EXHIBIT 10.1  
 HARDWARE AND DISPOSABLES  
 MANUFACTURING AGREEMENT  
  
  
 This HARDWARE AND DISPOSABLES MANUFACTURING AGREEMENT ("Agreement"), dated  
as of December 17, 1997, is entered into by and between Xxxxxx Healthcare  
Corporation, a Delaware corporation having a place of business at 0000 Xxxx Xxxx  
Xxxx, Xxxxxxxxx, Xxxxxxxx 00000 ("Baxter"), and BIT ACQUISITION CORP., a  
Delaware corporation having a place of business at Nine Parker, Xxxxxx,  
Xxxxxxxxxx 00000 ("Newco").  
  
 RECITALS  
  
 X. Xxxxxx and VIMRx Pharmaceuticals Inc., a Delaware corporation  
("VIMRx"), have agreed to enter into a strategic alliance in the ex vivo cell  
therapies business and have formed Newco for that purpose, pursuant to that  
certain Asset Purchase Agreement dated as of October 10, 1997, by and among  
Baxter, Newco and VIMRx (the "Acquisition Agreement").  
  
 B. Pursuant to the Acquisition Agreement, Baxter has transferred to Newco  
certain Isolex(R) and Maxsep(R) Technology (as that capitalized term is defined  
below) as well as other IT Assets relating to Isolex(R) and Maxsep(R) Products  
(as those capitalized terms are defined below).  
  
 C. Pursuant to the Acquisition Agreement, Baxter and Newco have entered  
into that certain sublicense of even date herewith relating to CD34+ cell  
population and related antibody and method patents licensed from Becton,  
Xxxxxxxxx and Company to Baxter (the "First BD Sublicense"); that certain  
sublicense of even date herewith relating to B cell antibodies licensed from  
Becton, Xxxxxxxxx and Company to Baxter (the "Second BD Sublicense"); that  
certain sublicense of even date herewith relating to breast cancer antibodies  
licensed from Cetus Oncology Corporation, d/b/a Chiron Therapeutics, to Baxter  
(the "Chiron Sublicense"); and that certain sublicense of even date herewith  
relating to B cells licensed from Xxxx. Xxxxx Xxxxxx to Xxxxxx Deutschland GmbH  
(the "Dorken Sublicense") (the First BD Sublicense, the Second BD Subicense, the  
Chiron Sublicense and the Dorken Sublicense are collectively referred to herein  
as the "Sublicense Agreements") pursuant to which Baxter has granted to Newco  
licenses to the Licensed Technology (as that capitalized term is defined in each  
of the Sublicense Agreements) as described therein.  
  
 X. Xxxxxx has agreed to manufacture for Newco certain antibodies, reagents  
and reagent kits which are components of or used in connection with certain of  
the Isolex(R) and Maxsep(R) Products (as such capitalized term is defined below)  
pursuant to the terms of that certain Antibody Manufacturing and Storage  
Agreement of even date herewith (the "Antibody Manufacturing and Storage  
Agreement") and certain prototype products for the research market pursuant to  
the terms of that certain Services Agreement of even date herewith (the  
"Services Agreement").  
  
   
 X. Xxxxxx also has agreed to supply to Newco certain other products and  
components which are utilized in connection with the Isolex(R) and Maxsep(R)  
Products, pursuant to the terms of that certain Hardware and Disposables Supply  
Agreement of even date herewith (the "Hardware and Disposables Supply  
Agreement").  
  
 F. Newco desires that Baxter manufacture for Newco the Isolex(R) and  
Maxsep(R) Products as described herein and subject to the terms hereof and  
Baxter is willing to manufacture for Newco certain Isolex(R) and Maxsep(R)  
Products as described herein and subject to the terms hereof.  
  
  
 AGREEMENT  
  
 NOW, THEREFORE, in consideration of the premises and the mutual covenants  
contained herein, Baxter and Newco hereby agree as follows:  
  
   
1. DEFINITIONS.  
  
 1.1 Terms Defined in Preamble and Recitals: As used herein, all  
capitalized terms defined in the Preamble and Recitals of this Agreement shall  
bear the meanings ascribed to such terms as set forth therein.  
  
 1.2 Other Terms: As used herein, the following capitalized terms shall  
have the following meanings:  
  
 A. "Affiliate" of a party shall mean any entity (i) which  
 directly or indirectly through one or more intermediaries Controls, is  
 Controlled by or is under common Control with the party or (ii) fifty  
 percent (50%) or more of the voting capital stock (or in the case of an  
 entity which is not a corporation, fifty percent (50%) or more of the  
 equity interest) of which is beneficially owned or held by a party or any  
 of such party's Subsidiaries. The term "Control" means the possession,  
 directly or indirectly, of the power to direct or cause the direction of  
 the management and policies of an entity (other than a natural person),  
 whether through the ownership of voting capital stock, by contract or  
 otherwise.  
  
 B. "Device History Record" shall have the meaning ascribed to it  
 by the regulations of the FDA, as may be amended or changed from time to  
 time.  
  
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 C. "Ex Vivo Cell Processing" shall mean the active selection, and  
 any subsequent modification, genetic alteration, activation and/or  
 expansion, of nucleated cells outside the body for therapeutic purposes  
 such as cellular therapy or gene therapy. For the purpose of this  
 definition, "active selection" shall mean processing involving the action  
 of a biological component, such as an antibody or modified antibody, a  
 lectin, or a ligand, to selectively and specifically bind to a particular  
 molecule on the surface of the cells to be selected so as to confer  
 specificity or selectivity for such cells in the cell selection process.  
  
 D. "FDA" means the United States Food and Drug Administration.  
  
 E. "FDA-Regulated Non-Baxter Component" shall mean any component  
 of a Manufactured Product which is manufactured by a third party for or on  
 behalf of Baxter and which is either (a) deemed, under applicable law and  
 FDA regulations, to be "intended for use" in an FDA-regulated product or  
 (b) manufactured at any FDA-registered establishment.  
  
 F. "Fenwal" means the Fenwal Division of Baxter.  
  
 G. "Field of Distribution" shall bear the meaning ascribed to  
 such capitalized term in the Marketing, Sales & Distribution Agreement.  
  
 H. "Form FDA-483" shall have the meaning ascribed to it by FDA  
 policy, as may be amended or changed from time to time.  
  
 I. "Fully Loaded Cost" means, for either party, such party's cost  
 of manufacturing, performing or acquiring any items or services, in  
 accordance with generally accepted accounting principles, consistently  
 applied ("GAAP"), and, with respect to each party, in accordance with such  
 party's normal accounting policies, all consistently applied, including any  
 royalties payable by such party in connection with manufacturing,  
 performing or acquiring any items or services, but excluding, in the case  
 of Xxxxxx'x Fully Loaded Cost, any royalty obligations of Baxter that are  
 paid or reimbursed by Newco pursuant to the Sublicense  
  
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 Agreements. Fully Loaded Cost shall not include general corporate  
 allocations or other allocations which are not directly related to the  
 manufacture, performance or acquisition of the item or service, however  
 designated. A charge for the cost of funding the party's working capital  
 needs for such manufacture, performance or acquisition of items or  
 services, including capital expenditures for facilities and/or equipment  
 and capitalized manufacturing costs, will be included in Fully Loaded Cost,  
 which charge will be made at the interest rate paid by Baxter on its then  
 most recent issuance of commercial paper; provided, however, that no charge  
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 shall be made for any cost of, or the cost of funding any, changes in the  
 site of manufacturing any Manufactured Products. In the event any item is  
 acquired or any service is provided for a party from or by an Affiliate of  
 such party, the cost of acquiring such items or services shall be deemed to  
 mean such Affiliate's actual cost of manufacturing, performing or acquiring  
 such items or services in accordance with the principles set forth in this  
 definition of "Fully Loaded Cost." Current costs of developing any items  
 or services shall be included in Fully Loaded Cost, but in no event shall  
 any historic development costs be included in Fully Loaded Cost.  
  
 J. "Isolex(R) and Maxsep(R) Products" means, individually and  
 collectively, the products listed on Schedule 1 attached hereto, which  
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 Schedule 1 includes Isolex(R) and Maxsep(R) instruments and Isolex(R) and  
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 Maxsep(R) disposable sets (other than those products or components to be  
 acquired by Newco from third parties or manufactured or supplied by Baxter  
 under the Hardware and Disposables Supply Agreement or the Antibody  
 Manufacturing and Storage Agreement), in each case as currently produced by  
 Baxter utilizing the Isolex(R) and Maxsep(R) Technology, and such new  
 products as are currently under development, are in research, or have been  
 identified as proposed new products as indicated in Schedule 1, or as  
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 Baxter may otherwise agree to develop pursuant to the Services Agreement,  
 in each case as consistent with the nature of the Isolex(R) and Maxsep(R)  
 Products existing at the date of this Agreement and with Xxxxxx'x legal  
 obligations and technological capabilities (including, without limitation,  
 regulatory requirements applicable to Baxter) during the Term of this  
 Agreement.  
  
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 K. "Isolex(R) and Maxsep(R) Technology" means automated systems  
 for positive and negative immunomagnetic cell selection.  
  
 L. "IT Assets" means those Assets set forth in Schedule 2.1(A) of  
 the Acquisition Agreement that consist of personal property currently  
 utilized by Baxter solely in connection with manufacturing the Isolex and  
 Maxsep(R) Products, including equipment, molds and tools.  
  
 M. "Manufactured Products" means all Isolex(R) and Maxsep(R)  
 Products and/or any components thereof, other than those products or  
 components to be acquired by Newco from third parties or manufactured or  
 supplied by Baxter under the Hardware and Disposables Supply Agreement, the  
 Antibody Manufacturing and Storage Agreement, or the Services Agreement.  
  
 N. "Manufacturing Facility" means any production site selected by  
 Baxter or a third party subcontractor of Baxter for manufacture of the  
 Manufactured Products.  
  
 O. "Marketing, Sales & Distribution Agreement" means the  
 Marketing, Sales & Distribution Agreement by and between Baxter and Newco  
 of even date herewith.  
  
 P. "Master Scheduling System" shall mean the computerized master  
 scheduling system currently used by Baxter in connection with the  
 production of the Isolex(R) and Maxsep(R) Products, as such system may be  
 changed by Baxter from time to time.  
  
