

425 WOODSMILL ROAD, ST. LOUIS, MISSOURI

63017

(Address of Principal executive offices)

(Zip Code)

(314) 579-9899

Registrant's telephone number, including area code

(Former Name or Former Address; if Changed Since Last Report)

ITEM 5. OTHER EVENTS.

On June 15, 1998, Sheffield Pharmaceuticals, Inc. (the "Company") announced that it had entered into a sublicense and development agreement (the "Agreement") with Inpharzam International, S.A. of Switzerland ("Inpharzam") (an affiliate of Zambon Group, SpA) for the testing and development of the Company's rights in its MSI technology in respect of therapies for respiratory diseases. A copy of the press release disclosing information relating to the Agreement and certain other matters is attached as an exhibit to this report.

ITEM 7. FINANCIAL STATEMENTS, PRO FORMA FINANCIAL INFORMATION AND EXHIBITS.

(c) EXHIBITS

1. Press Release of the Company dated June 16, 1998.
2. Form of Sublicense and Development Agreement between Sheffield Pharmaceuticals, Inc. and Inpharzam International, S.A. (portions of this exhibit are omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SHEFFIELD PHARMACEUTICALS INC.

Date: June 22, 1998

By: /S/ JUDY ROESKE BULLOCK

Judy Roeske Bullock
Vice President and Chief Financial
Officer

EX-1
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PRESS RELEASE

For further information:

SHEFFIELD PHARMACEUTICALS, INC.	ZAMBON GROUP SPA
425 South Woodsmill Road, Suite 270	20091 Bresso
St. Louis, MO 63017	Via Lillo del Duca, 10
(314) 579-9899	Milan, Italy

Contact: Thomas Fitzgerald	Contact: Mario Galbiati
(716) 385-0810	011-39-266-52-4269

JOHN MUIR ASSOCIATES
5400 Kincheloe Drive
Los Angeles, CA 90041

Contact: John Muir
(213) 257-4701

SHEFFIELD AND ZAMBON ANNOUNCE STRATEGIC ALLIANCE FOR MSI
DELIVERY SYSTEM

ST. LOUIS, MISSOURI AND MILAN, ITALY, JUNE 16, 1998 -- Sheffield Pharmaceuticals, Inc. (AMEX:SHM) and Zambon Group SpA announced today the formation of a strategic alliance for the worldwide development and commercialization of respiratory drugs using Sheffield's proprietary Metered Solution Inhaler (MSI) system. Zambon is one of Europe's top five prescription respiratory companies.

Specific terms of the agreement, the potential value of which is in excess of \$25 million exclusive of the royalty stream or U.S. co-promotion rights, include:

- o A \$2.15 million equity investment by an affiliate of Zambon in Sheffield, which includes \$650,000 previously invested, that will result in ownership of 13% of Sheffield's outstanding common shares. In addition, upon the achievement of certain early technical milestones,

Zambon will provide Sheffield with \$2 million of interest-free loans as advances against future milestone payments.

- o Zambon assumes all development costs, which Sheffield had estimated at approximately \$20 million, for respiratory disease therapies in the MSI system, including the four drugs that are Sheffield's current focus: albuterol, ipratropium, cromolyn and beclomethasone, as well as other respiratory compounds that may be suitable for use with the MSI.
- o Zambon may designate a member of Sheffield's Board of Directors.
- o Sheffield receives milestone payments upon NDA approval of each of its current four drugs and for the first European product licenses for each of the four drugs.
-more-
- o Sheffield receives a royalty from Zambon, ranging from 5%-7%, on all Zambon sales of the MSI system.
- o Sheffield receives co-promotion rights in the United states and will be compensated in the form of a profit sharing arrangement.
- o Sheffield retains the rights to non-respiratory disease application of the MSI.

Commenting on the alliance, Thomas Fitzgerald, Sheffield's Chairman said, "We are pleased to establish this alliance with Zambon for respiratory disease applications of our MSI delivery system on a global basis. Zambon is a well-respected pharmaceutical company with extensive respiratory expertise and the resources to develop and commercialize products using our unique MSI technology. We are especially pleased to partner with a company that has a significant presence in Europe and ambitions to be a major competitor in the U.S. market." Added Fitzgerald, "This alliance allows us to focus on expanding the scope and depth of our pulmonary delivery technology portfolio while ensuring that our core MSI respiratory products progress to market in a timely fashion."

"The MSI system is an important component in the achievement of Zambon's overall strategic business objectives. The MSI system offers tangible patient benefits and represents an exciting opportunity for Zambon to develop a broad respiratory product range on a global basis. This alliance is an important step in the continued growth and development of Zambon's worldwide respiratory business," said Andrea Zambon, President and CEO, Zambon Group.

Zambon Group SpA, headquartered in Milan, Italy, is a research-intensive, multinational pharmaceutical firm. The group researches, develops and manufactures healthcare products and fine chemicals, which it markets worldwide either directly or through license.

Sheffield Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of later stage, lower risk pharmaceutical opportunities, particularly those utilizing unique pulmonary delivery technologies over a range of therapeutic areas.

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are intended to be

covered by the safe harbors created hereby. Investors are cautioned that all forward-looking statements involve risks and uncertainty, including without limitation, the ability of the company to successfully develop and commercialize its technologies. Although the Companies believes that the assumptions underlying the forward-looking statements contained herein are reasonable, any assumptions could be inaccurate, and therefore, there can be no assurance that the forward-looking statements included in this press release will prove to be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by the company or any other person that the objectives and plans of the Companies will be achieved.

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FORM OF SUBLICENSE AND DEVELOPMENT AGREEMENT

SUBLICENSE AND DEVELOPMENT AGREEMENT

BETWEEN

SHEFFIELD PHARMACEUTICALS, INC.

AND

INPHARZAM INTERNATIONAL, S.A.

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SUBLICENSE AND DEVELOPMENT AGREEMENT

AGREEMENT (this "Agreement"), made June 15, 1998, between Inpharzam International, S.A., a corporation organized under the laws of Switzerland and having its principal executive offices at Via Industria 1, 6814 Cadempino, Switzerland, and its Affiliates (as hereinafter defined)(hereinafter referred to as "Inpharzam"), and Sheffield Pharmaceuticals, Inc., a corporation organized under the laws of the State of Delaware and having offices at 37 South Main Street, Pittsford, New York 14534 (hereinafter referred to as "Sheffield").

WHEREAS, Sheffield holds i) the exclusive worldwide right to be supplied with Devices (as hereinafter defined) pursuant to the terms of Sheffield's Basic Supply Agreement with Siemens Aktiengesellschaft Keramik und Porzellanwerk (hereinafter "Siemens") dated March 21, 1997 and ii) the exclusive worldwide rights in and to the Sublicensed Patent Rights and Technology (as hereinafter defined) pursuant to the terms of Sheffield's License Agreement with Siemens dated March 21, 1997 and by virtue of its own development work; and

WHEREAS, Sheffield disclosed to Inpharzam's Affiliate (as hereinafter defined) Zambon Group, S.p.A. (hereinafter "Zambon") under a Confidentiality Agreement dated [TEXT OMITTED] (hereinafter the "Confidentiality Agreement"), information relating to a Delivery System and certain Formulations (as hereinafter defined); and

WHEREAS, Inpharzam wishes to be supplied with Devices and sublicensed under the Sublicensed Patent Rights and Technology

exclusively in the Field in the Territory (as hereinafter defined), and Inpharzam and Sheffield desire to complete testing and development of Licensed Products (as hereinafter defined); and

WHEREAS, Sheffield granted to Inpharzam an option for such supply and

sublicense under an Option Agreement dated April 14, 1998 and both parties desire to perform certain studies on various Formulations of medicines to be used in the Delivery System and to seek regulatory approval to market, distribute and sell Licensed Products in the Field in the Territory.

NOW, THEREFORE, in consideration of the promises and mutual covenants hereinafter set forth, the parties hereby agree as follows:

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1. Definitions

1.1 "AFFILIATE" means any entity which directly or indirectly controls, is controlled by or is under common control with a party to this Agreement. "Control" for the purposes of this definition means the ownership of at least fifty percent (50%) of the outstanding voting stock of a corporate entity or voting interest in a non-corporate equity.

