Exhibit 10.5  
CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH “[\*\*\*]”. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934.  
Execution Copy  
MANUFACTURING AND SUPPLY AGREEMENT  
by and between  
ETHYPHARM S.A.  
and  
AMPIO PHARMACEUTICALS, INC.  
\* \* \*  
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 MANUFACTURING AND SUPPLY AGREEMENT  
THIS MANUFACTURING AND SUPPLY AGREEMENT (the “Agreement”), dated as of September 10, 2012 (the “Effective Date”), is entered into by and between ETHYPHARM S.A., a corporation organized under the laws of France with an address at 194 Bureaux xx xx Xxxxxxx, X00000 Xxxxx-Xxxxx, Xxxxxx (“Ethypharm”), and AMPIO PHARMACEUTICALS, INC., a corporation organized under the laws of the state of Delaware with an address at 0000 XXX Xxxxxxx, Xxxxx 000, Xxxxxxxxx Xxxxxxx, Xxxxxxxx 00000, XXX (“Ampio”).  
WHEREAS, Ethypharm and Valeant International (Barbados) SRL (formerly Biovail Laboratories International, SRL) (“Valeant”) entered into that certain NDA Assignment and License Agreement dated as of February 6, 2009 (the “License Agreement”) under which Valeant was given rights from Ethypharm to use the Technology (as defined below) to develop and commercialize the Product (as defined below) on a worldwide basis;  
WHEREAS, pursuant to that certain Contract Assignment and License Agreement, dated December 20, 2011, between Valeant and Ampio, Ampio was assigned all of Valeant’s rights under the License Agreement;  
WHEREAS, pursuant to the terms of the License Agreement, Ampio has developed the Product and its related Regulatory Documentation (as defined below) and is in the process of registration of the Product in different countries of the Territory (as defined below).  
WHEREAS, pursuant to the terms of the License Agreement, Ampio has engaged Ethypharm, who has accepted, as its exclusive manufacturer and supplier of the Product in the Territory;  
NOW, THEREFORE, in consideration of the foregoing premises and mutual covenants of the Parties hereinafter set forth, the parties agree as follows:  
ARTICLE 1  
DEFINITIONS  
“Affiliate” means, with respect to any Person, any other Person that (directly or indirectly) is controlled by, controls, or is under common control with such Person. For purposes of this definition, the term “control” (including, with correlative meanings, the terms “controlled by” and “under common control with”) as used with respect to a Person means direct or indirect beneficial or legal ownership of more than fifty percent (50%) of the voting interest in, or more than fifty percent (50%) of the equity of or the right to appoint more than fifty percent (50%) of the directors or managers of the corporation or other business entity or the power to direct or cause the direction of the management and policies of such corporation or entity, whether pursuant to the ownership of voting securities, by contract or otherwise.  
“cGMP” shall mean the practices required with respect to the manufacture of the Product by the provisions of EC Commission Directive 2003/94/CE together with the Guide to Good Manufacturing Practice published by the EC Commission in 1992 (ISBN 92-826-3180-X) and by the Food and Drug Administration in the provisions of 21 C.F.R., parts 210 and 211.  
“Commercial Manufacturing Site” means Ethypharm’s manufacturing site at Châteauneuf en Thymerais, France, or any other manufacturing site to be agreed upon by both parties pursuant to the terms of this Agreement.  
“Commercially Reasonable Efforts” means, with respect to the efforts to be expended by a party with respect to any objective, reasonable, diligent, good faith efforts to accomplish such objective that such party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that with respect to the research, development or commercialization of the Product, such efforts shall be substantially equivalent to those efforts and resources commonly used by a party for a similar pharmaceutical product owned by it or to which it has rights, which product is at a similar stage in its development or product life and is of similar market potential taking into account efficacy, safety, anticipated labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval, commercial value of the product, alternative products and other relevant factors.  
“Confidential Information” means all trade secrets, processes, formulae, data, know-how, improvements, inventions, chemical or biological materials, techniques, marketing plans, strategies, customer lists, or other information that has been created, discovered, or developed by a party or its Affiliate, or has otherwise become known to a party or its Affiliate, or to which rights have been assigned to or by a party or its Affiliate (including, without limitation all information and materials of a party’s (or its Affiliates’) customers and any other third party and their consultants), in each case that are disclosed by such party or its Affiliate to the other party, regardless of whether any of the foregoing is marked “confidential” or “proprietary” or communicated to the other by the disclosing party in oral, written or graphic, or electronic form; provided, however, that Confidential Information shall not include any information:  
(A) that, at the time of its disclosure, is generally available within the industry;  
(B) that, after its disclosure in connection herewith, becomes generally available within the industry, through no act or failure to act on the part of the receiving party or its Affiliates;  
(C) that becomes available to the recipient of such information from a third party that does not owe a duty of confidentiality to the disclosing party in relation to that Confidential Information; or  
(D) that the recipient of which can demonstrate was independently developed by or for such recipient without the aid, application or use of the Confidential Information disclosed to the recipient by the disclosing party or its Affiliates in connection herewith.  
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“Defect” means any flaw making the Product dangerous or unsuitable for use or otherwise unsuitable for sale.  
“Deficiency Notice” has the meaning set forth in Section 4.7.  
“Due Delivery Date” has the meaning set forth in Section 4.6.  
“Effective Date” means the date hereof.  
“EX Works” or :EXW” has the meaning provided in INCOTERM rules of the International Chamber of Commerce of 2010.  
“FDA” means the United States Food and Drug Administration or any successor government agency.  
“First Commercial Sale” means the first sale of the Product under this Agreement by Ampio, its Affiliates or Licenses in arms’ length transaction to an unaffiliated Person.  
“Forecast Report” has the meaning set forth in Section 4.1.  
“Ineligible Person” has the meaning set forth in Section 5.6.  
“Infringement Notice” has the meaning set forth in Section 11.1.  
“Intellectual Property” means all (i) patent applications, continuation applications, continuation in part applications, divisional applications, any corresponding foreign patent applications to any of the foregoing, and any patents that may grant or may have been granted on any of the foregoing, including reissues, re-examinations and extensions; (ii) rights in know-how, trade secrets, inventions (whether patentable or otherwise), data, processes, techniques, procedures, compositions, devices, methods, formulas, protocols and information, whether patentable or not; (iii) copyrightable works, copyrights and applications, registrations and renewals; (iv) other intellectual proprietary rights; in each case, whether or not registered, applied for or granted; and (v) copies and tangible memorializations of any one or more of the foregoing.  
“Losses” has the meaning set forth in Section 6.1.  
“Notice of Observations” has the meaning set forth in Section 3.6.  
“Person” means a natural person, corporation, partnership, company or other entity.  