 Q. "MDR" shall mean Medical Device Reports, as such term is  
 defined by the rules and regulations of the FDA, as may be amended or  
 changed from time to time.  
  
 R. "Non-Compete Agreement" means the Non-Competition and  
 Confidentiality Agreement by and among Baxter, VIMRx and Newco of even date  
 herewith.  
  
 S. "Post-Market Approval ("PMA") Post-Approval Requirements"  
 shall have the meaning ascribed to it by the regulations and policy of the  
 FDA, as may be amended or changed from time to time.  
  
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 T. "Product Field" means use of the Isolex(R) and Maxsep(R)  
 Technology in the treatment, mitigation or prophylaxis of diseases,  
 including research into such activities, through Ex Vivo Cell Processing.  
  
 U. "Quality Manual" shall mean the quality manual currently used  
 in connection with the production of the Isolex(R) and Maxsep(R) Products  
 or components thereof, as such manual may be changed from time to time.  
  
 V. "Quality System Regulation" ("QSR") shall have the meaning  
 ascribed to it by the rules and regulations of the FDA, as may be amended  
 or changed from time to time.  
  
 W. "Regulatory Approval" means (1) in the United States, approval  
 from the FDA and any other United States governmental authority (or agency  
 or other political subdivision thereof) necessary for Newco to have the  
 right to market, sell or distribute the Isolex and Maxsep(R) Products in  
 the United States to the public at large for use in the Product Field  
 (including the Field of Distribution) and (2) outside the United States, an  
 analogous order by a non-U.S. governmental authority (or agency or other  
 political subdivision thereof) necessary for Newco to have the right to  
 market, sell or distribute, and the right to be paid or reimbursed for, the  
 Isolex(R) and Maxsep(R) Products in a country (other than the United  
 States) to the public at large for use in the Product Field (including the  
 Field of Distribution).  
  
 X. "Section 305 Hearing" shall have the meaning ascribed to it by  
 the Federal Food, Drug and Cosmetic Act (the "Act") and implementing  
 regulations of the FDA, as may be amended or changed from time to time.  
  
 Y. "Standard Operating Procedure System" shall mean the standard  
 operating procedures used in connection with the production of the  
 Isolex(R) and Maxsep(R) Products, as such procedures may be changed from  
 time to time.  
  
 Z. "Subcontractor" means a third party who produces and/or  
 supplies any of the Isolex(R) and Maxsep(R) Products or any FDA-Regulated  
 Non-Baxter Component of a Manufactured Product to or on behalf of Baxter  
 under contract.  
  
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 AA. "Subsidiary" means, as to any party, any corporation of  
 which more than fifty percent (50%) of the outstanding capital stock having  
 ordinary voting power to elect a majority of the board of directors of such  
 corporation (irrespective of whether or not at the time stock of any other  
 class or classes of such corporation shall have or might have voting power  
 by reason of the happening of any contingency) is at the time directly or  
 indirectly owned by the party, by one or more of its subsidiaries, or by  
 the party and one or more of its subsidiaries.  
  
 BB. "Supplied Products" means those products supplied by  
 Baxter to Newco under the terms of the Hardware and Disposables Supply  
 Agreement.  
  
 CC. "Term" shall mean, individually and collectively, the  
 term of this Agreement as provided in Section 2.  
  
 DD. "Value Improvement Process" shall mean the Value  
 Improvement Management System currently used in connection with the  
 production of the Isolex(R) and Maxsep(R) Products, as such system may be  
 changed from time to time.  
  
 EE. "Warning Letter" shall have the meaning ascribed to it  
 by FDA policy, as may be amended or changed from time to time.  
  
 2. TERM. The term of this Agreement shall be five (5) years from  
the date hereof. After the expiration of twelve (12) months following the date  
of this Agreement, Baxter and Newco shall commence to negotiate in good faith a  
renewal as well as the prices to be paid during such renewal for the  
Manufactured Products produced hereunder.  
  
 3. MANUFACTURING. During the Term, Baxter shall manufacture for  
Newco the Manufactured Products, and shall complete the manufacturing and  
assembly of the Isolex(R) and Maxsep(R) instruments and disposable sets using  
components to be acquired by Newco from third parties or supplied by Baxter  
under the Hardware and Disposables Supply Agreement and the Antibody  
Manufacturing and Storage Agreement, for use and sale in the Product Field,  
subject to the terms and conditions contained in this Agreement. In  
manufacturing such Manufactured Products, Baxter will produce finished goods.  
Nothing contained in this Agreement shall prevent Newco from having products  
with the same specifications as the Manufactured Products manufactured by Newco  
or third parties on behalf of Newco. Nothing herein contained shall oblige  
Baxter to continue producing or Newco to continue purchasing any Manufactured  
Product if such production is reasonably believed by Baxter or by Newco, as the  
case may be, to violate any applicable law, regulation, rule or license or if  
the Manufactured Products produced infringe  
  
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a third party's patent or other intellectual property rights, provided that  
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Baxter will cooperate with Newco, to the extent commercially feasible, to  
develop and implement such changes as may be necessary to bring a Manufactured  
Product into compliance or to prevent such infringement, and Baxter will  
continue to produce after a finding of infringement if Newco reaches an  
agreement with the third party which permits future production without  
infringement. Proposed new products identified on Schedule 1 as Isolex(R) and  
Maxsep(R) Products and manufactured by Baxter pursuant to the Services Agreement  
shall become Manufactured Products and shall be manufactured by Baxter hereunder  
in the event that, and at such time as, their specifications become sufficiently  
fixed to permit standardized production at commercial levels. In the event that  
Baxter, in its sole discretion, agrees to manufacture for Newco any other  
instruments, disposable sets or other products (other than proposed new products  
identified on Schedule 1 as Isolex(R) and Maxsep(R) Products agreed to be  
manufactured as Manufactured Products hereunder), and Baxter and Newco enter  
into a separate written agreement on mutually agreeable terms (including price)  
with respect to such manufacturing, then Baxter will manufacture such additional  
products as the two parties may so agree, and such additional products will be  
treated for all purposes of this Agreement as Manufactured Products.  
  
 4. MANUFACTURING LICENSE AND USE OF IT ASSETS.  
  
 4.1 Manufacturing License: Newco hereby grants to Xxxxxx and  
Xxxxxx accepts, a non-exclusive, royalty-free worldwide license, under the  
Isolex(R) and Maxsep(R) Technology, to make, have made, use and sell the  
Manufactured Products to or on behalf of Newco during the Term pursuant to the  
terms of this Agreement.  
  
 4.2 Use of IT Assets: During the Term, Newco shall provide to  
Baxter the use and possession of (at Xxxxxx'x Manufacturing Facilities described  
in Section 7.1 below), but not title to, those IT Assets (including equipment,  
molds or tools) which are required by, or may be useful for, Baxter in  
manufacturing the Manufactured Products pursuant to this Agreement, as set forth  
on Schedule 2 attached hereto.  
  
 5. TRADEMARK LICENSE AND LABEL COPY.  
  
 5.1 Trademark License: Newco hereby grants to Xxxxxx and Xxxxxx  
accepts a non-exclusive royalty-free worldwide license to use Newco's  
trademarks, trade names, service marks, corporate logos and copyrighted  
materials solely in connection with the manufacture, use and sale of the  
Manufactured Products to or on behalf of Newco during the Term pursuant to the  
terms of this Agreement, provided that Newco has reviewed and approved in  
writing each use or display of such Newco trademarks, trade names, service  
marks, logos and materials. If any such Newco trademark, trade name, service  
xxxx, logo or material is to be used in connection with the Manufactured  
Products, Baxter shall obtain prior written authorization from Newco (which  
authorization may be withheld by Newco in its sole discretion) for such use and  
for all subsequent changes to any art work, labels, inserts, advertising,  
packaging or marketing materials that incorporate such Newco trademark, trade  
name, service xxxx, logo or materials. No other use of Newco's trademarks, trade  
names, service marks, logos and copyrighted materials  
  
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is permitted during or after the Term of this Agreement. Except as provided in  
this Agreement, Baxter shall not use any trademark, trade name, service xxxx or  
logo claimed by Newco or any confusingly similar trademark, trade name, service  
xxxx or logo, during or after the Term of this Agreement.  
  
 5.2 Label Copy: Newco shall provide all labeling, product  
inserts and packaging for the Manufactured Products, provided that Baxter has  
reviewed and approved in writing each use or display on such labels, inserts or  
packaging of any trademark, trade name, service xxxx or logo used or owned by  
Baxter, other than any trademark, trade name, service xxxx or logo licensed to  
Baxter pursuant to Section 5.1 of this Agreement. If a trademark, trade name,  
service xxxx or logo owned or used by Baxter or its parent corporation, other  
than any trademark, trade name, service xxxx or logo licensed to Baxter pursuant  
Section 5.1 of this Agreement, is to be used in connection with the Manufactured  
Products (except to the extent such use is mandatory in connection with the  
labeling requirements of applicable law) Newco shall obtain prior written  
authorization from Baxter (which authorization may be withheld by Baxter in its  
sole discretion) for such use and for all subsequent changes to the art work,  
labels, inserts or packaging for the Manufactured Products that incorporate such  
a Baxter trademark, trade name, service xxxx or logo. Each use of such a Baxter  
trademark, trade name, service xxxx or logo shall inure to the benefit of Baxter  
and its parent company. Should any such use vest in Newco any rights in a  
trademark, trade name, service xxxx or logo used by Baxter, other than any  
trademark, trade name, service xxxx or logo licensed to Baxter pursuant to  
Section 5.1 of this Agreement, Newco shall transfer such rights to Baxter or its  
designee upon the request of Baxter. Except as provided in this Agreement, Newco  
shall not use any trademark, trade name, service xxxx or logo claimed by Baxter  
or any confusingly similar trademark, trade name, service xxxx or logo during or  
after the Term of this Agreement.  
  