1.2 "BASIC LICENSE AGREEMENT" means the License Agreement dated March 21, 1997 between Sheffield and Siemens.

1.3 "BASIC SUPPLY AGREEMENT" means the Basic Supply Agreement dated March 21, 1997 between Sheffield and Siemens.

1.4 "DELIVERY SYSTEM" means the multi-dose nebulizer comprising the Device and Dosator that conforms to the Specification, as may be modified and/or improved from time to time.

1.5 "DEVELOPMENT PLAN" shall mean the plan setting forth the timing and events relating to the development and registration in the Territory of four (4) mutually acceptable Licensed Products (which at this time include the Formulation for albuterol, ipratropium, cromolyn and beclomethasone, or any other Formulation mutually agreed to by the parties), as attached hereto as Appendix D.

1.6 "DEVICE" means that portion of the Delivery System to be manufactured and supplied by Siemens pursuant to the Basic Supply Agreement, as described in the Specification.

1.7 "DOSATOR" means a dosating system capable of dispensing a Formulation, as described in the Specification.

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1.8 "EFFECTIVE DATE" means the date upon which both parties sign this Agreement.

1.9 "FDA" means the United States Food and Drug Administration and any successor bodies.

1.10 "FIELD" means the use of various medicines for humans in treating respiratory disease and/or other lung disease including, but not limited to, anti-infectives.

1.11 "FIRST COMMERCIAL SALE" means the first sale by Inpharzam, its Affiliates or sublicensees of a Licensed Product to an independent third party.

1.12 "FISCAL QUARTER" means a quarter of a Fiscal Year.

1.13 "FISCAL YEAR" means the year commencing on the January 1 of the year during which the First Commercial Sale occurs.

1.14 "FORMULATION" means a preparation of a pharmaceutical capable of administration to a human by the Delivery System.

1.15 "LICENSED PRODUCT" means any combination of Dosator and Formulation in the Field which employs the Technology or which would infringe a Valid Claim of any Sublicensed Patent Rights, but for the sublicense granted in this Agreement.

1.16 "NDA" means a new drug application submitted to the FDA for approval to manufacture, promote, market, distribute and sell Licensed Products as medicine for humans in the Territory.

1.17 "NET SALES" means the total revenues received by Inpharzam or its Affiliates from the sale of Licensed Products to independent third parties less the following amounts (i) customary discounts, including cash discounts or rebates actually allowed or granted, (ii) customary credits or allowances actually granted upon claims or returns, regardless of the party requesting the return,

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(iii) separately itemized freight charges paid by Inpharzam or its Affiliates for delivery, to the extent included in revenue received. Net Sales shall not include the value of any promotional samples, including any affixed to or accompanying other products of Inpharzam.

1.18 "NON-US REGULATORY AUTHORITY" means any health agency or regulatory authority in and throughout the Territory, outside of the United States, authorized to grant marketing approval for the Licensed Products.

1.19 "SIEMENS AGREEMENTS" is a collective reference to the Basic Supply Agreement and the Basic License Agreement.

1.20 "SPECIFICATION" means the complete and detailed description of the Delivery System as set forth in Annex 2 to the Basic Supply Agreement.

1.21 "SUBLICENSSED PATENT RIGHTS" mean i) the patents and patent applications set forth in Appendix A; and ii) any and all extensions, renewals, continuations, continuations-in-part, divisions, patents-of-addition, reissues, reexaminations, supplementary protection certificates or foreign counterparts of any of the foregoing; and iii) any and all patents which are granted on any i) and ii); and iv) any and all patents and patent applications owned or controlled or licensed by Sheffield with the right to sublicense which contain claims, the practice of which would infringe the claims of a patent or patent application included in i), ii), or iii), or which are based upon or derived from the Technology.

1.22 "TECHNOLOGY" means any and all inventions, improvements, discoveries, claims, formulae, processes, data, trade secrets,

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technologies, and know-how owned or controlled or licensed by Sheffield with the right to sublicense and i) incorporated in or useful for the manufacture, use or sale of the Delivery System and/or Formulations in the Field or ii) claimed or disclosed in any patent or patent application included in Sublicensed Patent Rights.

1.23 "TERRITORY" means worldwide.

1.24 "VALID CLAIM" means a claim in any issued, unexpired patent within the Sublicensed Patent Rights which has not been held invalid or unenforceable by a nonappealed or unappealable decision by a court or other appropriate body of competent jurisdiction, and which is not admitted to be invalid through disclaimer, dedication to the public or otherwise.

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2. Conformance with Siemens Agreements

Sheffield's rights to be supplied with Devices, or in certain circumstances to manufacture Devices, and Sheffield's rights in and to the Sublicensed Patent Rights are derived from the Siemens Agreements; Sheffield's rights in and to the Technology are derived in part from the Siemens Agreements and in part from Sheffield's own development work. Any rights of Sheffield which are derived from the Siemens Agreements are subject to all of the terms and conditions thereof. It is the parties' express intent that the grant to Inpharzam by Sheffield of any rights derived from the Siemens Agreements be consistent with the terms and conditions thereof and with Sheffield's obligations thereunder.

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3. Development Program

3.1 Inpharzam agrees to carry out at its expense the development of Licensed Products set forth in the Development Plan attached as Appendix D hereto. Sheffield agrees that it shall assist Inpharzam in this development effort at no substantial cost to Sheffield, disclose to Inpharzam all Technology required by Inpharzam to evaluate Licensed Products and the marketability and regulatory status of various inhaled medicines for use with the Delivery System in the Field, and provide Inpharzam with updates of all newly-developed or newly-acquired Technology.

3.2(a) Inpharzam shall periodically provide to Sheffield copies of reports on all development work and testing performed. The reports shall include but not be limited to reports on clinical development, regulatory matters, manufacturing status and intellectual property. Sheffield shall promptly evaluate such reports and provide comments to Zambon based on the Technology, and on newly-developed or newly-acquired Technology. Representatives of the

parties shall meet at mutually convenient times to discuss planning and progress of the Development Plan.

(b) All activities of each party shall be carried out by each party in strict compliance with all applicable federal, state, or local laws, regulations or guidelines governing such activities. Without limiting the generality of the foregoing, neither party shall knowingly infringe any United States or foreign patent or copyright owned by any third party in connection with the performance of its obligations under this Agreement.

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3.3 Inventions

(a) All intellectual property rights such as patents, patent applications, inventions, data, know-how and the like (hereinafter "Intellectual Property"), owned or controlled by either party prior to the parties entering into this Agreement or the Option Agreement, shall remain the property of such party, subject only to the rights granted herein and to Sheffield's obligations under the Siemens Agreements.

(b) All Intellectual Property conceived and/or first reduced to practice during the term of this Agreement or the Option Agreement solely by personnel employed by or on behalf of either party shall remain the property of such party, subject only to the rights granted herein and to Sheffield's obligations under the Siemens Agreements.

(c) All Intellectual Property conceived and/or first reduced to practice during the term of this Agreement or the Option Agreement jointly by personnel employed by or on behalf of both parties shall be owned jointly, subject only to the rights granted herein and to Sheffield's obligations under the Siemens Agreements. Should the parties agree to file patent applications for the same, they shall do so, employing an attorney or agent mutually agreed upon to act in their joint behalf and shall share the costs related thereto equally. In the event that only one party seeks patent protection, then that party shall bear all costs and the other party shall cooperate fully in the prosecution and enforcement of any patent application or patent resulting therefrom.

3.4 Inpharzam has previously paid to Sheffield the option sum of Six Hundred Fifty Thousand Dollars (\$650,000.00), the receipt of

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which is hereby acknowledged, as an investment in the common stock of Sheffield. Sheffield has delivered to Inpharzam a Certificate for such common stock, the receipt of which is also hereby acknowledged.

3.5 Promptly after the Effective Date of this Agreement, Sheffield shall disclose to Inpharzam all of the Technology required by Inpharzam to practice the Sublicensed Patent Rights and Technology licensed to Inpharzam hereunder, and shall certify that all such information has been provided.

3.6 Sheffield and Inpharzam agree to form a Committee, which shall monitor the progress of the development program and the submissions of the NDA's

for the Licensed Products, as set forth in the Development Plan.

