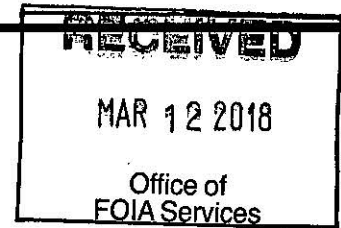


18-03130-E

Madison, Wilton

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Sunday, March 11, 2018 11:43 AM
To: foiapa
Subject: FOIA Request



I would like to request access to Exhibit 10.3 to the Form S-1 and amendments thereto, filed by Ventrus Biosciences, Inc. on 7/20/2010. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to \$61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397



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

Office of FOIA Services

April 25, 2018

Mr. Mark G. Edwards
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-03130-E

Dear Mr. Edwards:

This letter is in response to your request, dated March 11, 2018 and received in this office on March 12, 2018, for Exhibit 10.3 to the Form S-1 and amendments thereto, filed by Ventrus Biosciences, Inc., on July 20, 2010.

The search for responsive records has resulted in the retrieval of 47 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at johnsonee@sec.gov or (202) 551-8350. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Aaron Taylor at (202) 551-7900 as a FOIA Public Liaison for this office, or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

For 

Everene Johnson
FOIA Research Specialist

Enclosure

10.3

Portions of this exhibit marked []
are requested to be treated confidentially.

EXECUTION COPY

LICENSE AGREEMENT

THIS LICENSE AGREEMENT is entered into as of the 10th day of March, 2008 (the "Effective Date") between and among **SAM AMER & CO, INC.**, a California company, having its principal place of business at P.O. Box 5685, Montecito, CA 93150 ("**Sam Amer**"), **VENTRUS BIOSCIENCES, INC.**, a Delaware corporation, having a place of business at 8400 E Crescent Pkwy, Suite 600, Greenwood Village, CO 80111 ("**Licensee**") and Paramount BioSciences, a New York limited liability company, having a place of business at 787 Seventh Avenue, 48th Floor, New York, NY 10019 ("**Guarantor**"). Sam Amer and Licensee may be referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

Sam Amer owns or controls the rights to a patented, proprietary drug product, more particularly described hereafter as "**Iferanserin**";

Licensee desires to exclusively license certain rights to utilize Iferanserin to deliver a rectal ointment compound for the treatment of hemorrhoids in humans, and Sam Amer desires to grant such license pursuant to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the premises and covenants hereafter recited, the Parties, intending to be legally bound, agree as follows:

1. DEFINITIONS. As used in this Agreement, each of the following terms shall have the meanings as set forth below:

"**Acceptable FDA Response**" means that, after submission of a request for an SPA by Licensee, the final protocol accepted by FDA is within 150% (One Hundred Fifty Percent) of the expected study protocol cost set forth in the initially submitted SPA to FDA. For clarification purposes, to establish the expected study protocol cost, Ventrus will select a Clinical Research Organization (CRO) using JDC (as defined below) input for a quote on the Phase III trial(s) and based on the initially submitted SPA protocol. Once the final FDA accepted protocol is received, it shall be submitted to the same CRO for a follow-up quote. As long as that quote is less than 150% (One Hundred Fifty Percent) of the original quote, the FDA response shall be considered acceptable and the Phase III trial(s) shall proceed.

"**Affiliate**" means, with respect to a Party, any Person that, directly or indirectly, whether through one or more intermediaries, controls, is controlled by, or is under common control with such Party, where "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management or the policies of a Person, whether through ownership of voting securities or by agreement or otherwise, but only for so long as such Person meets these requirements.

"**Agreement**" means this Agreement, schedules, exhibits and/or attachments to this Agreement.

"**Applicable Authority**" means any governmental authority, agency or other governmental body of a country in the Territory responsible for administering Applicable Laws relating to the Licensed Product in the Field of Use. An example, and not in limitation of the foregoing, is the FDA in the United States.

"**Applicable Laws**" means all federal, state, and local laws, rules and regulations of a country in the Territory applicable to (i) the development, Commercialization, manufacture, sale, use, marketing, distribution and importation of the Licensed Products (including without limitation the United States Food, Drug and Cosmetics Act and all applicable rules and regulations of the FDA related thereto), or (ii) the performance of either Party's obligations under this Agreement.

"**Calendar Quarter**" means each calendar quarter ending on March 31, June 30, September 30, or December 31.

"Calendar Year" means the twelve-month period ending on December 31.

"Commercialization" (and its correlative term, "Commercialize") shall have the meaning set forth in Section 4.1.

"Commercial Launch" means the First Commercial Sale of such Licensed Product.

"Commercially Reasonable Efforts" means such efforts which are commensurate with the efforts that, applying customary pharmaceutical company practice, a pharmaceutical company of equivalent capitalization would expend or has expended with respect to a product at a similar stage taking into account its safety and efficacy, the cost to develop and commercialize the product, the establishment of the product in the marketplace, the competitiveness of the marketplace, the patent and other proprietary position of the product, the regulatory structure involved and likelihood of obtaining Regulatory Approval, the profitability of the product and all other relevant factors. These efforts shall be made irrespective of the product's position in Licensee's product or pipeline portfolio.

"Confidential Information" means, with respect to each Party, any non-public proprietary data or information which belongs in whole or in part to such Party and/or information designated as Confidential Information of such Party hereunder.

"Development Costs" means the costs incurred in development of the Licensed Product(s).

"Data" shall mean any and all results, studies and information, including test results (including but not limited to pre-clinical and patient tests), and developmental, manufacturing and pharmaceutical information, whether or not proprietary, and any related technical data or operating information with respect to any of the foregoing, generated by or resulting or derived from the efforts or obligations of either Sam Amer or Licensee as set forth herein and as solely and directly related to Ifersanserin. Licensee will provide Data to Sam Amer upon request and no more than two (2) times per calendar year and all such Data shall be deemed to be Confidential Information.

"Ex-U.S. Gross Sales" means invoiced sales to or by Third Parties outside the United States ("ex-U.S."), as to which Licensee or its Third Party Sublicensee has received payment, for each applicable period.

"Effective Date" means with respect to the Licensed Product, the date as set forth in the Preamble.

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

"Field of Use" means the field consisting of the topical treatment of any anorectal disorders in humans.

"First Commercial Sale" means the first sale of a Licensed Product by or on behalf of Licensee to a Third Party in the United States or any other country in the Territory after such Licensed Product has been granted Regulatory Approval (including marketing authorization). First Commercial Sale shall not include any sales or other distribution for use in clinical trials.

"GAAP" means United States Generally Accepted Accounting Principles, applied consistently with past practices.

"Ifersanserin" means the serotonin (5-HT₂) receptor antagonist S-MPEC (ifersanserin (INN) = (E)-2'-{2-[(2S)-1-methyl-2-piperidyl]ethyl}cinnamanilide serotonin receptor antagonist C₂₃H₂₈N₂O, CAS 58754-46-4). The definition includes all its various chemical forms, including derivatives acids, bases, esters, salts, isomers, enantiomers, pro-drug forms, metabolites, hydrates, solvates, polymorphs and degradants thereof in crystal, powder or other form and improvements, including new formulations and combinations and in addition, any back-up compounds to be provided by Sam Amer.

"Improvements" means any improvement, modification, or variation of the inventions, methods, apparatuses, or technology (each whether patentable or not) claimed or described in the Sam Amer Patents, and relating to Iferanserin including all patent applications and patents resulting there from.

"Intellectual Property Rights" means all intellectual property rights throughout the world, whether existing now or in the future, including without limitation: (a) all patent rights and other rights in inventions and ornamental designs; (b) all copyrights and other rights in works of authorship, software, mask works, databases, compilations, and collections of information; (c) all rights in trademarks, service marks, and other proprietary trade designations; and (d) all rights in know-how and trade secrets.

"Joint Commercialization Committee" or "JCC" shall have the meaning set forth in **Section 4.2.1**.

"Joint Development Committee" or "JDC" shall have the meaning set forth in **Section 3.2.1**.

"Know-How" means with respect to Iferanserin, any and all Sam Amer Improvements, technical information, know-how, processes, procedures, devices, methods, protocols, techniques, designs, drawings, algorithms, schematics, trade secrets, technical information and specifications owned or controlled by Sam Amer (not including Licensee Improvements), relating to and embodying Sam Amer's experience in the manufacture, processing, formulation and quality control for the Iferanserin, together with any additions, alterations, modifications, Sam Amer Improvements, design changes or other improvements thereto created by or for Sam Amer or licensed to Sam Amer, whether or not patentable. Without limiting the foregoing, the Sam Amer Know-How shall include the technical information in all current patent applications, manuals, formulae, batch records, specifications, test data and procedures, methods, processes, apparatus plans, drawings and designs owned or controlled by Sam Amer to Licensee during the term of this Agreement, whether contained in documentary form or electronic media, communicated orally, or by giving access to facilities at which the Sam Amer Know-How is practiced; provided, however that the Sam Amer Know-How shall not include any information of Third Parties which is subject to confidentiality or non-disclosure obligations between Sam Amer and such Third Parties.

"Know-How License" shall mean the Licensed Know-How and Intellectual Property Rights embodied therein.

"Knowledge" means the actual knowledge of the management personnel of a Party.

"Licensee Intellectual Property" means any Patent or technology or Improvement discovered or reduced to practice by Licensee that embody inventions arising under this Agreement invented solely by Licensee that would be infringed by an unlicensed Third Party's manufacture, use, sale, importation, development or commercialization of a Licensed Product.

"Licensed Know-How" means the Sam Amer Know-How.

"Licensed Patents" means the Sam Amer Patents, together with all Patents resulting from the Sam Amer Improvements.

"Licensed Product(s)" means collectively, (i) a product containing Iferanserin as an active ingredient, and (ii) any additional licensed products as agreed to by the Parties from time to time.

"License Fees" shall have the meaning set forth in **Section 6.1**.

"Net Sales" means, with respect to sales of Licensed Products by Licensee or a Third Party Sublicensee within the United States, the gross sales to Third Parties ("Gross Sales"), less only the following documented expenses (such deductible expenses referred to herein as **"Permitted Deductions"**):

- (i) credits or allowances actually granted for damaged products, returns or rejections of product;

- (ii) governmental and other rebates (or equivalents thereof, including chargebacks) granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), federal, state/provincial, local and other governments, their agencies and purchasers and reimbursers;
- (iii) normal and customary trade, cash and quantity discounts, allowances and credits actually allowed or paid;
- (iv) chargebacks;
- (v) discounts, allowances, and credits actually allowed or paid for wholesaler fee for service agreements or inventory management agreements;
- (vi) transportation costs, including insurance, for outbound freight related to delivery of the product to the extent included in the gross amount invoiced;
- (vii) monies actually paid for product liability insurance specific to Iferserin; and
- (viii) Cost of goods sold, which shall mean the direct, incremental costs incurred by Licensee in manufacturing or purchasing Licensed Products, sales taxes, VAT taxes and other taxes directly linked to the sales of products to the extent included in the gross amount invoiced.

Rebate reductions (item (ii) above) to Gross Sales shall not exceed twenty percent (20%) of Gross Sales. The maximum total reduction to Net Sales from all items listed above shall not exceed thirty percent (30%) of Gross Sales.

Permitted Deductions shall not include any development, research, formulation, marketing, or promotional expenses expended by Licensee. The Permitted Deductions shall be verified by reference to the books and records of Licensee maintained in accordance with GAAP. Net Sales shall not include sales between or among Licensee and Licensee Affiliates. Licensed Products shall be deemed sold when accounted for as a sale in the books and records of Licensee in accordance with GAAP.

If Permitted Deductions for a calendar quarter (a **"Prior Quarter"**) are not known to Licensee or its Third Party Sublicensee until the next calendar quarter (a **"Subsequent Quarter"**), then Licensee or its Third Party Sublicensee may credit the amount of Permitted Deductions for the Prior Quarter against Net Sales computed for purposes of determining the royalties due to Licensor in the Subsequent Quarter.

"Patent(s)" means any and all (a) U.S. or foreign patents, (b) U.S. or foreign patent applications, including, without limitation, all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, and all patents granted thereon, (c) all U.S. or foreign patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including, without limitation, supplementary protection certificates or the equivalent thereof, and (d) any other form of government-issued right substantially similar to any of the foregoing.

"Patent License" shall mean the Licensed Patents and the Intellectual Property Rights embodied therein.

"Permitted Deductions" shall have the meaning set forth in the definition of Net Sales.

"Person" means any individual, corporation, partnership, firm, limited liability company, trust, or other organization or entity.

"Product License(s)" shall have the meaning set forth in **Section 2.1** below.

"Reduced Royalty Period" shall mean, with respect to any particular Licensed Product in any particular country in the Territory, the period of time beginning on the date of expiration of the last to expire of any

Valid Claim included in the Patent License in such country which would be infringed but for the license granted hereunder and extending so long as Licensee is engaged in sales of Licensed Product in such country.

"Regulatory Approval" means (a) in the United States, approval by the FDA of a New Drug Application ("NDA"), Abbreviated New Drug Application ("ANDA") or similar application, for marketing approval, together with satisfaction of any related applicable FDA registration and notification requirements necessary to permit the sale of Licensed Products commercially in the United States in accordance with Applicable Laws, and (b) in any country other than the United States, approval by Applicable Authorities having jurisdiction over such country of a single application or set of applications comparable to a NDA or ANDA, together with satisfaction of any related applicable regulatory and notification requirements and other approvals required under the Applicable Laws, including, without limitation, approvals necessary to permit the manufacture and sale of the Licensed Products commercially in such country.

"Royalty Rate" means the percent (%), specified in this Agreement and subject to adjustment as set forth in this Agreement.