 6. ADMINISTRATION  
  
 6.1 Production Operating Teams: Administration of this  
Agreement will be accomplished by the establishment of three "Production  
Operating Teams," to include the Xxxxxx Production Operating Team, the Tampa  
Production Operating Team and the Mountain Home Production Operating Team. The  
Production Operating Teams will consist of representatives from each of Newco  
and Baxter, who typically would include the individuals identified in Schedule  
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3, or other persons of an appropriate level of authority and responsibility.  
Each party will select representatives and shall notify the other party of such  
selections and any changes thereto. The Production Operating Teams will meet in  
person or by teleconference at least once in each calendar quarter to review the  
progress of Newco and Baxter in the execution of this Agreement and to develop,  
review and agree on specific plans and programs designed to assure that Baxter  
can fulfill orders placed by Newco. Each Production Operating Team will develop  
a process to agree upon short-term and long-term forecasts, orders and  
production planning schedules and to conduct any other business to discharge its  
responsibilities pursuant to the provisions of this Agreement. Regardless of  
the number of representatives selected by each of Newco and Baxter for service  
on any of the Production Operating Teams, the representatives of each party  
shall have, in the aggregate, a single vote in all matters to be decided by any  
  
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Production Operating Team. If, in the course of conducting the activities  
contemplated in these Agreements, any Production Operating Team cannot resolve a  
matter of difference between Baxter and Newco representatives, or cannot reach  
agreement on a matter within its area of responsibility under the terms of this  
Agreement, the Production Operating Team shall promptly refer the matter to the  
Manufacturing Oversight Committee for resolution in accordance with this  
Agreement.  
  
 6.2 Manufacturing Oversight Committee: The "Manufacturing  
Oversight Committee" will consist of representatives from each of Newco and  
Baxter, and typically would consist of Newco's Director/Vice President,  
Manufacturing and Logistics; Newco's Vice President, Global Marketing; Newco's  
Vice President, Business Development; Xxxxxx'x Vice President, Monoclonal and  
Plasma Operations from Xxxxxx; Xxxxxx'x Renal Division Plant Manager, Tampa; and  
Xxxxxx'x Renal Division Plant Manager, Mountain Home, or such other personnel as  
may be designated by Newco and Baxter, respectively. The Manufacturing  
Oversight Committee will meet once a year or more often as necessary to carry  
out its responsibilities hereunder, and shall review and approve the plans,  
programs and recommendations prepared by the Production Operating Teams. The  
Manufacturing Oversight Committee will review and decide any matter in dispute  
referred to it by a Production Operating Team. Regardless of the number of  
representatives selected by each of Newco and Baxter for service on the  
Manufacturing Oversight Committee, the representatives of each party shall have,  
in the aggregate, a single vote in all matters to be decided by the  
Manufacturing Oversight Committee. When the Manufacturing Oversight Committee  
cannot agree on the resolution of any matter within its area of responsibility  
hereunder, it shall promptly refer the matter to the Corporate Committee for  
resolution in accordance with this Agreement.  
  
 6.3 Corporate Committee: The "Corporate Committee" will consist  
of one representative each from VIMRx and Baxter, who ordinarily will be the  
President and CEO of VIMRx and the President of Fenwal, respectively. The  
Corporate Committee will meet only as needed to resolve any dispute or otherwise  
undecided matter referred to it by the Manufacturing Oversight Committee. If  
the Corporate Committee cannot come to agreement with respect to any matter, the  
matter will be referred to arbitration as provided in this Agreement.  
  
 6.4 Responsibilities: Newco and Baxter will cooperate to  
identify their separate responsibilities hereunder, and will diligently execute  
those responsibilities to assure a continuous, uninterrupted supply to the  
market for all Manufactured Products. For guidance and illustrative purposes, a  
list of the various functional responsibilities to be performed by Newco and  
Baxter for purposes of this Agreement are attached as Schedule 4. Whenever the  
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need for functions and responsibilities not previously identified or assumed by  
either Newco or Baxter becomes evident, the relevant Manufacturing Oversight  
Committee will assign such functions or responsibilities.  
  
 7. PRODUCTION AND PRODUCTION SITES.  
  
 7.1 Production Sites: Xxxxxx'x and its Subcontractors'  
manufacture of the Manufactured Products (and components thereof) may be carried  
out at any Manufacturing  
  
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Facility, with the original Manufacturing Facilities selected by Baxter and its  
Subcontractors set forth on Schedule 5 attached hereto, provided that the cost  
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of effecting any change of the Manufacturing Facilities from the original sites  
selected, or of effecting any subsequent change, shall not be included in the  
Fully Loaded Cost, the new facilities meet any applicable QSR and other  
regulatory requirements (or, in the case of a Baxter Subcontractor, to Xxxxxx'x  
knowledge the new facilities meet any applicable QSR and other regulatory  
requirements), and any change in facilities does not require submission and  
approval of a PMA supplement or foreign marketing application by Newco. If  
Newco determines a PMA supplement approval or foreign marketing authorization or  
approval is necessary, Baxter (and/or its Subcontractor) and Newco shall agree  
to the allocation of costs related to preparation and submission of the PMA  
supplement or other application and Baxter or the relevant Subcontractor shall  
continue to use and supply Newco from existing facilities, pending PMA  
supplement or foreign approval.  
  
 7.2 Production of Manufactured Products: In manufacturing the  
Manufactured Products, Baxter and its Subcontractors shall comply with all  
applicable QSR or applicable state or foreign regulatory requirements except to  
the extent a relevant requirement has been allocated to Newco under the  
Agreements between Newco and Baxter. More specifically, as applicable, Xxxxxx'x  
or a Subcontractor's QSR responsibilities, include but are not limited to:  
  
 A. Complying with all relevant materials, manufacturing and in-  
 process controls, label control and quality control specifications, product  
 drawings/blueprints and operating procedures which are applicable at the  
 time of production to the manufacture of the Manufactured Products or as  
 they are changed by Newco with the prior written consent of Baxter or a  
 Subcontractor with respect to material changes (which consent shall not be  
 unreasonably withheld).  
  
 B. Performing the release function for each lot of Manufactured  
 Product.  
  
 C. Preparing and maintaining the Device Master Record and Device  
 History Record or state, local or foreign equivalent for each Manufactured  
 Product, including records of any product retentions which may have been  
 issued against a lot during the manufacturing process, the action taken,  
 and the disposition of the retention.  
  
 D. Maintaining and complying with the quality system as described  
 in its current Quality Manual applicable to the Manufactured Products, or  
 as subsequently changed generally for all products of that type  
 manufactured by such manufacturer.  
  
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 E. Maintaining and complying with its Standard Operating  
 Procedure System which is currently applicable to the Manufactured Products  
 (relating to product manufacturing, testing and critical engineering,  
 system monitoring and control, cleaning/sanitization, calibration of  
 equipment, preventative maintenance, employee training, pest control,  
 environmental control/monitoring, equipment and process validation,  
 labeling/packaging control, failure investigations, internal quality  
 audits, handling of customer calls and complaint forwarding, computer  
 systems validation and maintenance, product release, product/process change  
 control and delegation of authority), or as subsequently changed generally  
 for all products of that type manufactured by such manufacturer.  
  
Baxter or a Baxter Subcontractor may change the product specifications for any  
Manufactured Product only with the prior written consent of Newco, which consent  
shall not be unreasonably withheld. If Baxter or its Subcontractor proposes to  
make a material change in product specifications (including in design,  
materials, or suppliers), it shall give Newco not less than six months' prior  
notice of any such change (including, without limitation, any change which may  
affect the PMA or state, local or foreign regulatory approval of any  
Manufactured Product or that requires any regulatory review). If any such  
change is unacceptable to Newco (in its reasonable discretion), Newco shall give  
Xxxxxx and, if applicable, the Subcontractor notice of its objection within  
thirty (30) days after receipt of the notice given hereunder by Xxxxxx or its  
Subcontractor, as the case may be. In the event that Newco objects to a  
proposed change because it would require a PMA supplemental approval or state,  
local or foreign marketing authorization or approval or for any other reason,  
Xxxxxx or its Subcontractor will continue to provide the Manufactured Products  
without any change in product specifications, provided that if Newco objects to  
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the change because it determines a PMA supplemental approval or state, local or  
foreign marketing application or approval would be necessary, Xxxxxx or its  
Subcontractor may prepare and bear the cost of the PMA supplement or other  
foreign application which Newco will file with the FDA or other appropriate  
authority. In such a case, modified Manufactured Products may be provided upon  
PMA supplement or state, local or foreign approval or when otherwise consistent  
with the FDA or other applicable regulations.  
  
 7.3 Materials and Services: Xxxxxx and its Subcontractors shall  
purchase all materials and services required to manufacture the Manufactured  
Products (the cost of which will be reimbursed by Newco as part of Fully Loaded  
Cost). Xxxxxx and its Subcontractors may change suppliers of materials or  
services without the prior consent of Newco, provided that (i) there is no  
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material increase in the price of the Manufactured Products to Newco, (ii) a PMA  
supplemental approval or state, local or foreign marketing authorization or  
approval for any of the Manufactured Products is not necessary, and (iii) the  
production of the Manufactured Products otherwise conforms to the terms of this  
Agreement (including Sections 7.2 and 12.1).  
  
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 7.4 Title to Specifications: The specifications, product  
drawings/blueprints and procedures that relate solely to the Manufactured  
Products (and components thereof) referred to in Section 7.2A, other than any  
such specifications, drawings/blueprints or procedures that relate solely to  
those products or components to be supplied by Xxxxxx under the Hardware and  
Disposables Supply Agreement, are and shall remain the property of Newco. Newco  
shall provide copies of such documents to Xxxxxx or a relevant Subcontractor in  
quantities sufficient to permit Xxxxxx or the Subcontractor to carry out its  
obligations hereunder. Specifications, product drawings/blueprints and  
procedures that were not transferred to Newco as part of the IT Assets and that  
relate both to the Manufactured Products (and components thereof) and to other  
Xxxxxx products are and shall remain the property of Xxxxxx or any relevant  
subcontractor. Xxxxxx and its Subcontractors shall provide copies of such  
documents to Newco in quantities sufficient to permit Newco to manufacture, or  
have manufactured on its behalf, products with the same specifications as the  
Manufactured Products.  
  