“Pain Field” means the prevention and/or treatment of pain in human beings.  
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“Product” means an oral rapid dissolve or oral disintegrating tablet formulation of TRAMADOL as the only active pharmaceutical ingredient in [\*\*\*] dosage strengths for indication outside the Pain Field manufactured in accordance with the Specifications.  
“Quality Agreement” has the meaning set forth in Section 3.9.  
“Regulatory Approval” means the approvals or authorizations of relevant Regulatory Authorities, necessary for the import, marketing and sale of the Product in the Territory.  
“Regulatory Authority” means any competent regulatory authority or other governmental body responsible for approving and authorizing the import, manufacture or marketing of Product in the Territory.  
“Regulatory Documentation” means all submissions to the FDA or other Regulatory Authorities as applicable, including, without limitation, any clinical data, clinical studies, tests, and biostudies, NDAs, as well as all correspondence with regulatory authorities, registrations and licenses, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files, manufacturing records and inspection reports, in each case related to or used in connection with the Product.  
“Specifications” means all those manufacturing, testing, packaging, labeling, storage and quality control specifications established for the Product by Ampio in compliance with the requirements of the cGMPs and other regulatory requirements, as set forth in Exhibit C hereto as may be supplemented or amended from time to time by agreement of the parties, as further defined in the Quality Agreement.  
“Supply Interruption” has the meaning set forth in Section 4.6.  
“Supply Price” has the meaning set forth in Section 4.5 hereof.  
“Technology” means Ethypharm’s proprietary [\*\*\*] technology, and all patents, patent applications, trademarks, copyrights, proprietary know-how and all other related Intellectual Property rights owned by Ethypharm relating to the Product.  
“Term” has the meaning set forth in Section 9.1 hereof.  
“Territory” means all the different countries where the Product will be marketed by Ampio or its Licenses.  
“Third Party Manufacturer” has the meaning set forth in Section 2.2.  
 \* Confidential Information indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities and Exchange Commission.  
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ARTICLE 2  
APPOINTMENT OF MANUFACTURER  
2.1 Requirements. During the Term, subject to Section 4.6 below, Ampio, itself or through its Affiliates or Licensees, shall purchase all of their requirements for Product exclusively from Ethypharm, or its Third Party Manufacturer as applicable, and Ethypharm, and its Third Party Manufacturer as applicable, shall manufacture and supply to Ampio, its Affiliates and Licenses all of their requirements for Product. All Product manufactured and supplied hereunder whether by Ethypharm or Third Party Manufacturer shall be performed in compliance with the Quality Agreement and Specifications including cGMP and all applicable laws, rules and regulations.  
2.2 Third Party Manufacturer. Ethypharm shall not subcontract its manufacturing and supply obligations hereunder to any third party; provided, however, upon the prior written consent of Ampio, Ethypharm shall be entitled to contract with a third party for the purposes of such party’s producing part or all of the Product, and maintaining quality control with respect to such Product, in lieu of and on behalf of Ethypharm (a “Third Party Manufacturer”) in which case Ethypharm shall remain liable to Ampio for all of its obligations, including but not limited to the performance of the Third Party Manufacturer, herein, and Ampio shall either (at Ethypharm’s discretion) start purchasing the Product directly from the Third Party Manufacturer (according to the same terms and conditions as apply to the supply of Product by Ethypharm to Ampio hereunder), or continue purchasing the Product through Ethypharm. Ethypharm shall give Ampio reasonable notice of any proposal to appoint a Third Party Manufacturer and shall satisfy all legal and regulatory requirements relating to any variation of the Regularity Approval relating to such appointment at its own cost and shall procure for Ampio reasonable inspection and audit rights (which rights are no less favorable to Ampio than those it possesses hereunder with respect to Ethypharm) in respect of the Third Party Manufacturer’s Manufacturing Site. Ethypharm shall warrant in writing to Ampio that the Third Party Manufacturer: (i) has and will maintain the requisite capacity to satisfy Ethypharm’s production and delivery obligations, and to meet Ampio’s order requirements, hereunder with respect to the Product in accordance with the Specifications and the terms and conditions of this Agreement; (ii) complies and will comply with all applicable laws and holds all applicable licensees and permits necessary for the manufacture of the Product in compliance with cGMP; (iii) has and will have the right to use all related intellectual property and Confidential Information of Ethypharm necessary to manufacture the Product in accordance with the Specifications and the terms and conditions of this Agreement.  
2.3 Joint Manufacturing Committee. On the Effective Date, the parties will establish a Joint Manufacturing Committee consisting of four members, two of whom shall be appointed by Ethypharm and two of whom shall be appointed by Ampio. Initially, Ethypharm’s representatives to the Committee shall be Xxxxx Xxxxx and Xxxxxxx Xxxxx, and Ampio’s representative shall be Xxx Xxxxxxxx and one additional to be named. The Committee shall meet, either in person or by teleconference, at least quarterly to discuss the following matters relating to the manufacture and supply of the Product:  
1. coordinate forecasting, ordering and other supply-related logistics;  
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2. discuss supply-related issues, including shortfalls and quality issues;  
3. discuss and coordinate manufacturing-related complaints, recalls and any other supply related issues;  
4. review and discuss proposals to engage, qualify and maintain Third Party Manufacturers and Additional Manufacturing Facilities;  
5. discuss the content and scope of any quality audit undertaken, or to be undertaken, relating to Third Party Manufacturers;  
6. review and agree on budgets for any additional technical assistance agreed to by the parties;  
7. discuss requirements for supply of Product and mechanisms to maintain supply, e.g., by increasing batch sizes and/or capacity or through additional sources;  
8. discuss technology and regulatory issues including tech transfer, changes in Specifications, API sourcing, stability studies, inspections and audits; and  
9. perform such other functions as may be appropriate with respect to the manufacture of the Product.  
All decisions of the Joint Manufacturing Committee will be made by unanimous vote. If the Committee cannot reach agreement on any particular issue, the issue will be brought to the Chief Executive Officers of the parties, who shall have a period of 30 days to find an acceptable resolution to the issue. If the issue is not resolved during such 30 day period, either party may bring the issue to a court of competent jurisdiction for resolution, in accordance with Section 11.1 below.  
ARTICLE 3  
REGULATORY AND QUALITY UNDERTAKINGS  
3.1 Regulatory. Ampio, as the holder of the Regulatory Approval, shall be responsible for obtaining, maintaining and fulfilling all legal and regulatory requirements in the Territory at its own cost, with respect to the Product during the Term, as required by all applicable laws and regulations in the Territory.  
