply with all Applicable Laws, ordinances, rules and regulations including those of the applicable Regulatory Authorities and governmental entities including but not limited to DEA in the performance of its obligations hereunder.
 - (n) ICS Agreement. All amounts due under the ICS Agreement as of or prior to the Effective Date have been paid in full. PPI is not in, nor has PPI given or received notice of, any default or claimed, purported or alleged default, or facts that, with notice or lapse of time, or both, would constitute a default (or give rise to a termination right) on the part of any person in the performance of any obligation to be performed under the ICS Agreement. A true and complete copy of the ICS Agreement, including any amendments thereto, has been delivered to EKR.

10. **Liability, Insurance and Indemnities**

10.1 **Indemnification of EKR**. PPI shall be liable for and shall defend, indemnify and hold harmless EKR and its Affiliates and their officers, directors, agents, representatives, consultants and employees (individually an “**EKR Indemnified Party**” and collectively the “**EKR Indemnified Parties**”) and any of them from and against any and all Claims (as defined below), arising in connection with or relating to:

- (a) The development, manufacture, sale and supply of the Product prior to the Effective Date (including Claims arising after the Effective Date to the extent they are based on events occurring prior to the Effective Date);

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- (b) The manufacture of the Product by or on behalf of PPI (including, but not limited to, any manufacture of Product or any other product by EKR for the Other PPI Customers pursuant to Section 3.20(1)) except to the extent that such Claims arise from (i) the negligence or willful misconduct of EKR or its Affiliates, (ii) the breach by EKR of the terms of this Agreement or (iii) the manufacture of Product by EKR in accordance with EKR's exercise Step-in Right for supply of Product to EKR or its Affiliates;
 - (c) Claims which arise outside the Territory (except to the extent that the Claim has arisen from any act or omission by EKR);
 - (d) A breach by PPI of any representation, warranty, covenant or agreement contained in this Agreement, the Supply Agreement or the Transition Services and Inventory Agreement;
 - (e) PPI's failure to comply with any Applicable Law in connection with the performance of its obligations hereunder or under the Supply Agreement or the Transition Services and Inventory Agreement, or prior to the Effective Date; and
 - (f) Any Claims related to Product sold by parties other than EKR prior or subsequent to the Effective Date.
 - (g) Liabilities arising under the ICS Agreement prior to the Effective Date and subsequent to the Effective Date for Products sold by parties other than EKR or under the direction of EKR or arising under the Transition Services and Inventory Agreement.

10.2 Indemnification of PPI. EKR shall be liable for and shall defend, indemnify and hold harmless PPI from and against any and all Claims arising from (i) EKR's exercise of the Distribution Rights or arising under the Transition Services and Inventory Agreement, (ii) a breach by EKR of any representation, warranty, covenant or agreement contained in this Agreement, the Supply Agreement or the Transitions Services and Inventory Agreement, or (iii) EKR's failure to comply with Applicable Laws in connection with its performance of its obligations hereunder, or (iv) Claims related to the manufacture of Products by EKR or by a Third Party Manufacturer designated by EKR pursuant to Section 11.5 of the Supply Agreement, except to the extent that such Claims:

- (a) relate to any act or circumstance occurring prior to the Effective Date;
- (b) relate to Intellectual Property infringement proceedings with Third Parties in connection with the PPI IP and Trademarks (except to the extent that the Claim has arisen from EKR's use of the PPI IP or Trademarks other than in accordance with this Agreement);
- (c) arise outside the Territory (except to the extent that the Claim has arisen from any act or omission by EKR);
- (d) relate to the development or manufacture of the Product by PPI or its Affiliates or its or their agents or sub-contractors;
- (e) Arise under the ICS Agreement after the Effective Date for Products sold by EKR.
- (f) result from the negligence, willful default or material breach of any representation or warranty given under this Agreement, the Supply Agreement, or the Transition Services and Inventory Agreement by PPI, its Affiliates or sub-contractors; or
- (g) are the responsibility of PPI under Section 10.1 above.

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- 10.3 Conditions to Indemnification. Promptly after receipt by a Party of any Claim or alleged claim or notice of the commencement of any action, administrative or legal proceeding, or investigation as to which the indemnity provided for in this Section 10 may apply, the indemnified Party shall give written notice to the indemnifying Party of such fact. The indemnifying Party shall have the option to assume the defense thereof by election in writing within thirty (30) days of receipt of such notice. If the indemnifying Party fails to make such election, the indemnified Party may assume such defense and the indemnifying Party will be liable for reasonable legal and other expenses subsequently incurred in connection with such defense. The Parties will co-operate in good faith in the conduct of any defense, provide such reasonable assistance as may be required to enable any Claim to be properly defended, and the Party with conduct of the action shall provide promptly to the other Party copies of all proceedings relating to such action.
- 10.4 Assumption of Defense. Should the indemnifying Party assume conduct of the defense:
- (a) the indemnified Party may retain separate legal advisors in the event that it reasonably concludes that it may have defenses available to it which are additional to, different from or inconsistent with those available to the indemnifying Party, in which case the indemnifying Party shall not be liable for the indemnified Party's reasonable costs and expenses so incurred; and
 - (b) the indemnifying Party will not, except with the consent of the indemnified Party (such consent not be unreasonably withheld or delayed), consent to the entry of any judgment or enter into any settlement (other than for the payment of damages by the indemnifying Party, which includes as an unconditional term a release from the claimant to the indemnified Party from all liability in respect of all claims).

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- 10.5 Settlement of Claims. The indemnified Party shall not admit liability in respect of, or compromise or settle any such action without the prior written consent of the indemnifying Party, such consent not to be unreasonably withheld or delayed.
- 10.6 Insurance. Each Party shall maintain, at its own cost, comprehensive product liability insurance, general commercial liability insurance and business interruption insurance at a level which is reasonable and customary taking into account the nature of the Product but which shall have combined limits of not less than \$[**] per occurrence. Such insurance shall be with a reputable insurance company and where reasonably possible (taking into account the availability of such insurance) shall be maintained for not less than [**] ([**]) years following the expiry or termination of this Agreement. During the Term, neither Party shall do or omit to do any act, matter or thing which could prejudice or render voidable any such insurance. Each Party will provide to the other Party evidence of its insurance and thirty (30) days prior written notice of any cancellation of its coverage or reduction in coverage from the requirements stated herein.
- 10.7 Third Party Liability. Each of the Parties shall be liable to the other for legal liability to Third Parties in respect of all claims, actions, judgments, damages, lawsuits, costs or expenses or professional fees for death or personal injury incurred by such other Party in relation to or arising out of any breach of this Agreement, the Transition Services and Inventory Agreement or the Supply Agreement by the first Party or of any gross negligence or willful act of the first Party, or its employees in the course of their employment.
- 10.8 PPI Liability Limitation. Any and all liability of PPI to EKR howsoever arising in respect of this Agreement, the Transition Services and Inventory Agreement or the Supply Agreement and their performance, in contract tort or otherwise, shall be limited (except for death or personal injury caused by the negligence of PPI or its employees while acting in the course of their employment) to [**] US Dollars (\$[**]); provided

however that such limitation shall not apply to the extent that EKR or any EKR Indemnified Party is required to pay in excess of such amount to a third party in respect of a final judgment or order obtained by the third party or as a result of PPI's breach of Section 7.2.12 of the Supply Agreement.