"Royalty Period" means with respect to any particular Licensed Product in any particular country in the Territory, the period of time beginning on the First Commercial Sale of such Licensed Product in such country and extending until the date of expiration of the last to expire of any Valid Claim included in the Patent License in such country which would be infringed but for the license granted hereunder.

"Sam Amer Confidential Technical Information" means and includes all technical information of Sam Amer (not including Licensee Improvements) relating to the Sam Amer Patents and/or Ifersanserin, including, without limitation, the Sam Amer Know-How, and all technology, intellectual property, mechanisms, technical drawings, algorithms, research, techniques, chemical formulations, recipes, batch records, architecture, know-how, formulas, processes, ideas, inventions (whether or not patentable), Sam Amer Improvements, schematics and other similar technical information, including the manner in which any such information may derive or be combined with other information, or synthesized, or used by Sam Amer, regardless of whether (i) disclosed to Licensee orally, in writing, electronically or visually after the Effective Date of this Agreement or in connection with the Mutual Confidentiality Agreements dated June 24, 2005 and June 6, 2006, or (ii) such information is marked or designated as "confidential" or "proprietary."

"Sam Amer Improvement(s)" means Improvements inside the Field of Use conceived, made, reduced to practice, invented or developed by or on behalf of Sam Amer or owned or controlled by Sam Amer during the term of this Agreement.

"Sam Amer Know-How" means Know-How and Sam Amer Confidential Technical Information.

"Sam Amer Patents" means the (i) Patents listed on **Schedule A**, and (ii) any Patents relating to Ifersanserin owned or controlled by Sam Amer after the Effective Date during the term of this Agreement which are necessary or useful within the Field of Use.

"SPA" means Special Protocol Assessment by the FDA.

"Successful Completion of Phase III Trials" means that the Licensed Product achieved a statistically significant improvement of the primary endpoint with a p-level of less than or equal to 0.05, as defined in a protocol for such trial to be designed by the Licensee and the JDC, and no safety issues arose that would inhibit filing of the NDA.

"Territory" means all countries of the world.

"Third Party" means any Person that is not a Party or an Affiliate of a Party.

"Trademark" means any means any U.S. or foreign trademark, brand, logo, trade dress or design, whether registered or unregistered, owned by or registered to Licensee.

"Valid Claim" means any claim of an unexpired Patent included in the Licensed Patents or Sam Amer Improvements that (i) has not been held unenforceable, unpatentable or invalid by a final decision of a court or other governmental agency of competent jurisdiction following exhaustion of all possible appeal processes, (ii) has not been admitted to be invalid or unenforceable through reissue, reexamination or disclaimer and (iii) would be infringed by the making, having made, using, selling or importation of the Licensed Products.

2. LICENSE

2.1 Grant. Subject to the terms and conditions set forth in this Agreement, Sam Amer hereby grants to Licensee, and Licensee hereby accepts from Sam Amer, a non-transferable, non-sublicensable (except in accordance with **Section 2.3** or **Section 5.1**), royalty-bearing license under the Patent License and the Know-How License (the **"Product License"**), *solely* within the Field of Use within the Territory to:

- (i) Research, develop or Commercialize, or have researched, developed or commercialized the Licensed Products;
- (ii) Make and use the applicable Licensed Products;
- (iii) Have made the applicable Licensed Products in accordance with **Section 5.1** below;
- (iv) Sell, offer for sale, promote and market the applicable Licensed Products (by itself, an Affiliate or through one or more Third Parties); and
- (v) Import or have imported each Licensed Product.

2.2 Exclusivity. Unless otherwise set forth in this Agreement, the Product License shall be exclusive (even as to Sam Amer and its Affiliates) within the Field of Use in the Territory. By way of clarification, Licensee shall have no rights in, and Sam Amer shall be free to use and/or license, the Licensed Patents and Licensed Know-How for any purpose whatsoever, outside of the Field of Use. Amer retains the right to license and/or develop a water-based product to be indicated for wound healing or uses other than hemorrhoids. Such product will not be packaged in a single use, application tube for insertion into the rectum. Amer retains the right to develop Ifeferanserine for other indications. Notwithstanding the foregoing, Sam Amer shall not use and/or license the Licensed Patents and Licensed Know-How to develop or commercialize a product which would be deemed pharmaceutically or therapeutically equivalent to a Licensed Product by an Applicable Authority and which is to be sold for (whether on an approved or off-label use or other basis), or after being sold is used for, the same indication(s) as a Licensed Product.

2.3 Right of Sublicense. Licensee shall have the right to engage Third Party sublicensees to develop and Commercialize Licensed Products provided that Licensee satisfies the conditions of this Section. At Licensee's request, Sam Amer shall permit Licensee to grant a Third Party sublicensee (**"Third Party Sublicensee"**) a sublicense under the Licensed Patents and Licensed Know-How to develop and Commercialize, solely for Licensee, Licensed Products and components thereof, provided, however that (i) Licensee provides Sam Amer with a reasonably detailed description of the proposed sublicense arrangement, (ii) said Third Party Sublicensee agrees to protect the confidential information of Sam Amer consistent with the terms and provisions of Section 10; and (iii) Licensee obtains the prior written approval of Sam Amer of said Third Party Sublicensee, such approval not to be unreasonably withheld or delayed. Sam Amer shall not be deemed to have unreasonably withheld such approval if such proposed sublicense (i) is contrary to or negates the effect of any provision of this Agreement or (ii) puts Sam Amer in a less advantageous position than it would be absent such sublicense, including with respect to the guarantee obligations of the Guarantor. For avoidance of doubt Third Party Sublicensees shall not include CROs or contract manufacturers.

2.4 License Restrictions. The Product License is intended to permit Licensee and its Third Party Sublicensee to sell Licensed Products at wholesale or retail for its own account. Except as otherwise set forth herein, a Product License is not intended to permit or enable any development or manufacturing activities by Third Parties, or to permit Licensee to undertake any development or manufacturing activities on behalf of any Third Parties. Notwithstanding the foregoing or any other provision herein to the contrary, Licensee shall be free to enter into agreements with CROs and Third Party manufacturers (as further set forth in **Section 5.1**) to facilitate and/or satisfy Licensee's obligations under this Agreement without the prior written consent of Sam Amer.

2.5 Modifications to Licensed Products. The Parties contemplate: (i) the addition of at least one over-the-counter ("OTC") formulation of a Licensed Product; (ii) development of formulations and specifications for additional licensed products; and (iii) modification from time to time of the formulations and specifications to the Licensed Product as well as any additional Licensed Products, all within the applicable Field of Use. Licensee shall notify Sam Amer of any modifications to a Licensed Product at least sixty (60) days prior to the First Commercial Sale of such Licensed Product as modified. For the avoidance of doubt, multiple License Fees or royalties shall not be payable on such modified Licensed Products unless such Licensed Products are mutually agreed by the Parties to be new Licensed Products.

3. DEVELOPMENT AND REGULATORY APPROVALS

3.1 Commencement; Roles; Efforts. Licensee will commence and pay for the pre-clinical and clinical studies and development of Licensed Product as soon as practicable following the Effective Date, including the following studies and development steps (within the meaning of FDA regulations as applicable and, if no FDA regulation is applicable, customary pharmaceutical industry practice):

3.1.1 Submission of an SPA to the FDA within ninety (60) days of the Effective Date.

3.1.2 Conducting, as required by the FDA, all remaining, clinical and pre-clinical studies needed for inclusion in the NDA dossier for submission to the FDA, including the following (which are listed without reference to sequence and may be conducted simultaneously):

(i) QTC Study;

(ii) Pharmacology Studies:
Pharmacokinetic/Pharmacodynamic
Age Related
Hemorrhoid
Hepatic
Renal
Drug-Drug;

(iii) Efficacy Trial(s) ((phase III) 700-1,000 patients);

(iv) Long term toxicology (rats and dogs) and carcinogenicity (rats and mice); and

(v) Segment III pre and post-natal reproductive toxicity studies in rats.

Procurement of clinical supply of Licensed Product will be initiated within ninety (90) days of Effective Date. The first patient will be enrolled within ninety (90) days of the later to occur of (i) Licensee receiving an Acceptable FDA Response to the SPA and (ii) when clinical supplies of Licensed Product are reasonably available so that clinical trials can be conducted. All pre-clinical and clinical trials are to be completed not later than completion of the carcinogenicity studies and final reports.

Licensee shall be solely responsible for the pre-clinical and clinical studies, final development, manufacturing scale-up and production of Licensed Product and all other development costs related thereto.

Licensee shall use Commercially Reasonable Efforts to develop and prepare each Licensed Product for Commercial Launch, and will provide the Joint Development Committee, with reasonably detailed updates as set forth in **Section 3.2** on the development, manufacturing scale-up, manufacturing of sufficient supplies of the each Licensed Product for commercial distribution, and other progress toward Commercial Launch of such Licensed Product until the actual First Commercial Sale thereof. Licensee will notify Sam Amer promptly upon the discovery or identification of any obstacles to achieving First Commercial Sale of a Licensed Product.

3.2 Joint Development Committee. The Parties recognize that it is in both of their interests to (i) foster the development of the Licensed Product in the Territory, including regulatory submissions; (ii) minimize the time to First Commercial Sale of the Licensed Product in the Territory during the term of this Agreement; and (iii) coordinate the activities of both Parties with respect to the development and time to First Commercial Sale of the Licensed Product in the Territory.

3.2.1 Accordingly, the Parties hereby establish a development committee made up of an equal number of representatives of each Party set forth in **Schedule B** hereto (the "Joint Development Committee" or "JDC"). Both Parties shall have the right from time to time to substitute individuals, on a permanent or temporary basis, for any of its previously designated members of the JDC. The members appointed by each Party shall be vested with appropriate decision-making authority and power by such Party. Either Party shall have the right to engage Third Parties to assist as members of the JDC, provided, however, (i) said Third Party agrees to protect the confidential information of both Parties consistent with the terms and provisions of **Section 10**; and (ii) the applicable Party obtains the prior written approval of the other Party of said Third Party, such approval not to be unreasonably withheld or delayed.

3.2.2 The JDC shall meet: (i) once every six months prior to the First Commercial Sale, or more often as needed, on a date and at a location to be agreed to by the JDC, and (ii) upon written notice by either Party to the other that a meeting is required or requested, in which case a meeting will be held within fourteen (14) calendar days of such notice on a date and at a location to be agreed to by the Parties. After the First Commercial Sale the JDC shall meet on an as needed basis. Notice requesting a meeting shall include adequate information describing the activity to be reviewed. Any meetings of the JDC may be held in person at a location to be agreed to by the Parties, or by videoconference or teleconference. Other representatives of the Parties may attend JDC meetings as participants. The Parties shall agree, at the first meeting of the JDC, upon procedures for maintaining meeting minutes.

3.2.3 The purpose of the JDC is to serve as an advisory committee and to make recommendations and to coordinate the development and clinical study efforts of the Parties with respect to the development effort of the Licensed Product in the Territory and to minimize the time to First Commercial Sale thereof. Accordingly, the JDC shall discuss and resolve, to the extent possible, any issues that arise under this Agreement including, without limitation, the following:

- (a) Review of the Licensee's development plan for the Licensed Product, including clinical study requirements and protocol needed for FDA approval ;
- (b) Determining the analytical methods, validation, and stability of Licensed Product to be provided by Licensee for use in the Territory; and
- (c) Determining the optimal concentration of Licensed Product and packaging of the Licensed Product in preparation for First Commercial Sale.

3.2.4 In the event of a JDC dispute that cannot be otherwise resolved, Licensee's President shall have final authority. That authority may be exercised in Licensee's President's discretion, provided it is consistent with the terms of this Agreement.

3.3 Regulatory Approvals. Licensee shall be solely responsible for obtaining all Regulatory Approvals, if any, necessary to manufacture, market, sell and otherwise exploit the Licensed Products in accordance with this Agreement. Licensee shall use Commercially Reasonable Efforts to conduct all tests

and field trials necessary to obtain any necessary Regulatory Approvals of the Licensed Products with the Applicable Authorities. Licensee shall use Commercially Reasonable Efforts consistent with Applicable Laws and this Agreement to file for and obtain all necessary Regulatory Approvals. Licensee shall be solely responsible for all matters with Applicable Authorities concerning the Licensed Products, and to the extent permitted by law, will be the sole contact with such agencies. Regulatory Approvals for the Licensed Products shall be in Licensee's name, and Licensee shall own and control all submissions in connection therewith, provided, that Sam Amer shall be provided with copies of proposed submissions in advance of their submission to the FDA, and Sam Amer shall have the opportunity to comment thereon to Licensee. In the event Licensee is provided short notice with which to provide submissions to the FDA in respect of Regulatory Approvals, then Licensee shall use its best efforts to provide Sam Amer the opportunity to comment on such submissions.

3.4 Investigation, Testing and Research. Sam Amer shall not be responsible for the performance of any investigations, testing and research necessary to ensure that each Licensed Product and the manufacture thereof complies with all Applicable Laws or that the Licensed Product is suitable for the purposes for which it is intended.

3.5 Know-How Disclosure by Sam Amer. Sam Amer shall provide to Licensee, within thirty (30) days of the Effective Date and at no charge to Licensee, copies of any Licensed Know-How not already provided by Sam Amer to Licensee, to be used to assist Licensee in clinical trials, registration, manufacturing scale-up or other related development purposes (provided such disclosure will not breach any Third Party confidentiality or non-disclosure obligations) including, but not limited to research, synthesis, testing, pilot or laboratory scale manufacturing know-how, procedures manuals and regulatory data. All disclosures by Sam Amer under this **Section 3.5** shall be treated by Licensee as the Confidential Information of Sam Amer in accordance with **Section 10** below and subject to the restrictions on the Know-How License set forth herein.