3.2 Import and Packaging. Ampio shall be responsible for the shipping, freight and handling of Product following its delivery to Ampio at the Commercial Manufacturing Site and shall additionally be responsible for finished product packaging operations with respect to Product and shall ensure compliance with any and all laws and regulations in the Territory to the import and export of the Product in the Territory.  
3.3 Change in Specifications. In the event that a Regulatory Authority imposes any change affecting the manufacture of the Product, the parties, acting through the Joint Manufacturing Committee, shall discuss in good faith with a view to reaching agreement on the  
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actions and timing required to effect such change, which shall be at the costs and expense of Ampio. All such changes required by any Regulatory Authorities or by Ampio shall be made at Ampio’s costs and expenses. Any modifications to Specifications and /or the manufacturing instructions shall be implemented and validated in accordance with the terms of the Quality Agreement.  
3.4 Advertising, Promotional Materials, and Public Statements. Ampio shall be solely responsible for all sales, marketing and advertising activities related to the Product in the Territory and shall ensure that all advertising and promotional materials comply with applicable laws, rules and regulations in the Territory.  
3.5 Product Complaints and Adverse Drug Experiences. Ampio shall, at its sole cost and expense, be responsible for handling all customer Product complaints and all adverse event reporting, annual reporting, pharmacovigilance and other required, ongoing regulatory reporting activities normally and customarily associated with sales and marketing of pharmaceutical products in the Territory, in each case, in accordance with applicable laws.  
3.6 Facility Maintenance; Inspection; Reports. Each party shall maintain and operate its respective facilities and implement such quality control procedures so as to meet the requirements of applicable FDA or any other relevant regulations and so as to be able to perform timely its obligations hereunder. Each party shall (and shall cause its Third Party Manufacturers and packagers, if applicable, to) permit quality assurance representatives of the other party to inspect its facilities, including the Commercial Manufacturing Site, once per calendar year upon reasonable written notice, during normal business hours and on a confidential basis; provided, that, if an inspecting party finds any non-compliance during any such inspection with respect to the Product, the party subject to inspection shall (i) use Commercially Reasonable Efforts to promptly and diligently rectify such non-compliance and implement appropriate procedures with a view to avoiding such non-compliance and (ii) permit such additional inspection(s) by the inspecting party as such inspecting party shall deem reasonably necessary to verify that such non-compliance has been rectified. Each party shall promptly provide the other party with a copy of any correspondences exchanged with any Regulatory Authorities, together with the response and corrective action taken by the party with respect to the Product.  
3.7 Filing Requirements and Maintenance. Ampio shall promptly comply with all filing and reporting requirements with respect to the Product, including general reporting requirements necessary to keep and maintain the Regulatory Documentation for the Regulatory Approval current with the Regulatory Authority and any applicable clinical study. Ampio shall be responsible for conducting all stability studies at its own cost and expense that may be required for ongoing marketing and sale of the Product during the Term and such stability studies shall be conducted in compliance with the Regulatory Documentation, the Regulatory Approval and other Regulatory Authorities requirements.  
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3.8 Product Recall.  
 (a) Ampio or its Affiliates, licensees or Licenses shall be responsible for handling the recall or seizure of any Product distributed by or on behalf of Ampio hereunder at its own costs and expense. Notwithstanding the foregoing, in the event Ampio decides to recall or seize any Product distributed under this Agreement, and such recall or seizure is found to have been caused by a failure of Ethypharm to manufacture the Product in accordance with Specifications or cGMP, Ethypharm shall reimburse Ampio for all external costs associated with such recall or seizure (including shipping, handling costs and credits to customers). Any decision to recall, withdraw or cease distribution of Product shall be made by Ampio only following consultation with Ethypharm, taking such reasonable action as it considers to be appropriate under the circumstances to limit the risk to both parties and assure compliance by the parties with the requirements of applicable laws. For purposes of this Section 3.8, “recall” means (i) any action by Ethypharm, Ampio or any Affiliate of either to recover title to or possession of any Product sold or shipped (including, but not limited to, market withdrawal) and/or (ii) any decision by Ampio not to sell or ship any Products to third parties that would have been subject to recall if they had been sold or shipped, in each case taken in the good faith belief that such action was appropriate under the circumstances. For purposes of this Section 3.8, “seizure” means any action by any governmental authority to detain or destroy any Product.  
 (b) Following the First Commercial Sale, Ethypharm and Ampio shall keep the other fully informed in writing of any notification or other information, whether received directly or indirectly, that might (i) affect the Regulatory Authority’s approval to market the Product under the Regulatory Approval or the safety or effectiveness of the Product, (ii) result in liability issues or otherwise necessitate action on the part of either party, or (iii) result in the recall or seizure of the Product. Ampio will be responsible for assuring that such recall is closed-out with relevant Regulatory Authority.  
3.9 Quality Agreement. As promptly as practicable after the Effective Date, but in any event no later than six months following the date of receipt by Ampio or its distributors or licensees of the first Regulatory Approval for the Product in the Territory, the parties will negotiate in good faith and execute a Quality Agreement (the “Quality Agreement”) setting forth each party’s obligations for ensuring that the Product is manufactured and sold in compliance with cGMP and concerning the delimitation of pharmaceutical and quality responsibilities for the manufacturing operations of the Product. This agreement shall contain administrative information with responsibilities, supply and manufacturing (premises, materials, batch numbering, shelf life and other information), customary provisions, including change control, deviation, cGMP compliance, complaint handling and investigation, annual product review, QC testing (specification and method), documentations and inspections, batch release, product recalls, stability studies and other quality related items in accordance with applicable regulation and guidelines in the Territory.  
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ARTICLE 4  
FORECAST, ORDER, SUPPLY PRICE, SUPPLY INTERRUPTION  
4.1 Forecast Reports. No later than six months following the date of receipt by Ampio or its distributors or licensees of the first Regulatory Approval for the Product in the Territory, Ampio shall provide Ethypharm with a twelve (12) month forecast of its estimated requirements of the Product, which shall be updated quarterly during the Term to ensure that Ethypharm has at all times a twelve (12) month forecast for Ampio’s estimated requirements of the Product (the “Forecast Report”). The Forecast Report shall be expressed in quantities of bulk tablet units of Product. Forecast Reports shall be provided to Ethypharm for information purposes only and shall not constitute a firm commitment.  
4.2 Product Orders. Ampio shall provide Ethypharm with binding and non-cancellable orders of the Product four (4) months in advance, except for the first order to support the First Commercial Sale (the “Commercial Launch Supply”) which shall be placed six (6) months in advance. Ethypharm shall accept all orders by written notice no later than ten (10) days following receipt of each relevant order and shall deliver such quantities of Product ordered unless the quantities ordered by Ampio vary by more than twenty-five percent (25%) from the quantities indicated in the applicable Forecast Report. Ethypharm shall work with Ampio using Commercially Reasonable Efforts to deliver such quantities of Product that exceed more than twenty-five percent (25%) of the estimated quantities of Product of the concerned Forecast Report. Ampio shall provide Ethypharm in each order with the exact quantity of Product, delivery date and the address to which the Product must be sent. These binding orders shall be considered as firm offers and shall bind the Parties as soon as they are accepted in writing by Ethypharm.  