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4. Exclusive Sublicenses

4.1 Sheffield hereby grants to Inpharzam an exclusive sublicense in the Field under the Sublicensed Patent Rights and the Technology, with the rights to grant further sublicenses, to make, have made, use and have sold Licensed Products in the Territory, subject to the Co-Promotion Rights set forth in Section 4.10. Notwithstanding anything in this Agreement to the contrary, the parties hereby expressly agree that the sublicense granted to Inpharzam herein does not extend to chemical entities developed or acquired by Sheffield after the execution of this Agreement. However, Sheffield agrees that in the event that such compounds are developed or acquired (a) it shall negotiate in good faith for the licensing of such chemical entities for use with the Delivery System in the Field to Inpharzam; and (b) it shall not license such chemical entities for use with the Delivery System in the Field to any third-party.

4.2 As consideration for the rights granted herein by Sheffield to Inpharzam, Inpharzam hereby agrees to make the following payments to Sheffield:

(a) Upon execution of this Agreement, Inpharzam shall make an additional investment in the common stock of Sheffield in the amount of [TEXT OMITTED], in return for which Sheffield shall issue to Inpharzam in Inpharzam's name [TEXT OMITTED] shares of the common stock of Sheffield, all in accordance with the terms of a Subscription Agreement For Shares Of Common Stock ("Subscription Agreement") executed simultaneously herewith and attached hereto as Appendix B.

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(b) Said Subscription Agreement shall include a stock purchase option on the part of Inpharzam granting Inpharzam, in the event of a public or private sale of additional shares of common stock of Sheffield at a certain offering price, an option to purchase within ninety (90) days of that sale enough additional shares of common stock of Sheffield at that offering price, so that Inpharzam's percentage ownership of common stock of Sheffield immediately prior to such public or private sale may be maintained.

(c) In addition, Inpharzam shall be entitled as of the date hereof to designate one member of the Board of Directors of Sheffield, which member shall be reasonably acceptable to Sheffield, and which board shall consist of a maximum of seven members and which board shall not be expanded during the period in which Inpharzam has the right to designate a member of the board of Sheffield, in accordance with a resolution of the Board of Directors of Sheffield dated July 15, 1998, a copy of which shall be attached hereto as Appendix C. Inpharzam shall have the right to maintain its designee on the board only for so long as Inpharzam or its Affiliates hold [TEXT OMITTED].

(d) Upon execution of this Agreement Inpharzam agrees to extend to Sheffield an interest free line of credit loan in the amount of [TEXT OMITTED]. Such line of credit loan may be drawn down and received by Sheffield in two payments as follows, with each payment being secured by a promise by

Sheffield in the form of the Promissory Note attached as Appendix E hereto to repay the amount drawn down by October 1, 2002, in accordance with the schedule set forth therein, or earlier as hereinafter provided:

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1. [TEXT OMITTED] upon proof of principle of delivery of albuterol and the issuance of a report of the type set forth in Appendix F attached hereto.

2. [TEXT OMITTED] upon the conclusion of successful beclomethasone formulation studies demonstrating technical feasibility and the issuance of a study report of the type set forth in Appendix G attached hereto.

(e) The parties agree that in the event that marketing approvals for Licensed Products are not obtained prior to [TEXT OMITTED], they will discuss in good faith whether and to what extent the repayment schedule set forth in this Agreement and its Appendix E should be modified.

(f) Inpharzam shall make up to [TEXT OMITTED] additional milestone payments to Sheffield, each in the amount of [TEXT OMITTED], on the first business day following receipt by Inpharzam of a written approval letter from the FDA with respect to the first [TEXT OMITTED] mutually acceptable Licensed Products in the U.S. and on the first business day following receipt by Inpharzam of a written approval letter from a Non-US Regulatory Authority in any of the major countries in Europe, specifically Italy, France, Germany, Spain and the U.K., with respect to the first [TEXT OMITTED] mutually acceptable Licensed Products to be incorporated into the Development Plan. The mutually acceptable Licensed Products include at this time the Formulation for the following:

1. albuterol
2. ipratropium
3. cromolyn
4. beclomethasone,

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or any other medicines mutually agreed to by both parties. It is expressly understood that the receipt of a written approval letter from a Non-US Regulatory Authority in a major European country of any Licensed Product that has already been approved in a different major European country shall not trigger an additional milestone payment. Moreover, under no circumstances shall Inpharzam be required to make payments to Sheffield under this subsection in excess of [TEXT OMITTED].

(g) At the time of receipt of each of the milestones set forth in subsection 4.2(f), Sheffield shall, if applicable, make a payment of [TEXT OMITTED] to Inpharzam to pay down the balance of any outstanding loans set forth under subsection 4.2(d). The payments set forth in this subsection 4.2(g) shall be applied equally to the balances of any of the loans set forth in subsections 4.2(d)(1) and 4.2(d)(2) of this Agreement that were drawn down by Sheffield, to

reduce or eliminate (as may be applicable) the earliest of any payments that may be due. Under no circumstances shall Sheffield be required to pay to Inpharzam more than the outstanding loan amount.

(h) It is hereby expressly acknowledged that Sheffield has paid to Siemens the 1998 annual license fee of DM 2,000,000.00, in accordance with Section 3.2 of the Option Agreement between Sheffield and Zambon. At the time of execution of this Agreement and, thereafter, at the time each of the above milestone payments shall be due and payable to Sheffield, and as a condition precedent to payment by Inpharzam, Sheffield shall submit to Inpharzam a letter from Siemens confirming that the Siemens Agreements are in

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full force and effect and that there are no material defaults thereunder.

(i) Sheffield agrees to use reasonable commercial efforts to cooperate with Inpharzam in any and all efforts involving contacts with and negotiations with third party suppliers of raw materials, component parts, formulators and manufacturers of Dosators or other items related to Licensed Products including but not limited to [TEXT OMITTED] Sheffield further agrees that it shall use its best efforts to cause Siemens to extend the Basic License Agreement and Basic Supply Agreement beyond their initial terms, in accordance with Sections 9.1 and 13.1, respectively, thereof.

4.3 Royalties

(a) Royalties shall be paid to Sheffield within 45 days of the end of each Fiscal Quarter as follows:

(1) [TEXT OMITTED] of Net Sales made that Fiscal Quarter of Licensed Products for all sales less than [TEXT OMITTED] in any Fiscal Year;

(2) [TEXT OMITTED] of Net Sales made that Fiscal Quarter of Licensed Products for all sales in excess of [TEXT OMITTED] but less than [TEXT OMITTED] in any Fiscal Year;

(3) [TEXT OMITTED] of all Net Sales made that Fiscal Quarter of Licensed Products for all sales in excess of [TEXT OMITTED] in any Fiscal Year;

(4) [TEXT OMITTED] of all payments received by Inpharzam or its Affiliates from sublicensees for the sale of Licensed Products; and

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(5) During a time in which there are no Valid Claims under the Sublicensed Patent Rights, the royalty rates set forth above shall be [TEXT OMITTED].

(b) Royalties shall be earned and paid by Inpharzam to Sheffield, until the last Valid Claim under the Sublicensed Patent Rights expires. No royalties

shall be payable on sales transactions between Inpharzam and any Affiliate or sublicensee. Only one applicable royalty payment shall be due on the sale of each Licensed Product.

4.4 For purposes of determining the amount of royalties payable under Section 4.3, a sale in a foreign currency shall be converted into U.S. dollars at an exchange rate as published on the last business day of the applicable Fiscal Quarter in the Exchange Rate section of the U.S. edition of the WALL STREET JOURNAL. In the event such rate is not available, a comparable exchange rate shall be mutually agreed upon by the parties.

4.5 Royalty payments due to Sheffield from Inpharzam shall be accompanied by a written report of all Net Sales during the applicable Fiscal Quarter and will be paid in U.S. dollars.

4.6 Records

Both parties shall maintain accurate and complete records, which shall be available for review and audit by the other party at reasonable times, as set forth hereinafter.

4.7 Upon the request of Sheffield, Inpharzam will permit, and will cause its sublicensees to permit, an independent certified public accountant selected by Sheffield and reasonably acceptable to Inpharzam to have access, not more than twice in each calendar year, during regular business hours and upon reasonable notice to

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Inpharzam and its sublicensees, to the records of Inpharzam and its sublicensees, which may be necessary to verify the accuracy of the quarterly reports made during the previous Fiscal Year. Said accountant shall not disclose to Sheffield any information except that which, in the reasonable judgment of Inpharzam, should properly have been contained in such quarterly report.