 8. CHANGE OF PRODUCTION SITES/OUTSOURCING MANUFACTURE. After  
consultation with the Manufacturing Oversight Committee and after written notice  
to Newco (but without the requirement of prior consent), Xxxxxx or a Xxxxxx  
Subcontractor may change the current production site of any Manufactured Product  
and Xxxxxx may outsource the production of any Manufactured Product, provided  
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that (i) there is no material increase in the price of the Manufactured Products  
to Newco, (ii) a PMA supplemental approval or state, local or foreign marketing  
authorization or approval is not required, (iii) Newco's rights to any IT Assets  
are not materially adversely affected thereby, and (iv) the manufacturing of the  
Manufactured Products otherwise conforms to the terms of this Agreement with  
respect to Manufactured Products (including Sections 7.2 and 12), or Xxxxxx  
causes a relevant third party to comply with the terms of this Agreement in  
connection with outsourced manufacturing of a Manufactured Product, as the case  
may be. Newco and Xxxxxx agree that nothing contained in this Agreement shall  
require Xxxxxx or a Subcontractor to change, or to open any new or additional  
Manufacturing Facilities, apart from any upgrades in its Manufacturing  
Facilities that Xxxxxx or a Subcontractor may make in order to meet the  
specifications for production of the Manufactured Products applicable at any  
time and any changes as may be necessary to enable Xxxxxx or a Subcontractor to  
satisfy its obligations hereunder to deliver Manufactured Products to Newco.  
Both Newco and Xxxxxx acknowledge and agree that the production of certain  
components of the Manufactured Products is currently outsourced by Xxxxxx to  
manufacturers other than Xxxxxx. With respect to production site changes, new  
outsourcing, and facility upgrades, Xxxxxx or a Subcontractor shall provide  
Newco with sufficient advance notice to allow Newco to comply with any  
applicable regulatory requirements. If Newco determines a PMA supplement  
approval or foreign marketing authorization or approval is necessary, Xxxxxx  
(and/or its Subcontractor) and Newco shall agree to the allocation of costs  
related to preparation and submission of the PMA supplement or other  
application. New production sites, outsourcing and facility upgrades shall not  
be utilized relative to Manufactured Products, pending PMA supplement or foreign  
approval, unless consistent with FDA and other applicable regulations.  
  
 9. FACILITY ACCESS AND AUDITS.  
  
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 9.1 Facility Access: During the Term, Xxxxxx and its Subcontractors  
shall permit Newco access to all areas of the Manufacturing Facilities in which  
the Manufactured Products are manufactured, upon reasonable prior notice and  
scheduling by Newco during normal business hours, for the examination of  
production or quality records or to perform QSR audits. Newco's access to such  
Manufacturing Facilities shall be coordinated through the Production Operating  
Teams.  
  
 9.2 Audit: Newco may audit Xxxxxx'x and Xxxxxx Subcontractors'  
books and records for the purpose of determining compliance with the terms of  
this Agreement. Newco may use independent outside auditors (who may participate  
fully in such audit). In the event that an audit is proposed with respect to  
information which Xxxxxx or a Xxxxxx Subcontractor wishes not to disclose to  
Newco ("Restricted Information"), then on the written  
  
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demand of Xxxxxx or such Subcontractor the individuals conducting the audit with  
respect to the Restricted Information will be limited to Newco's independent  
auditors. In such event, Xxxxxx or such Subcontractor shall pay the costs of the  
independent auditors conducting such audit, but only with respect to that  
portion of the audit relating to the Restricted Information. Such independent  
auditors shall enter into an agreement with the relevant parties, on terms that  
are agreeable to the parties, under which such independent auditors shall agree  
to maintain the confidentiality of the information obtained during the course of  
such audit and establishing what information such auditors will be permitted to  
disclose in reporting the results of any audit of Restricted Information. Any  
such audit shall be conducted during regular business hours in a manner that  
does not interfere unreasonably with the operations of Xxxxxx or such  
subcontractor. The aggregate number of audits of Xxxxxx'x books and records  
conducted under this Agreement and the Sublicense Agreements, the Antibody  
Manufacturing and Storage Agreement, the Services Agreement, the Marketing,  
Sales and Distribution Agreement and the Hardware and Disposables Supply  
Agreement shall not exceed one (1) per facility in any twelve (12) month period  
unless the next preceding audit disclosed a failure to conform to the terms of  
any such Agreement or unless a Manufacturing Facility receives a Form FDA-483  
during the twelve (12) months following any audit. Subject to the foregoing  
limitations, any such audit shall be conducted when requested by notice given  
not less than thirty (30) days prior to the commencement of the audit.  
  
 9.3 Xxxxxx Subcontractors: Newco's rights to facility access  
and to audit books and records pursuant to this Section 9, process validation  
pursuant to Section 10 below, and certain regulatory compliance matters pursuant  
to Sections 12.1(D), (E), (F), (G), (H), (I) and (J) below are, in the case of  
Xxxxxx'x Subcontractors, subject to the limits on Xxxxxx'x rights under its  
agreements with such Subcontractors. Xxxxxx will use its best efforts, without  
the requirement of payment of money, to cause all of its Subcontractors to  
permit facility access, the right to audit books and records, process  
validation, and certain regulatory compliance matters as set forth herein with  
respect to the Manufactured Products as provided in this Section 9, Section 10  
below and Sections 12.1(D), (E), (F), (G) (H), (I) and (J) below.  
  
 10. PROCESS VALIDATION. During the Term, at Newco's request, Xxxxxx  
and its Subcontractors shall permit Newco to review production validation  
protocols and results with respect to the Manufactured Products. Such review  
shall be arranged by the Production Operating Teams.  
  
 11. REGULATORY RESPONSIBILITY. Except as allocated to Xxxxxx or its  
Subcontractors as a QSR obligation or otherwise under the agreements between  
Xxxxxx and Newco, Newco will obtain Regulatory Approval for, and shall maintain  
all regulatory files on, every Manufactured Product (except Supplied Products)  
manufactured by Xxxxxx or a Subcontractor exclusively for Newco.  
  
 12. COMPLIANCE WITH REGULATORY REQUIREMENTS.  
  
 12.1 Xxxxxx Responsibilities: Notwithstanding any provision of  
Section 11 hereof to the contrary, Xxxxxx shall and, as applicable, shall  
require any Subcontractor to:  
  
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 A. Appropriately register its manufacturing establishments with  
 the FDA and other regulatory agencies when required.  
  
 B. Maintain its required IS0 and EN certification for each  
 Manufacturing Facility and comply with all European Union and other foreign  
 regulatory requirements, as applicable.  
  
 C. Comply with the QSR requirements and other relevant  
 regulations issued by the FDA, state, local or other regulatory agencies  
 and in effect from time to time except to the extent that a QSR or other  
 regulatory obligation has been allocated to Newco under the agreements  
 between Xxxxxx and Newco.  
  
 D. When practicable, permit Newco to send a representative to  
 attend, or when such attendance is not permitted or practicable, provide  
 Newco with periodic progress reports on, every visit to a relevant  
 Manufacturing Facility by the FDA or other regulatory agency which affects  
 or concerns the manufacture of the Manufactured Products (such reports to  
 be given as frequently as reasonably possible, but not more often than once  
 in each 24-hour period, during that portion of the visit which directly  
 affects or concerns any Manufactured Products). Newco shall be provided  
 with a copy of any Form FDA-483, Establishment Inspection Report and/or  
 Warning or "untitled" Letter generated as a result of an FDA visit, or any  
 equivalent foreign, state or local document generated as a result of an  
 inspection visit, and responses thereto (which copies may be redacted to  
 the extent necessary to protect confidential information unrelated to the  
 Manufactured Products, provided that such redaction does not prevent Newco  
 from discerning any information that is related to the Manufactured  
 Products). Newco shall also be apprised as soon as possible of the time and  
 place of any FDA "close out" meeting at the end of an FDA or other agency  
 visit and allowed to attend the meeting when the meeting directly affects  
 or concerns any Manufactured Product, provided that, in the discretion of  
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 Xxxxxx'x or its Subcontractor's regulatory professionals, the presence of a  
 Newco representative would not prejudice Xxxxxx'x or its Subcontractor's  
 interests.  
  
 E. Respond, in a timely manner, after consultation with Newco, to  
 any Form FDA-483, Warning or "untitled"  
  
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 Letter or Section 305 Notice received, and any other notices or letters  
 received from the FDA, a state or local regulatory authority, or an  
 analogous regulatory authority outside the United States, which relate to  
 the Manufactured Products.  
  
 F. Communicate to Newco product complaints received relating to  
 the Manufactured Products and cooperate, as mutually agreed by the parties,  
 with Newco in the resolution of such product complaints.  
  
 G. Maintain and store production records relating to the  
 Manufactured Products as required by its record retention policy, as  
 amended from time to time.  
  
 H. Cooperate with Newco, as mutually agreed by the parties, in  
 connection with mandatory notifications, repairs, replacements, and  
 refunds, safety alerts, "cease distribution and notification" and mandatory  
 recall actions, voluntary recalls, market withdrawals and stock recoveries,  
 and device removals and corrections, as defined or understood under law or  
 FDA policy, related to the Manufactured Products produced for Newco. Such  
 cooperation shall be at Newco's expense, subject to the provisions of  
 Section 12.3 below.  
  
 I. Cooperate with Newco in Newco's preparation and filing of MDRs  
 and compliance with PMA Post-Approval Requirements related to the  
 Manufactured Products. Such cooperation shall be at Newco's expense,  
 subject to the provisions of Section 12.3, below.  
  
 J. Provide Newco with reasonable access to and a copy of such  
 portions of its regulatory files relating to the Manufactured Products as  
 Newco shall reasonably request.  
  
  
 12.2 Newco Responsibilities: Newco shall:  
  
 A. Prepare, obtain approval of, and hold all applications,  
 notifications, submissions and regulatory files required by the FDA and the  
 Act relating to the Manufactured Products, except such files as are agreed  
 to be maintained by Xxxxxx or a Xxxxxx third party sub-contractor pursuant  
 to the other Agreements between Newco and Xxxxxx.  
  
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 B. Provide Xxxxxx with copy for all labeling related to the  
 Manufactured Products, which labeling shall comply with the Act and with  
 FDA and any relevant state or local regulatory requirements, as well as  
 with all applicable foreign regulatory requirements.  
  
 C. Be responsible for handling product complaints and maintenance  
 of complaint files and records related to Manufactured Products, and shall  
 notify Xxxxxx of complaints regarding Manufactured Products.  
  
 D. File with FDA medical device reports under 21 C.F.R. Part 803  
 regarding the Manufactured Products.  
  
 E. Administer all mandatory notifications, repairs, replacements  
 and refunds, safety alerts, "cease distribution and notification" and  
 mandatory recall actions, voluntary recalls, market withdrawals and stock  
 recoveries, and device removals and corrections, as defined or understood  
 under law or FDA policy, and related and analogous actions involving  
 Manufactured Products.  
  