- 10.9 **EKR Liability Limitation.** Any and all liability of EKR to PPI howsoever arising in respect of this Agreement, the Transition Services and Inventory Agreement or the Supply Agreement and their performance in contract tort or otherwise shall be limited (except for death or personal injury caused by the negligence of EKR or its employees while acting in the course of their employment, and except in relation to any specified payment, lump sum, milestone or royalty payment unpaid) to [**] US Dollars (\$[**]); provided however that such limitation shall not apply to the extent that PPI or any PPI Indemnified Party is required to pay in excess of such amount to a third party in respect of a final judgment or order obtained by the third party.
- 10.10 **Limitation of Damages.** Notwithstanding anything contained in this Agreement or the Transition Services and Inventory Agreement or the Supply Agreement in no circumstance shall either Party be liable to the other in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever, and whatever the cause thereof, for any special, indirect or consequential loss or damage of any nature whatsoever except in the cases of fraud or intentional misconduct or in the case of PPI as a result of PPI's breach of Section 7.2.12 of the Supply Agreement.
- 10.11 **Definition of Claims.** In this Section 10, "**Claims**" shall mean any and all claims, actions, demands, losses, damages, costs and reasonable expenses (including, without limitation, reasonable legal and expert fees) made or brought by Third Parties.
11. **Confidentiality, Press Releases and Publications**
- 11.1 **Confidential Information.** PPI and EKR undertake to each other to keep confidential, and to procure that their respective Affiliates, employees, directors, officers, contractors, lawyers and accountants (including those of their Affiliates) keep confidential, Confidential Information disclosed to it by or belonging to the other Party.

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- 11.2 **Third Party Disclosure.** Any Confidential Information received from the other Party shall not be disclosed to any Third Party or used for any purpose other than as provided or specifically envisaged by this Agreement or as required in connection with any securities offering, financing, merger, acquisition or other corporate transaction involving such Party provided that any Party to whom such disclosure is made is bound by obligations as to confidentiality that are at least as protective of Confidential Information as those contained herein.
- 11.3 **Duration.** The confidentiality and non-use obligations contained in this Agreement shall continue for the duration of this Agreement and for a period of [**] (**) years after termination for any reason of this Agreement.
- 11.4 **Public Announcements.** The Parties shall consult with each other, in advance, with regard to the terms of all proposed press releases, public announcements and other public statements with respect to the transactions contemplated under this Agreement. The Parties acknowledge that they have issued a joint press release in the form set out in Schedule VI of this Agreement.
- 11.5 **Exceptions to Disclosure of Confidential Information.** The Confidential Information may be disclosed by the other Parties to the extent that such disclosure has been ordered by a court of law or directed by a governmental authority, provided that, wherever practicable, the Party disclosing the Confidential Information has been given sufficient written notice in advance to the other Party to enable it to seek protection or confidential treatment of such Confidential Information, and may be disclosed only to the extent that such disclosure has been so ordered or directed.
12. **Patents**
- 12.1 **Maintenance.** PPI shall pay all costs and expenses of the filing, prosecution and maintenance of the PPI Patents in each country of the Territory so as to maintain the

PPI Patents in full force and effect. PPI will consult with EKR with respect to any notice from or correspondence with the USPTO or any other governmental entity with respect thereto and the development, filing and prosecution of any subdivisions, continuations, continuations in part or additional applications related to the Product for use in the Field in the Territory.

13. **Infringement of Third Party Rights**

13.1 **Notice of Infringement.** In the event of a Party becoming aware that the exercise of either Party's rights and obligations pursuant to this Agreement are infringing or may infringe the rights of a Third Party, it will promptly notify the other Party and provide it with such details of the Third Party rights and the extent of the infringement as are known to it.

13.2 **Infringement of Third Party IP.** In the event a claim of infringement of a Third Party's intellectual property rights arising out of the manufacture, use, sale, promotion or distribution of the Products is brought against either Party, PPI shall defend such action at its cost and expense and take one or more of the following actions simultaneously or sequentially:

- (a) Defend the claim and indemnify and hold harmless EKR, its Affiliates, officers, directors, shareholders, employees, representations, consultants and agents (the "**EKR Infringement Indemnitees**") as set forth in Section 13.3 below.
- (b) Obtain for itself as the benefit of EKR the right through license or otherwise to utilize the technology upon which the claim of infringement was based. Such rights obtained by PPI from a Third Party under this Section 13.2 shall be licensed or sublicensed to EKR at no additional cost to EKR.

13.3 **Infringement Indemnification.** Notwithstanding any other provisions of this Agreement, PPI will defend, indemnify and hold harmless the EKR Infringement

Indemnitees from and against all liabilities, losses, damages, actions, claims and expenses suffered or incurred by the EKR Infringement Indemnitees (including reasonable attorneys fees, court costs and expert witnesses' fees) resulting from any claims by any Third Party that EKR's exercise during the Term of the rights granted under this Agreement infringes or violates any license, patent, copyright, trademark or other intellectual property right of that Third Party.

14. **Infringement of PPI IP**

- 14.1 **Notice of Infringement.** In the event that either Party becomes aware of any actual or suspected infringement or misuse of the PPI IP or Trademarks in the Territory by a Third Party ("**Third Party Infringement**"), it shall promptly notify the other Party and provide it with all details thereof in its possession.
- 14.2 **Infringement Action.** Within a reasonable time of becoming aware of such Third Party Infringement, the Parties shall consult with each other and their respective counsel to develop a strategy for addressing the Third Party Infringement. In the event the Parties agree to the legal action to stop the Third Party Infringement, they shall agree upon legal counsel to prosecute such action and unless the Parties otherwise agree, PPI shall prosecute the action at its cost and expense. EKR shall provide all such assistance at PPI's cost and expense as PPI may reasonably require in the prosecution or defense of any such proceedings.
- 14.3 **Awards.** Any damages, award or settlement monies actually received by PPI in respect to such infringement and paid in compensation for sales lost by EKR shall be deemed Net Sales and be paid to EKR, subject to PPI deducting its costs and expenses in pursuing such infringement from such damages, award or settlement actually received. Any damages, award or settlement monies actually received by PPI in respect to such infringement and not paid in compensation for sales lost by EKR shall be shared equally by the Parties.