4.8 Sheffield and Inpharzam agree and acknowledge that all amounts payable to Sheffield under this Agreement shall be paid in full by Inpharzam to Sheffield without deduction for any withholding or similar tax. At the written request of Inpharzam made to Sheffield from time to time, Sheffield agrees to execute and deliver such forms as may be delivered to Sheffield to permit Inpharzam to take advantage of any withholding tax exemptions or reductions that may be available under applicable tax treaties or tax laws with respect to amounts payable to Sheffield under this Agreement.

4.9 Regulatory

Inpharzam or its Affiliates shall have, consistent with the guidelines set forth in the Development Plan, the exclusive authority over all clinical studies and for preparing, filing, and obtaining approval of the NDA in the United States and the appropriate marketing approvals throughout the Territory. Such authority shall include, but not be limited to, Inpharzam's or its Affiliates' determination of which medicines used in the Delivery Systems shall be filed for approval in which countries and when.

4.10 Co-promotion Rights

Concurrent with its execution of this Agreement, Inpharzam grants to Sheffield a right to co-promote Licensed

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Products in the U.S. market consistent with the principles set forth in Appendix H hereto ("Co-promotion Rights"). Prior to submission of the first application to the FDA for authority to market a Licensed Product, but in no event later than twelve months after the execution of this Agreement, Inpharzam or its designee and Sheffield shall conclude negotiations of the terms and conditions of such Co-promotion Rights and the parties shall agree upon a Commercialization Plan. The Commercialization Plan shall establish the minimum requirements for each of the marketing entities including but not limited to necessary personnel, geographic territories, and medical specialties, and provide for the establishment of a co-marketing committee. The co-marketing committee shall be chaired by Inpharzam or its designee, and Inpharzam shall choose the trademarks for the products and all details of the marketing program.

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5. Representations, Warranties and Additional Covenants

5.1 Sheffield hereby represents and warrants to Inpharzam that:

(a) Sheffield is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all corporate power and authority to carry on its business as now being conducted and to own its properties and is duly licensed or qualified as a foreign corporation in each jurisdiction in which its failure to qualify would have a material adverse effect on the business, financial condition or operations of Sheffield.

(b) Sheffield has full corporate power and authority to enter into this Agreement and to consummate the transactions contemplated hereby. The execution, delivery and performance of this Agreement by Sheffield have been duly authorized by all requisite corporate action. This Agreement has been duly executed and delivered by Sheffield and constitutes a valid and binding obligation enforceable in accordance with its terms, subject, as to enforcement, to applicable bankruptcy, reorganization, insolvency, moratorium, and other laws affecting creditors' rights generally from time to time in effect.

(c) Neither Sheffield nor any of its Affiliates is a party to, subject to or bound by any agreement or any judgment, award, order, writ, injunction or decree of any court, governmental body or arbitrator which would conflict with or be breached by the execution, delivery or performance of this Agreement by Sheffield or which could prevent the carrying out of this Agreement.

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(d) There is (i) no action, suit, dispute or governmental, administrative, arbitration or regulatory proceeding pending or, to Sheffield's

or its Affiliates' best knowledge, threatened nor (ii) to Sheffield's best knowledge, any investigation pending or threatened against or relating to Sheffield which, in each case, could prevent the carrying out of this Agreement.

(e) All consents of third parties, governmental authorities and non-governmental self-regulatory agencies, and all filings with and notifications of governmental authorities, regulatory agencies (including non-governmental self-regulatory agencies) or other entities which regulate the business of Sheffield necessary on the part of Sheffield to the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been obtained or effected.

(f) Subject to the terms and conditions of the Siemens Agreements, Sheffield is the sole and exclusive holder of the Sublicensed Patent Rights and Technology rights, and such rights granted herein to Inpharzam will not violate the rights of any third party. Further, the patents and patent applications set forth in Appendix A are all of the patents licensed from Siemens under the Basic License Agreement. Sheffield will promptly update Appendix A from time to time, as necessary.

(g) To the best of Sheffield's knowledge, as of the Effective Date, it knows of no facts which would make the sublicense granted herein or the patents or patent applications which are the subject thereof invalid or defective, and it knows of no third party patents which would, or patent applications which if

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issued would, be infringed by either party operating under the terms of this Agreement. Sheffield agrees to make Inpharzam aware of any such third party patents and applications promptly upon becoming aware of the same.

5.2 Inpharzam hereby represents and warrants to Sheffield that:

(a) Inpharzam is a corporation duly organized, validly existing and in good standing under the laws of Switzerland and has all corporate power and authority to carry on its business as now being conducted and to own its properties and is duly licensed or qualified as a foreign corporation in each jurisdiction, in which its failure to qualify would have a material adverse effect on the business, financial condition or operations of Inpharzam.

(b) Inpharzam has full corporate power and authority to enter into this Agreement and to consummate the transactions contemplated hereby. The execution, delivery and performance of this Agreement have been duly authorized by all requisite corporate action. This Agreement has been duly executed and delivered by Inpharzam and constitutes a valid and binding obligation of Inpharzam, enforceable in accordance with its terms, subject, as to enforcement, to applicable bankruptcy, reorganization, insolvency, moratorium, and other laws affecting creditors' rights generally from time to time in effect.

(c) Neither Inpharzam, nor any Affiliate of Inpharzam, is a party to, subject to or bound by any agreement or any judgment, award, order, writ, injunction or decree of any court, governmental body or arbitrator, which would conflict with or be breached by the execution, delivery or performance of

this

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Agreement by Inpharzam or which could prevent the carrying out of this Agreement.

(d) There is (i) no action, suit, dispute or governmental, administrative, arbitration or regulatory proceeding pending or, to Inpharzam's best knowledge, threatened nor (ii) to Inpharzam's best knowledge, any investigation pending or threatened against or relating to Inpharzam or its Affiliates which, in each case, could prevent the carrying out of this Agreement.

(e) All consents of third parties including, without limitation, governmental authorities and non-governmental self-regulatory agencies, and all filings with and notifications of governmental authorities, (including non-governmental self-regulatory agencies) regulatory agencies or other entities, which regulate the business of Inpharzam or its Affiliates necessary on the part of Inpharzam to the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been obtained or effected.

(f) All Licensed Products labeled, advertised, and sold by Inpharzam, its Affiliates and its sublicensees shall be in compliance with all applicable requirements of the Food, Drug and Cosmetic Act and all other laws and regulations applicable thereto.

5.3 The representations and warranties of the parties set forth in Sections 5.1 and 5.2 shall survive the termination, cancellation or expiration of this Agreement without limitation.

5.4 Sheffield and Inpharzam and its Affiliates further agree as follows:

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(a) Licensed Products will be manufactured, stored and sold in compliance with all applicable requirements of the Food, Drug and Cosmetic Act and regulations promulgated thereunder.

(b) Sheffield shall disclose to Inpharzam and Inpharzam and its Affiliates shall disclose to Sheffield any reports or other knowledge they receive with respect to adverse drug experiences, mislabeling, stability failures or contaminations, to the extent that those items relate to the Delivery System or the Licensed Products. Sheffield, Inpharzam and its Affiliates shall comply with FDA requirements for reporting adverse drug experiences.

(c) Except as otherwise expressly provided herein, all data pertaining to the Technology generated prior to the Effective Date of this Agreement and pursuant to this Agreement shall be available to Inpharzam, which shall have the unrestricted right to use such data in the Field anywhere in the Territory.

(d) Any written information, submitted by one party, or by an Affiliate of one party, to the other party, or to an Affiliate of the other party, that is designated "Confidential" shall be treated as confidential, and reasonable diligence will be used not to disclose or make available any such confidential information to any third party for the term of this Agreement, and for a period of five (5) years following termination, cancellation or expiration hereof.

An oral disclosure, if reduced to writing by the disclosing party and submitted to the party that received the oral disclosure within thirty (30) days of the oral disclosure, will be deemed confidential.