4. COMMERCIALIZATION

4.1 Efforts. Licensee shall use Commercially Reasonable Efforts, consistent with Applicable Laws and this Agreement, to manufacture or have manufactured (in accordance with **Section 5.1** below), promote or have promoted, market, sell, and distribute or have distributed the Licensed Products (collectively, "Commercialize" or "Commercialization"), and maintain a sales and marketing organization of personnel knowledgeable about the Licensed Products and experienced in the use, promotion and sales of similar products. Beginning four (4) Calendar Quarters prior to the anticipated First Commercial Sale, Licensee shall provide Sam Amer each Calendar Quarter, a non-binding (except for purposes of **Section 6.3** below), rolling forecast of Licensee's good faith estimates of unit sales of Licensed Products for the next following four (4) Calendar Quarters.

4.2 Joint Commercialization Committee. The Parties recognize that it is in both of their interests to (i) maximize the sales of the Licensed Product in the Territory; (ii) maximize the marketing of the Licensed Product in the Territory during the term of the Agreement; and (iii) to coordinate the activities of both Parties with respect to the promotion of the Licensed Product in the Territory.

4.2.1 Accordingly, the Parties hereby establish a commercialization committee made up of an equal number of representatives of each Party set forth in **Schedule B** hereto (the "Joint Commercialization Committee" or "JCC"). Both Parties shall have the right from time to time to substitute individuals, on a permanent or temporary basis, for any of its previously designated members of the JCC. The members appointed by each Party shall be vested with appropriate decision-making authority and power by such Party. Either Party shall have the right to engage Third Parties to assist as members of the JCC, provided, however, (i) said Third Party agrees to protect the confidential information of both Parties consistent with the terms and provisions of **Section 10**; and (ii) the applicable Party obtains the prior written approval of the other Party of said Third Party, such approval not to be unreasonably withheld or delayed.

4.2.2 The JCC shall meet: (i) once every six months after filing of the NDA by Licensee, or more often as needed, on a date and at a location to be agreed to by the JCC, and (ii) upon written notice by either Party to the other that a meeting is required or requested, in which case a meeting will be held within fourteen (14) calendar days of such notice on a date and at a location to be agreed to by the Parties. Notice requesting a meeting shall include adequate information describing the activity to be reviewed. Any meetings of the JCC may be held in person at a location to be agreed to by the Parties, or by videoconference or teleconference. Other representatives of the Parties may attend JCC meetings as participants. The Parties shall agree, at the first meeting of the JCC, upon procedures for maintaining meeting minutes.

4.2.3 The purpose of the JCC is to serve as an advisory committee to make recommendations and to coordinate the marketing and promotional efforts of the Parties with respect to the promotional effort of the Licensed Product in the Territory and to maximize the sales thereof. Accordingly, the JCC shall discuss and resolve, to the extent possible, any issues that arise under this Agreement including, without limitation, the following:

- (a) Review of the Licensee's annual detailed marketing plan for the Licensed Product, including product and appropriate sales force training;
- (b) Determining the reasonable quantities of Licensed Product samples to be provided by Licensee for use in the Territory; and
- (c) Determining the schedule of delivery of Licensed Product samples and promotional sales, marketing, and educational materials for the Licensed Product to Licensee's sales representatives and to physicians called upon by Licensee's sales force.

4.2.4 In the event of a JCC dispute that cannot be otherwise resolved, Licensee's President shall have final authority. That authority may be exercised in Licensee's President's discretion, provided it is consistent with the terms of this Agreement

4.3 **Commercialization Costs.** Licensee shall be responsible for and shall pay all costs incurred by it in connection with the marketing, development and Commercialization of the Licensed Products.

4.4 **Know-How Disclosure by Sam Amer.** Sam Amer shall provide to Licensee, within thirty (30) days of the Effective Date and at no charge to Licensee, copies of any Licensed Know-How not previously provided by Sam Amer to Licensee, to be used to assist Licensee in manufacturing scale-up or other related commercial purposes (provided such disclosure will not breach any Third Party confidentiality or non-disclosure obligations). All disclosures by Sam Amer under this **Section 4.4** shall be treated by Licensee as the Confidential Information of Sam Amer in accordance with **Section 10** below and subject to the restrictions on the Know-How License set forth herein.

4.5 Consistent with **Section 2.5** of this Agreement, Licensee shall use Commercially Reasonable Efforts to develop at least one OTC formulation of a Licensed Product.

5. MANUFACTURING

5.1 **Manufacturer.** Licensee shall be solely responsible for the manufacture of the Licensed Products for all development and Commercialization purposes at a cGMP-licensed facility. Licensee may subcontract the manufacturing to a Third Party manufacturer at a cGMP-licensed facility provided that said Third Party agrees to protect the confidential information of Sam Amer consistent with the terms and provisions of **Section 10**.

5.2 **Patent Marking.** Licensee agrees to mark or cause to be marked labeling for Licensed Products sold or otherwise distributed pursuant to this Agreement in accordance with the Applicable Laws of the country or countries of manufacture and sale thereof, including without limitation Section 287(a) of the United States Patent Act in the United States, as to any Patents within the Licensed Patents that may be embodied in such Licensed Products.

6. LICENSEE FEES, ROYALTIES AND ACCOUNTING

6.1 License Fees. As consideration for the licenses granted hereunder, including of the Sam Amer Patents and the Sam Amer Know-How, Licensee shall pay Sam Amer the license fees ("License Fees") as set forth below within thirty (30) days after achievement of the applicable milestone event. Each License Fee shall be payable one time only, regardless of the number of Licensed Products that satisfy the condition that triggers such payment.

Milestone U.S. Territory	License Fee to Amer
Execution this Agreement.	
No contingencies on initial License Fee beyond execution of this Agreement.	\$2,050,000 to be paid as follows; (a) Initial payment of \$550,000 upon execution of this Agreement; and (b) remaining \$1,500,000 to be paid in three equal installments of \$500,000 every 4 months thereafter.
Successful Completion of Phase III Trials.	\$1 (one) million
If the Phase III Trials are not successfully completed by July 2009, Licensee shall pay \$7,500 per month to Sam Amer until the Successful Completion of the Phase III Trials. Such payments will begin at July 2009.	
Notwithstanding the foregoing, if safety, efficacy or other regulatory issues prevent the completion of the Phase III Trials (a "Non-completion Event"), then Licensee's payment of \$7,500 per month shall cease upon the Non-Completion Event.	
Upon Licensee's Submission of an NDA to the FDA.	\$1 (one) million
If an NDA is not submitted by September 2010 \$7,500 per month will be paid until such submission. Payment will begin at September 2010.	
Notwithstanding the foregoing, if safety, efficacy or other regulatory issues prevent the submission of NDA (a "Non-completion Event"), then Licensee's payment of \$7,500 per month shall cease upon the Non-Completion Event.	
NDA Approval by FDA	\$[4 (four) million]
At one (1) Year Anniversary following NDA Approval by FDA	\$[2 (two) million]
At \$[20 million] cumulative lifecycle Net Sales attainment	\$[1 (one) million]
At \$[50 million] cumulative lifecycle Net Sales attainment	\$[2 (two) million]

[] Confidential treatment requested.

At \$[75 million] cumulative lifecycle Net Sales attainment	\$[4 (four) million]
At Regulatory Approval for OTC sale	\$[5 (five) million]

6.2 Royalties. (a) As additional consideration for the Product License granted hereunder, during the Royalty Period Licensee shall pay to Sam Amer the royalty percentages for each applicable country or countries as set forth below:

U.S. Sales Royalties

Royalty Payments on U.S. Sales:	
\$[0] to \$[75 million] annual Net Sales	[9]% ([nine] percent)
Over \$[75 million] to \$[150 million] annual Net Sales	[10]% ([ten] percent)
Over \$[150 million] to \$[225 million] annual Net Sales.	[11]% ([eleven] percent)
Over \$[225 million] annual Net Sales	[12]% ([twelve] percent)

Ex-U.S. Sales Royalties

Ex-U.S. sales royalties shall be based on Ex-U.S. Gross Sales.

Royalties on Ex-U.S. Gross Sales within the Ex-U.S. Territory	Royalty fee to Amer
\$[0] to \$[30 million] annual Ex-U.S. Gross Sales	[3]% ([three] percent)
Over \$[30 million] to \$[60 million] annual Ex-U.S. Gross Sales	[3.5]% ([three and one-half] percent)
Over \$[60 million] to \$[90 million] annual Ex-U.S. Gross Sales	[3.75]% ([three and three-quarter] percent)
Over \$[90 million] annual Ex-U.S. Gross Sales	[4]% ([four] percent)

(b) As additional consideration for the license of Sam Amer Know-How granted hereunder, during the Reduced Royalty Period, Licensee shall pay to Sam Amer royalties on Net Sales in each applicable country or countries at a rate equal to [fifty] percent ([50]%) of the rate applicable to such country or countries pursuant to **Section 6.2(a)** of this Agreement.

(c) Royalties shall be reported and paid quarterly in accordance with **Section 6.4** below.

6.3 Guaranteed Minimum Royalty. As additional consideration for the licenses granted hereunder, during the Royalty Period and the Reduced Royalty Period, Licensee shall guarantee to Sam Amer a minimum yearly royalty. The guaranteed minimum royalty shall be the royalty that would have been received if Net Sales equaled fifty percent (50%) of the Net Sales expectations set forth in the applicable forecast referred to in **Section 4.1** of this Agreement Such guaranteed minimum royalty shall apply to both expected U.S. Net Sales and expected Ex-U.S. Gross Sales.

6.4 Accounting.

(a) **Payment of Royalties.** Royalties shall be due and payable at the same time as Quarterly Reports are due as provided below.

(b) **Sales and Royalty Reports.** Within sixty (60) days after the end of each Calendar Quarter during the Term, Licensee shall deliver to Sam Amer an accurate and complete written accounting of (i) Licensee's and Third Party Sublicensee's U.S. Net Sales and (ii) Licensee's and Third Party Sublicensees'

[] Confidential treatment requested.

Ex-U.S. Gross Sales, and (iii) the royalties due to Sam Amer for such quarter ("Quarterly Reports"). The Quarterly Reports shall be in English and include the applicable Net Sales or Ex-U.S. Gross Sales of each Licensed Product on a country-by-country basis (expressed in United States Dollars). Quarterly Reports shall be provided for each Calendar Quarter after the First Commercial Sale of the Licensed Products, regardless of whether any sales occur during such Calendar Quarter.

(c) **Audits.** Licensee shall keep complete and accurate records of the latest three years of sales of Licensed Products on which royalties are due hereunder as well as records supporting Licensee's calculation of Net Sales with respect to such sales. Sam Amer shall have the right, no more than once each calendar year, to retain an independent certified public accountant reasonably acceptable to Licensee, to review such records in the location where such records are regularly maintained, upon reasonable notice and during regular business hours, for the purpose of certifying the amount of royalties due hereunder. Before permitting such independent certified public accountant to have access to such books and records, Licensee may require such accounting firm and its personnel involved in such review to sign confidentiality agreement in form and substance reasonably acceptable to Licensee. Each such review shall be limited to the pertinent books and records for any year ending not more than three years prior to the first day of the calendar year during which such request was made, and Sam Amer shall not be permitted to review the same period of time more than once. Results of such review shall be made available to Sam Amer and to Licensee. The accounting firm may not reveal any information learned in the course of such audit other than the amount of discrepancies in payments of royalties under this Agreement. If such independent certified public accountant determines there was an underpayment to Sam Amer, such underpayment shall be promptly remitted to Sam Amer, together with interest at LIBOR plus two percent. If such independent certified public accountant determines there was an overpayment to Sam Amer, Sam Amer shall promptly refund the amount of the overpayment, together with interest calculated at LIBOR plus two percent. Such review shall be at the sole expense of Sam Amer; provided, however, that if the underpayment of royalties is equal to or greater than five percent, then Licensee shall promptly reimburse Sam Amer for all of the reasonable costs of such review.

(d) **Exchange Rates and Currency Translation.** All payments shall be made and reported in United States Dollars. The rate of exchange to be used in computing the amount of the royalties due Sam Amer on Ex- U.S. Gross Sales shall be the rate of exchange published in the Wall Street Journal on the first day of the month that the calculations are initiated.

(e) **Withholding Taxes.** Licensee shall have no liability for any income taxes levied against Sam Amer on account of royalties or other payments paid hereunder. If laws or regulations require that any such taxes be withheld by Licensee, Licensee shall deduct such taxes from the payment due Sam Amer, pay the taxes so withheld to the proper taxing authority, and send proof of payment to Sam Amer with the next applicable quarterly payment. If Sam Amer desires to obtain a refund of any taxes so withheld and paid to a taxing authority, Licensee shall reasonably cooperate at Sam Amer's expense in the pursuit of such refund.

6.5 Consulting Fee. Licensee will pay Sam Amer a consulting fee of \$7,500 per month for the first twelve (12) months following the Effective Date of this Agreement.

7. TRADEMARKS AND TRADE NAMES

7.1 Selection; License; Expenses. Licensee may select and file a U.S. trademark application with the U.S. Patent and Trademark Office in its name, for one or more Trademarks, as appropriate, for the marketing of the Licensed Products; provided that such Trademarks do not reflect unfavorably on the Licensed Products. Such Trademarks and any and all Intellectual Property Rights embodied therein shall be owned solely by Licensee. Expenses for registration of the Trademarks shall be borne solely by Licensee. Sam Amer shall have no right or license under this Agreement to use any Trademarks owned or controlled by Licensee or its Affiliates. All goodwill attributable and/or accruing to the Trademarks shall be owned by and inure to the benefit of Licensee.

7.2 Sam Amer Trademarks. Notwithstanding the provisions of Section 7.1, Licensee shall have no right or license under this Agreement to use any trademarks owned or controlled by Sam Amer or its

Affiliates. Any use of any such Trademarks shall be pursuant to a separate mutually acceptable trademark license agreement executed by the Parties.