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- 14.4 **Non Participation.** Should in accordance with Section 14.2, PPI decide not to participate in any such infringement action, EKR may require PPI to bring the action, subject to reimbursement by EKR for reasonable out-of-pocket expenses incurred by PPI in connection with such action. The selection of counsel and all other material decisions with respect to such action shall be subject to EKR's prior, written approval, such approval not to be unreasonably withheld. In addition, EKR shall have the right to discontinue the prosecution of any such action at any time upon written notice to PPI. Except as provided above in this Section 14.4, PPI shall have control of such action but shall consult with EKR regarding the conduct of such action and shall not settle such action without the prior written consent of EKR, which consent shall not be unreasonably withheld, and EKR may, in such instance, retain any award or settlement in its entirety. Notwithstanding the foregoing, PPI shall offer reasonable assistance to EKR at no charge except for reimbursement of reasonable out of pocket expense including reasonable attorneys fees.
- 14.5 **Cooperation.** Each Party shall keep the other Party reasonably informed and consult with the other Party with regard to any infringement action under this Article 14.
15. **Term**
- 15.1 This Agreement shall commence on the Effective Date and, subject to earlier termination in accordance with the provisions of Section 16, shall continue in force for a period being the longer of fifteen (15) years from first Commercial Launch of the Product in the Territory or until the expiration of the last valid claim in the PPI Patents covering the Product in any country of the Territory (the "**Initial Term**"). Thereafter the term of this Agreement shall automatically renew for consecutive periods of two (2) years each. Notwithstanding the foregoing, this Agreement can be terminated by EKR at the end of the Initial Term by delivery of written notice to PPI at least one hundred eighty (180) days prior to the end of the Initial Term or any renewal term. As used herein "**Term**" refers to the Initial Term and any renewal terms.

16. **Termination**

16.1 **Prior Termination by Either Party.** Either Party shall be entitled forthwith to terminate this Agreement by notice to the other if:

- (a) the other Party commits a material breach of any material obligation under this Agreement or the Supply Agreement, and in the case of a breach which is capable of remedy fails to remedy it within sixty (60) days of receipt of notice from the first Party of such breach and of its intention to exercise its rights under this Section; or
- (b) any representation or warranty made herein or in the Supply Agreement by such other Party proves to be incorrect when made which has a material adverse effect on the performance of the other Party's obligations hereunder and in the case of a breach which is capable of remedy fails to remedy it within sixty (60) days of receipt of notice from the first Party of such breach and of its intention to exercise its rights under this Section; or
- (c) the entry of a decree or order for relief by a court having jurisdiction in the premises in respect of the other Party in an involuntary case under the United States Bankruptcy Code, as now constituted or hereafter amended, or any other applicable foreign, federal or state insolvency or other similar law and the continuance of any such decree or order unstayed and in effect for a period of sixty (60) consecutive days; or
- (d) the filing by the other Party of a petition for relief under the United States Bankruptcy Code, as now constituted or hereafter amended, or any other applicable foreign, federal or state insolvency law or other similar law; or
- (e) the other Party becomes insolvent or takes the benefit of any statute for insolvent debtors or any steps are taken or proceedings commenced by any person for the dissolution, winding-up or other termination of such other Party's existence or the liquidation of its assets; or

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- (f) a trustee, receiver, receiver-manager or like person is appointed with respect to the business or assets of the other Party; or
 - (g) the other Party proposes or makes any composition or arrangement or composition with, or any assignment for the benefit of, its creditors; or
 - (h) anything analogous to any of the events described in Sections 16.1(c)-(k) – 16.1.6, inclusive, occurs under the laws of any applicable jurisdiction; or
 - (i) the other Party ceases or threatens to cease to carry on the whole or any material part of its business; or
 - (j) for reasons unrelated to any breach of either Parties' duties or obligations under or in connection with this Agreement, the other Party is prevented from performing any of its material obligations hereunder by any law, governmental or other action (other than laws of general application) and has not resumed performance in compliance with all Applicable Laws within one hundred twenty (120) days following the date on which such performance was first provided; or
 - (k) in accordance with Section 18.2 below.

16.2 Prior Termination by PPI.

- (a) Reserved.
- (b) PPI may terminate this Agreement with immediate effect in any country of the Territory where EKR is obligated to launch the Product pursuant to Section 4.5 if within [**] months of the receipt of the Marketing Authorization for such country, EKR has not made its first Commercial Launch of the Product in that country.
- (c) In the event PPI has terminated the Supply Agreement pursuant to Section 10.2 thereof and EKR or its designee is manufacturing Products pursuant to Section 11.5 of the Supply Agreement, PPI shall have the right to terminate such rights of manufacture and this Agreement upon thirty (30)

days prior, written notice to EKR only in the event Royalties and Additional Royalties paid hereunder in any one year period following the date of such termination are less than \$[**], unless the difference between \$[**] and the actual Royalties and Additional Royalties paid by EKR is paid to PPI within thirty (30) days of notice of such termination.

16.3 Prior Termination by EKR.

- (a) EKR may terminate this Agreement with immediate effect in any country of the Territory if the Products are withdrawn from the market in such country of the Territory as a result of regulatory action by FDA or other governmental entities or there are significant adverse reactions from use of the Products.
- (b) EKR may terminate this Agreement for convenience at any time upon [**] ([**]) days prior, written notice to PPI.

16.4 Effect of Termination. The termination or expiration of this Agreement shall not release either of the Parties from any liability which at the time of termination or expiry has already accrued to the other Party, nor affect in any way the survival of any other right, duty or obligation of the Parties which is expressly stated elsewhere in this Agreement to survive such termination or expiry.

17. Consequences of Termination

17.1 Upon termination of this Agreement for any reason except as set forth in Section 17.4 below (and, if applicable, in respect of that country in respect of which termination occurs):

- (a) the licenses and rights granted and appointments made under Sections 2.1, 2.2 and 2.3 shall terminate and EKR shall (and shall procure that its Affiliates, sub-distributors and sub-licensees shall) cease all activities licensed or appointed hereunder, subject to Sections 17.2 and 17.3;

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- (b) the following provisions of this Agreement shall continue in full force and effect: Article 1 (“Definitions”), Section 3.20(k), Section 3.20(l), Article 9 (“Representations and Warranties”), Article 10 (“Liability, Insurance and Indemnities”) (excluding Section 10.6 (“Insurance”)), Article 11 (“Confidentiality, Press Releases and Publications”), Article 13 (“Infringement of Third Party Rights”), Section 16.4 (“Effect of Termination”), Article 17 (“Consequences of Termination”), Article 18 (“Force Majeure”), Article 19 (“Notices”), Article 20 (“Assignment and Change of Control”) and Article 21 (“General Provisions”);
 - (c) EKR shall return to PPI all PPI IP in its possession;
 - (d) EKR shall assign to PPI free of charge any domain name registrations it has registered pursuant to Section 8.5; and
 - (e) Except in the event of termination of this Agreement by EKR pursuant to Section 16.1(a), EKR shall promptly transfer to PPI or its nominee, each and every Marketing Authorization (to the extent not held by PPI) relating to the Product, together with all communications with the relevant Regulatory Authorities, and all notes and record thereof.
- 17.2 Sale of Remaining Inventory. Where this Agreement has expired or has been terminated for any reason other than by PPI in accordance with Section 16.1 or EKR in accordance with Section 16.3(b), EKR and its Affiliates and sub-distributors and sales agents shall be entitled to continue to sell existing stocks of the Product in the Territory for a period of not longer than 12 months following the date of termination, provided that, EKR continues to make any Royalty payments due to PPI in respect of such sales in accordance with the provisions of this Agreement.
- 17.3 Other Rights upon Termination. In the event that this Agreement is terminated by PPI in accordance with Section 16.1 or EKR in accordance with Section 16.3(b), EKR and its Affiliates, sub-distributors and sub-licensees shall be entitled to continue to sell

existing stocks of the Product in the Territory for so long as PPI deems necessary to ensure that sale of the Product is not disrupted provided that EKR and its Affiliates shall cease such sale immediately upon notification from PPI and in any event EKR shall not so sell for a period of longer than three (3) months following the date of termination. Immediately upon notification from PPI, such post termination sales shall cease.