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Confidential Information shall not include information:

(i) that can be demonstrated to have been in the public domain prior to the date of its receipt;

(ii) that becomes part of the public domain by publication, or otherwise, not due to any unauthorized act or omission;

(iii) that is supplied by a third party lawfully in possession of same and not under any obligation of confidentiality to Sheffield or Inpharzam or its Affiliates with respect to the information; or

(iv) that was known to Sheffield or Inpharzam or its Affiliates prior to the date of its disclosure, such knowledge being evidenced by written records.

However, nothing set forth in this subsection shall prevent any party or its Affiliates from making a disclosure that is required by applicable laws or regulations.

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6. Business Decisions and Commercial Efforts

6.1 Subject to the Co-promotion Rights set forth in Section 4.10, all business decisions related to the Licensed Products in the Field including, without limitation, regulatory activities, sale price and promotion of products covered under this Agreement shall be within the sole discretion of Inpharzam.

6.2 Inpharzam hereby agrees that it shall use commercially reasonable efforts, or shall cause its Affiliates to use commercially reasonable efforts, to seek FDA approval for and to market and sell Licensed Products in the Field in the U.S., and to seek Non-US Regulatory Authority approval for and to market and sell Licensed Products in the Field in the remainder of the Territory.

6.3 In the event that Inpharzam makes a decision not to seek FDA approval for and/or a decision not to market and sell any Licensed Products in the U.S. or sublicense a third-party to do the same, Inpharzam shall grant to

Sheffield an exclusive sublicense, with the right to grant further sublicenses, in the U.S. in and to all of the rights acquired by Inpharzam under this Agreement, for which exclusive sublicense Sheffield shall pay to Inpharzam either:

(a) in the event that Sheffield does not grant a further sublicense, (i) [TEXT OMITTED] Inpharzam's total expenditures, based upon Inpharzam's normal accounting methods, in developing Licensed Products for and seeking FDA approval for the U.S. market and (ii) [TEXT OMITTED] of Sheffield's Net Sales (as defined in subsection 1.17 of this Agreement, substituting Sheffield for Inpharzam) of Licensed Products; or

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(b) in the event that Sheffield does grant further sublicenses, [TEXT OMITTED] of all milestone, royalty and other payments received from sublicensees.

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7. Data

Sheffield and Inpharzam agree as follows with respect to the data related to the Technology generated pursuant to this Agreement and the NDA's:

(a) Subject to the Co-Promotion Rights sets forth in Section 4.10, Inpharzam shall have the exclusive right to use such data in the Field in connection with its commercialization of the Licensed Products.

(b) Sheffield shall have the right to use such data outside of the Field.

(c) Upon the expiration of the last Valid Claim under the Sublicensed Patent Rights, Inpharzam shall have the right to use all data related to the Technology generated pursuant to this Agreement for all purposes, and shall have the right to make, have made, use and sell Licensed Products [TEXT OMITTED].

(d) Inpharzam agrees that it will share, and will cause its Affiliates and sublicensees to share, data relating to the Delivery System, but not to Formulations, with Sheffield and other licensees of Sheffield if such other licensees similarly agree to and do in fact share their such data with Inpharzam.

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8. Indemnification and Infringement

8.1 Inpharzam and Sheffield shall each indemnify and hold the other harmless from and against any costs, expenses or damages which arise from a breach of their respective obligations, covenants, representations or warranties herein, excluding, however, any amounts representing loss of profits.

8.2 Inpharzam agrees to indemnify and hold Sheffield harmless from and against any costs, expenses or damages resulting from or otherwise arising out of manufacturing defects in Licensed Products. Sheffield agrees to indemnify and hold Inpharzam harmless from and against any costs, expenses or damages resulting from or otherwise arising out of manufacturing defects in the Device. Notwithstanding the provisions of this Section 8.2, in no event shall either party be liable to the other party for any indirect or consequential damages, including but not limited to loss of profit or interest, production stoppages, operation breakdowns, handling or labor costs or loss of data and retrieval costs, nor for any punitive damages, except where such liability is mandatory by law due to intent or gross negligence.

8.3 The party obligated to provide indemnity pursuant to this Article 8 is hereinafter referred to as the "Indemnifying Party". Promptly after the receipt by any party hereto of notice of (a) any claim or (b) the commencement of any action or proceeding, such party will, if a claim with respect thereto is to be made against any party obligated to provide indemnification pursuant to this Agreement, give such Indemnifying Party written notice of such claim or the commencement of such action or proceeding. Such Indemnifying Party shall have the right, at its option, to

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compromise or defend, at its own expense and by its counsel, any such matter involving the asserted liability of the party seeking such indemnification. Such notice, and the opportunity to compromise or defend, shall be a condition precedent to any liability of the Indemnifying Party under the indemnification agreement contained in this Agreement.

In the event that any Indemnifying Party shall undertake to compromise or defend any such asserted liability, it shall promptly notify the party seeking indemnification of its intention to do so, and the party seeking indemnification agrees to cooperate fully with the Indemnifying Party and its counsel in the compromise of, or defense against, any such asserted liability. In any event, the indemnified party shall have the right, at its own expense, to participate in the defense of such asserted liability, provided that the Indemnifying Party's counsel shall make all final decisions concerning the defense or compromise or settlement of such claim or litigation.

8.4 In the event a third party appears to be infringing one or more Licensed Patents, Sheffield shall, at its own expense, take whatever steps in its own and sole discretion it deems advisable including, but not limited to, settlement or the filing of suit for damages or to enjoin such sales or offers for sale by such third party. Inpharzam agrees, upon reasonable notice, to cooperate and, to the extent deemed necessary or desirable by Sheffield and at Sheffield's expense, participate in any suit to enjoin such infringement and to collect, for Sheffield's sole and exclusive benefit any and all damages, profits and awards of any nature recoverable for such infringement.

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8.5 Should Sheffield elect not to take any action, or fail to take action within thirty (30) days following notice by Inpharzam of an apparent

infringement, Inpharzam shall have the right, at its expense, to take whatever steps in its own and sole discretion it deems advisable including, but not limited to, settlement or the filing of suit for damages or to enjoin such sales or offers for sale by such third party. Sheffield agrees to perform all acts which are or may become necessary to vest in Inpharzam the right to institute any such suit and will, upon reasonable notice, cooperate and, to the extent deemed necessary or desirable by Inpharzam and at Inpharzam's expense, participate in any suit to enjoin such infringement and to collect, for Inpharzam's sole and exclusive benefit, any and all damages, profits and awards of any nature recoverable for such infringements.

8.6 In the event a third-party is infringing a Valid Claim of the Sublicensed Patent Rights, then on request from Inpharzam Sheffield shall, at Sheffield's sole discretion, take reasonable action to remove such infringing activity or grant Inpharzam the right to bring suit. In the event that Sheffield elects to grant Inpharzam the right to bring suit, Inpharzam shall have during the pendency of the suit the right to deposit in an interest-bearing escrow account fifty-percent (50%) of the royalties payable to Sheffield with respect to the Net Sales of Licensed Products in the country in which the infringement is occurring. Upon final determination of the suit, all royalties held in escrow shall be released to Sheffield, less the reasonable costs and attorney fees incurred by Inpharzam in connection with such suit, which costs and fees shall not exceed the total amount of royalties held in escrow.

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8.7 In the event that any third-party raises claims against or sues Inpharzam in connection with the Device, Sheffield shall defend, indemnify, and hold harmless Inpharzam from and with respect to any claim, demand, damage, liability, cause of action, costs and/or expenses (including reasonable attorneys' fees) of whatever kind or nature, whether arisen, arising or to arise in the future from or directly or indirectly related to, patents, patent applications, copyrights, or similar. Sheffield shall at its sole discretion and cost acquire a license on such intellectual property rights. Sheffield shall alternatively cause the Devices to be modified so as to become noninfringing provided such modification does not violate Inpharzam's regulatory approvals, with the written consent of Inpharzam. In any event, Sheffield shall take form Inpharzam Devices which are not salable due to infringement and reimburse Inpharzam the price paid therefor. The aforementioned liability shall, however, only be valid if Inpharzam informs Sheffield to this effect without any delay and in writing, does not acknowledge or accept of its own accord any such claims and does not conduct negotiations with such third-party without the prior consent of Sheffield and in accordance with the instructions of Sheffield.