 F. Register with the FDA as a specifications developer and  
 register with other authorities, as applicable.  
  
 G. List the Manufactured Products with the FDA or other  
 authorities, as necessary.  
  
 H. Comply with any PMA Post-Approval Requirements applicable to  
 the Manufactured Products.  
  
 I. Respond in a timely manner, after consultation with Xxxxxx or  
 a relevant Xxxxxx third party sub-contractor, to any Form FDA-483, Warning  
 Letter or Section 305 Notice received, and any other notices or letters  
 received from the FDA, a state or local regulatory authority, or an  
 analogous regulatory authority outside the United States, which relate to  
 the Manufactured Products.  
  
 J. Provide Xxxxxx with reasonable access to and a copy of such  
 portions of Newco's regulatory files relating to the Manufactured Products  
 as Xxxxxx shall reasonably request.  
  
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 K. Comply with all European Union and other foreign regulatory  
 requirements, as applicable to the Manufactured Products.  
  
 12.3 Regulatory Actions: In the event that Newco takes a  
regulatory action relative to any Manufactured Product (or component thereof)  
and such action is due solely to Xxxxxx'x or its Subcontractor's failure to  
produce the Manufactured Product (or component) in accordance with its  
responsibilities under Sections 7.2, 8 or 12 of this Agreement, then Xxxxxx  
shall pay or reimburse Newco for all out-of-pocket costs and expenses incurred  
by Newco in connection with such action, including expenses or obligations to  
third parties, the cost of notifying customers, costs associated with the return  
of Manufactured Products (or components thereof) by customers, and costs related  
to otherwise addressing, handling or correcting the Manufactured Products (or  
components thereof). In the event that such action is due in part to Xxxxxx'x  
or its Subcontractor's failure to manufacture the Manufactured Product (or  
component) in accordance with its responsibilities under this Agreement, Xxxxxx  
shall pay or reimburse Newco for such part of Newco's out-of-pocket costs and  
expenses as shall be agreed by the parties or by the Corporate Committee, or as  
shall be determined in binding arbitration pursuant to Section 32 of this  
Agreement to be attributable to Xxxxxx'x failure. For purposes of this  
paragraph, "regulatory action" means mandatory notifications, repairs,  
replacements and refunds, safety alerts, "cease distribution and notification"  
and mandatory recall actions, voluntary recalls, market withdrawals, and stock  
recoveries, and device removals and corrections, as defined or understood under  
law or FDA policy, and related and analogous actions.  
  
 13. ACTIVITY PLANNING/FORECASTS AND ORDERS.  
  
 13.1 Forecasts: Prior to the beginning of each calendar month  
during the Term, Newco shall give Xxxxxx a forecast of the orders Newco expects  
to place with Xxxxxx for Manufactured Products during each of the next eighteen  
(18) months, using data supplied to Newco by Xxxxxx from the Master Scheduling  
System currently employed by Xxxxxx and reviewed by the appropriate Production  
Operating Teams. The forecast for the first two (2) months contained in such  
eighteen month forecast shall constitute firm orders. The forecast for the first  
of the eighteen (18) months in such eighteen month forecast must be the same as  
the forecast for the second month in the previous eighteen month forecast; and  
the forecast for the second of the eighteen (18) months in such eighteen month  
forecast may not vary from the forecast for such month in the previous eighteen  
month forecast by more than [Confidential Information Omitted], without the  
prior consent of Xxxxxx after consultation with each of the Production Operating  
Teams. The eighteen month forecast for the eighteen month period beginning on  
the date hereof was delivered to Xxxxxx on the date hereof.  
  
 13.2 Production Schedule: Based on the forecasts and orders  
received by Xxxxxx from Newco, Xxxxxx shall develop and maintain detailed  
production schedules for the Manufactured Products which shall be presented for  
review by the Production Operating Teams at least quarterly.  
  
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 13.3 Production in Excess of Orders: If Xxxxxx'x actual production of  
Manufactured Products exceeds Newco's firm orders, Newco shall purchase such  
excess, up to [Confidential Information Omitted] above Newco's firm orders,  
provided that Newco's firm orders  
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for the next month shall be reduced by such excess unless Newco requests that  
such reduction not be made.  
  
 13.4 Production Below Amount of Orders: If, due to the fault or  
error of Xxxxxx or a third-party supplier or subcontractor of Xxxxxx, and  
subject to the provisions of Section 29 of this Agreement, Xxxxxx fails to  
deliver Manufactured Products in the quantities specified in Newco's firm  
orders, Xxxxxx shall take action as may be necessary to cure such failure as  
rapidly as is commercially reasonable, including without limitation, the actions  
specified with respect to various fill rates as follows:  
  
 A. If production for any month is [Confidential  
 Information Omitted] of Newco's firm orders or lower,  
 Xxxxxx shall (i) increase its production in the next  
 following month as reasonably necessary to satisfy both  
 the unfilled orders and the firm orders for such next  
 following month and (ii) pay air freight and other  
 extraordinary shipping costs reasonably necessary to  
 deliver delayed Manufactured Products to Newco's  
 customers until Xxxxxx has brought production into  
 compliance with firm orders. Increased production  
 required under this Section 13.4(A) shall not be  
 subject to the limits on variance of orders set forth  
 in Section 13.1. The [Confidential Information  
 Omitted]fill rate commitment established pursuant to  
 this Section 13.4(A) may be adjusted by the parties  
 during the Term hereof as may be appropriate to reflect  
 actual manufacturing experience.  
  
 B. If production for any month is [Confidential  
 Information Omitted] of Newco's firm orders, (as  
 increased by the number of unfilled orders, if any,  
 carried over from the previous month) or lower, or if  
 production for any three consecutive months is  
 [Confidential Information Omitted] of Newco's firm  
 orders (as increased by the number of unfilled orders,  
 if any, carried over from the previous month) or lower,  
 Xxxxxx shall (i) take the remedial measures set forth  
 in Section 13.4(A), (ii) promptly prepare and present  
 to the Production Operating Teams a plan for restoring  
 compliance firm orders, and (iii) promptly implement  
 such measures to restore compliance with firm orders as  
 are directed by the Production Operating Teams,  
 including without limitation changing, or allocating  
 additional manufacturing resources.  
  
 C. If, after the first twelve (12) months of the Term  
 hereof, production for any three consecutive months is  
 [Confidential Information Omitted] of Newco's firm  
 orders (as increased by the number of unfilled  
  
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 orders, if any, carried over from the previous month)  
 or lower, or if production for any six consecutive  
 months is [Confidential Information Omitted] of Newco's  
 firm orders (as increased by the number of unfilled  
 orders, if any, carried over from the previous month)  
 or lower, Xxxxxx shall, at Newco's option, either (i)  
 take the remedial measures set forth in Section 13.4(B)  
 or (ii) assist Newco to transfer, at Xxxxxx'x sole  
 expense, all manufacturing of Manufactured Products to  
 a third party alternative manufacturer selected by  
 Newco, with such assistance to include without  
 limitation the transfer of such inventory, raw  
 materials, work in process, IT Assets, specifications,  
 drawings/blueprints, copy of the Device History Record,  
 and such other property owned by Newco or owned by  
 Xxxxxx and previously charged to Newco as part of   
 Fully-Loaded Cost; transfer all information and  
 technical know-how concerning Xxxxxx manufacturing  
 processes required for production of the Manufactured  
 Products; provide the services of technical personnel  
 as needed to effect such transfers of information and  
 technical know-how; and continue to manufacture the  
 Manufactured Products during the transition to an  
 alternative manufacturer until such alternative  
 manufacturer is able to meet market demand for the  
 Manufactured Products, provided that Newco and such  
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 alternative manufacturer are making good faith efforts  
 to effectuate the transition and to enable such  
 alternative manufacturer to meet market demand for the  
 Manufactured Products. Any third party alternative  
 manufacturer selected by Newco must (a) agree to be  
 bound, to the same extent that Newco is bound, by the  
 provisions of that certain Non-Competition and  
 Confidentiality Agreement among Xxxxxx, VIMRx and Newco  
 of even date herewith; and (b) be approved by the  
 Corporate Committee.  
  
The provisions of this Section 13.4 shall not apply to Manufactured Products  
manufactured for use in clinical trials. Except with respect to Manufactured  
Products manufactured for use in clinical trials (as to which Section 13.4 does  
not apply), the provisions of Section 13.4 shall be the sole remedy available to  
Newco in the event that Xxxxxx fails to satisfy Newco's firm orders made  
pursuant to this Section 13, provided that Xxxxxx is endeavoring in good faith  
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to satisfy its obligations to Newco in accordance with the terms of this  
Agreement, including, without limitation, this Section 13.4.  
  
 13.5 Long Range Forecasts: The parties shall cooperate in good  
faith in providing other, longer range, forecasts, which shall be useful in  
budget planning for the parties.  
  
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 13.6 Transition Period: Xxxxxx and Newco acknowledge that during the  
first twelve (12) months of the Term of this Agreement, it may not be  
commercially feasible for Xxxxxx (a) to immediately strictly comply with the  
labeling, product inserts and packaging requirements of Section 5 of this  
Agreement by changing the label copy, product inserts and packaging for Supplied  
Products to include Newco's label copy, product inserts, packaging, trademarks,  
trade names, service marks, logos or materials or (b) to fulfill the production  
rate requirements of Section 13.4A through 13.4C, inclusive, of this Agreement.  
Accordingly, Xxxxxx and Newco agree that during the first twelve (12) months of  
the Term of this Agreement, Xxxxxx will use its commercially reasonable best  
efforts to achieve full compliance with (a) the labeling, product inserts and  
packaging requirements of Section 5 of this Agreement and (b) the production  
rate requirements of Section 13.4A of this Agreement but shall not be deemed to  
be in breach of Sections 5 or 13.4 of this Agreement during such twelve (12)  
month period unless Xxxxxx fails to comply with this Section 13.6. Any dispute  
between Xxxxxx and Newco relating to Xxxxxx'x non-compliance with this Section  
13.6 shall be referred to the Production Operating Teams for resolution pursuant  
to Section 6.1 of this Agreement.  
  