4.3 Batch Sizes of Product And Inventories.  
(a) Each binding order placed by Ampio shall correspond to one full batch or multiple full batches of the Product. A full batch size of Product is defined in Exhibit A of this Agreement.  
(b) Any proposed change in batch size shall be discussed with the Joint Manufacturing Committee before implementation. Ethypharm shall be responsible for implementing at its own discretion, any change in batch size during the Term taking into account the Forecast Reports. Ampio shall be responsible for obtaining all regulatory approvals, required, to implement changes in full batch size required hereunder.  
4.4 Inventories. Ampio shall at all times use reasonable efforts to keep adequate inventories of Product to meet the market demand in the Territory. These inventories shall be sufficient to cover the estimated requirement for at least four (4) months. At Ampio’s request, such inventories shall be kept at Ethypharm’s facility on Ampio’s behalf.  
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4.5 Supply Price of the Product.  
(a) All Product manufactured by Ethypharm or a Third Party Manufacturer, shall be supplied in bulk tablet form ready for packaging and shall be delivered EX WORKS Ethypharm’s Commercial Manufacturing Site. Ethypharm Supply Price to Ampio is defined in Exhibit B of this Agreement. Ampio or its designated distributor or sublicensee shall be responsible for the shipping, freight and handling of the Product from Ethypharm’s Commercial Manufacturing Site and finished dosage packaging. Ampio (a) shall pay Product invoices within thirty (30) days of date of invoice. Ethypharm shall supply the Product in bulk tablet forms ready for packaging and shall deliver the Product to Ampio, EX WORKS (Ethypharm’s Commercial Manufacturing Site) (Incoterm 2010). The Supply Price as determined above includes the active ingredient, excipients, testing and manufacturing workmanship according to Ethypharm’s usual standards and in compliance with cGMPs.  
(b) [\*\*\*]  
(c) Ampio shall be responsible for all duties, tariffs, import and similar charges other than sales and use taxes arising out of or related to the manufacture of the Product. None of these costs shall be subject to recoupment by Ampio from Ethypharm under this Agreement.  
(d) At any time during the Term of this Agreement, in the event that one of the Parties produces the written proof that an unforeseeable event beyond the control of the Parties affects the economical conditions of the present Agreement so as to modify substantially the contractual balance of this Agreement for the sole benefit of one of the Party, the Parties agree to revise the Supply Prices in good faith, taking into consideration the market of the Product in the Territory, in order to put back both Parties in a situation similar to the existing situation at the date of signature of the Agreement. Each Party reserves the right to terminate this Agreement if the Parties are unable to reach an agreement within three (3) months starting from the first demand of conciliation by the most diligent Party.  
4.6 Supply Interruption. A “Supply Interruption” shall be deemed to have occurred if Ampio has not received ordered Product for more than sixty (60) days past the scheduled and agreed upon due delivery date (“Due Delivery Date”) and Ampio holds no saleable stock of the Product after attempting to maintain at least four (4) months of sealable stock through binding orders made pursuant to Section 4.3 (subject to Ethypharm’s delivery thereof), unless such Supply Interruption is caused by (a) a delay due to a shortage in supply of usable active pharmaceutical ingredient or any other manufacturing material supplied by a third party through no fault of Ethypharm, (b) a material breach of this Agreement by Ampio for which Ethypharm has provided written notice thereof to Ampio or (c) a Force Majeure Event. During a Supply Interruption, Ampio, shall be entitled to claim from Ethypharm a penalty of one per cent (1%) of the amount of the late deliveries value of Product from the third week of delay, per each week of delay. The total amount of penalty to be paid by Ethypharm shall not exceed twenty per cent (20%) of the late deliveries value of Bulk Product not delivered. Such payment shall be made to Ampio within thirty (30) days date of Ampio’s invoice. Notwithstanding the other provisions of  
 \* Confidential Information indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities and Exchange Commission.  
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this Agreement, if a Supply Interruption lasts for more than three (3) months, Ampio shall be permitted, at its discretion, (i) to require Ethypharm to use a different supplier for the Product, once Ampio has provided reasonable notice to Ethypharm of such requirement and/or (ii) to thereafter purchase some or all of its requirement for the Product from a third party of its choosing and Ethypharm shall grant all necessary licenses and provide all necessary and reasonable cooperation to effect such transfer to the new manufacturing site, on conditions to be agreed in writing by the Parties and subject to appropriate confidentiality agreements being entered into by such third party.  
4.7 Deficiency Notice. Ampio shall have the right to reject any portion of any delivery of Product that deviates from Specifications without invalidating any remainder of such delivery. Ampio shall inspect the Product upon receipt thereof and shall give Ethypharm written notice (a “Deficiency Notice”) of all claims for Product that deviates from the Specifications within thirty (30) days after Ampio’s receipt thereof (or, in the case of any Defect not reasonably susceptible to discovery upon receipt by Ampio, within thirty (30) days after discovery thereof by Ampio, up until the final release of the Product in its commercial packaging). Should Ampio fail to provide Ethypharm with a Deficiency Notice within the applicable period, then the delivery shall be deemed to have been accepted by Ampio upon the expiration of such period. Notwithstanding the foregoing, if Ampio discovers that any Product materially deviates from Specifications after final release of the Product in its commercial packaging, such deviation was not reasonably susceptible to discovery upon receipt of the Product from Ethypharm, and Ampio reasonably determines that such deviation was due to Ethypharm’s manufacturing, Ampio may reject the delivery of such Product within thirty (30) days after discovery thereof by Ampio, up until the final expiration date of the Product.  
4.8 Determination of Deficiency. Upon receipt of a Deficiency Notice, Ethypharm shall have ten (10) business days to advise Ampio by notice in writing that it disagrees with the contents of such Deficiency Notice. Should Ethypharm fail to provide Ampio with a response to such Deficiency Notice within the applicable period, then the delivery shall be deemed to have deviated from the Specifications upon the expiration of such period. If Ethypharm responds to such Deficiency Notice during such period and Ampio and Ethypharm fail to agree within ten (10) business days of the date of Ethypharm’s response to Ampio as to whether any Product identified in the Deficiency Notice deviates from the Specifications, the parties shall mutually select an independent laboratory to analyze the Product for compliance with the Specifications. Such analysis shall be binding on the parties, and Ampio may reject such Product if such analysis determines that the Product in question deviates from the Specifications. If such analysis certifies that the Product does not deviate from the Specifications, Ampio shall be deemed to have accepted delivery of such Product on the fortieth (40th) day after delivery (or, in the case of any Defect not reasonably susceptible to discovery upon receipt of the Product or Defect discovered after final release by Ampio of the Product in its commercial packaging pursuant to Section 4.7 above, on the fortieth (40th) day after discovery by Ampio, but in no event after the expiration date of the Product).  