- 17.4 Other Remedies of EKR. Notwithstanding anything contained herein to the contrary, in the event that EKR is entitled to exercise its right to terminate this Agreement pursuant to Section 16.1(a), in addition to the right to terminate as provided therein and any other remedies EKR may have hereunder, PPI shall assist EKR in the transfer of the manufacture of the Products, including the Specifications from PPI to EKR or EKR's designee. In such event, the Royalty payments payable hereunder shall continue to be paid; provided, however, that all costs incurred by EKR in the transfer of manufacturing information from PPI and obtaining FDA approval of the manufacture of the Products by EKR or EKR's designee, and any other amounts due to EKR, shall be deducted from any royalties payable to PPI. In addition, PPI shall during the remainder of the Term and for a period of up to [**] ([**]) years thereafter continue to manufacture and supply the Product to EKR at cost without mark-up until such time that EKR can secure an FDA approved manufacturing facility for the Product. PPI shall provide such advice as necessary for EKR to arrange for an alternative manufacturer and shall provide EKR with access to all relevant PPI Know-How, and any other information necessary for EKR to transfer such manufacturing to an alternate manufacturer. In addition, (i) PPI shall transfer to EKR any Marketing Authorizations held by PPI and (ii) the Trademark license granted under Section 2.3 shall continue in effect following such termination on a perpetual basis and EKR shall be responsible for all costs associated with the maintenance of such Trademark.

17.5 EKR Step-In Rights.

- (a) During the Term, in the event EKR has the right to terminate this Agreement under Section 16.1(a) – (i) hereof (the “**Step-in Right Trigger Event**”), and EKR does not exercise its right to terminate this Agreement under such Section, EKR shall have the option to exercise step-in rights to manufacture the Product for the remainder of the Term (the “**Step-in Right**”) by providing PPI written notice of such election within ninety (90) days after the Step-in Right Trigger Event (or such longer period as mutually agreed by the Parties) (the “**Step-in Right Notice**”); provided that in the event such Step-in Right Trigger Event has been cured prior to EKR’s exercise of the Step-in Right, the Step-in Right shall terminate with respect to such Step-in Right Trigger Event. The Step-in Right Notice shall specify the date which EKR intends to exercise the rights associated with the Step-in Right.
- (b) In the event EKR exercises the Step-in Right, PPI shall, at EKR’s cost and expense, cooperate in the exercise of such rights and EKR shall reimburse PPI for the reasonable costs PPI incurs in assisting EKR in the exercise of such rights within thirty (30) days of EKR’s receipt of invoice.
- (c) The Step-in Right shall include, without limitation, and to the extent allowable under Applicable Law, PPI’s grant to EKR of such additional license rights, rights of access, rights of observation and rights of management, direction and control, in each case solely with respect to the manufacture and supply of Product and as reasonably necessary to enable and permit EKR (or EKR’s designee) to ensure that the supply of Product shall continue to be available to EKR under this Agreement and the Supply Agreement; provided that EKR in exercising the Step-in Right shall not (i) unreasonably interfere with PPI’s other activities at the facilities at which the Product is manufactured, tested, labeled, stored or

otherwise handled (“**Product Facilities**”) or (ii) require PPI to take any action or fail to take any action that does or could reasonably be expected to interfere with PPI’s other activities at the Product Facilities. The foregoing rights shall apply with respect to any Product Facility to the extent necessary for EKR to preserve and protect supply of the Product as contemplated by this Agreement and the Supply Agreement. For the avoidance of doubt, (i) upon termination of the Lease Term, PPI shall maintain responsibility and control over all other products manufactured by PPI and nothing in this Section 17.5 shall give EKR any rights to direct, manage or control the manufacture of such products (ii) PPI shall maintain responsibility and control over the facilities where Product is manufactured, tested, labeled, stored or otherwise handled and nothing in this Section 17.5 shall give EKR general oversight or control of the facilities where Product is manufactured, tested, labeled, stored or otherwise handled.

- (d) In the event EKR exercises the Step-in Right, EKR shall comply with all policies applicable to the facilities where Product is manufactured, tested, labeled, stored or otherwise handled and all Applicable Laws with respect to the manufacture of the Product.

18. **Force Majeure**

- 18.1 **Obligation to Perform**. Except for payment obligations which shall not be excused or affected by any Force Majeure, neither Party shall be entitled to terminate this Agreement or shall be liable to the other under this Agreement for loss or damages attributable to any Force Majeure, provided the Party affected shall give prompt notice thereof to the other Party. Subject to Section 18.2, the Party giving such notice shall be excused from such of its obligations hereunder for so long as it continues to be affected by Force Majeure.

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- 18.2 **Duration.** If such Force Majeure continues unabated for a period of at least ninety (90) days, the Parties will meet to discuss in good faith what actions to take or what modifications should be made to this Agreement as a consequence of such Force Majeure in order to alleviate its consequences on the affected Party. If the affected Party is prevented by reason of any circumstances referred to in this Section of this Agreement from performing any of its obligations hereunder for a continuous period of six (6) months the other Party may terminate this Agreement.
19. **Notices**
- 19.1 **Form.** Any notice or other document given under this Agreement shall be in writing in the English language and shall be given by hand or sent by U.S. prepaid first class registered or certified mail, return receipt requested, recognized national overnight courier service, or by fax transmission to the address of the receiving Party as set out in Section 19.3 below unless a different address or fax number has been notified to the other in writing for this purpose.
- 19.2 **Delivery.** Each such notice or document shall:
- (a) if sent by hand, be deemed to have been given when delivered at the relevant address;
 - (b) if sent by prepaid airmail, be deemed to have been given 7 days after posting; or
 - (c) if sent by fax transmission be deemed to have been given when transmitted provided that a confirmatory copy of such facsimile transmission shall have been sent by hand, U.S. prepaid first class registered or certified mail, return receipt requested, or recognized national overnight courier service within 24 hours of such transmission.

19.3 Notice of Parties. The address for services of notices and other documents on the Parties shall be:

To EKR

Address: 1545 Route 206 South
Third Floor
Bedminster, NJ 07921

Fax:

Attention: Chairman & CEO

With a copy to:

Lowenstein Sandler
65 Livingston Avenue
Roseland, New Jersey 07068

Fax: 973-597-6395

Attention: Michael J. Lerner

To PPI

Address: 10450 Science Center
Drive, San Diego,
California 92121 USA

Fax: 858 623 0376

Attention: President

With a copy to:

Wilmer Cutler Pickering Hale & Dorr LLP
1117 S California Avenue
Palo Alto, CA 94304 USA

Fax: 650-858-6100

Attention: Joseph K. Wyatt

20. **Assignment and Change of Control**

20.1 Assignment. Subject to Section 20.2, neither Party shall, nor shall it purport to, assign, license, transfer or change any of its rights or obligations under this Agreement without the prior written consent of the other, such consent not to be unreasonably withheld conditioned or delayed; provided, however, that except as provided in Section 20.4 either Party may assign its rights hereunder to an Affiliate or to any successor by merger, consolidation, sale of stock or other equity interests or the sale of substantially all of the assets of such Party without the consent of the other Party. For the avoidance of doubt, either Party may grant a security interest with respect to its rights under this Agreement in connection with a secured financing or similar transaction.