8.10 The provisions of this Article 8 shall survive the termination, cancellation or expiration of this Agreement without limitation.

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9. Termination

9.1 In the event of any default by either party, or an Affiliate of either party, in the performance of any of the material terms or conditions of this Agreement, the other party may terminate this Agreement upon ninety (90)

days' written notice; provided, however, that (a) if during such ninety (90) day period the party against whom the default is claimed cures such default, or (b) if such breach cannot be cured within such ninety (90) day period, such party takes reasonable steps to commence and proceeds diligently after default, and, in fact, cures such default within a reasonable period of time, or (c) if such default is cured in any other manner satisfactory to the other party as a substitute for full performance, then this Agreement will continue in full force and effect as if the default had not occurred.

9.2 Upon termination of this Agreement for Sheffield's failure to cure a material breach, the NDA's and regulatory and marketing approval throughout the Territory shall be retained and owned by Inpharzam.

9.3 This Agreement may be terminated (a) in the event that a case or proceeding shall be commenced and continue undismissed or unstayed for a period of thirty (30) days against either party or either party shall commence a voluntary case, in either case seeking relief under the bankruptcy laws or any other law relating to bankruptcy, insolvency, reorganization, winding up or composition or adjustment of debts, in each case as now or hereafter in effect, or (b) either party shall apply for, consent to, or fail to contest, the appointment of a receiver, liquidator, custodian, trustee or the like of such party or for all or any part

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of its property, or (c) either party shall make a general assignment for the benefit of its creditors, or (d) either party shall fail, or admit in writing its inability, to pay, or generally not be paying, its debts as they become due, in each case, by the other party.

9.4 All rights and sublicenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for the purposes of Section 365(n) of Title 11, U.S. Code ("Bankruptcy Code") license rights to "intellectual property" as defined under Section 101(60) of the Bankruptcy Code. The parties agree that Inpharzam, as sublicensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code.

9.5 Termination of this Agreement for any reason shall not relieve either party of any obligations occurring prior to such termination.

9.6 The sublicenses granted hereunder shall terminate upon termination or cancellation of this Agreement.

9.7 Upon the expiration of the last Valid Claim under the Sublicensed Patent Rights, Inpharzam shall have a royalty free license to continue to market all Licensed Products royalty free.

9.8 Upon termination of this Agreement for Inpharzam's failure to cure a material breach of this Agreement, in addition to any other remedies that Sheffield may have available, all rights in and to the Sublicensed Patent Rights and the Technology granted by Sheffield to Inpharzam hereunder shall revert to Sheffield.

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9.9 The provisions of Sections 5.1 and 5.2, and Articles 8, 14 and 16 shall survive termination, cancellation or expiration of this Agreement without limitation. The provisions of subsection 5.4(e) shall survive termination, cancellation or expiration of this Agreement to the extent provided therein. In the event of termination each party shall return and/or destroy all copies and other tangible forms of the other's confidential information except that one copy may be retained by legal counsel for archival and evidentiary purposes.

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10. Events of Force Majeure

10.1 "Force Majeure" shall mean any cause which is beyond the reasonable control of the party invoking Force Majeure and which, by the exercise of reasonable diligence, such party is unable to prevent, including but not limited to, and whether or not of the same class or kind as, the following: any law, decree, regulation, order, or request of any governmental authority (national, state or regional), nationalization, expropriation, confiscation, requisition, riot, war, hostilities, public disturbance, act of the public enemy, act of terrorism, strike lockout or other labor dispute, fire, flood, earthquake, storm, tidal wave, explosion, Act of God, accident of navigation, breakdown or failure of transportation or transportation facilities.

10.2 If either party is prevented from or delayed in carrying out any provision of this Agreement by reason of Force Majeure, the party whose performance is so prevented, delayed, interfered with or restricted, upon prompt written notice thereof to the other party, shall be excused from such performance to the extent and during the period of such prevention, delay, interference or restriction.

10.3 The provisions of this Article 10 shall not be available to a party, if such party fails to use reasonable diligence to remedy the applicable situation described in subsection 10.1 above in an adequate manner and with all reasonable dispatch or if such applicable situation is caused by such party, except that this Article 10 shall not require the unreasonable settlement of controversies by acceding to the demands of the opposing party or parties.

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11. Specific Performance

Each party agrees that a violation by it of any of its covenants and undertakings contained in this Agreement may cause irreparable injury to the other, and that such other party shall be entitled, in addition to any other rights and remedies it may have hereunder or at law or in equity, to an injunction or similar equitable remedy enjoining and restraining any such violation or threatened violation thereof.

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12. Further Assurances

Each of the parties shall, from time to time during the term of the Agreement upon request by the other, execute and deliver all such further documents or instruments as may be required in order to give effect to the purpose and intent of this Agreement. Without limiting the generality of the foregoing, the obligations of the parties hereunder are undertaken with a principal objective of complying with all pertinent provisions of applicable law, orders and regulations relating to the manufacture, use or sale of pharmaceutical products, and the parties shall take all necessary action as may be required to comply with such provisions.

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13. Assignment

This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective assigns and successors in interest; provided, however, that neither party may assign or otherwise transfer its interest, or any part thereof, under this Agreement to any other person, firm or corporation without the written consent of the other party, which consent shall not be unreasonably withheld, except (a) in connection with the transfer of all or substantially all of the assets of Inpharzam or Sheffield to any other person, whether by means of a merger, asset or stock sale or otherwise, or (b) to an Affiliate, provided that the transferring party shall guaranty its transferee-Affiliate's performance and compliance hereunder and shall notify the other party in writing of such transfer.

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14. Choice of Law

This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York, without giving effect to its principles of conflicts of law.

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15. Contractual Relationship

Sheffield and Inpharzam are independent contractors and shall not be deemed to be partners, joint venturers or each other's agents, and neither shall have the right to act on behalf of the other except as expressly provided hereunder or otherwise expressly agreed to in writing.

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16. Notices

All notices and other communication required or permitted to be given under or in connection with this Agreement shall be in writing and shall be deemed given if delivered personally or by facsimile transmission (receipt verified), express courier service (signature required), telexed, or

mailed by registered or certified mail (return receipt requested), postage prepaid, to the parties at the following addresses (or at such other address for a party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof):

If To Inpharzam:

If To Sheffield:

Inpharzam International

Sheffield Pharmaceuticals

Via Industria 1

37 South Main Street

6814 Cadempino, Switzerland

Pittsford, NY 14534

Attn: Managing Director

Att: Chairman

Fax: 011 41919664351

Fax: 716-385-0813

With a copy to:

With a copy to:

Zambon Corporation

Sheffield Pharmaceuticals

One Meadowlands Plaza

425 South Woodsmill Road

East Rutherford, NJ 07073 USA

Suite 270

Att: General Manager

St. Louis, MO 63017

Fax: 201/896-2209

Att: Corporate Secretary

Fax: 314-579-9799

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17. Miscellaneous

17.1 This Agreement (including the Appendices attached hereto) and the Confidentiality Agreement constitute the entire agreement between the parties and, except as noted in Article 2 of this Agreement, supersede all prior written or oral agreements or understandings concerning the subject matter thereof or in conflict with their terms.

17.2 Any controversy or claim arising out of or relating to this Agreement, or the parties' decision to enter into this Agreement, or the breach thereof, including, without limitation, any dispute relating to patent validity or infringement arising under this Agreement, shall be settled by arbitration in accordance with the applicable rules of the American Arbitration Association, and judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. Such arbitration shall be conducted with a panel of three (3) arbitrators; each party shall select one arbitrator and the two selected arbitrators shall select the third. The arbitration shall be held in New York City and the arbitrators shall apply the substantive law of the State of New York, except that the interpretation and enforcement of this arbitration provision shall be governed by the U.S. Federal Arbitration Act. The arbitrators shall not award either party punitive damages and the parties shall be deemed to have waived any right to such damages.

17.3 Each party hereby consents that it shall be subject to jurisdiction in New York in any legal proceeding or equitable action that relates in any way to this Agreement, and further consents to venue for any such proceeding or action in the United

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States District Court for the Southern District of New York. Inpharzam hereby designates Zambon Corporation as its agent for service of process in connection with any legal action which may be brought hereunder and agrees to maintain such designation during the term hereof.

