Exhibit 10.14  
MANUFACTURING AND SUPPLY AGREEMENT  
THIS MANUFACTURING AND SUPPLY AGREEMENT (this “Agreement”) is made and entered into this 21st day of August 2008 (the “Effective Date”) by and between MIKART, INC. (“Mikart”) and TRANSCEPT PHARMACEUTICALS, INC. (“Transcept”). Mikart is a Georgia corporation with its principal place of business at 0000 Xxxxxxxxxxxxx Xxxxxx, Xxxxxxx, Xxxxxxx 00000. Transcept is a Delaware corporation with its principal place of business at 0000 X. Xxxxxxx Xxxxxxxxx, Xxxxx 000, Xx. Xxxxxxxx, Xxxxxxxxxx 00000.  
BACKGROUND  
A. Subject to the terms and conditions contained in this Agreement, Transcept desires to qualify and engage Mikart to manufacture Products (as defined below) for commercial sale by Transcept and/or its designees; and  
B. Mikart desires to accept such appointment and to perform certain qualification services to enable it to manufacture Products for Transcept and, following Mikart’s successful qualification as a manufacturer of Products, to manufacture and supply such Products to Transcept or its designee for commercial sale.  
NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants, agreements and promises contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Mikart and Transcept hereby agree as follows:  
ARTICLE 1  
DEFINITIONS  
Capitalized words, terms and phrases, which are not otherwise defined herein, shall have the following respective meanings:  
1.1 “Applicable Laws” shall mean all laws, ordinances, rules and regulations of any governmental or regulatory authority in the Territory (as such Territory may be expanded pursuant to Section 2.9 below) that apply to the Qualification Services, the Products or this Agreement, including without limitation (a) all applicable federal, state and local laws and regulations; (b) the U.S. Federal Food, Drug and Cosmetic Act (“FDCA”), (c) regulations and guidelines of the FDA and other Regulatory Agencies, and ICH guidelines and (d) GMP, and if applicable, current Good Laboratory Practices and current Good Clinical Practices promulgated by the FDA and other Regulatory Agencies.  
1.2 “Batch” shall mean: (i) in the case of Product containing 3.5 mg of Zolpidem Tartrate, the quantity of 1,500,000 tablets of such Product, or (ii) in the case of Product containing 1.75 mg of Zolpidem Tartrate, the quantity of 500,000 tablets of such Product, or (iii) such other quantity of a Product that may be mutually agreed to in writing by the Parties.  
 Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
1.3 “Confidential Information” shall mean the proprietary and confidential data or information of a party hereto which is of tangible or intangible value to such party, is not generally known by or available to the competitors of such party (including, without exclusion, the contents of this Agreement) and which is disclosed in writing, orally or in other form to the other party. For avoidance of doubt, all information transferred to Mikart pursuant to Section 2.1 below and all Product Information (as defined below) shall be deemed the Confidential Information of Transcept. Notwithstanding the foregoing, Confidential Information shall not include information which: (i) at the time of disclosure to the receiving party is in the public domain or thereafter enters the public domain through no wrongful act or omission of the receiving party; (ii) is already known by the receiving party at the time of disclosure by the disclosing party and such information is not otherwise subject to confidentiality obligations of the receiving party (provided that this exception (ii) shall not apply to Product Information); or (iii) is made available to the receiving party at the time of or following the disclosing party’s disclosure thereof by a third party who, to the receiving party’s reasonable knowledge, may disclose such information to the receiving party without violation of any confidentiality obligation.  
1.4 “Contract Year” shall mean a twelve (12) consecutive month period during the Term of this Agreement, and the first Contract Year shall commence as of the Commencement Date and subsequent Contract Years shall commence on each anniversary of the Commencement Date.  
1.5 “Commencement Date” shall mean the first day, following full FDA qualification and approval of Mikart and the Facility as a commercial manufacturer of Products, that a Product is manufactured and shipped by Mikart to Transcept (or its designee) for commercial distribution by Transcept or its designee.  
1.6 “Facility” shall mean Mikart’s GMP manufacturing facility located at 0000 Xxxxxxxx Xxxx., Xxxxxxx, XX 00000.  
1.7 “FDA” shall mean the United States Food and Drug Administration or any successor agency thereof.  
1.8 “GMP” shall mean current good manufacturing practice and standards as provided for (and as amended from time to time) in the Current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations Title 21 (21 CFR §§ 210 and 211) in relation to the production of biopharmaceutical products, as interpreted by the ICH Harmonized Tripartite Guideline, any U.S. or other applicable laws, regulations or respective guidance documents subsequently established by a governmental or regulatory authority in the Territory, and any arrangements, additions or clarifications agreed from time to time between the parties.  
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1.9 “Humidity Control System” means [\*\*\*].  
1.10 “Product(s)” shall mean the 1.75 mg or 3.5 mg Zolpidem Tartrate product(s) to be manufactured and supplied by Mikart hereunder, as further described in Exhibit A.  
1.11 “Product Information” means any deliverables, data, reports or other information generated by Mikart in the course of its performance of this Agreement (including in the course of the Qualification Services), including but not limited to Product IP (as defined in Section 11.1 below).  
1.12 “Regulatory Agency” shall mean any governmental regulatory authority involved in regulating any aspect of the Qualification Services or the development, manufacture, market approval, sale, distribution, packaging or use of the Products in the Territory (as such Territory may be expanded pursuant to Section 2.9) including the FDA.  
1.13 “Specifications” shall mean the specifications for the manufacturing, bulk packaging and bulk labeling of each Product that are set forth on Exhibit A attached hereto and that may be mutually agreed to in writing by Mikart and Transcept, in each case which are incorporated herein by reference, as the same may be modified pursuant to Section 2.5 below. In addition, the Specifications shall in all cases include compliance with all Applicable Laws and the Quality Agreement (as defined in Section 2.3(a) below).  
1.14 “Territory” shall mean the [\*\*\*].  
ARTICLE 2  
TESTING AND MANUFACTURE  
2.1 Qualification Services.  
(a) Promptly following Mikart’s full installation and qualification of the Humidity Control System and Transcept’s payment to Mikart of the total [\*\*\*] therefor as described in Sections 2.10(a) and 2.10(b) below, the parties will cooperate in the transfer of certain Product manufacturing processes and test methods to Mikart, and Mikart will evaluate such manufacturing processes and test methods and perform all necessary work required for such transfer to enable Mikart to successfully manufacture Product for Transcept for commercial supply, as described in more detail in Exhibit C (such services to be performed by Mikart, the “Qualification Services”). Notwithstanding anything to the contrary in this Agreement, the Parties acknowledge and agree that, as soon as possible following the Effective Date hereof, Mikart will provide to Transcept a written supplement to the Qualification Services that will contain a reasonable description of additional services (including, without limitation, dissolution  
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 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
testing) that will be necessary with respect to the successful manufacture of the Product, together with a list of Mikart’s standard rates for the performance of such additional services. If such services and rates are acceptable to Transcept, Transcept agrees to pay Mikart for such additional services at Mikart’s standard rates therefor and Mikart agrees to perform such services in accordance with the terms of this Agreement, and such services shall be considered Qualification Services for purposes of this Agreement. For the avoidance of doubt, if the Parties are unable to agree upon such services and rates following reasonable, good faith negotiations, then neither Party shall be in breach, or deemed to be in breach, of this Agreement.  
(b) Transcept and Mikart acknowledge that Mikart must validate [\*\*\*] of each strength of Product (1.75 mg or 3.50 mg tablet) prior to selling such Product to Transcept (each, a “Validation”) for a total of [\*\*\*]. Accordingly, as part of the Qualification Services, Mikart agrees to perform the Validation activities described in Exhibit C. After Mikart successfully completes each Validation, Transcept shall be obligated to purchase each of the [\*\*\*] so validated in accordance with the terms of this Agreement, provided that such Batches comply with the Specifications and the terms of this Agreement. The Parties acknowledge and agree that the Validation for each strength of the Product may occur at different times or during different calendar years of the Term. It is understood that, for each strength of Product, Transcept shall only be obligated to purchase the [\*\*\*] Validation Batches that were successfully manufactured consecutively by Mikart in accordance with the Specifications and the terms of this Agreement, and Transcept shall not be required to purchase any other Validation Batches (even Validation Batches successfully manufactured by Mikart). In the event that Mikart does not perform the activities described in the Validation Protocol (as defined in Section 2.11(c) below) as a result of Mikart’s negligence or failure to comply with Applicable Laws, the Specifications or the instructions of the Validation Protocol, Mikart agrees to re-perform such activities [\*\*\*] to Transcept. In the event that the Validation Batches manufactured in accordance with procedures of the Validation Protocol, Applicable Laws and the Specifications fail to meet the applicable statistical criteria, the Parties agree to negotiate in good faith regarding financial responsibility for any additional Validation work required to be performed as a result thereof. All Batches purchased by Transcept shall apply towards, and shall fully satisfy, Transcept’s Minimum Purchase Requirement (as defined in Section 3.5) for such Product for the applicable number of Contract Years (or portion thereof), and Transcept shall have the right to sell such Batches commercially. Mikart shall maintain Stability Testing (as defined below) and Validation data for such Batches at its Facility or at such other location as agreed to by Transcept and Mikart in accordance with Applicable Laws. All of Mikart’s costs incurred in connection with the Validation and the storage of data related thereto shall be as set forth in Exhibit C and shall be payable in accordance with the payment schedule included in Schedule C-3 of Exhibit C (the “Qualification Services Payment Schedule”). All of Mikart’s costs incurred in connection with the Stability Testing and the storage of data for such Batches shall be periodically billed to and paid by Transcept in accordance with the Qualification Services Payment Schedule.  