20.2 Sub-Distribution. EKR may appoint sub-distributors under this Agreement provided that EKR:

- (a) informs PPI of the identity of any Third Party sub-distributor (other than Affiliate companies) prior to the execution of any sub-distribution agreement;

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- (b) obtain a confidential nondisclosure agreement with the prospective Sub-Distributor in a form acceptable to PPI, which acceptance shall not be unreasonably withheld or delayed and containing terms at least as stringent as those terms included in Article 11 of this Agreement;
 - (c) deliver to the prospective Sub-Distributor a redacted copy of this Agreement (“**Redacted Agreement**”). Any sub-distribution agreement shall provide that such agreement is subject and subordinate to the rights of PPI under this Agreement; and
 - (d) provides PPI with a copy of written sub-distribution agreement as soon as reasonably practicable after the execution thereof by EKR.
- 20.3 **Responsibility of EKR.** Notwithstanding any such sub-distribution agreement, EKR shall remain primarily liable to PPI for its obligations hereunder, and for any act or omission of any sub-distributor.
- 20.4 **Change of Control.** Should there be a Change of Control of either Party resulting in the control of such Party by a Third Party which markets or sells a Competing Product in any part of the Territory, then the rights under this Agreement may not be assigned without the express consent of the other Party which consent shall not be unreasonably withheld. “**Change of Control**” shall mean (a) the sale, lease, exchange, license or disposition of all or substantially all of the Party’s assets in one transaction or series of related transactions or (b) a merger or consolidation with an unaffiliated Third Party as a result of which the holders of the Party’s issued and outstanding voting securities immediately before such transaction own or control less than a majority of the voting securities of the continuing or surviving entity immediately after such transaction. The issuance by either Party of securities in connection with any financing transaction or

public offering shall not be deemed a Change of Control under this Agreement. Notwithstanding the foregoing, for the purposes of Section 6.3(b)(iii): (i) references to a "Party" in the above definition of Change of Control shall be deemed to include PPI as well as any Affiliate of PPI and (ii) a Change of Control shall also include (in addition to any of the transactions described above in the definition of Change of Control), any sale of securities of PPI or its Affiliates directly by the holder (the "Holder") of such securities (other than to an Affiliate of such Holder) in which such sale results in a transfer of more than 50% of the outstanding voting stock of PPI or its Affiliates.

21. **General Provisions**

- 21.1 **Relationship of the Parties**. Nothing in this agreement is deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party shall incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein.
- 21.2 **Dispute Resolution**. If there is a disagreement between the PPI and EKR on the interpretation of this Agreement or any aspect of the performance by either Party of its obligations under this Agreement, the Parties shall resolve the dispute in accordance with the dispute resolution procedure set out in Schedule VIII.
- 21.3 **Cooperation**. Each of the Parties shall do execute and perform and shall procure to be done executed and performed all such further acts deeds documents and things as the other Party may reasonably require from time to time to give full effect to the terms of this Agreement.
- 21.4 **Expenses**. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this agreement.
- 21.5 **Entire Agreement**. This Agreement (together with the Transition Services and Inventory Purchase Agreement and the Supply Agreement) sets out the entire agreement and understanding between the Parties in respect of the subject matter hereof and thereof. This Agreement supersedes the Original Agreement and any heads of agreement which shall cease to have any further force or effect. It is agreed that:
- (a) no Party has entered into this Agreement in reliance upon any representation, warranty or undertaking of the other Party which is not expressly set out in this Agreement;

-
- (b) no Party shall have any remedy in respect of misrepresentation or untrue statement made by the other Party or for any breach of warranty which is not contained in this Agreement;
- (c) this Section shall not exclude any liability for, or remedy in respect of, fraudulent misrepresentation.
- 21.6 Amendment. No amendment, change or modification of any of the terms, provisions or conditions of this Agreement shall be valid unless it is in writing and signed by or on behalf of both Parties.
- 21.7 Waiver. Unless expressly agreed, no waiver of any term, provision or condition of this Agreement shall constitute a general waiver of any provisions of this Agreement, nor shall it affect any rights, obligations or liabilities under or pursuant to this Agreement which have already accrued up to the date of variation, and the rights and obligations of the Parties under or pursuant to this Agreement shall remain in full force and effect, except and only to the extent that they are so waived.
- 21.8 Unenforceability. If and to the extent that any provision of this Agreement is held to be illegal, void or unenforceable, such provision shall be given no effect and shall be deemed not to be included in this Agreement but without invalidating any of the remaining provisions of this Agreement.
- 21.9 Delay. No failure or delay by either Party in exercising any right or remedy provided by law under or pursuant to this Agreement shall impair such right or remedy or operate or be construed as a waiver or variation of it or preclude its exercise at any subsequent time and no single or partial exercise of any such right or remedy shall preclude any other or further exercise of it or the exercise of any other right or remedy.

-
- 21.10 Cumulative Rights. The rights and remedies of each of the Parties under or pursuant to this Agreement are cumulative, may be exercised as often as such Party considers appropriate and are in addition to its rights and remedies under general law.
- 21.11 Counterparts. This Agreement may be executed in any number of counterparts and by the Parties on separate counterparts, each of which is an original but all of which together constitute one and the same instrument.
- 21.12 Reserved.
- 21.13 Governing Law. This Agreement and the relationship between the Parties shall be governed by, and interpreted in accordance with New York law without regard to provisions related to conflicts of laws, and, except as provided in Section 21.2 above, the Parties agree to submit any dispute to the exclusive jurisdiction of the federal and state courts sitting in New York.
- 21.14 Successors and Assigns. Subject to Section 20.1, this Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective successors and assigns permitted under this Agreement.
- 21.15 Systems. Immediately upon the Effective Date, or as soon thereafter as practicable, the Parties shall implement a mutually acceptable operation plan to transfer the processing of chargebacks, federal releases, state releases and customer services from PPI to EKR.

(signature page follows)

AS WITNESS the hands of the Parties or their duly authorized representatives effective as of the Effective Date.

SIGNED for and by behalf of)
PACIRA PHARMACEUTICALS, INC.)

By: /s/ David Stack _____

David Stack _____
Print Name

SIGNED for and by behalf of)
EKR THERAPEUTICS, INC.)

By: /s/ Richard DeSimone _____

Richard DeSimone, CFO _____
Print Name

SCHEDULE I

PATENTS

Attorneys' Ref.	Country	Application date	Application no.	Patent/ Publication no.	Grant date	Expiry date	Status
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***

Attorneys' Ref.	Country	Application date	Application no.	Patent/ Publication no.	Grant date	Expiry date	Status
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***

Attorneys' Ref.	Country	Application date	Application no.	Patent/ Publication no.	Grant date	Expiry date	Status
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***

Attorneys' Ref.	Country	Application date	Application no.	Patent/ Publication no.	Grant date	Expiry date	Status
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***

Attorneys' Ref.	Country	Application date	Application no.	Patent/ Publication no.	Grant date	Expiry date	Status
***	***	***	***	***		***	***
***	***	***	***	***	***	***	***

* Publication date of Application – 13 Apr 06.