17.4 No modification or waiver of any of the terms of this Agreement shall be deemed valid unless it is in writing and signed by the party against whom such modification is sought to be enforced. The failure of either party to insist upon the strict performance of any term of this Agreement or the waiver by either party of any breach under this Agreement shall not prevent the subsequent strict enforcement of such term and shall not be deemed a waiver of any subsequent breach.

17.5 In the event any court declares illegal or unenforceable, as written or applied, any provision or portion hereof, such provision shall be treated as if it had been deleted or rendered inapplicable to the situations to which such provision cannot be legally applied.

17.6 Neither party shall publicly disclose, directly or through any of its representatives, the subject matter or terms and conditions hereof without the prior consent of the other, except to the extent of disclosures which either party may be required to make by applicable laws or regulations.

17.7 Each party agrees that, unless the other party has given its written consent thereto, no public announcement or other disclosure shall be made by either party or any of their representatives, including their consultants, that might prejudice the rights of the other.

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17.8 Inpharzam shall cause all Licensed Products or the packaging therefor sold in the Territory by it, its Affiliates and its sublicensees to be labelled in accordance with any obligations undertaken by Sheffield in the Siemens Agreements, and in accordance with all applicable laws and regulations, including but not limited to the marking provisions set forth in Title 35 Section 287 of the United States Code.

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IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the respective dates written below.

SHEFFIELD PHARMACEUTICALS, INC.

By: /S/ THOMAS M. FITZGERALD

Name: THOMAS M. FITZGERALD

Title: CHAIRMAN

Dated: JUNE 15, 1998

INPHARZAM INTERNATIONAL, S.A.

By: /S/ ANDREA ZAMBON

Name: ANDREA ZAMBON

Title: CHIEF EXECUTIVE OFFICER

Dated: JUNE 15, 1998

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CONFIDENTIAL

APPENDIX A

PATENTS AND PATENT APPLICATIONS

[TEXT OMITTED]

CONFIDENTIAL

APPENDIX B

FORM OF SUBSCRIPTION AGREEMENT

FOR

SHARES OF COMMON STOCK OF

SHEFFIELD PHARMACEUTICALS, INC.

INSTRUCTIONS

IMPORTANT: PLEASE READ CAREFULLY BEFORE SIGNING ON PAGE 8.
SIGNIFICANT REPRESENTATIONS ARE
CONTAINED HEREIN

SUBSCRIPTION AGREEMENT

Sheffield Pharmaceuticals, Inc.
425 South Woodsmill Road
St. Louis, Missouri 63017

Ladies and Gentlemen:

1. SUBSCRIPTION. The undersigned (sometimes referred to herein as the "Investor") hereby subscribes for and agrees to purchase shares of Common Stock, par value, \$.01 per share, of Sheffield Pharmaceuticals, Inc. (the "Company"), on the terms and conditions described herein and in the Confidential Private Placement Memorandum ("Memorandum") dated June , 1998 of the Company, together with all supplements, if any, relating to this offering.

2. SUBSCRIPTION AGREEMENT; PURCHASE PRICE. The undersigned herewith delivers to the Company two manually executed copies of this Subscription Agreement. The undersigned hereby agrees to remit to the Company (\$ per share) (the "Purchase Price") on the date hereof by wire transfer to the following account: Chase Manhattan Bank, 11 West 51st Street, New York, New York 10119, Account No. , ABA .

3. DELIVERY OF SHARES. The Shares subscribed for herein shall not be deemed issued to or owned by the undersigned until two copies of this Subscription Agreement have been executed and delivered to the Company by the undersigned, such agreements have been countersigned by the Company and the Purchase Price has been remitted to the Company. Upon such execution, delivery and remittance a certificate representing the Shares shall promptly be delivered to the undersigned.

4. DISCLOSURE. Because this offering is limited to accredited investors as defined in Section 2(15) of the U.S. Securities Act of 1933, as amended ("Securities Act"), and Rule 501 promulgated thereunder, in reliance upon the exemption contained in Sections 3(b), 4(2) or 4(6) of the Securities Act and applicable state securities laws, the Shares are being sold without registration under the Securities Act. The undersigned acknowledges receipt of the Memorandum and all exhibits listed therein and represent that the undersigned has carefully reviewed and understand the Memorandum and its exhibits. The undersigned has received all information and materials regarding the Company that the undersigned has requested.

The undersigned fully understands that an investment in the Shares is a speculative investment that involves a high degree of risk of loss of its entire investment. The undersigned fully understands the nature of the risks involved in purchasing the

Shares and the undersigned is qualified by its knowledge and experience to evaluate investments of this type. The undersigned has carefully considered the potential risks relating to the Company and purchase of the Shares and have, in

particular, reviewed each of the risks set forth or incorporated by reference in the Memorandum. The undersigned has had the opportunity to ask questions of and receive answers from officers and other representatives of the Company concerning the Company and the terms and conditions of a proposed investment in the Company and the undersigned's advisors, if any, and the undersigned has also had the opportunity to obtain additional information necessary to verify the accuracy of information furnished about the Company. Accordingly, the undersigned has independently evaluated the risks of purchasing the Shares.

5. INVESTOR REPRESENTATIONS AND WARRANTIES. The undersigned acknowledges, represents and warrants to, and agrees with, the Company as follows:

(a) The undersigned is aware that an investment in Shares involves a high degree of risk, and the undersigned has read and fully understands the Memorandum, including the section entitled "Risk Factors" (Exhibit E).

(b) The undersigned acknowledges and is aware that there is no assurance as to the future performance of the Company.

(c) The undersigned is purchasing the Shares for its own account for investment and not with a view to or for sale in connection with the distribution of the Shares, nor with any present intention of selling or otherwise disposing of all or any part of the Shares. The undersigned agrees that (i) the purchase of the Shares is a long-term investment, (ii) the undersigned may have to bear the economic risk of investment for an indefinite period of time because the Shares have not been registered under the Securities Act and the Shares may never be registered and cannot be resold, pledged, assigned, or otherwise disposed of unless they are subsequently registered under said Securities Act and under applicable securities laws of certain states or an exemption from such registration is available. The undersigned understands that the Company is under no obligation to register the Shares or to assist the undersigned in complying with any exemption from such registration under the Securities Act or any state securities laws. The undersigned acknowledges that the Company will place a legend on the certificate representing the Shares denoting the restrictions on the Shares.

(d) The undersigned has been given full and complete access to information regarding the Company and has utilized such access to its satisfaction for the purpose of obtaining information in addition to, or verifying information included in, the Memorandum and exhibits thereto, and the undersigned has met with

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officers of the Company for the purpose of asking questions of, and receiving answers from, such officers concerning the terms and conditions of the offering of the Shares and the business and operations of the Company and to obtain any additional information, to the extent reasonably available.

(e) The undersigned has such knowledge and experience in financial and business matters as to be capable of evaluating the merits and risks of an investment in the Shares and has obtained, in its judgment, sufficient information from the Company to evaluate the merits and risks of an

investment in the Company.

(f) The undersigned has relied solely upon its own investigation of the Company in making a decision to invest in the Company.

(g) The undersigned has received no representation or warranty from the Company or any of its officers, directors, employees or agents in respect of its investment in the Company and has received no information (written or otherwise) from the Company relating to the Company or its business other than as set forth in the Memorandum. The undersigned is not participating in the offer as a result of or subsequent to: (i) any advertisement, article, notice or other communication published in any newspaper, magazine or similar media or broadcast over television, radio or the internet or (ii) any seminar or meeting whose attendees have been invited by any general solicitation or general advertising.

(h) The undersigned has had full opportunity to ask questions and to receive satisfactory answers concerning the offering and other matters pertaining to its investment and all such questions have been answered to the undersigned's full satisfaction.

(i) The undersigned has been provided an opportunity to obtain any additional information concerning the offering and the Company and all other information to the extent the Company possesses such information or can acquire it without unreasonable effort or expense.

(j) The undersigned is an "accredited investor" as defined in Section 2(15) of the Securities Act and in Rule 501 promulgated thereunder.