(c) Mikart agrees to perform the Qualification Services, develop and perform the Validation Protocol and to deliver to Transcept the completed deliverables described in Exhibit C, all in accordance with Exhibit C, this Agreement, Transcept’s written instructions and Applicable Laws. As used in this Section 2.1, “Validation Protocol” shall mean a document  
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 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
developed by Mikart and approved by Transcept which shall: (i) describe the manufacturing process, (ii) describe objective and measurable criteria for control of the manufacturing process, (iii) define the length and duration of the validation, and (iv) describe the equipment used in the manufacturing process.  
2.2 Limited Warranties. Mikart hereby represents and warrants to Transcept that the Products manufactured and sold to Transcept hereunder (including the Validation Batches) shall conform to the Specifications (including, without limitation, the terms of the Quality Agreement (as defined in Section 2.3(a) below)) and shall be free of all defects in materials and workmanship. Mikart represents and warrants that: (i) all Products, when manufactured and picked up for delivery from Mikart’s Facility, shall comply with all Applicable Laws; and (ii) Mikart’s performance of all activities under this Agreement (including the Qualification Services) shall comply with all Applicable Laws. Without limiting the foregoing, at the time of shipment to Transcept, none of the Product shall be adulterated or misbranded within the meaning of the FDCA, as amended and in effect at the time of shipment. Mikart further represents and warrants that: (x) all Product shall be manufactured and stored at the Facility and that the Facility shall, during the Term, comply with Applicable Law; and (y) title to all Products and deliverables provided to Transcept under this Agreement shall pass as provided in this Agreement, free and clear of any security interest, lien, or other encumbrance. Mikart represents and warrants to Transcept that neither Mikart nor any of its employees have been “debarred” by the FDA, or subject to a similar sanction from another Regulatory Agency, nor have debarment proceedings against Mikart or any of its employees been commenced. Mikart will promptly notify Transcept in writing if any such proceedings have commenced or if Mikart or any of its employees are debarred by the FDA or other Regulatory Agencies. EXCEPT AS SET FORTH IN THIS SECTION 2.2 AND SECTION 8.1 HEREOF, NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS OR WARRANTIES (EXPRESS, IMPLIED, STATUTORY OR OTHERWISE) WITH RESPECT TO THE SUBJECT MATTER HEREOF AND EACH PARTY SPECIFICALLY DISCLAIMS ALL SUCH OTHER REPRESENTATIONS AND WARRANTIES, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.  
2.3 Quality Control.  
(a) Mikart will perform quality control testing on each Product in accordance with normal industry standards to determine whether such Product conforms to the Specifications. Contemporaneously with each shipment of Products hereunder, Mikart will provide Transcept with a certificate of analysis with respect to such Product in a form reasonably acceptable to Transcept and describing all current requirements of the Specifications, results of tests performed certifying that the Product supplied has been manufactured, controlled and released at the Facility in accordance with the Specifications and Applicable Laws. Mikart will perform, at Transcept’s expense, any and all other testing relating to the Products which is reasonably requested by Transcept, and will promptly provide Transcept with the results thereof. The parties acknowledge that they will negotiate and enter into a commercially reasonable quality agreement with respect to the manufacture, testing, storage, release, quality assurance and supply of Products by Mikart hereunder, which shall be attached hereto as Exhibit E (the “Quality Agreement”).  
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(b) In addition, Mikart shall be responsible for conducting an ongoing stability program as required by Applicable Law (and, in the case of the Validation Batches, as described in Exhibit C) (“Stability Testing”). Mikart’s performance of Stability Testing for the Validation Batches shall be payable by Transcept pursuant to the Qualification Services Payment Schedule. Mikart’s performance of Stability Testing for all other Batches of Product shall be payable by Transcept pursuant to Schedule C-2 and the Quality Services Payment Schedule.  
(c) Mikart will, upon the reasonable request of Transcept, assay any Product returned to Transcept by a third party purchaser. Transcept shall reimburse Mikart for the costs of any such assay unless the results thereof reveal a patent or latent defect caused by a deviation by Mikart from the Specifications or breach by Mikart of the limited warranties contained in Section 2.2 hereof (a “Product Defect”).  
(d) In the event that any Batch of any Product manufactured by Mikart pursuant to this Agreement is subject to a recall, Transcept, at its expense, shall conduct the recall, except that Mikart shall reimburse Transcept for the costs thereof to the extent such recall results from Mikart’s non-compliance with the Specifications, the Quality Agreement or Applicable Laws, or Mikart’s breach of its representations and warranties under Section 2.2 or Article 8.  
(e) Each party hereto shall promptly notify the other of any recall of any Product which has been directed by it or by any Regulatory Agency in the Territory for any reason whatsoever. Such notice shall identify the reason for the recall and all relevant details thereof.  
2.4 Packaging Materials. Mikart shall order from time to time, at Transcept’s request and expense, labels and other bulk packaging materials required for the bulk packaging of the Products as described in the Specifications and Transcept’s written communications to Mikart (“Product Packaging”) in sufficient quantities to permit the bulk packaging of the Products scheduled for delivery pursuant to Purchase Orders placed in accordance with Section 3.3 hereof. Mikart shall not be responsible for the content of any packaging, including labels and any other packaging materials, to the extent that such packaging is consistent with the Specifications and such content shall be the sole responsibility of Transcept.  
2.5 Changes to the Specifications. As between the parties, Transcept shall have the sole right to modify the Product Specifications. All modifications shall be in writing and shall be signed by an authorized representative of Transcept and Mikart, and shall be effective for Purchase Orders for Product placed after the effective date of the changes. If the modifications result in a material change in Mikart’s manufacturing costs, the parties shall agree upon an appropriate adjustment to the price of the Product under this Agreement. If the modifications result in a delay in delivery, the parties will negotiate a reasonable extension of the affected lead times, provided that Mikart shall use diligent efforts to mitigate such delay. Notwithstanding  
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anything to the contrary set forth in this Section 2.5, changes to material and component Specifications and/or procedures that are required to comply with official or compendial revisions or directives of any Regulatory Agency will be made and implemented by Mikart on or before the published or stated effective date for such changes, and will require neither advance notice to nor approval by Transcept; provided, however, that Mikart will notify Transcept in writing of any changes related to the Active Materials (as defined in Section 2.11 hereof), and Mikart will include all changes described in this Section 2.5 in the documentation provided to Transcept for inclusion in the annual report for the Product. Should such changes require advance notice to or approval by any Regulatory Agency, Mikart shall also notify Transcept promptly in writing after identification of such changes, and Mikart will provide support to Transcept in order to effect such changes by the published or stated effective date therefor.  
2.6 Batch Records; Samples. Mikart shall maintain batch records sufficient to trace the history of each Batch, and representative samples from each Batch of Product manufactured hereunder, for record keeping, stability testing, and other regulatory purposes, including as may be required by the Specifications or Applicable Laws. Such records and samples shall be maintained for a minimum of [\*\*\*] after which time Mikart may make arrangements for the confidential disposition of the same, unless Transcept provides a prior written request for longer retention of such records or samples. Alternatively, Transcept shall have the option of having such records and samples delivered to Transcept or its designee. Upon the request of Transcept, Mikart shall provide Transcept reasonable access to and copies of such records and samples.  
2.7 Records. Mikart shall maintain laboratory notebooks and all technical, scientific, and other manufacturing-related records in sufficient detail and (as appropriate, in good scientific manner) which shall reflect work done and results achieved in the course of performing activities under this Agreement, including all data in the form required by Applicable Law. Such records shall be kept for a period of [\*\*\*] after completion or termination of the activity or such longer period as Applicable Laws may require.  
2.8 Inspections. Upon reasonable prior written notice given by Transcept to Mikart, but not more frequently than [\*\*\*] during each [\*\*\*] period following the Effective Date hereof, Mikart shall permit Transcept or its representatives to inspect and audit, during Mikart’s business hours, the performance of the activities hereunder (including the Qualification Services), the facilities used, and documentation relevant to ensure Mikart’s ongoing GMP compliance, including those documents kept under Sections 2.6 and 2.7 above, in order to determine Mikart’s compliance with Applicable Laws and this Agreement. In addition, Transcept shall be entitled to review Mikart’s standard operating procedures applicable to the Qualification Services during such audits.  
2.9 [\*\*\*]  
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 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
[\*\*\*]  
2.10 Humidity Control System.  
(a) Promptly following the Effective Date and before the [\*\*\*] thereof, Mikart shall purchase, install, qualify and maintain a Humidity Control System (which shall be owned by Mikart) in pharmaceutical manufacturing room [\*\*\*] of the Facility (the “Blending Room”) to enable it to manufacture Products under appropriate relative humidity conditions of [\*\*\*]. Thereafter and during the Term, Mikart shall maintain and ensure the full function of such Humidity Control System for the Blending Room. Subject to Section 2.10(c) below, Mikart shall only use the Blending Room for the manufacture of Product(s) for Transcept or its designees.  