Attorneys' Ref.	Country	Application date	Application no.	Patent/ Publication no.	Grant date	Expiry date	Status
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***

**SCHEDULE II
TRADEMARKS**

File Date: [**]
Serial No.:
International Class:
First Use:
First Use in Commerce:
Registration Date:
Registration No.:
Mark:

File Date: [**]
Serial No.:
International Class:
First Use:
First Use in Commerce:
Registration Date:
Registration No.:
Mark:

File Date: [**]
Serial No.:
International Class:
First Use:
First Use in Commerce:
Registration Date:
Registration No.:
Mark:

***[**] Trademark Application**

File Date: [**]
Serial No.:
International Class:
Mark:

[**] – Owner of Record, United States Patent Trademark Office website. Record of Assignment from [**]. to [**] is in process.

SCHEDULE III

COPYRIGHTS

There are no recorded copyrights

SCHEDULE IV
DOMAIN NAMES

DepoDur.com

SCHEDULE V

MARKETING AUTHORIZATIONS

United States Food and Drug Administration New Drug Application: []**



SCHEDULE VI

PRESS RELEASE

News Release

**EKR Therapeutics Achieves Key Growth Milestone with the
Acquisition of Rights to DepoDur®, a Novel Extended-Release Opioid
Analgesic for Post Operative Pain**

Cedar Knolls, N.J., August X, 2007 – EKR Therapeutics, Inc., a specialty pharmaceutical company focused on acquiring, developing, and commercializing proprietary products to enhance patient quality-of-life in the acute care setting, today announced it has acquired exclusive marketing and distribution rights to DepoDur® for the Americas from San Diego-based Pacira Pharmaceuticals who retains manufacturing rights to the product.

Formerly a business unit of SkyePharma, plc, Pacira Pharmaceuticals is an independent private company focused on developing and manufacturing controlled-release injectable products based on their DepoFoam™ and Biosphere™ drug delivery platforms.

DepoDur, which utilizes the DepoFoam technology, is a sterile injectable suspension of multivesicular liposomes formulated to provide extended release of morphine sulfate. It is the only extended-release opioid that is approved by the Food and Drug Administration for epidural use. A single injection of DepoDur into the lumbar epidural space may provide pain relief for up to 48 hours following major surgery without the restrictions and potential complications associated with an indwelling epidural catheter.

“The product characteristics of DepoDur fit exceptionally well with EKR’s acquisition model,” said Howard Weisman, EKR’s Chairman & CEO. “DepoDur is patent protected, addresses an important medical need in our market space, and has growth prospects that can be fully exploited through the application of EKR’s expertise and strengths in the acute care market.”

Mr. Weisman further noted, “EKR is commencing a number of pre-launch activities, including interacting with opinion leaders, and we expect to fully deploy our sales force in support of DepoDur early next year.” He concluded, “We are very optimistic about EKR’s growth prospects in 2008 as we foresee a ramp up in sales for both DepoDur and Gelclair® and anticipate favorable market synergies between these products.” Gelclair, which is marketed to acute care facilities and cancer centers, is indicated for the management of pain associated with oral lesions of various etiologies, including chemotherapy and radiation induced oral mucositis/stomatitis.

Tong Zhang, Ph.D., Director of Business Development for EKR, added, “Acquiring the rights to DepoDur exemplifies EKR’s strategy of focusing on building a portfolio of premier products in the acute care space.” He further noted, “Our strict acquisition criteria center on high-margin, innovative products that offer value to healthcare providers and their patients, thus, representing excellent opportunities for EKR to realize strong returns on investment.”

“Pacira Pharmaceuticals is delighted to have EKR Therapeutics as our marketing and commercialization partner for DepoDur in the Americas,” commented Fred Middleton, Pacira’s Chairman of the Board. “This product was clinically developed as a proprietary treatment by Pacira R&D and it received FDA approval in 2004 for long-acting post surgical pain management, for which it is known to be effective.”

Mr. Middleton further noted, “EKR Therapeutics has demonstrated in the past that they possess the strengths to successfully bringing a focused marketing and clinician targeting approach to DepoDur to help it reach its full commercial potential. We look forward to working with EKR, as our partner on the expanded commercial marketing of DepoDur.”

Detailed terms of the transaction were not disclosed. However, EKR did note that in addition to royalty payments on net sales, it has agreed to an upfront payment amounting to somewhat more than [**] times DepoDur’s 2006 U.S. sales. EKR has also agreed to certain milestone payments with the sum of upfront and milestone payments potentially worth up to \$20 million.

About EKR Therapeutics

EKR Therapeutics is a privately held specialty pharmaceutical company that has brought together a highly seasoned team of industry professionals. The Company focuses on the acquisition, development and commercialization of proprietary products for the acute care segment of the healthcare market, including oncology supportive care therapeutics. From its inception in late 2005, EKR has been organized to be a class leader in commercializing products to address unmet and under-satisfied medical needs or to otherwise enhance the therapeutic value of acute-care prescription products. EKR’s goal is to be the pre-eminent provider of acute-care specialty products, backed by a commitment to excellence in customer service. For additional information about EKR visit the Company’s website at <http://www.ekrtx.com>.

About Pacira Pharmaceuticals, Inc.

Pacira Pharmaceuticals, Inc. is a wholly owned subsidiary of Pacira Inc., a Delaware corporation, which is controlled and funded by a group of financial investors including Sanderling Ventures, HBM Bioventures (Cayman) Ltd, OrbiMed Advisors, and MPM Capital. This business is based in San Diego, CA, and focuses on formulating, developing and manufacturing controlled-release injectable products based on two proprietary drug delivery platforms: DepoFoam™ and Biosphere™. Revenues are generated from two marketed products: DepoCyt® for lymphomatous meningitis and DepoDur® for the treatment of post-surgical pain. For additional information about Pacira visit the Company’s website at <http://www.pacira.com>

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Contact for EKR Therapeutics

Stuart Z. Levine, Ph.D.
Corporate Communications
877-435-2524
s.levine@ekrtx.com

SCHEDULE VII

THE TERRITORY

all countries in North America including the United States, its territories as possessions including Puerto Rico, South America and Central America

SCHEDULE VIII

DISPUTE RESOLUTION

- 1.1 Representatives of the Parties will, within 14 days of receipt of a written request from either Party to the other, convene a meeting of the Committee to discuss in good faith and try to resolve the disagreement without recourse to legal proceedings.
- 1.2 If resolution does not occur within 7 days after meeting, the matter shall be escalated for determination by the respective Chief Executive Officer of the Parties who may resolve the matter themselves or jointly appoint a mediator or independent expert to do so.
- 1.3 Nothing in this Agreement restricts either Party's freedom to seek urgent relief to preserve a legal right or remedy, or to protect a proprietary, trade secret or other right.