8. OWNERSHIP

8.1 Ownership of Ifranserin Patent. Licensee acknowledges and agrees that, as between Sam Amer and Licensee, Sam Amer owns and will retain all right, title and interest in and to the Sam Amer Patents and the Intellectual Property Rights embodied therein, including without limitation the Licensed Patents and the Sam Amer Know-How.

8.2 Ownership of Improvements.

(a) **Sam Amer Improvements.** As between Sam Amer and Licensee, Sam Amer will own exclusively all Sam Amer Improvements. All Sam Amer Improvements within the Field of Use shall automatically be included in the Patent License or Know-How License as applicable. Sam Amer shall promptly provide Licensee with notice of any Sam Amer Improvement within the Field of Use and shall transfer any data and materials in respect of such Improvement to Licensee at no charge and for use solely in accordance with the terms and conditions set forth herein.

(b) **Licensee Intellectual Property.** Licensee shall own all right, title and interest in and to Licensee Intellectual Property. Upon expiration of this Agreement or termination by Sam Amer for cause, Licensee agrees to assign to Sam Amer all right, title and interest in and to Licensee Intellectual Property. In the event Licensee terminates this Agreement for cause, Licensee and Sam Amer shall negotiate the terms by which Licensee will grant to Sam Amer a license under the Licensee Intellectual Property.

9. PROSECUTION, ENFORCEMENT AND DEFENSE.

9.1 Maintenance. Licensee shall pay all government, counsel and other fees required to maintain the Licensed Patents in force ("**Maintenance**"). Sam Amer or its patent counsel shall promptly provide Licensee with information as to Maintenance as necessary to keep the Licensed Patents in good standing. Licensee shall prosecute ("**Prosecution**") all Licensed Patents as necessary and will pay all fees and costs related thereto. Sam Amer will reasonably cooperate with Licensee at Licensee's expense in the Prosecution of all Licensed Patents, including executing and delivering to Licensee, at Licensee's request, all instruments and documents, including powers of attorney, needed to Prosecute the Licensed Patents. If so requested by Sam Amer, Licensee will deal directly with Sam Amer's patent counsel with respect to Maintenance. Licensor's breach of its obligations under this **Section 9.1** and with respect to the countries of the United States, the United Kingdom, Germany, Italy, France, Spain and Japan shall be deemed to be a material breach.

9.2 Notice. Each Party shall give prompt written notice ("**Infringement Notice**") to the other if it becomes aware of any infringement or suspected infringement of the Licensed Patents or misappropriation of the Licensed Know-How ("**Potential Infringement**") by any Third Party ("**Potential Infringer**").

9.3 Enforcement Against Infringers.

(a) By Sam Amer, Sam Amer shall have the right (but not the obligation) to take and thereafter diligently pursue in good faith such actions, as it reasonably deems appropriate, whether by action, suit, proceeding or otherwise, at its own expense to prevent or eliminate the Potential Infringement by the Potential Infringer and to collect damages. Licensee agrees to cooperate with Sam Amer in any reasonable manner including, but not limited to, being named as a co-plaintiff in an action brought by Sam Amer. Any damages recovered by Sam Amer shall be used to compensate Sam Amer and Licensee for their respective out-of-pocket expenses incurred in the prosecution of any such action, suit, or proceeding for infringement. Any remaining damages recovered by Sam Amer shall be apportioned to Sam Amer and Licensee so that Sam Amer

receives the Royalty Rate then in effect on such remaining damages which shall be considered Net Sales and Licensee receives the remainder.

(b) By Licensee. In the event that Sam Amer does not take or declines to take such actions to prevent or eliminate such Potential Infringement pursuant to **Section 9.3(a)** within thirty (30) days after the Infringement Notice, then (i) Licensee may, at its option, take such action as it deems appropriate against the Potential Infringer to prevent or eliminate such infringement and recover damages, and (ii) the Royalty Rate in any applicable jurisdiction affected by the Potential Infringement will be reduced by twenty-five percent (25%) for so long as such Potential Infringement is continuing. If Licensee gives notice to Sam Amer of Licensee's intent to take action as set forth in this subsection, Sam Amer shall no longer have the right to take action as set forth in **Section 9.3(a)** unless otherwise agreed by Sam Amer and Licensee. Such action by Licensee may be undertaken in the name of Sam Amer, if necessary, and Sam Amer agrees to cooperate with Licensee, and execute any necessary documents relating to such action. Licensee may deduct the reasonable costs and expenses (including, without limitation, attorneys' fees) of the prosecution of any such action from the royalty payment due hereunder. Licensee shall submit written reports showing the expenses of such litigation. Any recoveries in any such action shall be used to compensate Licensee and Sam Amer for their respective expenses incurred in the prosecution of any such action, suit or proceeding and the remainder shall be retained by Licensee and shall be considered Net Sales with respect to the quarter in which such recovery was received.

9.4 Participation and Cooperation. The Party not prosecuting a Potential Infringer or defending a Third Party suit against the Licensed Patents shall be entitled to participate therein with counsel of its choice and at its own cost and expense (subject to reimbursement out of any recovery in such action).

10. CONFIDENTIALITY AND NONDISCLOSURE

10.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, for the term of this Agreement and for five (5) years thereafter, each Party receiving any Confidential Information of the other Party hereunder shall keep such Confidential Information confidential and shall not publish or otherwise disclose or use such Confidential Information for any purpose other than as provided for in this Agreement. Each Party will protect the other Party's Confidential Information from unauthorized use, access, and disclosure in the same manner that it protects its own Confidential Information of a similar nature, and with no less than a reasonable degree of care. The Confidentiality Agreement previously entered into by the Parties shall remain in effect coextensively with this Agreement.

10.2 Exceptions. Any particular item of information shall not be considered Confidential Information for purposes of this Agreement at such time, and to the extent, such information is: (a) known to the receiving Party prior to any disclosure by or on behalf of the disclosing Party; (b) rightfully acquired by the receiving Party on a non-confidential basis from a Third Party legally entitled to disclose such information; (c) placed in the public domain through no wrongful act or fault of the receiving Party; or (d) independently developed by the receiving Party without reference to or reliance on the Confidential Information of the disclosing Party.

10.3 Required Disclosures. If either Party is requested to disclose any Confidential Information of the other Party under any Applicable Law or in any judicial or administrative proceeding, then, except as otherwise required to comply with any court order or other Applicable Law, the Party agrees to promptly notify the other Party of such request so that the Party may resist such disclosure or seek an appropriate protective order. If either Party is nonetheless compelled to disclose any Confidential Information of the other Party under Applicable Law or in such judicial or administrative proceeding, the Party shall limit its disclosure to that which is required by Applicable Law or the relevant judicial or administrative body.

10.4 Return or Destruction. Upon the expiration or termination of this Agreement for any reason, each Party shall, at the election of the other Party, promptly return or destroy any and all Confidential Information of the other Party in its possession or control (including copies thereof) related to the

Agreement provided that each Party may retain one archival copy of the Confidential Information for its records, which copy shall be subject to the restrictions on access, use and disclosure set forth above.

11. TERM AND TERMINATION

11.1 Term of Agreement. The term of this Agreement shall commence as of the Effective Date and shall continue in full force and effect unless and until terminated in accordance with the provisions of this Section 11.

11.2 Termination for Cause. Either Party may terminate this Agreement for cause upon written notice to the other Party if the other Party materially breaches this Agreement and fails to cure the breach within (i) thirty (30) days with respect to a failure to pay amounts when due ("**Payment Default**"), and (ii) sixty (60) days with respect to all other breaches, in each case after written notice of such breach from the non-breaching Party and failure to cure such breach within such sixty (60) day cure period; provided, however, that if any breach other than Payment Default is not reasonably curable within sixty (60) days and so long as the breaching party is using Commercially Reasonable Efforts to cure such breach, the breaching party shall be permitted a reasonable time to cure such breach before termination of this Agreement becomes effective.

11.3 Termination for Safety or Regulatory Issues. Licensee shall have the right to terminate this Agreement with thirty (30) days written notice:

- (i) if, applying customary pharmaceutical company practice, documented safety or efficacy issues prevent development or Commercialization of the Licensed Product; or
- (ii) if, applying customary pharmaceutical company practice, documented and regulatory issues raised in writing by the FDA prevent development or Commercialization of the Licensed Product.

11.4 Termination of the Know-How License. At any time subsequent to expiration of the Royalty Period for any Licensed Product either Licensee or Sam Amer may terminate the Know-How License for such Licensed Product by providing ninety (90) days prior written notice to the other Party. Upon any such termination, neither Licensee nor any Person acting for or on behalf of Licensee shall have any further right under this Agreement to use the Licensed Know-How with regard to such Licensed Product for any purpose including sale of Licensed Product in such country of the Territory.

11.5 Termination Upon Insolvency. Either Party may, subject to the provisions set forth herein, terminate this Agreement by giving the other Party written termination notice if, at any time, the other Party shall: (a) file in any court pursuant to any statute a petition for bankruptcy or insolvency, or for reorganization in bankruptcy, or for an arrangement or for the appointment of a receiver, trustee or administrator of such Party or of its assets; (b) be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof; (c) propose or be a Party to any dissolution; or (d) make an assignment for the benefit of its creditors. Should Sam Amer become a Party to a bankruptcy proceeding and such proceeding is not dismissed within sixty (60) days then, to the extent permitted by law, this Agreement and the licenses granted by Sam Amer hereunder shall be adopted by any bankruptcy trustee or relevant Third Party charged with the disposition of same, and shall not be rejected by same, it being the Parties' intent that, in such event, Licensee and its Affiliates and sub licensees shall be entitled to retain the rights granted to them hereunder by Sam Amer. In this regard, the Parties acknowledge that this Agreement is an executory contract as provided in Section 365(n) of the Bankruptcy Code, that the Licensed Know-How, Licensed Patents and other intellectual property licensed hereunder are "intellectual property" as defined in Section 101(a)(35) of the U.S. Bankruptcy Code and that Licensee will have the right to exercise all rights provided by Section 365(n) with respect to the licensed intellectual property. Sam Amer acknowledges and agrees that if it as debtor in possession or a trustee in bankruptcy in a case under the Bankruptcy Court rejects this Agreement, Licensee may elect to retain its rights under this Agreement as provided in Section 365(n) of the Bankruptcy Code, including the right to the Licensed Know-How, Licensed Patents and other

intellectual property licensed hereunder to the fullest extent permitted by law, Sam Amer or such bankruptcy trustee shall not interfere with the rights of Licensee as provided in this Agreement except as otherwise permitted by law or equity.

11.6 Effects of Termination. Upon termination or expiration of this Agreement for any reason or no reason: (i) all rights and licenses granted in this Agreement shall immediately and automatically cease; (ii) each receiving Party shall return the Data and any other information (Confidential or Non-Confidential) of the other Party in accordance with the provisions of **Section 10.5**; and (iii) **Sections 6.1, 6.2, 6.4, 8, 9, 10, 11.8, 12, 13, 14, 15 and 16** of this Agreement will survive the termination or expiration of this Agreement for any reason. Expiration or termination of this Agreement for any reason shall be without prejudice to any right which shall have accrued to the benefit of either Party prior to such termination. Notwithstanding the foregoing, Sam Amer shall permit Licensee to sell any remaining inventory of Licensed Products remaining in the system following termination of this Agreement with appropriate royalties paid. Data generated by Licensee shall be delivered to Sam Amer at no cost.

12. INDEMNIFICATION AND INSURANCE

12.1 By Licensee. Licensee shall indemnify, defend and hold harmless Sam Amer and its Affiliates, and their respective officers, directors, managers, agents and employees from and against any and all claims (including any claims for personal injury or property damage), demands, suits, actions, prosecutions and other proceedings brought by or on behalf of a third Party, and all resulting damages, liabilities, losses, fines, penalties, judgments, awards, settlements, costs and expenses (including reasonable attorneys' fees and costs), arising from or related to (i) the gross negligence or willful misconduct of Licensee in performing its obligations hereunder, (ii) Licensee's breach of any representation, warranty or covenant set forth in this Agreement, (iii) the manufacture, use, distribution, handling, storage, sale or other disposition of any Licensed Products by Licensee, its Affiliates, agents or sublicensees, except to the extent arising out of or relating to Iferanserin in the Licensed Product, or (iv) any claim or allegation of infringement of any Third Party's Intellectual Property Rights arising from or related to any inactive ingredients in any Licensed Products not originally an ingredient in such Licensed Product prior to the Effective Date; provided, however, Licensee shall have no such obligation under this **Section 12.1** to the extent any claim, suit or proceeding arises out of result from any claim for which Sam Amer is required to indemnify Licensee pursuant to **Section 12.2**.

12.2 By Sam Amer. Sam Amer shall indemnify, defend and hold harmless Licensee and its Affiliates, and their respective officers, directors, managers, agents and employees from and against any and all claims (including any claims for personal injury or property damage), demands, suits, actions, prosecutions and other proceedings brought by or on behalf of a third Party, and all resulting damages, liabilities, losses, fines, penalties, judgments, awards, settlements, costs and expenses (including reasonable attorneys' fees and costs), arising from or related to (i) the gross negligence or willful misconduct of Sam Amer in performing its obligations hereunder, (ii) Sam Amer's breach of any representation, warranty or covenant set forth in this Agreement, or (iii) any claim or allegation that Iferanserin, standing alone and with or without the addition of inactive ingredients included in any Licensed Product, or the Product Licenses infringe, misappropriate or otherwise violate the Intellectual Property Rights of a Third Party; provided, however, Sam Amer shall have no such obligation hereunder to the extent any claim, suit or proceeding arises out of or results from any claim for which Licensee is required to indemnify Sam Amer pursuant to **Section 12.1**. Without limiting the other obligations of Sam Amer under this Agreement, Sam Amer will exercise its best efforts to obtain licenses from any Third Party of such Third Party's Intellectual Property Rights as may be necessary for Sam Amer to license the Product Licenses to Licensee and otherwise perform its obligations under this Agreement.