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4.9 Rejection for Deficiency. If any delivery of Product is deemed or agreed upon to deviate from the Specifications, at Ampio’s option, Ethypharm shall either (a) accept a return of such delivery, correct such delivery with replacement Product, if required, as soon as reasonably practicable and reimburse Ampio for its shipping costs in connection with such delivery and such returns within thirty (30) days, or (b) shall reimburse Ampio for Ampio’s costs (including the purchase price of the Product and shipping costs with respect thereto within thirty (30) days.  
ARTICLE 5  
WARRANTIES AND COVENANTS  
5.1 Certain Representations and Warranties of Ethypharm. Ethypharm represents and warrants to Ampio that as of the Effective Date (i) Ethypharm is duly organized and validly existing under the laws of the jurisdiction of its incorporation or organization; (ii) Ethypharm has the full right, power and authority to enter into this Agreement and to perform the activities required to be performed by it in accordance with this Agreement; (iii) this Agreement is legally binding upon Ethypharm and enforceable in accordance with its terms, and the execution, delivery and performance of this Agreement by Ethypharm does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation or order of any court, governmental body or administrative or other agency having jurisdiction over it; (iv) there is no action, suit, proceeding or investigation pending or threatened, against Ethypharm that questions the validity of this Agreement or the right of Ethypharm to enter into this Agreement or consummate the transactions contemplated hereby, nor does Ethypharm have knowledge that there is any basis for the foregoing; (v) Ethypharm is not in violation of any law or regulation, nor is it aware of any violation of any law or regulation by any other person, which violation could reasonably be expected to adversely affect its performance of its obligations hereunder and (vi) Ethypharm is the owner or licensee of its Intellectual Property and Technology pertaining to the Product, which is free and clear of any liens, charges and encumbrances.  
5.2 Certain Representations and Warranties of Ampio. Ampio represents and warrants to Ethypharm that as of the Effective Date (i) Ampio is duly organized and validly existing under the laws of the jurisdiction of its incorporation or organization; (ii) Ampio has the full right, power and authority to enter into this Agreement, to perform the activities required to be performed by it in accordance with this Agreement; (iii) this Agreement is legally binding upon Ampio and enforceable in accordance with its terms, and the execution, delivery, and performance of this Agreement by Ampio does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; (iv) there is no action, suit, proceeding or investigation pending or threatened against Ampio that questions the validity of this Agreement or the right of Ampio to enter into this Agreement or consummate the transactions contemplated hereby, nor does Ampio have knowledge that there is any basis for the foregoing; (v) Ampio is not in violation of any law or regulation, nor is it aware of any violation of any law or regulation by any other person, which violation could reasonably be expected to adversely affect its performance of its obligations  
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hereunder; (vi) Prior to First Commercial Sale in any particular jurisdiction, Ampio or its distributor or licensee shall secure the right under the relevant Regulatory Approval to pursue marketing and sale of the Product in such jurisdiction.  
5.3 Certain Covenants of Ampio . Ampio covenants and agrees, on behalf of itself and its Affiliates, that during the Term (i) any Intellectual Property of Ampio, including in particular trademarks of Ampio that are to be utilized by Ampio in connection with the labeling and packaging of the Product are (or will be) the property of Ampio, may be lawfully used as directed by Ampio; (ii) it will not develop or perform any formulation or any developmental or other work or studies on or with respect to the Product for its own use or benefit or for the use or benefit of any Person in the Territory, other than pursuant to the development and commercialization of the Product pursuant to the terms of the License Agreement.  
5.4 Certain Covenants of Ethypharm . Ethypharm covenants and agrees on behalf of itself and its Affiliates and Third Party Manufacturer that it will not during the Term, directly or indirectly alone, with or through a Third Party, sell, develop, manufacture or market a product containing tramadol anywhere in the world that is a dosage strength that is not a multiple of 25mg or not in the Pain Field, without the prior written consent of Ampio.  
5.5 Storage. Tablets of the Product under Ethypharm’s or Ampio’s control (as the case may be) prior to distribution by Ampio in the Territory shall be stored by Ethypharm or Ampio in a compliant manner and handled in accordance with the Regulatory Documentation and applicable cGMP requirements.  
5.6 Representation and Warranties with Regard to Status . Ampio and Ethypharm each hereby represent and warrant to the other that, subject to the receipt by Ampio or its distributors or sublicensees of relevant Regulatory Approvals, neither it, their Affiliates, nor in the case of Ethypharm the Third Party Manufacturer nor any of the officers, directors or employees of the foregoing is prohibited by any law, rule or regulation or by any order, directive or policy from selling the Product or other pharmaceutical products within the Territory and that neither it nor any of its officers, directors, employees or Affiliates or Third Party Manufacturer is a Person that is listed by a United States federal agency as debarred, suspended or otherwise ineligible for federal programs in the United States, its territories and protectorates (an “Ineligible Person”) or proposed for such debarment or suspension.  
5.7 Compliance with Specifications and cGMP . Ethypharm covenants and agrees that the Product, when delivered to Ampio, will be manufactured, controlled and supplied in accordance with the Specifications and with cGMP; the Product will meet Ethypharm’s quality assurance standards; Product ingredients and contents will conform with the list and Specifications for ingredients set forth in the Regulatory Approval. Ethypharm will sell the Product to Ampio free of all liens and encumbrances. Ethypharm and Ampio shall execute the Quality Agreement in accordance with the terms hereof.  
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5.8 Limitation of Warranty. EITHER PARTY GIVES NO OTHER WARRANTY UNDER THIS AGREEMENT, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF NON-INFRINGEMENT, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE.  
ARTICLE 6  
INDEMNIFICATION AND LIMITATION OF LIABILITY  
6.1 Ethypharm’s Indemnification Obligations . Ethypharm shall indemnify and hold Ampio and its Affiliates and their respective officers, directors, stockholders, employees and agents harmless from and against, and pay or reimburse, any claim, action, suit, proceeding, loss, liability, damage or expense (including reasonable attorneys’ fees) (collectively, “Losses”) related to claims asserted by any third party, directly or indirectly, as a result of Ethypharm’s or its Affiliates’ or Third Party Manufacturer’s failure to manufacture the Product in accordance with the Specifications or cGMP or of Ethypharm’s breach of any of its representations, warranties, covenants hereunder; provided, however, that Ethypharm shall not be required to indemnify Ampio with respect to any such Losses to the extent such Losses arise from or relate to Ampio’s or its Affiliates’ negligent acts or omissions, willful wrongful acts or Ampio’s breach of its representations, warranties, covenants or other obligations hereunder.  