(b) In consideration for Mikart’s performance of the activities and assumption of the obligations described in Section 2.10(a), Transcept shall pay to Mikart a fee of [\*\*\*] as detailed in Exhibit F, payable as follows: (i) [\*\*\*] payable by Transcept upon execution of the Agreement by both parties; (ii) [\*\*\*] payable by Transcept on or before the date that is [\*\*\*] following the execution of this Agreement by both parties; (iii) [\*\*\*] payable by Transcept on or before the date that is [\*\*\*] following the execution of this Agreement by both parties; (iv) [\*\*\*] payable by Transcept on or before the date that is [\*\*\*] following the execution of this Agreement by both parties; and (v) [\*\*\*] payable by Transcept upon both (x) Mikart’s installation and qualification of the Humidity Control System in the Blending Room and completion of the Qualification Services and (y) Transcept’s reasonable satisfaction that the Blending Room maintains the appropriate humidity and other conditions for the manufacture of Product in accordance with the Specifications.  
(c) If Mikart wishes to use the Blending Room containing the Humidity Control System for other customers during the Term and such use is not reasonably likely to result in a Supply Failure (as defined in Section 6.4(a) below) or to otherwise interfere with Mikart’s obligations to Transcept hereunder, and such use is to manufacture products for customers whose products require the use of the Humidity Control System, the parties will negotiate in good faith an arrangement in which Mikart reimburses Transcept for its use of such room in the form of a credit or payment of [\*\*\*] for each batch of third party product produced in such room, until Mikart has reimbursed to Transcept the mutually agreed-upon, estimated value of the Humidity Control System (taking into account the Humidity Control System’s remaining useful life at the time and other relevant factors); provided, however, that no such reimbursement shall be required for the [\*\*\*] of product [\*\*\*] that Mikart makes for each of its customers. After Mikart has reimbursed Transcept such estimated  
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 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
value of the Humidity Control System, Mikart shall be free to use the Blending Room containing such Humidity Control System for its other customers whose products require the use of the Humidity Control System, provided that such use is not reasonably likely to result in a Supply Failure or to otherwise interfere with Mikart’s obligations to Transcept hereunder. For the avoidance of doubt, the parties acknowledge and agree that Mikart shall be free to use the Blending Room, without any payment to Transcept, for any products that do not require the use of the Humidity Control System.  
(d) In the event that Transcept’s primary supplier of Products fails (in Transcept’s reasonable judgment) to supply Product to Transcept and thereafter Transcept provides to Mikart forecasts for Product above the Minimum Purchase Requirement (as defined in Section 3.5 below) and provides a written request to Mikart to upgrade an additional room at Mikart’s Facility with a Humidity Control System, Mikart agrees to use its commercially reasonable efforts to upgrade such additional room as soon as possible and shall assume the obligations described in Section 2.10(a) above with respect to the installation, qualification and maintenance of such Humidity Control System. The price payable by Transcept for such upgrade and use of such room shall be Mikart’s estimated cost to install such system, such cost to be mutually agreed upon by Mikart and Transcept and to be paid as follows: (i) [\*\*\*] of such cost shall be paid by Transcept to Mikart upon mutual agreement of such estimated cost by Mikart and Transcept, as described above; (ii) [\*\*\*] of such cost shall be paid by Transcept to Mikart on or before the date that is [\*\*\*] following such mutual agreement; (iii) [\*\*\*] of such cost shall be paid by Transcept Mikart on or before the date that is [\*\*\*] following such mutual agreement; (iv) [\*\*\*] of such cost shall be paid by Transcept to Mikart on or before the date that is [\*\*\*] following such mutual agreement; and (ii) the remaining [\*\*\*] of such cost shall be paid by Transcept to Mikart upon both (x) Mikart’s installation and qualification of the Humidity Control System and (y) Transcept’s reasonable satisfaction that such upgraded room maintains the appropriate humidity and other conditions for the manufacture of Product in accordance with the Specifications. Such room shall only be used for Transcept’s Product(s), subject to Mikart’s ability to reimburse Transcept for the use of such room for its other customers whose products require the use of the Humidity Control System, under the same terms described in Section 2.10(c) above.  
2.11 Active Materials Supply and Use.  
(a) Transcept or its designee shall supply to Mikart sufficient quantities of the Zolpidem Tartrate active ingredient (the “Active Materials”) for Mikart to perform the Qualification Services and to manufacture and supply Products ordered by Transcept hereunder, such shipments of Active Materials to be made to Mikart DDP (Incoterms 2000). Transcept or its designee shall supply the quantity of Active Materials necessary to meet Transcept’s forecasted requirements for the Products pursuant to Section 3.2 hereof, and mutually agreed upon by Mikart and Transcept. Upon shipment of each shipment Batch of Product hereunder, Transcept shall receive a credit from Mikart for the value of the Active Materials contained in such Batch, such value to be based upon the purchase price paid by Transcept for such Active  
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 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
Materials (as evidenced by the invoices received by Transcept for such Active Materials), which shall be credited against amounts owed for Product hereunder. As of the Effective Date, the purchase price paid by Transcept for Active Materials is [\*\*\*]. Upon any expiration or termination of this Agreement, Mikart shall return to Transcept, at Transcept’s reasonable expense, any Active Materials that have not been used in the manufacture of Products hereunder.  
(b) Mikart shall use and store all Active Materials solely at the Facility and solely as necessary to perform the Qualification Services and manufacture Product ordered hereunder, in each case in accordance with Transcept’s reasonable instructions, the Quality Agreement and Applicable Laws.  
(c) Upon Mikart’s receipt of Active Materials, Mikart shall conduct a reasonable inspection and release testing of such Active Materials in accordance with mutually agreed procedures. Mikart shall promptly conduct chemical identity testing for all Active Materials received at the Facility, as applicable. Further, Mikart shall conduct full release testing of all Active Materials received at the Facility, as applicable, not later than [\*\*\*], after the date of receipt in accordance with the procedures and using the analytical testing methodologies set forth in Exhibit D and the Quality Agreement. Mikart shall promptly (and in any event within [\*\*\*] following completion of applicable testing) notify Transcept in writing of any failure of the Active Materials to conform to the: specifications therefor, and any other problem it may identify with the Active Materials detected during the inspection and testing process. Mikart shall ensure that the Active Materials do not become subject to any lien or other security interest. The parties acknowledge and agree that title to all Active Materials shall at all times belong to and remain in Transcept. All Active Materials in Mikart’s possession shall be subject to disposition by Transcept upon expiration or termination of this Agreement, and in either such event, Mikart shall deliver the Active Materials to Transcept or its designee, at Transcept’s expense.  
(d) Commencing on the Effective Date, Mikart shall monitor on a calendar year basis the inventory of the Active Materials held by Mikart and shall provide Transcept, within [\*\*\*] following the last day of the applicable calendar year, with an inventory report of the Active Materials held by Mikart. In addition, within [\*\*\*] after the end of each Contract Year, Mikart shall provide to Transcept a reconciliation report evaluating on hand Active Materials against Active Materials received by Mikart less withdrawals for analysis, retention samples, other samples (FDA/DEA), Active Materials for R&D use and Active Materials needed to meet Batch requirements. Such evaluation will be done separately for each lot of Active Materials received by Mikart. Once a lot is depleted, the non-recoverable Active Materials are calculated and evaluated against Specifications. Transcept acknowledges and agrees that Mikart’s reconciliation specifications for controlled substances are [\*\*\*] of the amount received.  
2.12 Buffered Soda Supply. Without limiting any of Mikart’s obligations under the Buffered Soda Supply and Sublicense Agreement between the parties dated January 22, 2008 and subject to Mikart’s fulfillment of its obligations thereunder, it is understood that Transcept (or its designee) shall supply Mikart with the quantities of buffered soda reasonably necessary for Mikart’s manufacture of Products hereunder.  
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 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
ARTICLE 3  
ORDERS AND SALES  
3.1 Product Supply. Subject to the terms and conditions of this Agreement, Mikart shall supply to Transcept all quantities of the Products ordered by Transcept or its designee(s) under this Agreement pursuant to Purchase Orders placed by Transcept or such designee(s) in accordance with Section 3.3 below. Transcept agrees that, in the event that it delegates one or more of its responsibilities hereunder to a third party pursuant to this Section 3.1 or any similar provision hereunder involving a designee of Transcept, unless otherwise agreed to in writing by the parties, Transcept shall remain fully responsible for the performance of such responsibilities.  
3.2 Forecasts. Commencing upon full FDA qualification and approval of Mikart and the Facility as a commercial manufacturer of Products and thereafter throughout the Term, at least [\*\*\*] prior to the commencement of each calendar quarter, Transcept shall provide Mikart with a non-binding, rolling twelve (12) month forecast of its requirements for each Product.  
3.3 Purchase Orders. Transcept shall place its orders for each Product no later than [\*\*\*] prior to the requested delivery date using separately numbered, written purchase orders (each, a “Purchase Order”). Each Purchase Order must be for [\*\*\*] All packaging sizes shall be a size mutually agreed to by the parties. Purchase Orders shall be transmitted to Mikart via U.S. mail, private courier, or facsimile transmission. Each Purchase Order shall include complete and accurate information with respect to quantity, packaging size, shipment dates, shipment method and delivery destination. Mikart and Transcept shall work together in good faith to schedule orders and deliveries of each Product in a manner which is reasonably acceptable to both parties, and Mikart shall promptly notify Transcept upon its receipt of any Purchase Order containing delivery dates which need to be rescheduled. Notwithstanding the foregoing, Mikart shall deliver all quantities of Product ordered under each Purchaser Order within [\*\*\*] of the date of Mikart’s receipt of such Purchaser Order unless otherwise agreed to by the Parties. ANY ADDITIONAL OR INCONSISTENT TERMS OR CONDITIONS OF ANY PURCHASE ORDER, ACKNOWLEDGMENT OR SIMILAR STANDARDIZED FORM GIVEN OR RECEIVED PURSUANT TO THIS AGREEMENT WILL HAVE NO EFFECT AND SUCH TERMS AND CONDITIONS ARE HEREBY EXCLUDED.  