Appointment of an Expert

- 1.4.1 In the event that the Chief Executive Officers are unable to resolve the dispute and the dispute has a monetary value of cost of [**] dollars (\$[**]) or more, the dispute shall be submitted to the federal or state courts located in the State of California, which shall have exclusive jurisdiction over such dispute.
- 1.4.2 In the event that the Chief Executive Officers are unable to resolve the dispute and the dispute has a monetary value of cost of less than [**] dollars (\$[**]), and the Parties do not agree on the appointment of an expert to resolve the dispute, or mediation has failed to resolve the dispute, one Party shall serve on the other a written Referral Notice requesting that the matter be referred to an expert for resolution, and the following procedure shall be followed.
 - 1.4.1 The dispute shall be determined by a single independent impartial expert who shall be agreed between the Parties or, in the absence of agreement between the Parties within 30 days of the service of a Referral Notice, be appointed by the American Arbitration Association or any successor thereto, or such other competent body agreed by the Parties.
 - 1.4.2 30 days after the appointment of the expert pursuant to paragraph 1.4.1 both Parties shall exchange simultaneously statements of case in no more than 10,000 words, in total, and each side shall simultaneously send a copy of its statement of case to the expert.
 - 1.4.3 Each Party may, within 30 days of the date of exchange of statement of case pursuant to paragraph 1.4.2, serve a reply to the other side's statement of case in no more than 10,000 words. A copy of any such reply shall be simultaneously sent to the expert.
 - 1.4.4 Subject to paragraph 1.4.6, there shall be no oral hearing. The expert shall issue his decision in writing to both Parties within 30 days of the date of service of the last reply pursuant to paragraph 1.4.3 above or, in the absence of receipt of any replies, within 60 days of the date of exchange pursuant to paragraph 1.4.2.

-
- 1.4.5 The seat of the dispute resolution shall be the normal place of residence of the expert.
- 1.4.6 The expert shall not have power to alter, amend or add to the provisions of this Agreement, except that the expert shall have the power to decide all procedural matters relating to the dispute, and may call for a one day hearing if desirable and appropriate.
- 1.4.7 The expert shall have the power to request copies of any documents in the possession and/or control of the Parties which may be relevant to the dispute. The Parties shall forthwith provide to the expert and the other Party copies of any documents so requested by the expert.
- 1.4.8 The decision of the expert shall be final and binding upon both Parties except in the case of manifest error. The Parties hereby exclude any rights of application or appeal to any court, to the extent that they may validly so agree, and in particular in connection with any question of law arising in the course of the reference out of the award.
- 1.4.9 The expert shall determine the proportions in which the Parties shall pay the costs of the expert's procedure. The expert shall have the authority to order that all or a part of the legal or other costs of a Party shall be paid by the other Party.
- 1.4.10 All documents and information disclosed in the course of the expert proceedings and the decision and award of the expert shall be kept strictly confidential by the recipient and shall not be used by the recipient for any purpose except for the purposes of the proceedings and/or the enforcement of the expert's decision and award.

SCHEDULE IX
SALES FORECAST



Date: July 25, 2007
From: [**], EKR Therapeutics, Inc.
To: [**], Pacira
Re: DepoDur Unit Sales Forecast, as of July 25, 2007

While we continue to work on our marketing plan and forecast, based on the current run rate of approximately [**] to [**] units per month, you can expect that our plan will call for the following forecast:

<u>Period</u>	<u>Unit Sales Forecast</u>
August 1 – December 31, 2007	[**]
January 1 – December 31, 2008	[**]
January 1 – December 31, 2009	[**]

SCHEDULE X

PHASE IV STUDIES

A DepoDur study in pediatric patients. Pacira has requested a waiver and is awaiting a response from the FDA

SCHEDULE XI
NDA TRANSFER LETTERS

A. Transfer Letter to be Filed by PPI

[PACIRA PHARMACEUTICALS, INC. LETTERHEAD]

_, 2009

VIA OVERNIGHT MAIL

[NAME AND ADDRESS OF APPROPRIATE FDA CONTACT TO BE PROVIDED]

Re: **DepoDur® NDA [**]**
General Correspondence: Transfer of NDA Ownership

Dear _:

Effective _, 2009, pursuant to 21 CFR 314.72, DepoDur® NDA [**] is hereby transferred from Pacira Pharmaceuticals, Inc. to EKR Therapeutics, Inc., 1545 Route 206 South, Third Floor, Bedminster, New Jersey 07921 (Regulatory Contact: _, telephone _).

As a condition of this transfer of ownership, Pacira will provide to EKR Therapeutics all available information pertaining to the above-referenced NDA to be kept under 21 CFR 314.70, including all previous correspondence to and from the Agency. A signed 356h form is attached

If you have any questions or require any additional information, please do not hesitate to contact me at _.

Sincerely,

PACIRA PHARMACEUTICALS, INC.

B. Transfer Letter to be Filed by EKR

[EKR THERAPEUTICS, INC. LETTERHEAD]

_, 2009

VIA OVERNIGHT MAIL

[NAME AND ADDRESS OF APPROPRIATE FDA CONTACT TO BE PROVIDED]

RE: NDA No. []
DepoDur®
General Correspondence: Transfer of NDA Ownership**

Dear _:

Pursuant to 21 CFR 314.72 the above-mentioned NDA has been transferred from Pacira Pharmaceuticals, Inc. to EKR Therapeutics, Inc. effective _, 2009. EKR has received a complete copy of the approved application, including all supplements and records that are required to be kept under 21 CFR 314.81. EKR agrees to abide by all agreements, promises and conditions made by the former owner, which are contained in the application. EKR will advise the FDA about any changes in the conditions in the approved application as required by 21 CFR 314.70, or in the next annual report, if appropriate. EKR will consider the date of transfer to be the new date for annual reporting purposes. A new signed 356h form is attached.

Please contact me by phone at _, by email at _ or by fax at _, if you have any questions or if you require additional information.

Sincerely,

[Name / Title]

SCHEDULE XII
TRANSFERRED EQUIPMENT

DepoDur processing equipment:

1. ST-01 ([**], [**] rated to [**], equipped with agitator used in preparation of [**] prior to [**])
2. ST-02 ([**], [**] rated to [**], equipped with agitator used in preparation of [**] [**] prior to [**])
3. ST-03 ([**], [**] rated to [**], equipped with agitator used in preparation of [**] prior to [**])
4. ST-04 ([**], [**] rated to [**], equipped with agitator used in preparation of [**] [**] prior to [**])
5. ST-22 ([**], [**] rated to [**], [**])
6. EV-01 ([**], [**] rated to [**], equipped with [**] used to produce [**] [**])
7. EV-02 ([**], [**] rated to [**], equipped with [**] and [**] [**] used to produce [**])
8. FV-01 ([**], [**] rated to [**], used [**] during [**])
9. [**] skid, including [**] lobe pumps, [**] manifold system, and [**] flometers
10. Interconnective valves and piping between vessels
11. Pressure gauges, temperature probes, other small instrumentation for in-process measurements.
12. HMI / PLC / automation

Exhibit 3.20(a)
Form of Bill of Sale

BILL OF SALE

THIS BILL OF SALE, dated October 2, 2009 (this "**Bill of Sale**"), is made by Pacira Pharmaceuticals, Inc. ("**Seller**"), in favor of EKR Therapeutics, Inc. ("**Purchaser**").