12.3 Procedure. Each Party shall promptly notify the other Party of any notice of the commencement or filing of any claim for which the other Party is entitled to indemnification hereunder. Failure to give or delay in giving such notice shall not relieve either Party of its indemnification obligations hereunder, except to the extent that the defense of such claim is prejudiced thereby. The indemnifying Party shall have sole control of the defense and settlement of any claim; provided, however, that (a) if Sam Amer is the indemnifying Party, Sam Amer shall have demonstrated, to the reasonable satisfaction of Licensee, Sam

Amer's financial capacity and capital resources to prosecute the defense and settlement, and (b) no compromise or settlement may be committed to without the indemnified Party's prior written consent unless (i) it includes a full discharge and release of liability for the indemnified Party, (ii) it has no effect on any rights or obligations of the indemnified Party, or on any claims that may be made by or against the indemnified Party, and (iii) there is no injunctive or other equitable relief entered against the indemnified Party. The indemnifying Party shall defend any claim hereunder with counsel reasonably acceptable to the indemnified Party. The indemnified Party shall provide reasonable assistance, at the indemnifying Party's request and sole expense, needed in the defense or settlement of any claim. The indemnified Party also may elect to participate in the defense of any claim at its own expense with counsel of its choice.

12.4 Insurance.

(a) At all times while this Agreement is in effect, Licensee shall: (a) maintain Commercial General Liability insurance (including, without limitation, bodily injury and property damage coverage) at limits not less than US \$10,000,000 per occurrence/US \$10,000,000 aggregate; (b) maintain Clinical Trial insurance; (c) maintain Product Liability Insurance (together the "Insurance Policies") at limits not less than US \$10,000,000 per occurrence/US \$10,000,000 aggregate; (d) if Licensee terminates the Insurance Policies during the term of this Agreement, obtain and maintain the maximum available Extended Discovery Period insurance; (e) include Sam Amer as "Additional Insured" under the Insurance Policies; (f) provide, within thirty (30) days of Sam Amer's request, Certificates of Insurance verifying insurance limits agreed upon as well as a thirty (30) day Notice of Cancellation or Non-Renewal; (g) maintain Property insurance at limits not less than US \$10,000,000 per occurrence/US \$10,000,000 aggregate; and (h) maintain Automobile/Fleet insurance (with a third Party liability including bodily injury and property damage of aggregate for Automobile) at limits not less than US \$1,000,000 per occurrence/US \$1,000,000 aggregate. Licensee shall obtain all the insurance policies described in clauses (a) through (g) from insurers having A.M. Best ratings reasonably satisfactory to Sam Amer.

13. REPRESENTATIONS AND WARRANTIES

13.1 Effective Date. The representations and warranties of each Party made in this Section 13, shall be deemed made as of the Effective Date of this Agreement.

13.2 Existence and Power. Each Party hereto, including Guarantor, represents and warrants to the other Party that it (a) is duly organized, validly existing and in good standing under the laws of the state in which it is created, and (b) has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted hereunder. Guarantor further represents and warrants that it has the financial resources to perform its guarantee obligations hereunder.

13.3 Authority. Each Party hereto, including Guarantor, represents and warrants to the other Party that (i) it has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation of such Party and is enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity whether enforceability is considered in a proceeding at law or equity.

13.4 Absence of Litigation. Each Party represents and warrants to the other Party that to the best of its Knowledge there is no pending or threatened litigation (and has not received any communication) which alleges that such Party's activities under this Agreement or the Licensed Patents have violated, or that by conducting the activities as contemplated herein such Party would violate, any of the Intellectual Property Rights of any Third Party.

13.5 No Approvals or Consents. Except as otherwise described in this Agreement, each Party represents and warrants to the other that it has all necessary consents, approvals and authorizations of all applicable persons or entities required to be obtained by such Party in order to enter into this Agreement.

13.6 Additional Representations of Sam Amer. Sam Amer represents and warrants that: (i) Sam Amer exclusively owns all rights, title, and interests in the Licensed Patents and the Licensed Know-How free and clear of any liens, charges, encumbrances, licenses, or other claim of right or ownership by any Third Party. (ii) to the best of its Knowledge, Iferanserin and the Licensed Products do not violate any Intellectual Property Rights of any other Person; (iii) Sam Amer has received no communication alleging that it has violated or, by conducting its business as contemplated by this Agreement would violate, any of the Intellectual Property Rights of any other Person; (iv) Sam Amer has not previously granted and will not grant any rights inconsistent with the rights and license granted herein; (v) Sam Amer has provided and will provide to Licensee all documents in its files, as well as all other information, that are included within the Licensed Know-How and Licensed Patents, including, without limitation, any information that relates to the patentability or validity of the Licensed Patents; (vi) to the best of Sam Amer's knowledge, the Licensed Patents are valid and enforceable, and there are no patent rights or similar intellectual property rights of a Third Party that the development, manufacture, use or sale of the Licensed Products would infringe if Licensee did not have a license thereto; and (vii) the Licensed Patents and Licensed Know-How is not subject to any funding agreement with any government or governmental agency.

13.7 Iferanserin. Licensee represents and warrants that: (i) to its Knowledge, its use of Iferanserin alone or in conjunction with inactive ingredients, as contemplated by this Agreement does not violate any Intellectual Property Rights of any other Person; and (ii) it has received no communication alleging that it has violated or by conducting its business as contemplated by this Agreement would violate any of the Intellectual Property Rights of any other Person.

13.8 Compliance. Each Party represents and warrants to the other Party that it shall, and shall cause its Affiliates to, comply in all material respects with all applicable federal, state, local and foreign laws, statutes, rules and regulations applicable to their and their Affiliates' respective activities under this Agreement.

13.9 No Conflict. Each Party represents and warrants to the other Party that the execution and delivery of this Agreement and the performance of its obligations hereunder: (a) does not conflict with or violate any requirement of applicable law or regulation or any provision of the limited liability company agreements of such Party, and (b) does not conflict with, violate or breach or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

13.10 Continuous Nature. Except as expressly stated otherwise, all representations and warranties made by the Parties in this Agreement shall be deemed first made on the Effective Date and shall run continuously thereafter. Each Party shall promptly notify the other Party if any material change in circumstance makes any representation inaccurate, or causes or is likely to cause a breach any warranty, and shall provide any and all information and cooperation reasonably requested in connection therewith.

14. LIMITATIONS OF LIABILITY.

14.1 NO PARTY WILL BE LIABLE TO THE OTHER PARTY FOR PUNITIVE, EXEMPLARY, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR OTHER INDIRECT DAMAGES (INCLUDING WITHOUT LIMITATION LOST PROFITS, BUSINESS OR GOODWILL) ATTRIBUTABLE TO ANY BREACH OR DEFAULT BY SUCH PARTY UNDER THIS AGREEMENT. THIS LIMITATION SHALL SURVIVE ANY FAILURE OF THE ESSENTIAL PURPOSE OF A LIMITED OR EXCLUSIVE REMEDY SET FORTH HEREIN.

14.2 THE LIMITATIONS ON LIABILITY SET FORTH IN SECTION 14.1 ABOVE SHALL NOT APPLY TO, AND NOTHING CONTAINED IN THIS AGREEMENT SHALL LIMIT THE LIABILITY OF EITHER PARTY FOR A PARTY'S INDEMNIFICATION AND DEFENSE OBLIGATIONS UNDER SECTION 12.

15. GOVERNING LAW; ALTERNATIVE DISPUTE RESOLUTION

15.1 Governing Law. This Agreement shall be governed by the laws in effect in the State of New York, without regard to its conflict of laws principles that would require the application of the laws of any other jurisdiction. The Parties expressly agree that the United Nations Convention on Contracts of the International Sale of Goods does not and shall not apply to this Agreement

15.2 Alternative Dispute Resolution.

(a) In the event of any dispute relating to this Agreement or a Product License, other than a dispute relating to the Intellectual Property Rights of any Party, the Parties shall, prior to instituting any arbitration proceeding or lawsuit (if applicable) on account of such dispute, refer such dispute to the President of Licensee and the President of Sam Amer, who shall, as soon as is practicable, and with the assistance of a mediator as provided below, attempt in good faith to resolve the dispute. The Parties shall select a mediator who shall serve as an impartial facilitator of such discussion. If the Parties are unable to agree upon a mediator, a mediator shall be designated by the American Arbitration Association ("AAA"). The mediation shall be treated as a settlement discussion and therefore will be privileged and confidential. The mediator may not testify for either Party or serve as an arbitrator in any later proceeding relating to the dispute, and no recording or transcript shall be made of the mediation proceedings. Each Party shall bear its own costs in the mediation and the fees and expenses of the mediator shall be shared equally by the Parties. If such dispute is not resolved within ninety (90) days of the first written request for mediation, either Party may seek arbitration of the matter as set forth herein. Notwithstanding anything in this Agreement to the contrary, any Party shall be entitled to seek equitable relief any time if the same shall be necessary to prevent irreparable harm to any Party.

(b) Except with respect to equitable relief and disputes relating to the Intellectual Property Rights of any Party, which may be obtained in a court of competent jurisdiction, if the Parties are unable to resolve any dispute through the mediation provisions set forth above, such dispute shall be finally resolved by arbitration. The arbitration shall be in accordance with the Commercial Arbitration Rules ("Rules") of the AAA which shall administer the arbitration and act as appointing authority; provided that the arbitrator(s) appointed with regard to the arbitration proceeding shall not be the same persons who served as mediated in any mediation between the Parties. In addition to such discovery as may be provided for in the Rules, the Parties agree to permit (i) up to three depositions per Party and (ii) up to 15 interrogatories per Party, provided that the arbitrator(s) agree that such depositions and interrogatories are appropriate after hearing the Parties on the subject thereof. In the event of any conflict between the Rules and the provisions of this **Section 15.2**, the provisions of this **Section 15.2** shall govern. If the amount in controversy exceeds \$50,000, then the arbitration shall be heard and determined by a panel of three arbitrators selected in accordance with the procedures of the AAA. The arbitration, including the rendering of the award, shall take place at such location as the Parties may agree and, if no location can be agreed, at such location as the AAA directs. Judgment upon the award of the arbitrators may be entered in any court having jurisdiction thereof. In the event of any arbitration or other legal proceeding brought by any Party against another Party with regard to any matter arising out of or related to this Agreement, each Party hereby expressly agrees that the final award may also provide for an allocation and division between or among the Parties to the arbitration, on a basis which is just and equitable under the circumstances, of all costs of arbitration, including court costs and arbitrators' fees but not attorneys' fees; provided, however, that attorneys' fees may be awarded against a Party if the arbitrators specifically find willful misconduct by that Party.

16. MISCELLANEOUS PROVISIONS

16.1 Press Releases. All press releases or other public communication by any Party relating to this Agreement or a Product License (other than those communications required by law) shall be subject to the prior written approval of each Party, such approval not to be unreasonably withheld or delayed. To the extent a disclosure is required by Applicable Laws or regulations (including SEC regulations), each Party shall provide the other with prior written notification of such disclosure. Licensee shall be free to develop and distribute marketing materials pertaining to Licensed Products without prior review and approval of Sam Amer. If Sam Amer is mentioned in marketing materials, distribution of such materials shall require Sam Amer's prior written consent (solely as to approval of use of Sam Amer's name in connection with such materials), not to be unreasonably withheld or delayed.

16.2 Use of Names, Logos or Symbols. Except as otherwise set forth herein and as required by Applicable Law or regulations, neither Party hereto shall use the name, Trademarks, logos, physical likeness, employee names or owner symbol of the other Party hereto for any purpose, without the prior written consent of the affected Party, such consent not to be unreasonably withheld or delayed so long as such use of name is limited to objective statements of fact, rather than for endorsement purposes. Notwithstanding the foregoing, Licensee may, without the consent of Sam Amer, identify Sam Amer as licensor under this Agreement to actual or potential investors and investment bankers.

16.3 Notices. All notices required or permitted to be given under this Agreement or any Product License shall be in writing and shall be deemed given, upon receipt, if mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by overnight delivery (receipt verified) to the address below, or given personally or transmitted by facsimile to the number indicated below (with confirmation). All notices to Licensee shall be addressed to Licensee as follows:

Ventrus Biosciences, Inc.
8400 E Crescent Pkwy, Suite 600
Greenwood Village, CO 80111
Attention: President

Paramount Biosciences, LLC
787 Seventh Avenue, 48th Floor
New York, NY 10019
Attention: Counsel

All notices to Sam Amer shall be addressed as follows:

Sam Amer & Co, Inc.
PO Box 5685
Montecito, CA 93150
Fax: 805/684-0344
Attention: Sam Amer

With a copy to:

Charles R. Jacob III, Esq.
Miller & Wrubel P.C.
250 Park Avenue
New York, NY 10177
Fax: 212/336-3555

Either Party may, by written notice to the other, designate a new address or fax number to which notices to it shall thereafter be mailed or faxed.

16.4 Force Majeure. If either Party is affected by any extraordinary, unexpected and unavoidable event such as acts of God, floods, fires, riots, war, accidents, labor disturbances, breakdown of plant or equipment, lack or failure of transportation facilities, unavailability of equipment, sources of supply or

labor, raw materials, power or supplies, infectious diseases of animals, or by the reason of any law, order, proclamation, regulation, ordinance, demand or requirement of the relevant government or any subdivision, authority or representative thereof, or by reason of any other cause whatsoever beyond its reasonable control (provided that in all such cases the Party claiming relief on account of such event can demonstrate that such event was extraordinary, unexpected and unavoidable by the exercise of reasonable care) ("Force Majeure") it shall as soon as reasonably practicable notify the other Party of the nature and extent thereof and take all reasonable steps to overcome the Force Majeure and to minimize the loss occasioned to that other Party. Neither Party shall be deemed to be in breach of this Agreement or otherwise be liable to the other Party by reason of any delay in performance or nonperformance of any of its obligations hereunder to the extent that such delay and nonperformance is due to any Force Majeure of which it has notified the other Party and the time for performance of that obligation shall be extended accordingly.