3.4 Packaging. Product shall be shipped packaged in containers in accordance with the applicable Specifications or as otherwise agreed by the Parties in writing. Each such container will be individually labeled with a description of its contents, including the manufacturer lot number, quantity of Product, date of manufacture and expiration date.  
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 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
3.5 Minimum Purchase. Commencing on the first Contract Year following full FDA qualification and approval of Mikart and the Facility as a commercial manufacturer of Products and during each Contract Year of the Term (including any Renewal terms thereof) thereafter, Transcept shall purchase from Mikart, on a take-or-pay basis, a minimum total of three (3) Batches of Product (the “Minimum Purchase Requirement”).  
ARTICLE 4  
PRICES AND TERMS OF PAYMENT  
4.1 Price.  
(a) The price to be paid by Transcept for the Qualification Services shall be as set forth in the Qualification Services Payment Schedule contained in Exhibit C.  
(b) The price to be paid by Transcept for each Product to Mikart during the first Contract Year shall be as set forth on Exhibit B.  
4.2 Price Adjustments. Mikart shall have the right to increase the price charged for each Product pursuant to Section 4.1(b) hereof one time at the end of each Contract Year for the following Contract Year to reflect any percentage increase [\*\*\*] at that time (“Total Product Costs”); provided, however, that (i) in the event Mikart increases any such price in any Contract Year, and (ii) after the effective date thereof but before the end of such Contract Year Mikart’s cost of raw materials or components for manufacturing such Product (“Materials Cost”) increases by more than [\*\*\*], Mikart shall have the right, by providing at least [\*\*\*] prior written notice to Transcept, to again increase the price charged for such Product in such Contract Year by a percentage amount equal to the portion of such percentage increase in Materials Cost that is in excess of [\*\*\*]; provided further, that (a) Mikart shall provide Transcept with documented evidence of any such Material Cost increases and shall use its commercially reasonable efforts to prevent any such cost increases from occurring, and (b) the price of Product shall not be increased to reflect increases in Mikart’s Total Product Costs to the extent such increases have already been incorporated into the Product price as Materials Cost increases. It is further understood that the price for Product hereunder includes the purchase price paid by Transcept to third parties for those Active Materials that are actually included in the composition of such Product. Accordingly, in the event of an increase or decrease in the price of such Active Materials, as evidenced by the written invoices received by Transcept for such purchased Active Materials, the Price for the applicable Product shall be adjusted accordingly. As of the Effective Date, the price paid by Transcept for Active Materials is [\*\*\*].  
4.3 Payment Terms. Mikart shall invoice Transcept for the Qualification Services in accordance with the Qualification Services Payment Schedule and for the price of the Products sold at the time of shipment. Transcept shall pay such invoices for the Qualification Services within thirty (30) days after its receipt thereof and shall pay such invoices for Product within thirty (30) days after its receipt thereof. All invoices for Qualification Services shall be sent to  
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 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
the Transcept address specified in this Agreement and shall contain a reasonable itemized description of the services performed and the associated charges. All invoices for Product will be sent to the address specified in the applicable Purchase Order, and each invoice will state the aggregate and unit price for Product in a given shipment, plus any costs incident to the purchase or shipment initially paid by Mikart but to be borne by Transcept under this Agreement.  
4.4 Taxes. If any tax is due with respect to the sale of Product under this Agreement, Transcept will have the sole responsibility to pay that tax and Mikart will have the sole responsibility to collect that tax from Transcept and remit that tax to the applicable authorities. In addition, any charges for insurance or other costs imposed by third parties incident to the purchase or shipment of Product hereunder shall be the sole responsibility of, and shall be paid by, Transcept. For clarity, and without limiting Transcept’s obligation in the foregoing sentence for costs or charges arising from the purchase or shipment of Product hereunder, it is understood that any costs or charges arising from the manufacture or storage of Product by Mikart shall be borne by Mikart.  
4.5 Currency. All amounts payable by Transcept hereunder will be made in United States Dollars. Unless otherwise set forth, all amounts specified in any Purchase Order shall be deemed specified in United States Dollars.  
ARTICLE 5  
SHIPPING DEFECTS, RETURNS  
5.1 Shipping. Mikart will ship all Products ordered hereunder to Transcept f.o.b. (UCC) Mikart’s Facility, at which point the risk of loss for such Product will pass to Transcept. Mikart shall ship Products to the location designated by Transcept on such Product’s respective Purchase Order. The parties agree that the method and route of shipment are at Mikart’s discretion unless Transcept furnishes Mikart explicit instructions with such Product’s respective Purchase Order; provided that, such location is authorized to receive and store such Product under Applicable Law. Transcept agrees to pay all costs of shipping and any costs of freight insurance obtained by Mikart at the request of Transcept. Mikart agrees to provide reasonable support to assist Transcept in pursuing any claims it may have against carriers relating to the shipment of the Products. All Product delivered hereunder shall be suitably packed for shipment by Mikart in accordance with good commercial practice with respect to protection of such Product during transportation and marked for shipment to Transcept’s specified receiving point.  
5.2 Notification of Defects. Acceptance by Transcept of Product delivered by Mikart shall be subject to inspection and applicable testing by Transcept or its designee. Transcept shall notify Mikart in writing as soon as practicable, but in any event (i) within [\*\*\*] after delivery to Transcept of any non-conforming Product containing obvious defects discoverable without affecting the integrity of such Product’s packaging and (ii) within [\*\*\*] of the earlier of discovery by Transcept or receipt of notification by Transcept from a third party of any latent defects. Transcept shall be responsible for its costs to inspect such Product, unless such inspection reveals a Product Defect (as defined in Section 2.3(c)). If upon inspection or testing  
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 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
of Product in accordance with this Section 5.2, Transcept or its designee discovers a Product Defect, Transcept or such designee may reject such Product, which rejection will be accomplished by giving written notice to Mikart. Such written notice shall include specific reasons and sufficient details regarding why Transcept, or its designee, considers such Product to be defective.  
5.3 Returns. At Mikart’s expense, Mikart shall accept for return and replacement any Product containing a Product Defect for which proper notice has been given in accordance with Section 5.2, provided that Transcept returns such rejected Product in accordance with Mikart’s reasonable instructions. All returns of Product with obvious defects shall be in the original manufactured condition, to the extent the preservation of such condition would be practicable given the nature of the testing or inspection reasonably necessary to confirm the existence of such defects. Mikart will pay reasonable return freight and shipping charges for returned Product containing a Product Defect, and shall assume the risk of loss in transit associated with such returns. Mikart shall use its commercially reasonable efforts to replace rejected Product within the shortest possible time after Mikart’s receipt of notice thereof. In the event all or part of a shipment of Product is rejected prior to Transcept’s payment therefor, Transcept may withhold such payment until receipt of replacement Products that conform with the Specifications therefor and to the warranties given by Mikart in Section 2.2 and Article 8.  
5.4 Disputed Returns. The parties shall use their reasonable efforts to resolve any dispute that may arise pursuant to Sections 5.2 and 5.3. If the parties fail to agree, within [\*\*\*] of Transcept providing notice of rejection, whether any delivery of the Product supplied by Mikart to Transcept contains a Product Defect, the dispute shall be determined by an independent laboratory/expert mutually selected by the parties and the decision of such independent laboratory/expert shall be final and binding on the parties with respect to whether the Product in question contains a Product Defect. In the event that the independent laboratory/expert decides that the Product in question does not contain a Product Defect, such Product shall be deemed accepted by Transcept. In the event that the independent laboratory/expert decides that the Product in question contains a Product Defect, Mikart shall use its commercially reasonable efforts to replace such Product within the shortest possible time after Mikart’s receipt of notice regarding the independent laboratory/expert’s decision. For purposes of clarity, only disputes between the parties regarding conformance of the Product as expressly described in this Section 5.4 above shall be resolved by an independent laboratory/expert, and all other disputes between the parties shall be governed by the provisions of Article 12 below. The independent laboratory/expert’s fees and the prevailing party’s reasonable out-of-pocket costs incurred in connection with the independent laboratory/expert’s decision shall be borne by the party against whom the independent laboratory/expert’s decision is given.  
ARTICLE 6  
TERM AND TERMINATION; SUPPLY FAILURE; FORCE MAJEURE  
6.1 Term. Unless earlier terminated in accordance with the provisions hereof, the initial term (the “Initial Term”) of this Agreement shall commence on the Effective Date and all thereafter continue until the tenth (10th) anniversary of the Commencement Date. Following the Initial Term, this Agreement shall automatically renew for additional, successive  
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 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
three (3) year renewal terms (each, a “Renewal Term” and each consecutive [\*\*\*] therein a Contract Year) unless either party delivers to the other party a written notice of it selection not to renew at least eighteen (18) months, prior to the end of the Initial Term or the then current Renewal Term, as the case may be. The “Term” of this Agreement shall be the period beginning on the Effective Date hereof and ending on the last day of the final Contract Year.  