 14. INVENTORY. Xxxxxx shall retain title to all raw materials and  
work in process relating to the Manufactured Products, except that any of such  
items relating solely to the Manufactured Products which become obsolete due to  
action of Newco or regulatory requirements shall, at Xxxxxx'x option, be  
purchased by Newco pursuant to Section 15 below to the extent they do not exceed  
ninety (90) days' normal usage, based on annual budgeted volume.  
  
 15. PRICING, BILLING AND PAYMENT.  
  
 15.1 Fully Loaded Cost: During the first three (3) full years of  
the Term, the prices to Newco for Manufactured Products shall be Xxxxxx'x Fully  
Loaded Cost for such Manufactured Products.  
  
 15.2 Fully Loaded Cost Plus: After the expiration of the first  
three (3) full years of the Term, the prices for Manufactured Products shall be  
Xxxxxx'x Fully Loaded Cost for such Manufactured Products plus [Confidential  
Information Omitted] of such Fully Loaded Cost (unless Xxxxxx and Newco  
otherwise agree in writing to a different price).  
  
 15.3 Price Adjustments: The prices for Manufactured Products  
shall be adjusted as of January 1 of each year of the Term, through Xxxxxx'x  
annual internal budgeting process, based on forecast changes in volume pursuant  
to the forecasting process set forth in Section 13, anticipated changes in  
materials prices and anticipated cost reductions resulting from Xxxxxx'x Value  
Improvement Process. The overall intent of the parties is that the Manufactured  
Products shall be transferred at the prices described in Sections 15.1 and 15.2,  
as adjusted for future changes in Xxxxxx'x costs of production (taking into  
account Section 15.4 hereof).  
  
 15.4 Unanticipated Volume, Materials Price or Overhead Changes:  
Cost variances shall be paid by or credited to the parties during the course of  
a calendar year based on unanticipated volume, materials price or overhead  
changes, as follows:  
  
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 A. Cost variances based on volume changes shall be made only when  
 firm orders exceed or are less than forecast activity by [Confidential  
 Information Omitted] or more (excluding any increases attributable to  
 earlier failures to supply firm orders) and shall cover only the difference  
 between [Confidential Information Omitted] of the budgeted activity and the  
 variance from budgeted activity. The adjustment will be based on  
 [Confidential Information Omitted] of Xxxxxx'x standard overhead  
 attributable to the difference from the planned volume.  
  
 B. Cost variances based on materials price changes shall be made  
 only when actual prices for total materials costs differ from those  
 anticipated in the budgeting process by more than [Confidential Information  
 Omitted]. The adjustment shall cover only the difference between  
 [Confidential Information Omitted] of total budgeted materials cost and the  
 variance from budgeted activity.  
  
 C. Cost variances based on overhead cost changes caused by  
 conditions, other than those described in Section 15.4(A) or 15.4(B) above,  
 beyond Xxxxxx'x control, shall be shared pro rata (based on changes in  
 total plant overhead) by the parties or as they shall otherwise agree.  
  
 D. Adjustments pursuant to this Section 15.4 will be determined  
 as of the end of each calendar quarter (on a year to date basis) and  
 reflected as an amount due and payable (or a credit receivable) spread  
 ratably over the following three months.  
  
 E. All pricing adjustments will be reviewed, but not for  
 approval, by the Production Operating Teams and any dispute concerning such  
 adjustments will be referred to the Manufacturing Oversight Committee and,  
 if necessary, to the Corporate Committee.  
  
 15.5 Spare Parts: Xxxxxx shall manufacture and make available  
for purchase by Newco spare parts for the repair of the Manufactured Products.  
Newco's purchases of such spare parts shall be subject to the pricing, billing  
and payment provisions of this Section 15. Notwithstanding the foregoing,  
Xxxxxx shall maintain a stock of spare parts to satisfy its obligations under  
service contracts entered into by Xxxxxx with purchasers of the Isolex(R) and  
Maxsep(R) Products, there shall be no charge to Newco for such spare parts  
manufactured by or at the direction of Xxxxxx for the purpose of satisfying such  
Xxxxxx obligations, and Xxxxxx shall be entitled to retain all revenues from  
such service contracts and from the sale of such spare parts pursuant to such  
service contracts.  
  
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 15.6 Billing and Payment: Xxxxxx shall xxxx Newco as of the end of  
each calendar month for Manufactured Products shipped during the month. Newco  
shall pay such invoices within sixty (60) days of Newco's receipt thereof.  
  
 16. FOREIGN CURRENCY CONVERSION. Where calculations of Xxxxxx'x  
Fully Loaded Cost relate to a currency other than United States dollars, all  
such calculations shall be calculated pursuant to Xxxxxx'x then current  
accounting policies and practices.  
  
 17. WITHHOLDING TAXES. Where required to do so by applicable law,  
Newco shall withhold taxes required to be paid to a taxing authority on account  
of any payments to Xxxxxx hereunder, and Newco shall furnish Xxxxxx with  
satisfactory evidence of such withholding and payment in order to permit Xxxxxx  
to obtain a tax credit or other relief as may be available under the applicable  
law. Newco shall cooperate with Xxxxxx in obtaining exemption from withholding  
taxes where available under applicable law.  
  
 18. INTEREST ON OVERDUE PAYMENTS. Interest shall accrue and be  
payable on all overdue payments owing by a party under this Agreement from the  
date due at the rate of [Confidential Information Omitted] percent [Confidential  
Information Omitted] per month (or the highest rate allowed by law, if lower),  
compounded annually, until fully paid (including full payment of such interest).  
  
 19. DELIVERY. All shipments of Manufactured Products shall be FOB  
the manufacturing facilities where such Manufactured Products are manufactured  
by or on behalf of Xxxxxx. Except as specified in Section 13.4 above, all  
freight, insurance, and other delivery costs (and any customs duties) shall be  
paid by Newco.  
  
 20. TITLE. Title to all Manufactured Products shall pass to Newco  
(or Newco's designated distributor) when the Manufactured Products are placed on  
Newco's truck or Newco's designated carrier (or Newco's designated distributor's  
truck or designated carrier) at Xxxxxx'x Manufacturing Facility or when  
Manufactured Products distributed by Xxxxxx pursuant to the Marketing, Sales and  
Distribution Agreement, of even date herewith, by and between Xxxxxx and Newco,  
are placed in Xxxxxx'x designated finished goods inventory.  
  
 21. CHANGES IN LABELING. Changes in Manufactured Product labeling  
requested by Newco and the cost of labeling made obsolete by such changes will  
be paid for by Newco at Xxxxxx'x Fully Loaded Cost.  
  
 22. WARRANTIES.  
  
 22.1 Warranty: Xxxxxx warrants to Newco that the Manufactured  
Products delivered to or at the direction of Newco hereunder (i) will have been  
manufactured in accordance with the applicable specifications, procedures and  
product drawings/blueprints and all applicable laws (including the Act), (ii)  
will not be adulterated or misbranded within the meaning of the Act as a result  
of acts or omissions by Xxxxxx, and (iii) are free from defects in workmanship.  
Notwithstanding the foregoing, Xxxxxx shall not be liable to Newco under subpart  
(ii) above as a  
  
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result of any labels supplied by or affixed to such Manufactured Products by  
Newco. This warranty shall be continuing and shall be binding on Xxxxxx and its  
permitted successors and assigns and shall inure to the benefit of Newco and its  
permitted successors and assigns.  
  
WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE NOT GIVEN  
BY XXXXXX AND ANY SUCH IMPLIED WARRANTIES ARE SPECIFICALLY DISCLAIMED.  
  
 22.2 Xxxxxx Indemnity: Subject to Section 28 below, Xxxxxx  
agrees to indemnify Newco and hold it harmless from any liability, loss,  
expense, cost, claim or judgment arising out of any claim for property damage,  
personal injury or death which is caused by Xxxxxx'x (or its Subcontractor's)  
failure to manufacture the Manufactured Products in accordance with the designs,  
specifications, procedures and product drawings/blueprints, with the laws,  
regulations, rules, orders and notices, or with the quality system and Standard  
Operating Procedure System described in Section 7.2 and Section 12 above and  
which are applicable to Xxxxxx or such Subcontractor thereunder, as the case may  
be. At Xxxxxx'x expense, Newco shall cooperate fully with Xxxxxx in defending  
or otherwise resolving any such claim. Xxxxxx shall have full control of any  
litigation brought against Newco with respect to any claim that is indemnifiable  
by Xxxxxx hereunder; but Newco may, at its expense, also be represented by its  
own counsel in any such litigation.  
  
 22.3 Newco Indemnity: Subject to Section 28 below, Newco agrees  
to indemnify Xxxxxx and hold it harmless from any liability, loss, expense,  
cost, claim or judgment arising out of any claim for property damage, personal  
injury or death which is caused by defects in the products, design,  
specifications, procedures, product drawings/blueprints, label copy or resulting  
from the use of the Manufactured Products; provided, however, that Newco will  
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have no liability to Xxxxxx whatsoever with respect to any liability, loss,  
expense, cost, claim or judgment arising out of any claim for property damage,  
personal injury or death which is caused by defects in the designs,  
specifications, procedures or product drawings/blueprints acquired by Newco from  
Xxxxxx pursuant to the Acquisition Agreement, except defects in modifications to  
such designs, specifications, procedures or product drawings/blueprints made by  
Newco subsequent to its acquisition thereof. At Newco's expense, Xxxxxx shall  
cooperate fully with Newco in defendng or otherwise resolving any such claim.  
Newco shall have full control of any litigation brought against Xxxxxx with  
respect to any claim that is indemnifiable by Newco hereunder; but Xxxxxx may,  
at its expense, also be represented by its own counsel in any such litigation.  
  
 22.4 Indemnification for Infringement: Newco shall defend,  
indemnify and hold Baxter harmless with respect to any liability incurred by  
Xxxxxx as a result of activities under this Agreement with respect to any claim  
of patent, trade name, trademark or copyright infringement or misuse (i) with  
respect to any Isolex(R) and Maxsep(R) Products, reagent kits, or other  
products which are not being manufactured or supplied by Xxxxxx (or its  
Subcontractor) for or to Newco under this Agreement or an agreement having the  
same date as this Agreement (or an extension or renewal thereof); or (ii)  
arising from any modification to product designs, specifications, procedures or  
product drawings/blueprints made by Newco subsequent to its acquisition thereof  
from Xxxxxx. At Newco's expense, Xxxxxx shall cooperate fully with Newco  
  
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in defending or otherwise resolving any such charges of infringement or misuse.  
Newco shall have full control of any litigation brought against Xxxxxx alleging  
such infringement or misuse; but Xxxxxx may at its expense, also be represented  
by its own counsel in any such litigation.  
  