16.5 Entirety of Agreement. This Agreement, including the exhibits and/or attachments, and the CDA set forth the entire agreement and understanding of the Parties relating to the subject matter contained herein and merge and supersede all prior and contemporaneous discussions and agreements between them, whether written or oral. No Party shall be bound by any representation other than as expressly stated in this Agreement, or by a written amendment to this Agreement signed by authorized representatives of both Parties.

16.6 Non-Waiver. The failure of a Party in any one or more instances to insist upon strict performance of any of the terms and conditions of this Agreement shall not be construed as a waiver or relinquishment, to any extent, of the right to assert or rely upon any such terms or conditions on any future occasion.

16.7 Construction. The section headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement. As used in this Agreement the words "include" and "including," and variations thereof, will not be deemed to be terms of limitation, but rather will be deemed to be followed by the words "without limitation." When used in this Agreement, the words "hereof," "herein," "hereunder" and words of similar import shall refer to the Agreement as a whole and not to any particular provision of this Agreement. Any rule of construction to the effect that ambiguities are to be resolved against the drafting Party will not be applied in the construction or interpretation of this Agreement.

16.8 Disclaimer of Agency. The Parties hereto are independent contractors. Nothing in this Agreement will be deemed to create an agency, employment, partnership, fiduciary or joint venture relationship between the Parties. Neither Party has, and nor will it represent to any Third Party that it has, the power or authority to represent, act for, bind or otherwise create or assume any obligation on behalf of the other Party for any purpose whatsoever.

16.9 Severability. If any term, covenant or condition of this Agreement or , or the application thereof to any Party or circumstance shall, to any extent, be held to be invalid or unenforceable, then: (a) such provision will be changed and interpreted to accomplish the objectives of such provision to the greatest extent possible under applicable law, and (b) the remainder of this Agreement, or the application of such term, covenant or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each term, covenant or condition of this Agreement shall be valid and be enforced to the fullest extent permitted by law.

16.10 Assignment. Neither Party may assign or transfer this Agreement, in whole or in part, by operation of law or otherwise, without the prior written consent of the other Party (which consent shall not be unreasonably withheld), except as set forth herein. Notwithstanding the foregoing, Sam Amer's approval shall not be required for (i) an assignment in connection with a sale of all or substantially all Licensee's assets to a Third Party, or a merger or other business reorganization of Licensee (in such instance, Licensee shall provide Sam Amer with notice thereof), or (ii) an assignment to an Affiliate of Licensee. Licensee shall not assign this Agreement prior to the termination or fulfillment of Guarantor's obligations under **Section 17.1** without the prior written consent of Sam Amer. The Parties may discharge any obligations and exercise any right hereunder through an Affiliate, provided that the Parties shall remain ultimately

responsible for the proper discharge of all obligations hereunder notwithstanding any assignment or delegation to any such Affiliate. Any attempted assignment or transfer in violation of the foregoing provisions shall be null and void from the beginning any of no force or effect. This Agreement shall be binding on and inure to the benefit of the Parties and their respective successors and permitted assigns.

16.11 Interpretation. This Agreement has been jointly prepared by the Parties and their respective legal counsel and shall not be strictly construed against either Party.

16.13 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be an original and all of which shall constitute together the same document.

16.14 Further Actions. Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate to carry out the purposes and intent of this Agreement (including any Product Schedule).

17. GUARANTEE

17.1 Guarantee. Subject to the terms and conditions set forth in this Section 17, Guarantor unconditionally and irrevocably guarantees to Sam Amer the full and timely payment of all License Fees set forth in Section 6.1 of this Agreement, the consulting fees set forth in Section 6.5 of this Agreement and all other payment obligations of Licensee hereunder. The guarantee obligation set forth in this Section 17 shall automatically terminate upon (i) Licensee's completion of financings resulting in Licensee's actual receipt of ten million dollars (\$10,000,000) in the aggregate or (ii) upon execution of a sublicense pursuant to Section 2.3.

17.2 Guarantor agrees that this Guaranty constitutes a guaranty of payment and waiver of any obligation of Licensor to pursue any remedies against Licensee otherwise available under Applicable Laws, provided that Licensor has made due demand upon Licensee and Licensee has defaulted upon payment.

17.3 Guarantor hereby expressly waives and surrenders any defense to Guarantor's liability hereunder based upon any of the following:

- (a) any extension or renewal of any of the obligations of Licensee, in whole or in part, without notice to, or further assent from, Guarantor;
- (b) the voluntary or involuntary liquidation, dissolution, receivership, insolvency, bankruptcy, assignment for the benefit of creditors, reorganization, arrangement, composition or readjustment of Licensee;
- (c) forbearance or delay or other act or omission of Sam Amer or its failure to proceed promptly or otherwise, or by reason of any further dealings between Licensee and Sam Amer, solely to the extent the foregoing does not materially affect the rights and/or remedies of Guarantor under Applicable Law; or
- (d) any other circumstances that might otherwise constitute a legal or equitable discharge of Licensee (including a discharge in bankruptcy), it being the purpose, intent and understanding of Guarantor that Guarantor's obligations hereunder are absolute and unconditional under any and all circumstances except as herein provided.

[Signatures on next page]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Agreement as of the date first written above.

THIS AGREEMENT CONTAINS A BINDING ARBITRATION PROVISION WHICH MAY BE ENFORCED BY THE PARTIES.

Ventrus, Inc.

By: /s/ Thomas Rowland

Thomas Rowland

Title: President

Date: 3-7-08

Sam Amer & Co, Inc.

By: /s/ Sam Amer

Sam Amer

Title: President

Date: 2-17-08

Guarantor hereby acknowledges and undertakes to perform the obligations described in **Sections 13 and 17.**

Paramount Biosciences, LLC

By: /s/ J. Jay Lobell 03/10/2008

J. Jay Lobell

Title: President & COO

SCHEDULE A

Licensed Patents

Annex 1A (AMR-11)

COUNTRY	APPLICATION NO.	FILING DATE	PATENT NO.	GRANT DATE	TITLE	STATUS
Australia	60377/98	01/23/93	750603	12/12/02	S-2-[2-(1-METHYL-2-PIPERIDYL) ETHYL] CINNAMANILIDE	Active
Canada	2282840	01/23/98			S-2-[2-(1-METHYL-2-PIPERIDYL) ETHYL] CINNAMANILIDE	Active
EPO	98903668.6	01/23/98	973741	6/11/03	S-2-[2-(1-METHYL-2-PIPERIDYL) ETHYL] CINNAMANILIDE	Active
France	98903668.6	1/23/98	0973741	6/11/03	S-2-[2-(1-METHYL-2-PIPERIDYL) ETHYL] CINNAMANILIDE	Active
Germany	98903668.6	1/23/98	69815518.1	6/11/03	S-2-[2-(1-METHYL-2-PIPERIDYL) ETHYL] CINNAMANILIDE	Active
Italy	98903668.6	1/23/98	EP973741	6/11/03	S-2-[2-(1-METHYL-2-PIPERIDYL) ETHYL] CINNAMANILIDE	Active
Spain	98903668.6	1/23/98	EP973741	6/11/03	S-2-[2-(1-METHYL-2-PIPERIDYL) ETHYL] CINNAMANILIDE	Active
Switzerland	98903668.6	1/23/98	EP973741	6/11/03	S-2-[2-(1-METHYL-2-PIPERIDYL) ETHYL] CINNAMANILIDE	Active

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United Kingdom	98903668.6	1/23/98	EP973741	6/11/03	S-2-[2-(1-METHYL-2-PIPERIDYL) ETHYL] CINNAMANILIDE	Active
Hong Kong	00104603.1	07/25/00			S-2-[2-(1-METHYL-2-PIPERIDYL) ETHYL] CINNAMANILIDE	Abandoned
Japan	520835/98	01/23/98	3492378		S-2-[2-(1-METHYL-2-PIPERIDYL) ETHYL] CINNAMANILIDE	Active
Korea	10-997007763	01/23/98			S-2-[2-(1-METHYL-2-PIPERIDYL) ETHYL] CINNAMANILIDE	Pending
Norway	19994181	01/23/98			S-2-[2-(1-METHYL-2-PIPERIDYL) ETHYL] CINNAMANILIDE	Pending
United States	08/810,503	02/28/97	5,780,487	07/14/98	S-2-[2-(1-METHYL-2-PIPERIDYL) ETHYL] CINNAMANILIDE	Active

Annex 1B (AMER 818389)

COUNTRY	APPLICATION NO.	FILING DATE	PATENT NO.	GRANT DATE	TITLE	STATUS
United States	07/818,389	01/09/92	5,266,571	11/30/93	Treatment of Hemorrhoids with 5-HT ₂ Antagonists	Active
United States	08/512,235	08/07/95	5,605,902	02/25/97	5-HT ₂ Receptor Antagonist Compositions Useful in Treating Venous Conditions	Active
EPO	9390697935	02/19/93	684816	02/04/04	5-HT ₂ Receptor Antagonist Compositions Useful in Treating Venous Conditions	Active

Korea	703438/95	02/19/93	0278522	10/20/00	5-HT2 Receptor Antagonist Compositions Useful in Treating Venous Conditions	Active
Japan	518914/94	02/19/93	2807092	07/24/98	5-HT2 Receptor Antagonist Compositions Useful in Treating Venous Conditions	Active
Australia	37748/93	02/19/93			5-HT2 Receptor Antagonist Compositions Useful in Treating Venous Conditions	Abandoned
Canada	2156481	2/19/93			5-HT2 Receptor Antagonist Compositions Useful in Treating Venous Conditions	Active

SCHEDULE B

Committee Members

Joint Development Committee (JDC)

Sam Amer members:

1. [Sam Amer, Ph.D.]
2. [C. Marguerite Amer]
3. [Tom Stribling]

Licensee members:

- 1.
- 2.
- 3.

Joint Commercialization Committee (JCC)

Sam Amer members:

1. [Sam Amer, Ph.D.]
2. [C. Marguerite Amer]
3. [Tom Stribling]

Licensee members:

- 1.
- 2.
- 3.

Confidential

☐ Confidential treatment requested.

AMENDMENT NO. 1 TO LICENSE AGREEMENT

AMENDMENT NO. 1 TO LICENSE AGREEMENT, dated July 31, 2008 (this "Amendment"), between **SAM AMER & CO., INC.** (the "Licensor"), **VENTRUS BIOSCIENCES, INC.** (the "Licensee"), and **PARAMOUNT BIOSCIENCES, LLC** (the "Guarantor").

WHEREAS, the Licensor, the Licensee, and the Guarantor have entered into that certain License Agreement, dated as of March 10, 2008 (the "License Agreement");

WHEREAS, the parties hereto desire to amend the License Agreement as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and for other consideration the sufficiency and receipt of which is hereby acknowledged by the parties, it is hereby agreed by and between the parties as follows:

1. **Capitalized Terms.** Terms used herein but not otherwise defined shall have the meaning ascribed thereto in the License Agreement

2. **Amendments.** Section 6.1 of the License Agreement is hereby deleted in its entirety and replaced with the following new Section 6.1:

6.1 **License Fees.** As consideration for the licenses granted hereunder, including of the Sam Amer Patents and the Sam Amer Know-How, Licensee shall pay Sam Amer the license fees ("License Fees") as set forth below within thirty (30) days after achievement of the applicable milestone event. Each License Fee shall be payable one time only, regardless of the number of Licensed Products that satisfy the condition that triggers such payment.

Milestone U.S. Territory	License Fee to Amer
Execution of this Agreement	\$2,050,000 to be paid as follows: (a) Initial payment of \$550,000 upon execution of this Agreement; and (b) remaining \$1,500,000 to be paid in three equal installments of \$500,000 on the following dates: September 15, 2008; November 10, 2008; and March 10, 2009. In addition, a one-time payment of \$15,000 to be paid on or before August 8, 2008.
No contingencies on initial License Fee beyond execution of this Agreement.	
Successful Completion of Phase III Trials.	\$1 (one) million
If the Phase III Trials are not successfully completed by July 2009, Licensee shall pay \$7,500 per month to Sam Amer until the Successful Completion of the Phase III Trials. Such payments will begin at July 2009.	
Notwithstanding the foregoing, if safety, efficacy or other regulatory issues prevent the completion of the	

Phase III Trials (a "Non-completion Event"), then Licensee's payment of \$7,500 per month shall cease upon the Non-Completion Event.

Upon Licensee's Submission of an NDA to the FDA. \$1 (one) million

If an NDA is not submitted by September 2010 \$7,500 per month will be paid until such submission. Payment will begin at September 2010.

Notwithstanding the foregoing, if safety, efficacy or other regulatory issues prevent the submission of NDA (a "Non-completion Event"), then Licensee's payment of \$7,500 per month shall cease upon the Non-Completion Event.

NDA Approval by FDA \$[4 (four) million]

At one (1) Year Anniversary following NDA Approval by FDA \$[2 (two) million]

At \$[20 million] cumulative lifecycle Net Sales attainment \$[1 (one) million]

At \$[50 million] cumulative lifecycle Net Sales attainment \$[2 (two) million]

At \$[75 million] cumulative lifecycle Net Sales attainment \$[4 (four) million]

At Regulatory Approval for OTC sale \$[5 (five) million]

3. **Counterparts.** This Amendment may be executed in any number of separate counterparts, each of which shall be an original and all of which taken together shall constitute one and the same instrument. Facsimile counterpart signatures to this Amendment shall be acceptable and binding.