6.2 Termination. Either party may terminate this Agreement on written notice to the other party, effective immediately if:  
(a) the other party commits a material breach of any of its obligations hereunder which is not cured within [\*\*\*] of written notice from the other party specifying the breach; or  
(b) the other party is dissolved or liquidated, files or has filed against it a petition under any bankruptcy or insolvency law and such petition isn’t withdrawn or dismissed within [\*\*\*] after filing, makes an assignment to the benefit of its creditors, or has a receiver appointed for all or substantially all of its property and such property is not released within [\*\*\*] after it is seized.  
In addition to the termination rights granted in parts (a) and (b) of this Section 6.2 above, Transcept may terminate this Agreement immediately upon written notice to Mikart: (i) in the event that Mikart and/or the Facility do not to receive full FDA qualification and approval as a commercial manufacturer of Products on or prior to [\*\*\*]: or (ii) in the event of a second occurrence of a Supply Failure (as defined in Section 6.4 below). Such rights of termination in this Section 6.2 and in Section 6.3 below shall be in addition to any other remedy the non-defaulting party may have at law, in equity or under this Agreement due to the other party’s breach of is obligations hereunder.  
6.3 Post-Termination.  
(a) Upon termination of this Agreement by Mikart pursuant to Section 6.2 Transcept shall purchase from Mikart (at the most recent applicable price hereunder therefor) Mikart’s remaining inventory of each Product, such amount not to exceed the forecasted requirements for such Product, pursuant to Section 3.2 hereof, for the [\*\*\*] immediately following such termination (for clarity, provided that such Product must conform to the Specifications and all Applicable Laws and subject to Transcept’s right to reject such Products pursuant to Section 5.2). In the event of a termination of this Agreement by Transcept pursuant to Section 6.2, Transcept shall not be responsible for any amounts payable by Transcept to Mikart under Section 2.10 that have not become due as of the date of such termination. In the event of a termination of this Agreement by Mikart pursuant to Section 6.2(a) or (b), Transcept shall immediately pay to Mikart any unpaid amounts related to Mikart’s installation of the Humidity Control System(s) pursuant to Sections 2.10(b) and 2.10(d) hereof.  
(b) Upon any termination or expiration of this Agreement, Mikart shall reasonably cooperate with Transcept and assist in the transfer to Transcept of all legal and  
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technical documents concerning Products, including copies of documents such as master batch records, validation reports, stability reports and relevant manufacturer authorizations, and existing retention samples, and all such other documents and materials as may be reasonably necessary or useful for Transcept to source Products from other qualified third parties. Mikart shall retain and maintain all original documents and retention samples as necessary to comply with Applicable Law.  
(c) Termination or expiration of this Agreement shall not relieve a party from any liability that, at the time of such termination or expiration, has already accrued to the other party. Upon any expiration or termination of this Agreement: Mikart shall, as promptly as practicable (i) cease all work on the Qualification Services, and (ii) turn over to Transcept all deliverables, Transcept Confidential Information and Product IP (whether in written, electronic or other tangible form, including all embodiments thereof) which are then in Mikart’s possession or control, except that Mikart may retain any documentation required to comply with Applicable Law.  
(d) The provisions of Articles 1, 5 and 7-14 and Sections 2.2, 2.3(d), 2.3(e), 2.6-2.8, 2.11(b)-(f), 4.3-4.5 and 6.3 of this Agreement shall survive the termination or expiration of this Agreement for any reason.  
6.4 Supply Failure.  
(a) Should Mikart not be able to supply at least [\*\*\*] of the quantities of Product ordered by Transcept pursuant to Purchase Orders in accordance with Section 3.3 for any ([\*\*\*] period within [\*\*\*] of the dates specified in such Purchase Orders in compliance with this Agreement for any reason (including due to a force majeure event), then such event shall be deemed a “Supply Failure.” Notwithstanding the foregoing, such event shall not be deemed a Supply Failure if such event is caused by a force majeure event (as described in Section 6.5), provided that (i) Mikart notifies Transcept immediately upon the occurrence of such force majeure event, and (ii) such force majeure event lasts no longer than [\*\*\*].  
(b) In the event of a Supply Failure, Transcept’s obligation under Section 3.5 to purchase the Minimum Purchase Requirement of Product from Mikart shall terminate, subject to the terms of Section 6.4(c) below.  
(c) In the event that a Supply Failure occurs and such Supply Failure is the first Supply Failure to occur during the Term of this Agreement, at the written request of Mikart, if Mikart has taken the necessary steps to ensure that a Supply Failure will not re-occur, the Parties shall discuss in good faith reinstating Transcept’s obligation under Section 3.5 to purchase the Minimum Purchase Requirement from Mikart. If the Parties mutually agree in good faith that Mikart has remedied the Supply Failure and has taken all steps necessary to ensure that a Supply Failure will not re-occur, Transcept’s obligation under Section 3.5 to purchase the Minimum Purchase Commitment from Mikart shall be reinstated, effective [\*\*\*] following the date of such agreement (such effective date of reinstatement, the “Minimum Purchase Requirement Re-instatement Date”); provided, however, that, (i) for the Contract Year  
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 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
that Transcept’s obligation to purchase the Minimum Purchase Requirement is re-instated, the Minimum Purchase Requirement shall be pro-rated for the time remaining in such Contract Year following the Minimum Purchase Requirement Re-instatement Date; and (ii) Transcept’s obligation to purchase the Minimum Purchase Requirement under Section 3.5 shall be subject to, and modified to the extent necessary to comply with, any obligations incurred by Transcept between the date of the Supply Failure and the date that the Parties agreed that the Minimum Purchase Requirement should be re-instated.  
(d) This Section 6.4 shall in no way limit any of Transcept’s legal, equitable or other remedies for Mikart’s breach of its obligations to supply Product to Transcept under Article 3.  
6.5 Force Majeure. The failure of either of the parties hereto to perform any obligation under this Agreement solely by reason of acts of God, acts of government, riots, wars, strikes, accidents in transportation or other causes beyond its control shall not be deemed to be a breach of this Agreement; provided, however, that the party so prevented from complying herewith shall continue to take all actions within its power, including payment of outstanding invoices, to comply as fully as possible herewith; provided, further, that no event of force majeure shall in any way affect the parties’ termination rights in Section 6.2 hereof. Availability or allocation of raw materials or labor that is within the reasonable control of a party shall not constitute a force majeure event. Any party desiring to invoke the protection of force majeure hereunder shall promptly notify the other party of such desire and shall use reasonable efforts to resume performance of its obligations.  
ARTICLE 7  
INDEMNIFICATION; INSURANCE  
7.1 Indemnification by Mikart. Mikart shall indemnify and agrees to defend and hold Transcept, its directors, officers, employees, agents, successors and assigns harmless from and against any losses, claims, damages, liabilities, costs and expenses (including, without limitation, attorneys’ fees and court costs) (collectively, “Losses”) incurred by Transcept arising from any claim, complaint, suit, proceeding, or cause of action brought against any of them by a third party (each, a “Claim”) resulting from breach of this Agreement by Mikart (including the untruth or inaccuracy of any of its representations or warranties herein) or Mikart’s gross negligence or willful misconduct, in each case subject to the requirements set forth in Section 7.3. Notwithstanding the foregoing, Mikart shall have no obligations under this Section 7.1 for any Losses to the extent resulting from a breach of this Agreement by Transcept (including the untruth or inaccuracy of any of its representations or warranties herein), any failure by Transcept to provide adequate instructions or warnings regarding the proper use of any Product to any user thereof, or Transcept’s gross negligence or willful misconduct.  
7.2 Indemnification by Transcept. Transcept shall indemnify and agrees to defend and hold Mikart, its directors, officers, employees, agents, successors and assigns harmless from and against any Losses incurred by Mikart arising from any Claim resulting from breach of this Agreement by Transcept (including the untruth or inaccuracy of any of its representations or warranties herein), the sale or distribution of any Product by Transcept, any failure by Transcept  
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to provide adequate instructions or warnings regarding the proper use of any Product to any user thereof, or Transcept’s gross negligence or willful misconduct, in each case subject to the requirements set forth in Section 7.3 below. Notwithstanding the foregoing, Transcept shall have no obligations under this Section 7.2 for any Losses to the extent resulting from a breach of this Agreement by Mikart (including the untruth or inaccuracy of any of its representations or warranties herein) or Mikart’s gross negligence or willful misconduct.  
7.3 Indemnification Procedure. A party that intends to claim indemnification (“Indemnitee”) under this Article 7 shall promptly notify the indemnifying party (“Indemnitor”) in writing of any Claim included within the indemnification described in this Article 7 with respect to which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense and settlement of the Claim, provided that the Indemnitor shall not enter into a defense or settlement that admits the fault of the Indemnitee without the Indemnitee’s prior written consent, such consent not to be unreasonably withheld. The Indemnitee shall have the right to participate, at its own expense, with counsel of its own choosing in the defense or settlement of the Claim. The indemnification obligations under this Article 7 shall not apply to amounts paid in settlement of any Claim if such settlement is effected without the consent of the Indemnitor, such consent not to be unreasonably withheld. The Indemnitee and its employees, at the Indemnitor’s request and expense, shall provide full information and reasonable assistance to Indemnitor and its legal representatives with respect to Claims.  