 23. INSURANCE.  
  
 23.1 Xxxxxx Insurance: During the Term, Xxxxxx shall procure and  
maintain, through self-insurance or a combination of self-insurance and  
commercially placed insurance, comprehensive general liability insurance  
covering each occurrence of bodily injury and property damage in the amount of  
not less than [Confidential Information Omitted] Dollars [Confidential  
Information Omitted] combined single limit, including coverage for product and  
completed operations, blanket contractual liability and vendor's liability.  
Xxxxxx shall, within sixty (60) days of the date of this Agreement, furnish a  
certificate of insurance to Newco evidencing the foregoing coverages and limits,  
and thereafter shall give at least thirty (30) days' prior notice to Newco of  
any termination, expiration without renewal, or material change to such  
insurance, coverage or limits.  
  
 23.2 Newco Insurance: During the Term, Newco shall procure  
andmaintain, through self-insurance or a combination of self-insurance and  
commercially placed insurance, comprehensive general liability insurance  
covering each occurrence of bodily injury and property damage in the amount of  
not less than [Confidential Information Omitted] Dollars [Confidential  
Information Omitted] combined single limit including coverage for product and  
completed operations, blanket contractual liability and vendor's liability.  
Newco shall, within sixty (60) days of the date of this Agreement, furnish a  
certificate of insurance to Xxxxxx evidencing the foregoing coverages and limits  
and thereafter shall give at least thirty (30) days' prior notice to Xxxxxx of  
any termination, expiration without renewal, or material change to such  
insurance, coverage or limits.  
  
 24. DISCONTINUANCE OF PRODUCT LINE. Subject to Section 25 below, if  
Newco wishes to discontinue a product or product line which includes any  
Manufactured Product (subject to Newco's obligations under the Marketing, Sales  
& Distribution Agreement), Newco shall give Xxxxxx six (6) months' prior written  
notice thereof and the parties will negotiate appropriate closure conditions  
which provide for recovery by Xxxxxx of the related overhead costs, any related  
investment (including any dedicated or additional equipment purchased by Xxxxxx  
exclusively to support the discontinued product line) and related direct out-of-  
pocket expenses.  
  
 25. RIGHT OF FIRST OFFER. In the event Newco elects to abandon  
and/or discontinues substantially all efforts to develop or market (or to have  
developed or marketed) the Manufactured Products, or any of them (the  
"Discontinued Products"), within the Product Field or any sub-field thereof, and  
 ---  
Newco elects to sell Newco's right to make, have made, use and sell the  
Discontinued Products in the Product Field or any sub-field thereof to a third  
party, Xxxxxx shall have a right of first offer to obtain an exclusive worldwide  
license to make, have made, use and sell in such Product Field or sub-field,  
those Discontinued Products. After Newco notifies Xxxxxx of Newco's intention  
to sell such right, Xxxxxx will have sixty (60) days to respond to Newco and to  
negotiate the material terms and conditions of such a license. The terms and  
conditions of such a license shall be negotiated by Newco and Xxxxxx, bargaining  
in good faith,  
  
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and documented in a written agreement, signed by authorized representatives of  
both parties. If, after notice to Xxxxxx and expiration of sixty (60) days  
without completed negotiation of the material terms of a license agreement,  
Newco desires to enter into an agreement with a third party on terms and  
conditions that are less favorable to Newco than the terms and conditions  
offered by or to Xxxxxx (a "New Offer"), then Newco must give Xxxxxx notice and  
an additional thirty (30) days to respond to Newco's offer on substantially the  
same terms and conditions as those of the New Offer. The culmination of any  
transaction pursuant to this Section 25 is subject to the parties entering into  
a definitive agreement on terms which are agreeable to each of the parties, in  
their sole discretion.  
  
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 26. TERMINATION.  
  
 26.1 Expiration: This Agreement, and any licenses granted  
hereunder, shall terminate upon the earlier to occur of the expiration of the  
Term or a termination pursuant to Section 26.2 below.  
  
 26.2 Early Termination: A non-breaching party may terminate this  
Agreement, and may terminate any licenses granted by such party hereunder, if  
any of the following events (each is herein referred to as a "Material Breach")  
occur:  
  
 A. A party fails to pay any amount owing under this Agreement on  
 the date(s) specified for such payment and such failure shall continue for  
 sixty (60) days after written notice of such failure by the other party to  
 this Agreement;  
  
 B. A party shall default in the performance of or compliance with  
 any material covenant contained in this Agreement or the Non-Compete  
 Agreement (other than a failure to make a payment described in Section  
 26.2A above) which shall continue uncured beyond the applicable grace  
 period therefor; a party shall default in the performance of or compliance  
 with any covenant contained in the Marketing, Sales and Distribution  
 Agreement and such default results in termination of such Marketing, Sales  
 and Distribution Agreement; or the Marketing, Sales and Distribution  
 Agreement is rejected in the course of the bankruptcy of the non-  
 terminating party;  
  
 C. A receiver, conservator, custodian, liquidator or trustee of a  
 party or of all or any of the property of a party, is appointed by court  
 order and such order remains in effect for more than ninety (90) days; or  
 an order for relief is entered under the federal bankruptcy laws with  
 respect to a party; or any of the material property of a party is  
 sequestered by court order and such order remains in effect for more than  
 ninety (90) days; or a petition is filed against a party under the  
 bankruptcy, reorganization, arrangement, insolvency, readjustment of debt,  
 dissolution or liquidation law of any jurisdiction, whether now or  
 hereafter in effect, and is not dismissed within ninety (90) days after  
 such filing;  
  
 D. A party files a petition in voluntary bankruptcy or seeking  
 relief under any provision of any bankruptcy,  
  
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 reorganization, arrangement, insolvency, readjustment of debt, dissolution  
 or liquidation law of any jurisdiction, whether now or hereafter in effect,  
 or consents to the filing of any petition against it under any such law; or  
  
 E. A party makes an assignment for the benefit of its creditors,  
 or admits in writing its inability to pay its debts generally as they  
 become due, or consents to the appointment of a receiver, conservator,  
 custodian, liquidator or trustee of the party, or of all or any part of its  
 property.  
  
 26.3 Return of IT Assets: In addition to any other rights or  
remedies the parties may have upon termination of this Agreement at law or in  
equity, Baxter agrees that Baxter shall, upon termination and payment in full to  
Baxter of any unpaid amounts due under this Agreement by Newco, deliver, at  
Newco's direction, and at Newco's sole risk of loss and expense, any and all IT  
Assets, any and all other specifications, drawings/blueprints and other  
documents relating solely to the Manufactured Products then held by, or under  
the control of, Xxxxxx pursuant to this Agreement and copies of any and all  
other specifications, product drawings/blueprints and procedures required for  
the manufacture of the Manufactured Products.  
  
 27. FORCE MAJEURE. Neither party to this Agreement shall be liable  
for delay or failure in the performance of any of its obligations hereunder if  
such delay or failure is due to causes beyond its reasonable control, including  
acts of God, fires, earthquakes, strikes and labor disputes, acts of war, civil  
unrest or intervention of any governmental authority, but any such delay or  
failure shall be remedied by such party as soon as is reasonably possible.  
  
 28. LIMITATION OF LIABILITY. IN NO EVENT, WHETHER AS A RESULT OF  
BREACH OF CONTRACT, TORT LIABILITY (INCLUDING NEGLIGENCE), OR OTHERWISE, SHALL  
EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, PUNITIVE, EXEMPLARY  
OR LIQUIDATED DAMAGES.  
  
 29. FOREIGN GOVERNMENT APPROVAL OR REGISTRATION. If this Agreement  
or any associated transaction is required by the law of any nation to be either  
approved or registered with any governmental authority, or any agency or  
political subdivision thereof, Xxxxxx shall assume all legal obligations to do  
so.  
  
 30. EXPORT CONTROL. Xxxxxx shall observe all applicable United  
States and foreign laws with respect to the transfer of all Manufactured  
Products to or on behalf of Newco between nations, countries or other sovereign  
states.  
  
 31. NOTICES. All notices required under this Agreement shall be in  
writing, and all such notices and other written communications (including  
product orders and invoices) shall be delivered either by hand, by a nationally  
recognized overnight delivery service (with delivery charges prepaid), by first  
class, registered or certified United States mail (postage prepaid), or by  
  
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facsimile transmission (provided that, in the case of facsimile transmission, a  
confirmation copy of the notice shall be delivered by hand, by a nationally  
recognized overnight delivery service (with delivery charges prepaid), or by  
first class, registered or certified United States mail (postage prepaid) within  
two (2) days of facsimile transmission), addressed to each party as follows:  
  
If to Baxter, such notices shall be delivered to: President  
 Baxter Biotech Group  
  
 with a copy to: General Counsel  
 Xxxxxx Healthcare Corporation  
  
  
If to Baxter, other written communications shall be delivered to:  
   
 President  
 Venture Management  
 Baxter Biotech Group  
  
 with a copy to: Associate General Counsel  
 Xxxxxx Healthcare Corporation  
  
If to Newco, such notices shall be delivered to: President  
 BIT Acquisition Corp.  
  
 with a copy to: Xxxxxxx Xxxxxx & Green, P.C.  
 000 Xxxx Xxxxxx  
 Xxx Xxxx, XX 00000  
 Attention: Xxxxxx X. Xxxxxxxxxx, Esq.  
  
If to Newco, other written communications shall be delivered to:  
   
 President  
 BIT Acquisition Corp.  
  
 with a copy to: Vice President  
 BIT Acquisition Corp.  
  
  
or such other address as any such party may designate in writing and delivered  
to the other party hereto pursuant to this Section 31. All such notices or  
other written communications shall be deemed to have been received by the  
addressee if delivered: by hand or by a nationally recognized overnight delivery  
service (with delivery charges prepaid) at the time of delivery; by first class,  
registered or certified United States mail (postage prepaid), three (3) business  
days after delivery  
  
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thereof to the United States Postal Service; or by facsimile transmission, at  
the time of transmission.  
  