4. **Applicable Law.** This Amendment shall be governed by and construed in accordance with the laws of New York without regard to its conflict of law principles that would require the application of the laws of any other jurisdiction. The parties hereto expressly agree that the United Nations Convention on Contracts of the International Sale of Goods does not and shall not apply to this Amendment.

5. **No Other Amendments.** Except as expressly set forth herein, the License Agreement remains in full force and effect in accordance with its terms and nothing contained herein shall be deemed to be a waiver, amendment, modification or other change of any term, condition or provision of the License Agreement.

☐ Confidential treatment requested.

6. **Effectiveness.** This Amendment shall become effective immediately upon the date hereof.

7. **References to the License Agreement.** From and after the date hereof, all references in the License Agreement and any other documents to the License Agreement shall be deemed to be references to the License Agreement after giving effect to this Amendment.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment No. 1 to License Agreement as of the date first written above.

SAM AMER & CO., INC.

By: /s/ M. S. Amer 7/30/08
Name: M. S. Amer
Title: President

VENTRUS BIOSCIENCES, INC.

By: /s/ Thomas Rowland
Name: Thomas Rowland
Title: President & CEO

PARAMOUNT BIOSCIENCES, LLC

By: /s/ Lindsay A. Rosenwald, MD
Name: Lindsay A. Rosenwald, MD
Title: Sole Member

Legal Approval
Initial: MHD
Date: _____

AMENDMENT NO. 2 TO LICENSE AGREEMENT

AMENDMENT NO. 2 TO LICENSE AGREEMENT, dated September 29, 2008 (this "Amendment"), between **SAM AMER & CO., INC.** (the "Licensor"), **VENTRUS BIOSCIENCES, INC.** (the "Licensee"), and **PARAMOUNT BIOSCIENCES, LLC** (the "Guarantor").

WHEREAS, the Licensor, the Licensee, and the Guarantor have entered into that certain License Agreement, dated as of March 10, 2008, and Amendment No. 1 to License Agreement, dated as of July 31, 2008 (together with all amendments and modifications to date, the "License Agreement");

WHEREAS, the parties hereto desire to amend the License Agreement as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and for other consideration the sufficiency and receipt of which is hereby acknowledged by the parties, it is hereby agreed by and between the parties as follows:

1. Capitalized Terms. Terms used herein but not otherwise defined shall have the meaning ascribed thereto in the License Agreement.

2a. Amendments. Section 6.1 of the License Agreement is hereby deleted in its entirety and replaced with the following new Section 6.1:

6.1 License Fees. As consideration for the licenses granted hereunder, including of the Sam Amer Patents and the Sam Amer Know-How, Licensee shall pay Sam Amer the license fees ("License Fees") as set forth below within thirty (30) days after achievement of the applicable milestone event. Each License Fee shall be payable one time only, regardless of the number of Licensed Products that satisfy the condition that triggers such payment.

Milestone U.S. Territory	License Fee to Amer
Execution of this Agreement. No contingencies on initial License Fee beyond execution of this Agreement.	\$2,050,000 to be paid as follows: (a) Initial payment of \$550,000 upon execution of this Agreement (which amount each of the parties acknowledge has been paid); and (b) remaining \$1,500,000 to be paid in two installments as follows: \$1,000,000 to be paid on or before November 15, 2008; \$500,000 to be paid on or before March 10, 2009. In addition, a one-time payment of \$15,000 to be paid on or before August 8, 2008 (which amount each of the parties acknowledge has been paid); and a one-time payment of \$25,000 to be paid on or before October 10, 2008. For the avoidance of doubt, the thirty (30) day payment period referenced in this Section 6.1 shall not apply to either the \$1,000,000

Successful Completion of Phase III Trials.	November 15 th payment or the \$25,000 October 10 th payment. Said 30 day payment period will continue to apply to the installment payment of \$500,000 due on or before March 10, 2009. \$1 (one) million
<p>If the Phase III Trials are not successfully completed by July 2009, Licensee shall pay \$7,500 per month to Sam Amer until the Successful Completion of the Phase III Trials. Such payments will begin at July 2009.</p> <p>Notwithstanding the foregoing, if safety, efficacy or other regulatory issues prevent the completion of the Phase III Trials (a "Non-completion Event"), then Licensee's payment of \$7,500 per month shall cease upon the Non-Completion Event.</p>	
Upon Licensee's Submission of an NDA to the FDA.	\$1 (one) million
<p>If an NDA is not submitted by September 2010 \$7,500 per month will be paid until such submission. Payment will begin at September 2010.</p> <p>Notwithstanding the foregoing, if safety, efficacy or other regulatory issues prevent the submission of NDA (a "Non-completion Event"), then Licensee's payment of \$7,500 per Month shall cease upon the Non-Completion Event.</p>	
NDA Approval by FDA	\$[4 (four) million]
At one (1) Year Anniversary following NDA Approval by FDA	\$[2 (two) million]
At \$[20 million] cumulative lifecycle Net Sales attainment	\$[1 (one) million]
At \$[50 million] cumulative lifecycle Net life cycle attainment	\$[2 (two) million]
At \$[75 million] cumulative life cycle Net Sales attainment	\$[4 (four) million]
At Regulatory Approval for OTC sale	\$[5 (five) million]

2b. Amendments. Section 6.5 of the License Agreement is hereby deleted in its entirety and replaced with the following new Section 6.5:

6.5 Consulting Fee. Licensee will pay Sam Amer a consulting fee of \$7,500.00 per month for the first sixteen (16) months following the effective date of this Agreement.

☐ Confidential treatment requested.

3. **Counterparts.** This Amendment may be executed in any number of separate counterparts, each of which shall be an original and all of which taken together shall constitute one and the same instrument. Facsimile counterpart signatures to this Amendment shall be acceptable and binding.

4. **Applicable Law.** This Amendment shall be governed by and construed in accordance with the laws of New York without regard to its conflict of law principles that would require the application of the laws of any other jurisdiction. The parties hereto expressly agree that the United Nations Convention on Contracts of the International Sale of Goods does not and shall not apply to this Amendment.

5. **No Other Amendments.** Except as expressly set forth herein, the License Agreement remains in full force and effect in accordance with its terms and nothing contained herein shall be deemed to be a waiver, amendment, modification or other change of any term, condition or provision of the License Agreement.

6. **Effectiveness.** This Amendment shall become effective immediately upon the date hereof.

7. **References to the License Agreement.** From and after the date hereof, all references in the License Agreement and any other documents to the License Agreement shall be deemed to be references to the License Agreement after giving effect to this Amendment.

* * * * *

IN WITNESS WHEREOF, the parties hereto have executed this Amendment No. 2 to License Agreement as of the date first written above.

SAM AMER & CO., INC.

By: /s/ Sam Amer
Name: Sam Amer
Title: President

VENTRUS BIOSCIENCES, INC.

By: /s/ Thomas Rowland
Name: Thomas Rowland
Title: President & CEO

PARAMOUNT BIOSCIENCES, LLC

By: /s/ Lindsay A. Rosenwald, MD
Name: Lindsay A. Rosenwald, MD
Title: Sole Member

Legal Approval
Initial: MHD
Date: _____

AMENDMENT NO. 3 TO LICENSE AGREEMENT

AMENDMENT NO. 3 TO LICENSE AGREEMENT, dated November 17, 2008 (this "Amendment"), between **SAM AMER & CO., INC.** (the "Licensor"), **VENTRUS BIOSCIENCES, INC.** (the "Licensee"), and **PARAMOUNT BIOSCIENCES, LLC** (the "Guarantor").

WHEREAS, the Licensor, the Licensee, and the Guarantor have entered into that certain License Agreement, dated as of March 10, 2008, and Amendment No. 1 to License Agreement, dated as of July 31, 2008, and Amendment No. 2 to License Agreement, dated as of September 29, 2008 (together with all amendments and modifications to date, the "License Agreement");

WHEREAS, the parties hereto desire to amend the License Agreement as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and for other consideration the sufficiency and receipt of which is hereby acknowledged by the parties, it is hereby agreed by and between the parties as follows:

1. Capitalized Terms. Terms used herein but not otherwise defined shall have the meaning ascribed thereto in the License Agreement.

2. Amendments. Section 6.1 of the License Agreement is hereby deleted in its entirety and replaced with the following new Section 6.1:

6.1 License Fees. As consideration for the licenses granted hereunder, including of the Sam Amer Patents and the Sam Amer Know-How, Licensee shall pay Sam Amer the license fees ("License Fees") as set forth below within thirty (30) days after achievement of the applicable milestone event. Each License Fee shall be payable one time only, regardless of the number of Licensed Products that satisfy the condition that triggers such payment.

Milestone U.S. Territory	License Fee to Amer
Execution of this Agreement.	\$2,050,000 to be paid as follows: (a) Initial payment of \$550,000 upon execution of this Agreement (which amount each of the parties acknowledge has been paid); and (b) remaining \$1,500,000 to be paid in installments as follows:
No contingencies on initial License Fee beyond execution of this Agreement,	\$50,000 to be paid on or before November 17, 2008; \$100,000 to be paid on or before January 15, 2009; \$100,000 to be paid on or before February 15, 2009; \$500,000 to be paid on or before March 10, 2009; and \$750,000 to be paid on or before March 15, 2009.
	In addition, (i) a one-time penalty payment of \$15,000 to be paid on or before August 8, 2008 (which amount each of the parties acknowledge has been paid), (ii) a one-

time penalty payment of \$25,000 to be paid on or before October 10, 2008 (which amount each of the parties acknowledge has been paid), and (iii) a one-time penalty payment of \$100,000 to be paid on or before November 17, 2008.

For the avoidance of doubt, the thirty (30) day payment period referenced in this Section 6.1 shall not apply to the installment payments listed in this section that are due November 17, 2008, January 15, 2009, February 15, 2009, or March 15, 2009. Said 30 day payment period shall continue to apply to the installment payment due March 10, 2009.

Notwithstanding any of the foregoing to the contrary, in the event Licensee has sold its equity securities to investors with aggregate gross proceeds to Licensee of at least \$10,000,000 (a "Financing") on or before March 15, 2009, then the Installment payments due as of March 15, 2009 shall be accelerated such that the balance of such remaining installments shall be due to Licensor within thirty (30) days of the closing of the Financing or March 15, 2009 whichever is earlier.

Successful Completion of Phase III Trials.

\$1 (one) million

If the Phase III Trials are not successfully completed by July 2009, Licensee shall pay \$7,500 per month to Sam Amer until the Successful Completion of the Phase III Trials. Such payments will begin at July 2009.

Notwithstanding the foregoing, if safety, efficacy or other regulatory issues prevent the completion of the Phase III Trials (a "Non-completion Event"), then Licensee's payment of \$7,500 per month shall cease upon the Non-Completion Event.

Upon Licensee's Submission of an NDA to the FDA.

\$1 (one) million

If an NDA is not submitted by September 2010 \$7,500 per month will be paid until such submission. Payment will begin at September 2010.

Notwithstanding the foregoing, if safety, efficacy or other regulatory issues prevent the submission of NDA (a "Non-completion Event"), then Licensee's payment of \$7,500 per month shall cease upon the Non-Completion Event.

NDA Approval by FDA

\$[4 (four) million]

At one (1) Year Anniversary following NDA Approval by FDA

\$[2 (two) million]

[] Confidential treatment requested.

At \$[20 million] cumulative lifecycle Net Sales attainment	\$[1 (one) million]
At \$[50 million] cumulative lifecycle Net life cycle attainment	\$[2 (two) million]
At \$[75 million] cumulative life cycle Net Sales attainment	\$[4 (four) million]
At Regulatory Approval for OTC sale	\$[5 (five) million]

3. **Consulting Fee.** The parties hereby agree that, in satisfaction of outstanding consulting fee payments due to the Licensor under Section 6.5 of the License Agreement, the Licensee (or the Guarantor on behalf of the Licensee) shall pay to the Licensor an amount of \$15,000 on or before November 17, 2008. Regular monthly payments to Licensor of consulting fees equal to \$7,500 per month pursuant to Section 6.5 of the License Agreement shall resume on a monthly basis beginning on or before December 1, 2008.

4. **Counterparts.** This Amendment may be executed in any number of separate counterparts, each of which shall be an original and all of which taken together shall constitute one and the same instrument. Facsimile counterpart signatures to this Amendment shall be acceptable and binding.

5. **Applicable Law.** This Amendment shall be governed by and construed in accordance with the laws of New York without regard to its conflict of law principles that would require the application of the laws of any other jurisdiction. The parties hereto expressly agree that the United Nations Convention on Contracts of the International Sale of Goods does not and shall not apply to this Amendment.

6. **No Other Amendments.** Except as expressly set forth herein, the License Agreement remains in full force and effect in accordance with its terms and nothing contained herein shall be deemed to be a waiver, amendment, modification or other change of any term, condition or provision of the License Agreement.

7. **Effectiveness.** This Amendment shall become effective immediately upon the date hereof.

8. **References to the License Agreement.** From and after the date hereof, all references in the License Agreement and any other documents to the License Agreement shall be deemed to be references to the License Agreement after giving effect to this Amendment.

* * * * *

☐ Confidential treatment requested.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment No. 3 to License Agreement as of the date first written above.

SAM AMER & CO., INC.

By: /s/ Sam Amer 11-18-08
Name: Sam Amer
Title: President

VENTRUS BIOSCIENCES, INC.