7.4 Insurance. On or prior to the Commencement Date, each party shall maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for a period of three (3) years thereafter, which insurance shall afford limits of not less than (i) [\*\*\*] for each occurrence for personal injury or property damage liability; and (ii) [\*\*\*] in the aggregate per annum with respect to product and completed operations liability. If requested each party will provide the other with a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits of liability. The insurance certificate shall further provide for a minimum of [\*\*\*]’ written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault on the part of such party, then such party shall forthwith notify the other party in writing and the parties shall in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.  
ARTICLE 8  
WARRANTIES AND REPRESENTATIONS OF THE PARTIES  
8.1 Additional Representations and Warranties of Mikart. Mikart hereby additionally represents and warrants to Transcept the following:  
(a) Mikart is a corporation duly organized and existing in good standing under the laws of the State of Georgia;  
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 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
(b) There are no material adverse claims pending or, to the best of Mikart’s knowledge, threatened against Mikart by any entity with respect to the Products; and  
(c) Mikart has full power to enter into this Agreement and to grant to Transcept the rights granted to it under this Agreement; has obtained all necessary corporate approvals to enter into and execute this Agreement; and is neither a party to nor otherwise bound by or subject to any agreement, understanding or other undertaking or instrument which prohibits or prevents it or Transcept from performing its obligations under this Agreement or under which such performance would constitute a breach, default or other violation.  
(d) To its knowledge, Mikart, by entering into and performing this Agreement, will not infringe (nor cause Transcept to infringe) the trademark, copyright, patent or other intellectual property rights of any third party.  
8.2 Additional Representations and Warranties of Transcept. Transcept hereby additionally represents and warrants to Mikart the following:  
(a) Transcept is a corporation duly organized and existing under the laws of the State of Delaware;  
(b) Transcept has full power to enter into this Agreement and to grant to Transcept the rights granted to it under this Agreement; has obtained all necessary corporate approvals to enter into and execute this Agreement; and is neither a party to nor otherwise bound by or subject to any agreement, understanding or other undertaking or instrument which prohibits or prevents it or Mikart from performing its obligations under this Agreement or under which such performance would constitute a breach, default or other violation; and  
(c) To its knowledge, Transcept, by entering into and performing this Agreement, will not infringe (nor cause Mikart to infringe) the trademark, copyright, patent or other intellectual property rights of any third party.  
ARTICLE 9  
CONFIDENTIALITY  
9.1 Protection of Confidential Information. Each party will hold the Confidential Information of the other party in complete confidence and will not without the prior written consent of the other party, or as expressly provided for in this Agreement, use or disclose them in whole or in part to any third party during the term of this Agreement and for a period ending seven (7) years following any expiration or termination of this Agreement. Each party will be entitled to disclose any such Confidential Information to such of its affiliates, professional advisers, directors, managers, officers and employees who are directly concerned with this Agreement and its implementation and whose knowledge of such information is necessary for these purposes. Each party will use its reasonable efforts to ensure that each individual to whom such a disclosure is made adheres to the terms of this undertaking as if he or she were a party hereto.  
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9.2 Other Permitted Disclosures of Confidential Information.  
(a) Each party may disclose Confidential Information to the extent such disclosure is required by law, regulations, stock exchange requirements, or court order; provided, however, that the disclosing party shall, as soon as is commercially reasonable, give the other party prior notice of such required disclosure and reasonably cooperate with such other party in order that such other party may seek a protective order or relief to prevent or limit the Confidential Information required to be disclosed; provided, further, that the disclosing party shall only disclose that portion of the Confidential Information that such party is required to disclose. Nothing contained in this Article 9 of this Agreement shall prevent either party from disclosing Confidential Information to Regulatory Agencies as reasonably necessary for the approval and/or commercialization of Products.  
(b) Notwithstanding anything to the contrary in this Agreement, each party may disclose the terms of this Agreement (a) to advisors, actual or potential investors, acquisition partners, licensees, and others on a need to know basis under circumstances that reasonably ensure the confidentiality thereof, or (b) as required by securities or other applicable laws or regulations or stock exchange rules. In the event that a party makes a disclosure of the terms of this Agreement deemed necessary under applicable federal or state securities laws or any rule or regulation of a nationally recognized securities exchange, the party shall use good faith efforts to obtain confidential treatment for the disclosure to the extent available. The party making such a disclosure shall provide the other party with reasonable advance written notice of its intent to make such a disclosure and shall provide the other party the opportunity to comment on any confidential treatment requested prior to the submission.  
ARTICLE 10  
REGULATORY MATTERS  
10.1 Regulatory Actions. Mikart shall permit the FDA and other Regulatory Agencies to conduct inspections of the Facility as they may request, including pre-approval inspections, and shall cooperate with such Regulatory Agencies with respect to the inspections and any related matters, in each case which is related to the Product and activities conducted by Mikart hereunder. Mikart shall give Transcept prior notice, to the extent practicable, of any such inspections, and keep Transcept informed about the results and conclusions of each regulatory inspection, including actions taken by Mikart to remedy conditions cited in the inspections. In addition, Mikart shall permit Transcept or its representative to be present at such inspections, if requested by Mikart and necessary in support of the inspection. Mikart will provide Transcept with copies of any written inspection reports issued by the regulatory agency and all correspondence between Mikart and the regulatory agency, including, but not limited to, FDA Form 483, Notice of Observation, and all related correspondence, in each case relating to the Product, activities performed by Mikart hereunder or general manufacturing concerns (i.e., facility compliance or the like). Mikart shall provide redacted copies of such documents to Transcept in the event Mikart reasonably determines that there are confidentiality concerns with respect to such documents, provided that Mikart shall not redact any information that would  
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reasonably be expected to affect the regulatory status of the Product or Mikart’s manufacture thereof. Similarly, Mikart agrees to promptly notify and provide Transcept copies of any request, directive or other communication of the FDA or other Regulatory Agency relating to the Product or activities conducted by Mikart hereunder, and to cooperate with Transcept in responding to such requests, directives and communications.  
10.2 Information. Mikart shall promptly provide Transcept as requested, at no additional charge, with all available information in Mikart’s control necessary or useful for Transcept to apply for, obtain, and maintain regulatory approvals for the Product in any country, including without limitation information relating to the facilities, or the process, methodology, raw materials and intermediates used in the manufacture, processing, or packaging of the Product and all information required to be submitted in the CMC section of an IND or a NDA or other regulatory filings, or required or requested to be provided to any Regulatory Agency. In addition, Mikart shall cooperate with Transcept with respect to all reporting obligations relevant to the Product under Applicable Laws. Transcept shall provide Mikart with a copy of relevant sections of the CMC section of an IND or a NDA or other regulatory filing (as related to chemistry, manufacturing and/or labeling) to the extent required for Mikart’s manufacture of the Product and shall also provide Mikart with future updates thereof on an ongoing basis to the extent such updates are required for Mikart’s manufacture of the Product, in each case during the Term. Transcept further agrees to promptly notify Mikart of, and to provide Mikart with copies of the relevant sections of any request, directive or other communication from the FDA or other Regulatory Agency having a material effect on any activities performed by Mikart hereunder.  
ARTICLE 11  
INTELLECTUAL PROPERTY  
11.1 Product IP and Non-Product IP. All inventions (whether or not patentable), ideas, improvements, discoveries, modifications, processes, technology, materials, know-how, data and information of any kind or description conceived, generated, made, or reduced to practice by Mikart, either alone or jointly with others, in connection with the performance of this Agreement (including the performance of the Qualification Services) and specific to the Product, including all intellectual property rights therein (collectively, the “Product IP”) shall be the sole and exclusive property of Transcept. All inventions (whether or not patentable), ideas, improvements, discoveries, modifications, processes, technology, materials, know-how, data and information of any kind or description conceived, generated, made, or reduced to practice by Mikart, either alone or jointly with others (excluding Transcept), in connection with the performance of this Agreement (including the performance of the Qualification Services) and not specific to the Product, including all intellectual property rights therein (collectively, the “Non-Product IP”) shall be the sole and exclusive property of Mikart. Mikart hereby assigns, and agrees to assign to Transcept all of Mikart’s right, title and interest in and to the Product IP and to execute all applications, assignments or other instruments reasonably requested by Transcept, in order for Transcept to establish Transcept’s ownership of the Product IP and to obtain whatever protection for the Product IP. Mikart further agrees to reasonably cooperate with Transcept in the process of securing and enforcing Transcept’s rights to the Product IP at Transcept’s request, and Transcept shall compensate Mikart for Mikart’s reasonable expenses incurred as a result thereof. Except as expressly set forth in Section 11.2 hereof, Transcept shall  
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not assert any claim to, or interest in, any Non-Product IP. Transcept agrees to reasonably cooperate with Mikart in the process of securing and enforcing Mikart’s rights to the Non-Product IP at Mikart’s request, and Mikart shall compensate Transcept for Transcept’s reasonable expenses incurred as a result thereof.  
11.2 Licenses. Transcept hereby grants to Mikart an irrevocable, perpetual, non exclusive, worldwide, royalty-free license, with the right to grant and authorize sublicenses, to the Product IP for the purpose of performing Mikart’s obligations hereunder and for use by Mikart in manufacturing any other products that do not compete with any of Transcept’s Products. Mikart hereby grants to Transcept an irrevocable, perpetual, non-exclusive, worldwide, royalty-free license, with the right to grant and authorize sublicenses, to the Non-Product IP for the purpose of making, using, selling, offering for sale, importing and otherwise exploiting the Products.  