6.2 Ampio’s Indemnification Obligations . Ampio shall indemnify and hold Ethypharm and its Affiliates and their respective officers, directors, stockholders, employees and agents harmless from and against, and pay or reimburse, any Losses related to claims asserted by any third party, directly or indirectly, as a result of: (a) Ampio’s or its Affiliates’ negligent acts or omissions, willful wrongful acts or breach of any of its representations, warranties, covenants or other obligations hereunder; (b) liabilities, expenses or damages arising from the actions of Ampio to promote, market, commercialize, distribute and sell the Product in the Territory; and (d) liabilities, expenses or damages arising from the actions of Ampio’s distributors, Affiliates and Licenses or brought by such distributors, Affiliates or Licenses; provided, however, that Ampio shall not be required to indemnify Ethypharm with respect to any such Losses to the extent such Losses arise from or relate to Ethypharm’s, its Affiliates’ or subcontractors’ negligent acts or omissions, willful wrongful acts or Ethypharm’s breach of its representations, warranties, covenants or other obligations hereunder.  
6.3 Indemnification Procedures . A party that intends to claim indemnification under this Article 6 (the “indemnitee”) with respect to any third-party action, claim or liability shall notify the other party (the “indemnitor”) promptly in writing of any action, claim or liability in respect of which the indemnitee believes it is entitled to claim indemnification; provided, that the failure to give timely notice to the indemnitor shall not release the indemnitor from any liability to the indemnitee except to the extent the indemnitor is materially prejudiced thereby. The indemnitor shall have the right, by written notice to the indemnitee, to assume the defense of any such action or claim, within the fifteen (15) day period after the indemnitor’s receipt of written notice of any action or claim, with counsel of the indemnitor’s choice and at the sole cost of the indemnitor. If the indemnitor so assumes such defense, the indemnitee may  
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participate therein through counsel of its choice, but at the sole cost of the indemnitee; provided, however, if the defendants in any such action include both the party seeking indemnification and the indemnifying party, and the party seeking indemnification shall reasonably conclude that there may be legal defenses available to it which are different from or additional to, or inconsistent with, those available to the indemnifying party, the party seeking indemnification shall have the right to select separate counsel to participate in the defense of such action on behalf of such party seeking indemnification, at the indemnifying party’s expense. If the indemnitor fails to assume such defense and/or to diligently prosecute the same, the indemnitee may assume such defense at the indemnitor’s sole expense. The party not assuming the defense of any such claim shall render all reasonable assistance to the party assuming such defense, and all reasonable out-of-pocket costs of such assistance shall be for the account of the indemnitor. No such claim shall be settled other than by the party defending the same, and then only with the prior written consent of the other party, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that the indemnitee shall have (i) no obligation to consent to any settlement of any such action or claim that (a) imposes on the indemnitee any monetary or other liability or obligation that is not assumed and agreed to be performed in full by the indemnitor or (b) adversely affects the indemnitee’s rights hereunder or damages its reputation or business, and (ii) no right to withhold its consent to any settlement of any such action or claim if the settlement involves only the payment of money by the indemnitor or its insurer without admission of liability by the indemnitee and the indemnitor or its insurer irrevocably agrees in writing to make such payment. If the parties are unable to agree as to the application of Sections 6.1 and 6.2 to any claim, pending resolution of the dispute in accordance with Section 11.1, the parties may conduct separate defenses of such claims, with each party retaining the right to claim indemnification from the other party in accordance with Sections 6.1 and 6.2 upon resolution of the underlying action.  
6.4 Limitation of Liability . NEITHER PARTY SHALL BE LIABLE WITH RESPECT TO ANY CLAIM RELATED TO THIS AGREEMENT FOR ANY SPECIAL, INCIDENTAL OR INDIRECT DAMAGES, INCLUDING ANY LOSS OF INCOME, LOSS OF PROFITS, COSTS OF SUBSTITUTION, COSTS OF COVER OR INCREASED CAPITAL COSTS, REGARDLESS OF THE FORM OR NATURE OF ACTION, WHETHER IN CONTRACT, BREACH OF WARRANTY, STRICT LIABILITY, EQUITY, INDEMNITY, NEGLIGENCE, INTENTIONAL CONDUCT, TORT OR OTHERWISE, EVEN IF SUCH DAMAGES WERE FORESEEABLE OR IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.  
ARTICLE 7  
INSURANCE  
Each of Ampio and Ethypharm shall (and shall cause their respective Affiliates and Sub-licensees, as required, to), upon the Effective Date, carry or be subject to coverage (as a named insured) under product liability insurance in an amount of not less than [\*\*\*] combined single limit, which insurance shall be written on a “claims-made” policy basis with an insurance carrier rated at least A- by Bests Rating Service or a comparable rating by a comparable rating service.  
 \* Confidential Information indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities and Exchange Commission.  
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Each party shall provide the other party with evidence of coverage contemplated hereby, in the form of certificates of insurance, as reasonably requested in writing. Each party shall provide written notice to the other party fifteen (15) days prior to any material change, cancellation or non-renewal of the policy.  
ARTICLE 8  
CONFIDENTIALITY  
8.1 Treatment of Confidential Information . Except as required by applicable laws and regulations or as otherwise provided in this Article 8, during the Term, and for ten (10) years thereafter, each party shall hold in confidence, and may not disclose, in whole or in part, to a third party (except as specifically set forth herein or with the express prior written consent of the other party) any and all Confidential Information of the other party and its Affiliates. During the Term, the parties may not use any Confidential Information of the other party and its Affiliates for purposes other than those permitted by this Agreement and the License Agreement.  
8.2 Limits on Disclosure . Without limiting the generality of the foregoing, each party may, with the exercise of reasonable discretion, (i) disclose Confidential Information to those employees or agents who need to receive the Confidential Information in order to further the activities contemplated by this Agreement; and (ii) make disclosures of such portions of Confidential Information to third-party consultants, attorneys, contractors, advisors, Affiliates and governmental authorities where, in such party’s judgment, such disclosure is beneficial to the development, approval or marketing of the Product pursuant to this Agreement; provided, that such party shall take reasonable precautions to safeguard the Confidential Information, including by obtaining appropriate commitments and enforceable confidentiality agreements having provisions no less stringent than those contained herein.  