WHEREAS, Purchaser and Seller have entered into that certain Amended and Restated Strategic Licensing, Distribution and Marketing Agreement, dated as of the date hereof (the "**Agreement**"), providing, among other things, for the sale of the Transferred Equipment (as defined therein) by Seller to Purchaser.

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, Seller and Purchaser agree as follows:

1. Definitions. Capitalized terms used in this Bill of Sale and not otherwise defined in this Bill of Sale shall have the respective meanings assigned to them in the Agreement.

2. Conveyance. In accordance with the terms of the Agreement, Seller hereby sells, transfers, conveys and assigns to Purchaser all right, title and interest in and to the Transferred Equipment. A list of the Transferred Equipment is set forth on **Schedule A** to this Bill of Sale.

3. Further Assurances. At any time and from time to time after the date of this Bill of Sale, Seller, at the Purchaser's request and subject to reimbursement by Purchaser of any out-of-pocket expenses, will do, execute, acknowledge and deliver, or will cause to be done, executed, acknowledged and delivered, any and all further acts, conveyances, transfers, assignments and assurances as may be reasonably required by Purchaser to further evidence and effectuate the sale, transfer, conveyance and assignment to the Purchaser of the Transferred Equipment.

4. Relationship With Agreement. The provisions of this Bill of Sale are subject, in all respects, to the terms and conditions of the Agreement and all of the representations, warranties, covenants and agreements contained in the Agreement. Nothing contained in this Bill of Sale shall be deemed to modify, limit or amend any such rights and obligations of the parties hereto under the Agreement. In the event of any conflict or inconsistency between this Bill of Sale and the Agreement, the Agreement shall govern.

5. Successors and Assigns. This Bill of Sale shall be binding upon and inure to the benefit of and be enforceable by Seller and Purchaser and their respective successors and assigns.

6. Governing Law. This Bill of Sale shall be governed by, and construed in accordance with, the laws of the State of New York, without regard to the conflicts of law principles thereof.

7. Counterparts; Facsimile Signature Pages. This Bill of Sale may be executed by each of Seller and Purchaser in separate counterparts, each of which when so executed and delivered shall be deemed to be an original and which together shall constitute one and the same instrument. Any signed counterpart of this Bill of Sale which is delivered by facsimile or other printable electronic transmission shall be deemed to be executed and delivered for all purposes.

[Signature Page Follows]

IN WITNESS WHEREOF, Seller has executed and delivered this Bill of Sale on the date first above written.

Pacira Pharmaceuticals, Inc.

By: _____

Print Name: _____

Title: _____

Acknowledged and Agreed to as
of the date first above written.

EKR Therapeutics, Inc.

By: _____

Print Name: _____

Title: _____

**Schedule A to Bill of Sale
Transferred Equipment**

DepoDur processing equipment:

1. ST-01 ([**], [**] rated to [**], equipped with agitator used in preparation of [**] prior to [**])
2. ST-02 ([**], [**] rated to [**], equipped with agitator used in preparation of [**] [**] prior to [**])
3. ST-03 ([**], [**] rated to [**], equipped with agitator used in preparation of [**] prior to [**])
4. ST-04 ([**], [**] rated to [**], equipped with agitator used in preparation of [**] [**] prior to [**])
5. ST-22 ([**] [**], [**] rated to [**], [**] [**])
6. EV-01 ([**], [**] rated to [**], equipped with [**] used to produce [**] [**])
7. EV-02 ([**], [**] rated to [**], equipped with [**] and [**] [**] used to produce [**])
8. FV-01 ([**], [**] rated to [**], used [**] during [**])
9. [**] skid, including [**] lobe pumps, [**] manifold system, and [**] flometers
10. Interconnective valves and piping between vessels
11. Pressure gauges, temperature probes, other small instrumentation for in-process measurements.
12. HMI / PLC / automation

Exhibit 3.20(b)
Form of Promissory Note

PROMISSORY NOTE

\$900,000

October __, 2009

FOR VALUE RECEIVED, EKR Therapeutics, Inc. (“**Maker**”), having an address at 1545 Route 206 South, Third Floor, Bedminster, New Jersey 07921, hereby promises to pay to Pacira Pharmaceuticals, Inc. (“**Payee**”), having an address at 10450 Sciences Center Drive, San Diego, California 92121, the principal sum of NINE HUNDRED THOUSAND DOLLARS (\$900,000.00), plus interest computed at the rate of FIVE PERCENT (5%) per annum, in accordance with the terms and conditions set forth in this Promissory Note (this “**Note**”).

1. **Payments.** On the fifth anniversary of the date of this Note, all principal and interest (calculated according to Paragraph 3 below) accrued on this Note and not sooner paid in accordance with the terms hereof shall be payable in full (the “**Payment**”).

2. **Place of Payment.** The entire amount due hereunder shall be payable to Payee at the address set forth above, or at such other place as Payee may designate in writing to Maker at the address set forth above.

3. **Interest Calculation:** Interest shall be calculated on the basis of a 360 day year based on the number of days elapsed.

4. **Optional Prepayment.** Maker may, at its option, prepay the entire amount due hereunder in whole at any time or in part from time to time without penalty or premium. At the option of Maker, prepayments pursuant to this Paragraph 4 shall (a) be applied to the outstanding principal balance in reverse order of maturity or (b) reduce the Payment installments set forth above for the balance of the term of this Note. In the event that Maker elects to reduce the Payment installments, Maker agrees to provide to Payee written notice of its election to do so at least thirty (30) days prior to making any prepayment and to execute and deliver to Payee an amendment to this Note setting forth a revised payment schedule.

5. **Defaults.** At the option of Payee, the entire amount due hereunder shall immediately become due and payable on any of the following events of default:

(a) Maker fails to make Payment as provided for in this Note and such failure to make Payment continues for thirty (30) days after Maker’s receipt of written notice from Payee that such Payment is due;

(b) Maker makes a general assignment for the benefit of creditors;

(c) A receiver is appointed for the assets of Maker upon request by any Person(s) other than Maker, or Maker makes a formal request for appointment of a receiver; or

(d) Any proceeding is brought by Maker in any court or under supervision of any court-appointed officer under any federal or state bankruptcy, reorganization, rearrangement, insolvency or debt readjustment law, or if any such proceedings are instituted against Maker and Maker fails to obtain dismissal of such proceeding within ninety (90) days after the same has been instituted.

6. Agreement. This Note is made pursuant to that certain Amended and Restated Strategic Licensing, Distribution and Marketing Agreement dated as of October 1, 2009 by and between Maker and Payee (the "**Agreement**") and is subject to the terms thereof. This Note is subject to offset as expressly provided for in the Agreement.

7. Nonnegotiability, Nontransferability. This Note shall be nonnegotiable. Further, this Note may not be transferred by either party except to a permitted transferee under the Agreement.

8. Governing Law. This Note shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflict-of-laws rule or principle that may refer the governance, construction or interpretation of this Note to the laws of another State.

IN WITNESS WHEREOF, the Maker has executed this promissory note as of _____.

, Maker