11.3 No Conflicting Rights. With respect to (a) any Product IP assigned to Transcept under this Article 11, and (b) any process for formulating finishing, manufacturing, analyzing, testing, validating or otherwise relating to the Product (collectively, “Delivered Technology”). Mikart will not, to its actual knowledge, incorporate or use therein any invention, discovery, process, technology or information that is covered in whole or in part by (i) any patent application or issued patent that is owned or controlled by Mikart, but not assigned to Transcept pursuant to this Agreement (“Mikart Background Patent Rights”), or (ii) any patent or patent application of a third party; except in each case, as specifically discussed with and approved in writing by Transcept. In the event any Delivered Technology incorporates or requires the use of Mikart Background Patent Rights, Mikart hereby grants Transcept an irrevocable, perpetual, non exclusive, worldwide, royalty-free license, with the right to grant and authorize sublicenses, to practice such Mikart Background Patent Rights for the purpose of making, using, selling, offering for sale, importing and otherwise exploiting the Products and/or Delivered Technology.  
ARTICLE 12  
ARBITRATION OF DISPUTES  
All disputes arising out of or in connection with the interpretation, application or enforcement of this Agreement shall be settled by final and binding arbitration. Such arbitration shall be conducted pursuant to the commercial arbitration rules of the Judicial Arbitration and Mediation Services (JAMS) in effect at the time the arbitration is commenced by one (1) arbitrator appointed in accordance with such rules. The location of such arbitration shall be determined as follows: in the event that such arbitration is filed for by Transcept, such arbitration shall be conducted in Atlanta, Georgia; and in the event that such arbitration is filed for by Mikart, such arbitration shall be conducted in San Francisco, California. The decision of the arbitrator, which may include interest, shall be final and binding on the parties hereto and may be entered and enforced in any court of competent jurisdiction by any party, and the arbitrator may grant injunctive or other relief in such dispute or controversy. The arbitration shall be pursued and brought to conclusion as rapidly as possible. The Parties agree that, any provision of applicable law notwithstanding, they will not request and the arbitrator shall have no authority to award, punitive or exemplary damages against either Party. The costs of the arbitration, including administrative and arbitrator’s fees, shall be shared equally by the Parties. Each Party  
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shall bear the cost of its own attorneys’ fees and expert witness fees. Nothing in this Article 12 shall preclude either Party from seeking interim or provisional relief in the form of a temporary restraining order, preliminary injunction, or other interim relief concerning a dispute prior to or during an arbitration pursuant to this Article 12 necessary to protect the interests of such Party.  
ARTICLE 13  
NOTICES  
13.1 Delivery. All notices, consents, requests and other communications hereunder shall be in writing and shall be sent by hand delivery, by certified or registered mail (return-receipt requested), or by a recognized national overnight courier service as set forth below:  
 If to Mikart:   
Mikart, Inc.  
0000 Xxxxxxxxxxxxx Xxxxxx  
Xxxxxxx, Xxxxxxx 00000  
Attention: Xx. Xxxxxx X. Xxxxxxx, Chairman & CEO  
Fax No.: 000-000-0000  
If to Transcept:   
Transcept Pharmaceuticals, Inc.  
0000 X. Xxxxxxx Xxxx., Xxxxx 000  
Xx. Xxxxxxxx, XX 00000  
Attention: Xx. Xxxxx X. Xxxxxxxx Xx., CEO  
Fax No.: 000-000-0000  
13.2 Effective Time. Notices delivered pursuant hereto shall be deemed given: (i) at the time delivered, if personally delivered; (ii) at the time received, if mailed; and (iii) one (1) business day after timely delivery to the courier, if by overnight courier service.  
13.3 Changes. Either party hereto may change the address to which notice is to be sent by written notice to the other party in accordance with the provisions of this Article 13.  
ARTICLE 14  
MISCELLANEOUS  
14.1 Severability; Non-waiver. If any provision of this Agreement is held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired, and the parties shall use their best efforts to substitute a valid, legal and enforceable provision, which, insofar as practical, implements the purpose of this Agreement. Any waiver of the terms and conditions hereof must be explicitly in writing. The waiver by either of the parties of any breach of any provision hereof by the other shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.  
14.2 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall be deemed one and the same instrument.  
 -23-  
14.3 Governing Law. This Agreement shall be governed by, and any matter or dispute arising out of this Agreement shall be determined by, the laws of the State of Delaware, without reference to conflict of laws principles and excluding the 1980 U.N. Convention on Contracts for the International Sale of Goods.  
14.4 Headings; Gender. “Article,” “Section” and other headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. All personal pronouns used in this Agreement shall include the other genders, whether used in the masculine, feminine or neuter gender, and the singular shall include the plural and vice versa, whenever and as often as may be appropriate.  
14.5 Entire Agreement. This Agreement, together with the Exhibits hereto, represents the entire agreement of the parties with respect to its subject matter. Any and all prior discussions or agreements with respect hereto are merged into and superseded by the terms of this Agreement, including the terms of that certain Confidentiality and Non-Disclosure Agreement between the parties dated October 25, 2006. Transcept expressly acknowledges and agrees that its exclusive right to purchase the Products from Mikart and to market and sell the Products in the Territory, each as set forth herein, shall be governed solely by the terms of this Agreement. This Agreement may be modified or amended only in writing signed by both parties which expressly refers to this Agreement and states an intention to modify or amend it. No such amendment or modification shall be effected by use of any Purchase Order, acknowledgment, invoice or other form of either party and in the event of conflict between the terms of this Agreement and any such form, the terms of this Agreement shall control. In the event of a conflict between any provision contained herein and the Quality Agreement or any other Exhibit to this Agreement, the parties hereby acknowledge and agree that the provisions of this Agreement shall control.  
14.6 Independent Contractors. The relationship of Transcept and Mikart established by this Agreement is that of independent contractors. Nothing in this Agreement shall be construed to create any other relationship between Transcept and Mikart. Neither party shall have any right, power, or authority to assume, create or incur any expense, liability, or obligation, express or implied, on behalf of the other.  
14.7 Subcontracting. Mikart shall not subcontract any Qualification Services or any of its obligations hereunder to another entity without Transcept’s prior written approval, which shall not be unreasonably delayed. Notwithstanding the foregoing, Mikart may subcontract to any third party without obtaining the consent of Transcept to the extent such third party is listed as an approved subcontractor under the NDA or other regulatory filing for the applicable work to be performed, and, for the first time that Mikart subcontracts work hereunder to any such third party, Mikart shall notify Transcept of the work being subcontracted and the name of the party to which such work is subcontracted within thirty (30) days after subcontracting such work. In any case, Mikart shall remain completely responsible for all services or other obligations that are subcontracted by Mikart. All subcontractors hereunder shall be bound by the terms and conditions herein, with respect to the subcontracted services or obligations, as if named together with Mikart.  
 -24-  
14.8 Assignment. Neither party hereto may assign this Agreement, in whole or in part, without the prior written consent of the other party, which consent shall not be unreasonably withheld; provided, however, that Transcept may assign its rights and obligations under this Agreement, without such consent, to a successor to all or substantially all of its business or assets relating to this Agreement (whether by sale, merger, operation of law or otherwise) that agrees in writing to be bound by the provisions of this Agreement. Any attempted assignment not in accordance herewith shall be null and void and of no force or effect.  
14.9 Binding Effect. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors, heirs, representatives and permitted assigns.  
14.10 Interpretation. This Agreement was fully negotiated by both parties hereto and shall not be construed more strongly against either party hereto regardless of which party is responsible for its preparation.  
14.11 Limitation of Liability. EXCEPT TO THE EXTENT SUCH PARTY MAY BE REQUIRED TO INDEMNIFY THE OTHER PARTY UNDER ARTICLE 7 ABOVE OR IN THE CASE OF WILLFUL BREACH OF THIS AGREEMENT, NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY OR ANY THIRD PARTY FOR ANY SPECIAL, CONSEQUENTIAL, EXEMPLARY, OR INCIDENTAL DAMAGES (INCLUDING LOST OR ANTICIPATED REVENUES OR PROFITS RELATING TO THE SAME), ARISING FROM ANY CLAIM RELATING TO THIS AGREEMENT, WHETHER SUCH CLAIM IS BASED ON CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE, EVEN IF AN AUTHORIZED REPRESENTATIVE OF SUCH PARTY IS ADVISED OF THE POSSIBILITY OR LIKELIHOOD OF SAME.  
14.12 Further Assurances. Upon the reasonable request of the other party, each party hereto agrees to take any and all actions necessary or appropriate to give effect to the terms set forth in this Agreement.  
[SIGNATURES APPEAR ON FOLLOWING PAGE]  
 -25-  
EXECUTION COPY  
IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Agreement as of the Effective Date.  
 “Mikart”  
MIKART, INC.  
By:   
/s/ Xxxxxx X. Xxxxxxx  
 Xxxxxx X. Xxxxxxx, Chairman & CEO  
“Transcept”  
TRANSCEPT PHARMACEUTICALS, INC.  
By:   
/s/ Xxxxx X. Xxxxxxxx  
 Xxxxx X. Xxxxxxxx, CEO, President & Director  
 /s/ Xxxxxx Xxxxxxx  
 Xxxxxx Xxxxxxx, CFO  
 -26-  
EXHIBIT A  
Specifications  
Product Specifications:  
The Product is either 1.75 mg or 3.50 mg Zolpidem Tartrate tablets, brand and generic, as requested by Transcept.  