(a) Each party understands and agrees that the wrongful disclosure of Confidential Information may result in serious and irreparable damage to the other party, that the remedy at law for any breach of this covenant may be inadequate, and that the party seeking redress hereunder shall be entitled to injunctive relief, without prejudice to any other rights and remedies to which such party may be entitled.  
(b) Except as otherwise set forth in this Agreement, upon the termination or expiration of this Agreement and at the written request of the disclosing party, the receiving party shall return all Confidential Information of the disclosing party (including all copies, excerpts and summaries thereof contained on any media) or destroy such Confidential Information at the option of the receiving party; provided, that the receiving party may retain one copy of all Confidential Information of the disclosing party for its legal records.  
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ARTICLE 9  
TERM AND TERMINATION  
9.1 Term. This Agreement shall be effective immediately upon the Effective Date and shall remain into effect for a period of ten (10) years from the Effective Date (the “Term”). Upon the expiry of the Term, this Agreement will be automatically renewed for one or more additional three (3) year periods, unless terminated by any of the Parties six (6) months prior to the end of the initial period, or any of the renewed period, by proper notice.  
9.2 Termination for Breach. If either party commits a material breach or default in the performance or observance of any of its obligations under this Agreement, other than nonpayment of a monetary obligation, and such breach or default continues for a period of sixty (60) days after delivery by the other party of written notice reasonably detailing such breach or default, or, if the non-performing party shall promptly, within such sixty (60) days, proceed with all due diligence to cure such failure, and such failure is not cured within such longer period (not to exceed one hundred eighty (180) additional days) as shall be reasonably necessary for such party to cure the same with all due diligence, then the non-breaching or non-defaulting party shall have the right to terminate this Agreement, with immediate effect, by giving written notice to the breaching or defaulting party. Nonpayment of a monetary obligation is deemed a material breach hereunder and the non-breaching party may terminate this Agreement if such breach continues for a period of thirty (30) days after delivery to the breaching party of written notice of non-payment, with termination effective on the date provided for in that. If either Ethypharm, its Third Party Manufacturer or Ampio becomes an Ineligible Person, such status shall constitute a material breach hereunder, and the non-breaching party may terminate this Agreement if such breach continues for a period of thirty (30) days after delivery to the breaching party of written notice of termination, with termination effective on the date provided for in that notice.  
9.3 Termination for Bankruptcy. To the extent permitted by law, this Agreement shall automatically terminate upon the initiation of any proceeding in bankruptcy, reorganization or arrangement for the appointment of a receiver or trustee to take possession of the assets of either party or a similar proceeding under law for the release of creditors by or against either party, or if either party makes a general assignment for the benefit of its creditors.  
9.4 Withdrawal of Regulatory Approval and NDA. This Agreement may be terminated with respect to relevant countries in the Territory by either party in the event that a Regulatory Authority in the Territory withdraws the concerned Regulatory Approval for future marketing of Product in the concerned country of the Territory.  
9.5 No Waiver of Termination Rights. The right of either party to terminate this Agreement, as provided in this Article 9, shall not be affected in any way by its waiver of, or failure to take action with respect to, any previous default.  
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ARTICLE 10  
FORCE MAJEURE  
10.1 Effects of Force Majeure. A party hereto shall be excused and shall not be held liable or responsible for failure or delay in fulfilling or performing any of its obligations under this Agreement (other than the payment of money) if such failure or delay is caused by acts of God, acts of the public enemy, fire, explosion, flood, epidemic or other natural physical disaster, drought, war, terrorists, riot, unavailability of raw material, sabotage, embargo, strikes or other labor disputes, intervention of governmental authority, impossibility of the use of railways, shipping, aircraft, motor transport or other means of public or private transport, failure or suspension of utilities, and political interference with the normal operation of either party or by any other event or circumstance of like or different character to the foregoing beyond the reasonable control and without the fault or negligence of the affected party (a “Force Majeure Event”). Such excuse shall continue as long as the Force Majeure Event continues. Upon cessation of such Force Majeure Event, such party shall promptly resume performance hereunder.  
10.2 Notice of Force Majeure. Each party agrees to give the other party prompt written notice of the occurrence of any Force Majeure Event, the nature thereof and the extent to which the affected party will be unable to perform its obligations hereunder. Each party further agrees to use reasonable efforts to correct or otherwise address the Force Majeure Event as soon as practicable and to give the other parties prompt written notice when it is again fully able to perform such obligations.  
ARTICLE 11  
Miscellaneous  
11.1 Dispute Resolution. Ethypharm and Ampio agree to irrevocably submit to the exclusive jurisdiction of (i) the Supreme Court of the State of New York, New York County, U.S.A., or (ii) the United States District Court for the Southern District of New York U.S.A., for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby. Each Party agrees to commence any such action, suit or proceeding either in the United States District Court for the Southern District of New York, U.S.A. or, if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the Supreme Court of the State of New York, New York County, U.S.A.  
EACH PARTY HERETO WAIVES, TO THE EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT TO ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT, AND EACH PARTY HERETO (i) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THAT FOREGOING WAIVER, AND (ii) ACKNOWLEDGES THAT IT AND THE OTHER PARTY HERETO HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS PARAGRAPH.  
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11.2. Independent Contractors. The relationship between Ethypharm, on the one hand, and Ampio, on the other hand, is that of independent contractors and nothing herein shall be deemed to constitute or create the relationship of partners, joint venturers nor of principal and agent between Ethypharm on the one hand and Ampio on the other hand. Neither party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other party or to bind the other party to any contract, agreement or undertaking with any third party.  
11.3. Assignment. This Agreement may be assigned and/or delegated by either party to an Affiliate of such party or in connection with any sale, merger or other business combination involving all or substantially all of such party’s assets or capital stock or of the assets to which this Agreement relates. Except as otherwise provided in this Agreement, neither this Agreement nor any other rights or obligations hereunder shall be assigned, transferred or delegated by either party without the prior written consent of the other party, not to be unreasonably withheld, conditioned or delayed. Any permitted assignee shall, upon the request of the other party hereto, expressly acknowledge, by written agreement, its assumption of all obligations and liabilities under this Agreement. Any attempted assignment in violation of the foregoing shall be null and void. This Agreement shall inure to the benefit of each party’s permitted successors and assigns.  
11.4. Governing Law. This contract shall be governed by, and construed in accordance with, the laws of the State of New York without reference to that state’s conflicts of laws rules. The parties expressly reject the application of the United Nations Convention on Contracts for the International Sale of Goods and all implementing legislation thereunder.  