By: /s/ Thomas Rowland
Name: Thomas Rowland
Title: President & CEO

PARAMOUNT BIOSCIENCES, LLC

By: /s/ Lindsay A. Rosenwald, MD
Name: Lindsay A. Rosenwald, MD
Title: Sole Member

Legal Approval
Initial: MHD
Date: _____

Execution VENTRUS BIOSCIENCES, INC.
8400 E. Crescent Pkwy, Suite 600
Greenwood Village, CO 80111

March 13, 2009

Sam Amer & Co., Inc.
P.O. Box 5685
Montecito, CA 93150
Attn: Sam Amer

Dear Sam:

Reference is hereby made to the License Agreement, dated as of March 10, 2008, between Sam Amer & Co., Inc. ("Amer"), Ventrus Biosciences, Inc. ("Ventrus"), and Paramount Biosciences, LLC ("Paramount") as amended by Amendment No. 1 to License Agreement, dated as of July 31, 2008, Amendment No. 2 to License Agreement, dated as of September 29, 2008, and Amendment No. 3 to License Agreement, dated as of November 17, 2008 (taken together, including all amendments and alterations to date, the "License Agreement"). To the extent this letter agreement is in conflict with any provision of the License Agreement, such provision of the License Agreement is hereby superseded and replaced in all respects by the content of this Letter Agreement.

Amer, Ventrus, and Paramount hereby agree that the payments due to Amer under the License Agreement by Ventrus (or Paramount, as guarantor) on (i) March 10, 2009 (subject to a 30-day payment period thereafter), and (ii) March 15, 2009 (not subject to any payment period) (together, the "Remaining Execution Payments") shall be, and are, hereby amended such that: (a) US\$110,000 shall be due to Amer by Ventrus (or Paramount, as guarantor) no later than March 25, 2009, with US\$100,000 of such payment to be applied to the balance of the Remaining Execution Payments, and US\$10,000 of such payment representing a late payment fee; (b) US\$110,000 shall be due to Amer by Ventrus (or Paramount, as guarantor) no later than April 20, 2009, with US\$100,000 of such payment to be applied to the balance of the Remaining Execution Payments, and US\$10,000 of such payment representing a late payment fee; and (c) US\$1,050,000, representing the entire combined amount still outstanding of the Remaining Execution Payments at such time, shall be due to Amer by Ventrus (or Paramount, as guarantor) no later than May 20, 2009. No payment period shall apply to such payment deadline.

Notwithstanding any of the foregoing to the contrary, in the event Ventrus has sold its equity securities to investors with aggregate gross proceeds to Ventrus of at least \$10,000,000 (a "Financing") on or before May 20, 2009, then the Remaining Execution Payments shall be accelerated such that they shall be due to Amer within thirty (30) days of the closing of the Financing, or May 20, 2009, whichever is earlier.

Except as specified herein, the License Agreement, including consulting fee payment obligations, remains in full force and in good standing among Amer, Ventrus, and Paramount.

* * * * *

If the foregoing correctly sets forth your understanding of our agreement with respect to the matters addressed above, please indicate your acceptance and approval below.

VENTRUS BIOSCIENCES, INC.

By: /s/ Thomas Rowland 3/20/09
Name: Thomas Rowland
Title: President & CEO

PARAMOUNT BIOSCIENCES, LLC

By: /s/ Lindsay A. Rosenwald, MD
Name: Lindsay A. Rosenwald, MD
Title: Sole Member

AGREED AND ACKNOWLEDGED:

SAM AMER & CO., INC.

By: /s/ Sam Amer 3/8/09
Name: Sam Amer
Title: President

VENTRUS BIOSCIENCES, INC.
8400 E. Crescent Pkwy, Suite 600
Greenwood Village, CO 80111

August 18, 2009

Sam Amer & Co., Inc.
P.O. Box 5685
Montecito, CA 93150
Attn: Sam Amer

Dear Sam:

Reference is hereby made to the License Agreement, dated as of March 10, 2008, between Sam Amer & Co., Inc. ("Amer"), Ventrus Biosciences, Inc. ("Ventrus"), and Paramount Biosciences, LLC ("Paramount") as amended by Amendment No. 1 to License Agreement, dated as of July 31, 2008, Amendment No. 2 to License Agreement, dated as of September 29, 2008, and Amendment No. 3 to License Agreement, dated as of November 17, 2008, and Letter Agreements dated as of March 13, 2009 and May 13, 2009 (taken together, including all amendments and alterations to date, the "License Agreement"). To the extent this letter agreement is in conflict with any provision of the License Agreement, such provision of the License Agreement is hereby superseded and replaced in all respects by the content of this Letter Agreement.

Amer, Ventrus, and Paramount hereby agree that the remaining payments due to Amer under the License Agreement by Ventrus (or Paramount, as guarantor) are: (i) \$1,115,000, which is due and payable on August 15, 2009 and constitutes the "Remaining Execution Payments" and (ii) a monthly consulting fee of \$7,500. In addition, Amer, Ventrus and Paramount acknowledge and agree that pursuant to the Letter Agreement dated May 13, 2009, Ventrus paid to Amer a \$10,000 interest fee for the months of June, July and August, as well as the \$7,500 monthly consulting fee for each such month.

In accordance with and upon execution of this Letter Agreement, the remaining payments due to Amer under the License Agreement shall consist of (i) \$1,115,000, less all Monthly Principal Payments (defined hereafter), which is due and payable on December 20, 2009 and constitutes the "Remaining Execution Payments" and (ii) an aggregate monthly fee of \$77,500, payable on the twentieth of each month commencing August 20, 2009 and continuing through and until December 20, 2009, which shall consist of (A) \$25,000 per month in Monthly Principal Payments to be offset against the Remaining Execution Payments, (B) \$7,500 per month in monthly consulting fees; and (C) \$45,000 in monthly interest fees. No payment period shall apply to any such payment deadline (provided that the first Monthly Principal Payment shall be permitted to be made within five (5) business days of August 20, 2009).

Notwithstanding any of the foregoing to the contrary, in the event Ventrus has sold its equity securities to investors with aggregate gross proceeds to Ventrus of at least \$10,000,000 (a "Financing") on or before December 20, 2009, then the Remaining Execution Payments shall be accelerated such that they shall be due to Amer within thirty (30) days of the closing of the Financing, or December 20, 2009, whichever is earlier.

Except as specified herein, the License Agreement, including consulting fee payment obligations, remains in full force and in good standing among Amer, Ventrus, and Paramount.

* * * * *

If the foregoing correctly sets forth your understanding of our agreement with respect to the matters addressed above, please indicate your acceptance and approval below.

VENTRUS BIOSCIENCES, INC.

By: /s/ Thomas Rowland
Name: Thomas Rowland
Title: President & CEO

PARAMOUNT BIOSCIENCES, LLC

By: /s/ Lindsay Rosenwald
Name: Lindsay Rosenwald
Title: Sole Member

AGREED AND ACKNOWLEDGED:

SAM AMER & CO., INC.

By: /s/ Sam Amer
Name: Sam Amer
Title: President 8/18/09

PARAMOUNT BIOSCIENCES, LLC

8400 E Crescent Pkwy, Suite 600
Greenwood Village, CO 80111

May 13, 2009

Sam Amer & Co., Inc.
P.O. Box 5685
Montecito, CA 93150
Attn: Sam Amer

Dear Sam:

Reference is hereby made to the License Agreement, dated as of March 10, 2008, between Sam Amer & Co., Inc. ("Amer"), Ventrus Biosciences, Inc. ("Ventrus"), and Paramount Biosciences, LLC ("Paramount") as amended by Amendment No. 1 to License Agreement, dated as of July 31, 2008, Amendment No. 2 to License Agreement, dated as of September 29, 2008, Amendment No. 3 to License Agreement, dated as of November 17, 2008 and Letter Agreement dated as of March 13, 2009 (taken together, including all amendments and alterations to date, the "License Agreement"). To the extent this letter agreement is in conflict with any provision of the License Agreement, such provision of the License Agreement is hereby superseded and replaced in all respects by the content of this Letter Agreement.

Amer, Ventrus, and Paramount hereby agree that the remaining execution payments due to Amer under the License Agreement as modified by the Letter of March 13, 2009 by Ventrus (or Paramount, as guarantor) are (i) April 20, 2009 payment of \$110,000 and (ii) May 20, 2009 payment of \$1,050,000 (together, the "Remaining Execution Payments"). The parties further agree that there is an outstanding unpaid balance of \$15,000 as April and May 2009 consulting fees (together "Past Due Consulting Fees").

Amer, Ventrus and Paramount hereby agree that the Remaining Execution Payments will be due to Amer by Ventrus (or Paramount as guarantor) no later than August 15, 2009. No payment period shall apply to such payment deadline.

Beginning June 1, 2009 and continuing on July 1, 2009 and August 1, 2009, Ventrus (or Paramount as guarantor) will pay Amer a \$10,000 interest fee per month and continue to pay Amer the \$7500 Consulting fee per month.

Upon execution of this Letter Agreement, Ventrus (or Paramount as guarantor) will pay Amer the \$15,000 past due Consulting fee together with \$10,000 representing interest on the past due Execution instalment of April 20, 2009.

Notwithstanding any of the foregoing to the contrary, in the event Ventrus has sold its equity securities to investors with aggregate gross proceeds to Ventrus of at least \$10,000,000 (a "Financing") on or before August 15, 2009, then the Remaining Execution Payments shall be accelerated such that they shall be due to Amer within thirty (30) days of the closing of the Financing, or August 15, 2009, whichever is earlier.

Except as specified herein, the License Agreement remains in full force and in good standing among Amer, Ventrus, and Paramount.

* * * * *

If the foregoing correctly sets forth your understanding of our agreement with respect to the matters addressed above, please indicate your acceptance and approval below.

VENTRUS BIOSCIENCES, INC.

By: /s/ Thomas Rowland
Name: Thomas Rowland
Title: President & CEO

PARAMOUNT BIOSCIENCES, LLC

By: /s/ Lindsay A. Rosenwald
Name: Lindsay A. Rosenwald, MD
Title: Sole Member

AGREED AND ACKNOWLEDGED:

SAM AMER & CO., INC.

By: /s/ Sam Amer
Name: Sam Amer
Title: President

VENTRUS BIOSCIENCES, INC.
8400 E. Crescent Pkwy, Suite 600
Greenwood Village, CO 80111

December 15, 2009

Sam Amer & Co., Inc.
P.O. Box 5685
Montecito, CA 93150
Attn: Sam Amer

Dear Sam:

Reference is hereby made to the License Agreement, dated as of March 10, 2008, between Sam Amer & Co., Inc. ("Amer"), Ventrus Biosciences, Inc. ("Ventrus"), and Paramount Biosciences, LLC ("Paramount") as amended by Amendment No. 1 to License Agreement, dated as of July 31, 2008, Amendment No. 2 to License Agreement, dated as of September 29, 2008, and Amendment No. 3 to License Agreement, dated as of November 17, 2008, and Letter Agreements dated as of March 13, 2009, May 13, 2009 and August 18, 2009 (taken together, including all amendments and alterations to date, the "License Agreement"). To the extent this letter agreement is in conflict with any provision of the License Agreement, such provision of the License Agreement is hereby superseded and replaced in all respects by the content of this Letter Agreement.

Amer, Ventrus, and Paramount hereby agree that the remaining payments due to Amer under the License Agreement by Ventrus (or Paramount, as guarantor) are: (i) \$1,015,000 which is due and payable on December 20, 2009 and constitutes the "Remaining Execution Payments" and (ii) a monthly consulting fee of \$7,500. In addition, Amer, Ventrus and Paramount acknowledge and agree that pursuant to the Letter Agreement dated August 18, 2009, Ventrus paid to Amer a \$45,000 interest fee for the months of September, October and November, as well as \$25,000 monthly principal payments and the \$7,500 monthly consulting fee for each such month.

Amer, Ventrus and Paramount further acknowledge and agree that the penalty late fee of \$7500/mo due to commence July 2009 has not been paid and continues to accrue under terms of the Licensing Agreement. Parties agree that this arrearage will be paid and these monthly late fees will commence June 20, 2010.

In accordance with and upon execution of this Letter Agreement, the remaining Execution payments due to Amer under the License Agreement shall consist of \$1,015,000 "Remaining Execution Payments" which shall be paid as follows: \$250,000 on December 28, 2009 with balance on June 20, 2010, which balance will be offset by Monthly Principal Payments as defined in (A) below. In addition Amer will receive an aggregate monthly fee of \$97,500 payable on the twentieth of each month commencing December 20, 2009 and continuing through and until the final payment on May 20, 2010, which shall consist of (A) \$25,000 per month in Monthly Principal Payments to be offset against the Remaining Execution Payments; (B) \$7,500 per month in monthly consulting fees; (C) \$45,000 in monthly interest fees; and (D) \$20,000 per month in additional Licensing Fees not to be offset against the balance of Execution Payments or any other payments originally appearing in the Licensing Agreement. No grace period shall apply to any payment deadline listed above. Notwithstanding the foregoing, the payments payable hereunder on January 20, 2010 shall be due and payable on January 31, 2010.

Amer, Ventrus and Paramount acknowledge the critical importance of prompt development of Product and agree and commit to submit the Special Protocol Assessment to the FDA no later than March 1, 2010.

Except as specified herein, the License Agreement, including consulting fee payment obligations, and late penalty fee payments obligations remains in full force and in good standing among Amer, Ventrus, and Paramount.

If the foregoing correctly sets forth your understanding of our agreement with respect to the matters addressed above, please indicate your acceptance and approval below.

VENTRUS BIOSCIENCES, INC.

By: /s/ Thomas Rowland
Name: Thomas Rowland
Title: President

PARAMOUNT BIOSCIENCES, LLC

By: /s/ Lindsay A. Rosenwald, MD
Name: Lindsay A. Rosenwald, MD
Title: Sole Member

AGREED AND ACKNOWLEDGED:

SAM AMER & CO., INC.

By: /s/ Sam Amer
Name: Sam Amer
Title: President