Specifications for Zolpidem Tartrate Lozenge 1.75 mg  
[\*\*\*]  
 -27-  
 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
Specifications for Zolpidem Tartrate Lozenge, 3.5 mg  
[\*\*\*]  
 -28-  
 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
EXHIBIT B  
Prices  
 Aggregate Tablets Purchased in a Given Contract Year  
 Price per  
Thousand  
Tablets  
 [\*\*\*]  
[\*\*\*]  
 -29-  
 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
EXHIBIT C  
Technology Transfer and Validation Services  
Qualification Services- General  
 •   
The Qualification Services to be performed by Mikart will include all of the following manufacturing process and test method transfer, validation and stability activities described in this Exhibit C. A detailed list of the Qualification Services is provided in Schedules C-1 and C-2 below.  
 •   
A [\*\*\*] will be required. Additionally, each strength will require [\*\*\*] and will be used for the stability studies in support the application.  
 •   
As part of the Qualification Services, Mikart shall prepare the documentation required for the CMC portion of Transcept’s New Drug Application (NDA).  
 •   
Batch sizes will be as specified herein. Mikart will prepare the Chemistry, Manufacturing and Controls (CMC) section of the Product NDA in CTD format. All FDA and ICH guidance documents are applicable.  
 •   
Product will be packaged in bulk for shipment to an outside packaging facility. Sufficient packaged product will be returned to Mikart for introduction into the stability program.  
 •   
The exhibit/registration batches will undergo ICH stability conditions: [\*\*\*].  
Notes:  
 1. Batch size may need to be adjusted based upon equipment capabilities.  
 2. The Qualification Services do not include commercial manufacturing, provided that Mikart acknowledges that the validation Batches purchased by Transcept under Section 2.1(b) of this Agreement are for commercial supply and shall meet all appropriate requirements as described in more detail in Section 2.1(b).  
 -30-  
 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
 Schedule C-1: Manufacturing Process and Test Method Transfer  
 [\*\*\*]  
A. Process Evaluation and Transfer of Analytical Methods  
1 [\*\*\*]  
2 [\*\*\*]  
3 [\*\*\*]  
 [\*\*\*]  
B. Manufacturing Process Transfer  
 1 [\*\*\*]  
 2 [\*\*\*]  
 3 [\*\*\*]  
 4 [\*\*\*]  
 5 [\*\*\*]  
 6 [\*\*\*]  
 7 [\*\*\*]  
 8 [\*\*\*]  
 C. Document Preparation of CMC Section  
Total for Transfer and Manufacturing  
 [\*\*\*]  
 -31-  
 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
Schedule C-2: Additional Charges: Process Validation and Stability Studies  
A. Process Validation 1st three batches, per strength (excludes COGS) [\*\*\*]  
 1 [\*\*\*]  
 2 [\*\*\*]  
 3 [\*\*\*]  
 4 [\*\*\*]  
 5 [\*\*\*]  
Note: Cost of Goods for first three batches is not included in this charge.  
B. Future Stability Costs  
The [\*\*\*] are subjected to long term CRT stability, followed by [\*\*\*] thereafter. Charge will be invoiced once the analysis is completed. Cost per [\*\*\*] = [\*\*\*].  
Stability Program for [\*\*\*]  
Per strength  
 Test Interval  
 Packaging  
Configurations  
Commercial size Total Samples  
per Interval Cost per Test  
Interval  
[\*\*\*]  
 C. Annual Stability Program [\*\*\*]  
In addition to the above program, [\*\*\*] thereafter will undergo a [\*\*\*] temperature stability program. Annual stability charges for commercial batches are dependent on the configurations packaged in any given year, and whether existing or new configurations are utilized. [\*\*\*] is added to the program on an ongoing basis as lots are packaged in existing configurations, so the program is always continuing. If new configurations are employed, then the program begins anew as applicable for that configuration (bulk or other). All work is billed when testing is complete. [\*\*\*]  
 -32-  
 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
Annual Stability Program  
[\*\*\*]  
 Test Interval  
 Packaging  
Configurations  
Commercial size Total Samples  
per Interval Cost per Test  
Interval  
[\*\*\*]  
 D. Accelerated Stability Studies (including [\*\*\*]  
The [\*\*\*] will be subjected to an accelerated stability program for a period of [\*\*\*]. The conditions will be according to ICH specifications at [\*\*\*]. These charges will be invoiced upon completion of testing at the [\*\*\*] station.  
Schedule C-3: Payment Schedule  
[\*\*\*], each representing [\*\*\*] of the charges for the Qualification Services described in Schedule C-l, will be invoiced upon completion and Transcept’s acceptance of the following milestones:  
 1. [\*\*\*]  
 2. [\*\*\*]  
 3. [\*\*\*]  
 C-4  
 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
Payments for process validation, ongoing stability studies and miscellaneous items described in Schedule C-2 are as follows:  
 1. Process validation charge will be invoiced upon successful completion of process validation of the [\*\*\*] (see section A of Schedule C-2) and [\*\*\*].  
 2. Cost of Goods charges for the validation batches will be invoiced upon product shipment.  
 3. Commercial stability costs will be invoiced at the applicable interval points once testing has been completed (see sections B and C of Schedule C-2).  
 4. The API will be supplied by Transcept. Any dedicated change parts used for development and exhibit batches will be billed [\*\*\*].  
 5. Project specific supplies, such as reference drugs, analytical standards, columns and/or reagents, will be billed [\*\*\*]. A copy of the purchase invoice may be provided, upon request, along with the request for payment.  
 6. Any necessary outside services, such as contract testing or consultation, will be billed [\*\*\*].  
 7. Costs associated with the Accelerated stability studies (see section D, validation batches) will be invoiced upon completion of the [\*\*\*] study.  
Notwithstanding anything in this Agreement to the contrary, Transcept will not be responsible for any charges not described in parts A, B and C of Schedule C-2 that exceed [\*\*\*] unless Mikart has obtained Transcept’s written authorization prior to incurring such charges.  
 C-5  
 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
EXECUTION COPY  
 Project Timeline  
 Specific dates and milestone lead-times for the Qualification Services will be established and agreed to by the parties following execution of this Agreement. Mikart will forward a preliminary timeline for review shortly after execution of the Agreement. Subsequent conferences will be held to establish definitive dates for the project’s timeline. Notwithstanding the foregoing, Mikart shall use commercially diligent efforts to complete the Qualification Services prior to the [\*\*\*] of the Effective Date.  
 C-6  
 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
EXECUTION COPY  
EXHIBIT D  
Active Materials Analytical Testing Methods  
Description  
Zolpidem Tartrate CIV occurs as white or almost white crystalline powder.  
Identification  
Responds to Identification tests A. and C. in the current European Pharmacopoeia.  
Specifications  
Meets the requirements of the current European Pharmacopoeia (Ph. Eur.) under Zolpidem Tartrate. In addition:  
 [\*\*\*]  
 Test Methods  
As listed in the current Ph. Eur. In addition:  
 [\*\*\*]  
 D-1  
 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
[\*\*\*]  
Particle size distribution  
Principle  
The method determines [\*\*\*].  
Equipment  
Instrumentation: [\*\*\*]  
Measuring cell: [\*\*\*]  
Experimental parameters  
Measuring range: [\*\*\*]  
Measuring range: [\*\*\*]  
Model: [\*\*\*]  
Presentation: [\*\*\*]  
Number of sweeps: [\*\*\*]  
Speed rate of the flow cell: [\*\*\*]  
Cleaning of the cell  
Cleaning the cell before starting the measurements  
[\*\*\*]  
Cleaning the cells between runs  
[\*\*\*]  
 D-2  
 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
Dilution and dispersion media  
[\*\*\*]  
Measurement  
Blank frequency  
[\*\*\*]  
Blank measurement  
[\*\*\*]  
Sample measurement  
Sample dispersion  
[\*\*\*]  
Start of the measurement  
[\*\*\*]  
Data save  
[\*\*\*]  
 D-3  
 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
Report of data  
[\*\*\*]  
 Bulk Density Record results from the manufacturer’s COA.  
Tapped Density Record results from the manufacturer’s COA.  
PURCHASING  
 Approved Manufacturer  
 Approved Supplier  
Teva Pharmaceutical Industries LTD  
Teva Active Pharmaceutical Ingredient Division  
Assia Chemical Industries Ltd. – Teva Tech Site  
Ramat Hovav  
X.X. Xxx 0000, Xxxx Xxxx  
Xxxx Xxxxx, 00000  
Israel  
 Plantex USA  
Xxx Xxxxxxxxxx Xxxxx Xxx. 000  
Xxxxxxxxxx, XX 00000  
 Purchasing: Zolpidem Tartrate CIV is manufactured by Teva Pharmaceutical Industries LTD, and supplied by Plantex USA. A Certificate of Analysis is required from the manufacturer.  
Storage: Store in an airtight container, protected from light.  
Recontrol: 12 Months from the date of manufacture as listed on the manufacturer’s certificate of analysis.  
 D-4  
 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.  
EXHIBIT E  
Quality Agreement  
[To be attached]  
 E-1  
EXHIBIT F  
Cost Breakdown For Humidity Control System  
 Company  
 Description of Service  
 Cost   
Approximate  
Timeframe  
[\*\*\*]  
 F-1  
 [\*\*\*] Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this exhibit and have been filed separately with the Securities and Exchange Commission.