11.5. No Implied Waiver. No failure or delay on the part of either party hereto to exercise any right, power or privilege hereunder or under any instrument executed pursuant hereto shall, in itself, operate as a waiver; nor shall any single or partial exercise of any right, power or privilege preclude any other or further exercise thereof or the exercise of any other right, power or privilege.  
11.6. Notice. All notices required to be given hereunder shall be in writing and shall be given by personal delivery, via facsimile transmission followed by U.S. mail, by a nationally recognized overnight carrier or by registered or certified mail, postage prepaid with return receipt requested. Notices shall be addressed to the parties as follows:  
If to Ethypharm:  
Ethypharm S.A.  
194 Bureaux de la Colline  
F92213 Saint-Cloud  
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France  
Attn: Xxxxxx XXXXX—Chairman of the Board—CEO  
Facsimile No.: x00 0 00 00 00 00  
With a copy (which shall not constitute notice) to:  
Ethypharm USA Corp.  
0000 Xxxxxx Xxxxxx, 00xx Xxxxx, Xxxx Xxxxx  
Xxxxxxxxxxxx, XX 00000  
Attn: Xxxxx Xxxxx-CEO  
Facsimile No.: (000) 000-0000  
If to Ampio:  
Ampio Pharmaceuticals, Inc.  
The Quadrant  
0000 XXX Xxxxxxx, Xxxxx 000  
Xxxxxxxxx Xxxxxxx, XX 00000  
X.X.X.  
Attn: Xxxxxxx Xxxxxxxx—Chairman of the Board and CEO  
Facsimile (000) 000-0000  
With a copy (which shall not constitute notice) to:  
Xxxxxxx Procter LLP  
Exchange Place  
Boston, MA 02109  
Attention: Xxxxx Xxxxxxxxxx  
Facsimile: 000-000-0000  
Notices delivered personally shall be deemed communicated as of actual receipt; notices sent via facsimile transmission shall be deemed communicated as of receipt by the sender of written confirmation of transmission thereof; notices sent via overnight courier shall be deemed received as of one business day following sending; and notices mailed shall be deemed communicated as of three (3) business days after proper mailing. A party may change his or its address by written notice sent in accordance with this Section 12.6.  
11.7. Amendments. Any amendment or modification of this Agreement shall be valid only if made in writing and signed by both parties hereto.  
11.8. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original and both of which shall constitute a single document. A facsimile signature of an authorized signatory of either party shall be valid and binding and constitute due execution and delivery of this Agreement by such party.  
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11.9. Interpretation. The Section headings contained in this Agreement are for the convenience of reference only and shall not affect the meaning or interpretation of this Agreement. As used in this Agreement, any reference to the masculine, feminine or neuter gender shall include all genders, the plural shall include the singular, and the singular shall include the plural. Unless the context otherwise requires, the term “party” when used herein means a party hereto. References herein to a party or other Person include its respective successors and permitted assigns. The words “includes” and “including” when used herein shall be deemed to be followed by the phrase “without limitation” unless such phrase otherwise appears. Unless the context otherwise requires, references herein to Articles, Sections, Exhibits and Schedules shall be deemed references to Articles and Sections of, and Exhibits and Schedules to, this Agreement. Unless the context otherwise requires, the words “hereof,” “hereby,” “hereunder” and “herein” and words of similar meaning when used in this Agreement refer to this Agreement in its entirety and not to any particular Section or provision hereof. All monetary amounts in this Agreement are expressed and shall be paid in U.S. dollars. With regard to each and every term and condition of this Agreement, the parties understand and agree that the same has or have been mutually negotiated, prepared and drafted, and that, if, at any time, the parties desire or are required to interpret or construe any such term or condition or any agreement or instrument subject thereto, no consideration shall be given to the issue of which party actually prepared, drafted or requested any term or condition of this Agreement.  
11.10. Entire Agreement. This Agreement and the License Agreement constitutes the entire understanding between the parties with respect to the subject matter hereof and supersedes all prior contracts, agreements and understandings related to the same subject matter between the parties. In particular, in case of inconstancies between the terms of the License Agreement and the terms of this Agreement with respect to the manufacture and supply of the Product, the terms of this Agreement shall prevail. The parties intend this Agreement to be a complete statement of the terms of their understanding.  
11.11. Benefit; Binding Effect. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and permitted assigns.  
11.12. Survival. Notwithstanding anything to the contrary contained in this Agreement, the provisions of Article 3 (to the extent of post-termination complaints and reporting obligations) and Articles 1, 5, 6, 7, 8 11and 12 shall survive, in accordance with their respective terms, any termination or expiration of this Agreement.  
11.13. Further Assurances. The parties agree that they shall take all appropriate actions, including the execution or filing of any documents or instruments, that may be reasonably necessary or advisable to carry out the intent and accomplish the purposes of any of the provisions hereof.  
11.14. Severability. In the event that any provision of this Agreement shall be held invalid or unenforceable for any reason by a court of competent jurisdiction, such provision or part thereof shall be considered separate from the remaining provisions of this Agreement, which shall remain in full force and effect. Such invalid or unenforceable provision shall be deemed revised to effect, to the fullest extent permitted by applicable law, the intent of the parties as set forth herein.  
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11.15. Use of Names; Publicity. Neither party will use the name of the other party or issue any press release or other publicity relating to this Agreement in any form without the written permission of the other, except as may be required by applicable law (including securities exchange rules) or as otherwise contemplated hereunder. Neither party will unreasonably withhold its written permission if the other party desires to issue such a press release or other publicity with respect to this Agreement.  
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IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the Effective Date.  
Date:  
 ETHYPHARM S.A.  
By: /s/ Xxxxxx XXXXX  
Name: Xxxxxx XXXXX  
Title: CEO—Chairman of Management Board  
 AMPIO PHARMACEUTICALS, INC.  
By: /s/ Xxxxxxx Xxxxxxxx  
Name: Xxxxxxx Xxxxxxxx  
Title: Chairman of the Board and CEO  
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EXHIBIT A  
BATCH SIZE DEFINITION  
A full batch size of Product represents [\*\*\*].  
 \* Confidential Information indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities and Exchange Commission.  
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EXHIBIT B  
SUPPLY PRICES  
Ethypharm Supply prices of Product expressed EX WORKS (Ethypharm Commercial Manufacturing Site) taxes excluded, in bulk tablets, to Ampio shall be:  
[\*\*\*]  
[\*\*\*]  
The Supply Price as determined above includes the supply of excipients and active drug, the analysis of active drug and excipient, the manufacturing operations according to the standards of ETHYPHARM and the delivery in bulk packaging Ex Works as indicated.  
 \* Confidential Information indicated by [\*\*\*] has been omitted from this filing and filed separately with the Securities and Exchange Commission.  
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EXHIBIT C  
PRODUCT SPECIFICATIONS  
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