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 32. DISPUTE RESOLUTION.  
  
 32.1 Provisional Remedies: The procedures specified in this  
Section 32 shall be the sole and exclusive procedures for the resolution of  
disputes between the parties arising out of or relating to this Agreement;  
   
provided, however, that a party, without prejudice to these procedures, may seek  
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a preliminary injunction or other provisional relief if, in its sole judgment,  
such action is deemed necessary to avoid irreparable damage or to preserve the  
status quo. During such action, the parties will continue to participate in  
good faith in the procedures specified in this Section 32.  
  
 32.2 Negotiations Between Executives: The parties will attempt  
in good faith to resolve promptly any claim or controversy arising out of or  
relating to the execution, interpretation or performance of this Agreement  
(including the validity, scope and enforceability of the provisions contained in  
this Section 32), by negotiations under the procedures set forth in Section 6  
concerning referral of disputes to the Corporate Committee.  
  
 32.3 Arbitration: In the event that any dispute arising out of  
or relating to this Agreement or its breach, termination or validity has not  
been resolved after good faith negotiation pursuant to the procedures of Section  
32.2, such dispute shall, upon written notice by either party to the other, be  
finally settled by arbitration administered by the Center for Public Resources  
in accordance with the provisions of its Commercial Arbitration Rules and the  
United Stated Federal Arbitration Act, as modified below:  
  
 A. The arbitration shall be heard by a panel of three (3)  
 independent and impartial arbitrators all of whom shall be selected from a  
 list of neutral arbitrators supplied by the Center for Public Resources.  
 From such list, each of Xxxxxx and Newco shall select one (1) arbitrator,  
 and the arbitrators so selected shall select a third. The panel shall  
 designate one (1) among them to serve as chair.  
  
 B. The arbitration proceedings shall be conducted in Los Angeles  
 County or Orange County in the State of California.  
  
 C. Any party may seek interim or provisional remedies under the  
 Federal Rules of Civil Procedure and the United States Federal Arbitration  
 Act as necessary to protect the rights or property of the party pending the  
 decision of the arbitrators.  
  
 D. The parties shall allow and participate in limited discovery  
 for the production of documents and taking of depositions, which shall be  
 conducted in accordance with the Commercial Arbitration Rules of the Center  
 for Public Resources. All discovery shall be completed within sixty  
  
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 (60) days following the filing of the answer or other responsive pleading.  
 Unresolved discovery disputes shall be brought to the attention of the  
 chair of the arbitration panel and may be disposed of by the chair.  
  
 E. Each party shall have up to fifty (50) hours to present  
 evidence and argument in a hearing before the panel of arbitrators,  
 provided that the chair of the panel of arbitrators may establish such  
 longer times for presentations as the chair deems appropriate.  
  
 F. The arbitration award shall be rendered by the  
 arbitrators within fifteen (15) business days after  
 conclusion of the hearing of the matter, shall be in  
 writing and shall specify the factual and legal basis  
 for the award. Judgment thereon may be entered in any  
 court having jurisdiction thereof.  
  
 G. The arbitrators are empowered to order money damages in  
 compensation for a party's actual damages, specific performance or other  
 appropriate relief to cure a breach; provided, however, that the  
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 arbitrators will have no authority to award special, punitive or exemplary  
 damages, or other money damages that are not measured by the prevailing  
 party's actual damages.  
  
 32.4 Performance During Dispute: Each party is required to  
continue to perform its obligations under this Agreement pending final  
resolution of any dispute arising out of or relating to this Agreement, unless  
to do so would be commercially impossible or impractical under the  
circumstances.  
  
 33. CHOICE OF LAW AND JURISDICTION. This Agreement shall be governed  
by and construed in accordance with the internal laws of the state of Delaware,  
without application of conflicts of law principles, and, subject to Section 32  
above, each party hereby submits to the jurisdiction and venue of any state or  
federal court in the State of Delaware. To the extent permissible by law, each  
of the parties hereby waives, releases and agrees not to assert, and agrees to  
cause its Affiliates to waive, release and not assert, any rights such party or  
its Affiliates may have under any foreign law or regulation that would be  
inconsistent with the terms of this Agreement as governed by Delaware law.  
  
 34. PROVISIONS CONTRARY TO LAW/SEVERABILITY. In performing this  
Agreement, the parties hereto shall comply with all applicable laws. Nothing in  
this Agreement shall be construed so as to require the violation of any law, and  
wherever there is any conflict between any provision of this Agreement and any  
applicable law, the applicable law shall prevail. In the event any provision of  
this Agreement conflicts with any applicable law or is otherwise determined by  
  
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an arbitrator or court having valid jurisdiction thereof to be unenforceable,  
the affected provision of this Agreement shall be deemed to have been modified  
to the extent necessary so as not to conflict with the applicable law or to be  
unenforceable or, if such modification is not possible, such provision shall be  
deemed to have been deleted herefrom, without affecting, impairing or  
invalidating the remaining provisions of this Agreement.  
  
 35. ENTIRE AGREEMENT. This Agreement, together with any exhibits or  
schedules attached hereto, constitutes the entire agreement between the parties  
as to the subject matter hereof, and all prior negotiations, representations,  
agreements and understandings are merged into, extinguished by and completely  
expressed by this Agreement.  
  
 36. WAIVERS AND MODIFICATIONS. The failure of any party to insist on  
the performance of any obligation hereunder shall not be deemed to be a waiver  
of such obligation. Waiver of any breach of any provision hereof shall not be  
deemed to be a waiver of any other breach of such provision or any other  
provision. No waiver, modification, release or amendment of any obligation  
under or provision of this Agreement shall be valid or effective unless in  
writing signed by the party to be bound by such waiver, modification, release or  
amendment.  
  
 37. NO OTHER LICENSES. Except as permitted by Section 4 or Section 5  
of this Agreement, or as may otherwise be agreed to by the parties in writing,  
neither party shall use the name of the other party in any promotional materials  
or advertising without the prior written consent of the other party. Except as  
necessary for the manufacture of the Manufactured Products as set forth in  
Sections 4 and 5 of this Agreement, and subject to Section 25 above, nothing in  
this Agreement shall grant to either party any right to the other party's  
intellectual property, including patents, patent applications, technology, know-  
how, inventions, copyrights, trademarks, service marks, logos or trade names  
("Intellectual Property"). Neither party shall at any time assert any claim to  
any goodwill, reputation or ownership of the other party's Intellectual Property  
and all uses of a party's Intellectual Property shall inure to the benefit of  
that party.  
  
 38. ASSIGNMENT. Newco may assign its rights and obligations under  
this Agreement to any Affiliate of Newco without the prior written consent of  
Xxxxxx, provided that such Affiliate is owned, directly or indirectly, by Xxxxxx  
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and VIMRx in substantially the same proportions as Newco is owned. Xxxxxx may  
assign its rights and obligations hereunder to any Affiliate of Xxxxxx without  
prior notice to or consent of Newco. No assignment by Xxxxxx or by Newco, or by  
any permitted assignee, shall be effective unless and until the assignee shall  
have agreed to become bound by the provisions of the Non-Compete Agreement to  
the same extent and in the same manner as Xxxxxx (in the case of a Xxxxxx  
assignee) or Newco (in the case of a Newco assignee) is bound. No party hereto  
may assign any of its rights or obligations under this Agreement, unless and to  
the extent expressly permitted by this Section 38. Subject to the foregoing,  
this Agreement shall inure to the benefit of and be binding on the parties'  
permitted successors and assigns.  
  
 39. INDEPENDENT PARTIES. By virtue of this Agreement, neither party  
constitutes the other as its agent (except as may otherwise be expressly  
provided herein), partner, joint  
  
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venturer, or legal representative, and neither party has express or implied  
authority to bind the other in any manner whatsoever.  
  
 40. COUNTERPARTS. This Agreement may be executed in any number of  
counterparts with the same effect as if all parties had signed the same  
document. All such counterparts shall be deemed an original, shall be construed  
together, and shall constitute one and the same instrument.  
  
 41. RULES OF CONSTRUCTION. In this Agreement, unless a clear  
contrary intention appears:  
  
 A. The singular number includes the plural number and vice versa;  
  
 B. Reference to any party includes such party's permitted  
 successors and assigns;  
  
 C. Reference to any gender includes the other gender;  
  
 D. Reference to any Section, Exhibit or Schedule means such  
 section of this Agreement, exhibit to this Agreement or schedule to this  
 Agreement, as the case may be, and references in any section or definition  
 to any clause means such clause of such section or definition;  
  
 E. "Herein," "hereunder," "hereof," "hereto," and words of  
 similar import shall be deemed references to this Agreement as a whole and  
 not to any particular section or other provision of this Agreement;  
  
 F. "Including" (and with the correlative meaning "include") means  
 including without limiting the generality of any description preceding such  
 term;  
  
 G. Relative to the determination of any period of time, "from"  
 means "from and including," "to" means "to but excluding" and "through"  
 means "through and including";  
  
 H. Reference to any law (including statutes and ordinances) means  
 such law as amended, modified, codified or reenacted, in whole or in part,  
 and in effect from time to time, including rules and regulations  
 promulgated thereunder;  
  
 I. Accounting terms used herein shall have the meanings  
 historically attributed to them by Xxxxxx International Inc., a Delaware  
 corporation, and its subsidiaries prior to the date hereof;  
  
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 J. In the event of any conflict between any of the provisions of  
 the body of this Agreement and any exhibit or schedule hereto, the  
 provisions of the body of this Agreement shall control;  
  
 K. The headings contained in this Agreement have been inserted  
 for convenience of reference only, and are not to be used in construing  
 this Agreement; and  
  
 L. Any rule of construction or interpretation which might  
 otherwise require this Agreement to be construed or interpreted against  
 either party shall not apply to any construction or interpretation hereof.  
  
  
 [THE REMAINDER OF THIS PAGE IS INTENTIONALLY LEFT BLANK]  
  
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 IN WITNESS WHEREOF, the parties have duly executed this Agreement as  
of the date first set forth above.  
  
  
 XXXXXX HEALTHCARE CORPORATION  
  
  
 By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
 Name:  
 Title:  
  
  
 BIT ACQUISITION CORP.  
  
  
 By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
 Name:  
 Title:  
  
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