(k) The undersigned understands that (i) the Shares have not been registered under the Securities Act or the securities laws of certain states in reliance on specific exemptions from registration, (ii) no securities administrator of any state or the federal government has recommended or endorsed this offering or made any finding or determination relating to the fairness of an investment in the Company, and (iii) the Company is relying on the undersigned's representations and agreements for the purpose of

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determining whether this transaction meets the requirements of the exemptions afforded by the Securities Act and certain state securities laws.

(l) The undersigned has been urged by the Company to seek independent advice from its professional advisors relating to the suitability of an investment in the Company in view of the undersigned's overall financial needs and with respect to the legal and tax implications of such investment.

(m) The undersigned is authorized and qualified to become an investor in the Company and the person signing this Subscription Agreement on behalf of the undersigned has been duly authorized by the undersigned to do so.

(n) The undersigned hereby acknowledges and is aware that, except for any rescission rights that may be provided under applicable laws, the undersigned is not entitled to cancel, terminate or revoke this subscription.

(o) The undersigned hereby agrees that the Memorandum and documents related thereto and attached as Exhibits thereto will be kept confidential by it; provided, however, that any such information may be disclosed (i) to the undersigned's officers, employees and advisors (collectively, the "Agents") who need to know such information for the purpose of evaluating the purchase of the Shares described in the Memorandum (it being understood that such Agents shall be informed by the undersigned of the confidential nature of such information and shall be directed by the undersigned to treat such information confidentially) or (ii) as required by law. In the event disclosure of the Memorandum and documents related thereto is required by law, the undersigned shall promptly notify the Company of any anticipated disclosure obligation, cooperate with the Company, at the Company's expense, in its efforts to obtain a protective order or other reliable assurance that confidential treatment will be accorded to that portion of the Memorandum or the documents related thereto that is required to be disclosed. In addition, the undersigned agrees that, without the prior written consent of the Company, neither the undersigned's Agents nor the undersigned will disclose to any other person the fact that the Memorandum or the documents related thereto has been made available to the undersigned or any of the terms, conditions or other facts with respect thereto (including the status thereof). The term "person" as used in this letter agreement shall be broadly interpreted to include the media and any corporation, partnership, group, individual or other entity.

The undersigned agrees to undertake reasonable precautions to safeguard and protect the confidentiality of the Memorandum and the documents related thereto and at the undersigned's sole expense to take all reasonable measures (including but not limited to court proceedings) to restrain its

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Agents from prohibited or unauthorized disclosure or uses of the Memorandum and the documents related thereto.

The undersigned shall promptly upon request redeliver to the Company or destroy all written material containing or reflecting any information in the Memorandum or the documents related thereto (whether prepared by the Company, its advisors or otherwise) and will not retain any copies, extracts or other reproductions in whole or in part of such written material.

6. INDEMNIFICATION. The undersigned hereby agrees to indemnify and hold harmless the Company and its respective officers, directors, stockholders, employees, agents, and attorneys against any and all losses, claims, demands, liabilities, and expenses (including reasonable legal or other expenses) incurred by each such person in connection with defending or investigating any such claims or liabilities, whether or not resulting in any liability to such person, to which any such indemnified party may become subject under the Securities Act, under any other statute, at common law or otherwise, insofar as such losses, claims, demands, liabilities and expenses (a) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact made by the undersigned and contained in this Subscription Agreement or (b) arise out of or are based upon any breach by the undersigned of any representation, warranty, or agreement made by the undersigned contained herein.

7. STOCK PURCHASE OPTION. In the event that the Company issues additional shares of Common Stock after the date hereof in either a private or

public offering (an "Additional Offering"), the Company shall offer the Investor the right to purchase an amount of additional shares of Common Stock determined based on the following formula:

$$AS = \frac{AO \times HS}{OT}$$

where "AS" means the number of additional shares to be offered for sale to the Investor, "AO" means the number of shares of Common Stock issued in the Additional Offering, "HS" means the number of shares of Common Stock held by the Investor immediately following the offering contemplated by this Subscription Agreement (I.E., shares) and "OT" means the number of shares of Common Stock outstanding on the date of the issuance of the Shares contemplated by this Subscription Agreement.

The Company shall give the Investor written notice of an issuance pursuant to any Additional Offering within ten days after the date of such issuance, which notice shall state the number of additional shares of the Common Stock that the Investor may purchase pursuant to this Section 7 as a result of such Additional Offering and the applicable purchase price (which shall be the same

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purchase price per share paid for the shares of Common Stock sold in the related Additional Offering), and the Investor shall have 80 days from the date of receipt of such notice to deliver the purchase price for such additional shares to the Company. Upon receipt of such purchase price, the Company shall promptly issue such additional shares of Common Stock to the Investor. In the event that the Investor fails to exercise its right to purchase all additional shares of Common Stock offered to the Investor under this Section 7 in connection with any Additional Offering, the Investor's rights under this Section 7 shall terminate.

Any additional shares of Common Stock issued to the Investor pursuant to this Section 7 shall be represented by a stock certificate that shall contain a restrictive legend in substantially the form set forth under "Restrictions on Resale" above.

As used in this Section 7, "Additional Offering" shall not include (i) the issuance of Common Stock issuable upon the exercise or conversion of options, warrants or other rights to purchase securities of the Company outstanding as of the date hereof or (ii) the issuance of Common Stock to officers, directors or employees of the Company or any of its subsidiaries.

8. SEVERABILITY: REMEDIES. In the event any parts of this Subscription Agreement are found to be void, the remaining provisions of this Subscription Agreement shall nevertheless be binding with the same effect as though the void parts were deleted.

9. GOVERNING LAW. This Subscription Agreement will be deemed to have been made and delivered in New York City and will be governed as to validity, interpretation, construction, effect and in all other respects by the internal laws of the State of New York.

10. COUNTERPARTS. This Subscription Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. The execution of this Subscription Agreement may be by actual or facsimile signature.

11. NOTICES. All notices, offers, acceptance and any other acts under this Subscription Agreement (except payment) shall be in writing, and shall be sufficiently given if delivered to the addressees in person, by overnight courier service, or, if mailed, postage prepaid, by certified mail (return receipt requested), and shall be effective five days after being placed in the mail if mailed, or upon receipt or refusal of receipt, if delivered personally or by courier, in each case addressed to a party. The addresses for such communications shall be:

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Investor: At the address designated on the signature page of this Subscription Agreement.

The Company: Sheffield Pharmaceuticals, Inc.
425 South Woodsmill Road
St. Louis, Missouri 63017
Attention: Loren Peterson
President and
Chief Executive Officer

In either case,
with a copy to: Olshan Grundman Frome & Rosenzweig LLP
505 Park Avenue
New York, New York 10022
Attention: Daniel J. Gallagher, Esq.

or to such other address as any of them, by notice to the others may designate from time to time.

12. ORAL EVIDENCE. This Subscription Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior oral and written agreements between the parties hereto with respect to the subject matter hereof. This Subscription Agreement may not be changed, waived, discharged, or terminated orally but, rather, only by a statement in writing signed by the party or parties against which enforcement or the change, waiver, discharge or termination is sought.

13. SURVIVAL OF REPRESENTATIONS, WARRANTIES AND AGREEMENTS. The representations, warranties and agreements contained herein shall survive the delivery of, and the payment for, the Shares.

RESIDENTS OF ALL STATES: THE SHARES OFFERED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE AND ARE BEING OFFERED AND SOLD IN RELIANCE ON EXEMPTIONS FROM THE REGISTRATION REQUIREMENTS OF SAID ACT AND SUCH LAWS. THE SHARES ARE SUBJECT TO RESTRICTION ON TRANSFERABILITY AND RESALE AND MAY NOT BE TRANSFERRED OR RESOLD EXCEPT AS PERMITTED UNDER SAID ACT AND SUCH LAWS PURSUANT TO REGISTRATION OR EXEMPTION THEREFROM. INVESTORS SHOULD BE AWARE THAT THEY WILL BE REQUIRED TO

BEAR THE FINANCIAL RISKS OF THIS INVESTMENT FOR AN INDEFINITE PERIOD OF TIME. THE SHARES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION, ANY STATE SECURITIES COMMISSION OR OTHER REGULATORY AUTHORITY, NOR HAVE ANY OF THE FOREGOING AUTHORITIES PASSED UPON OR ENDORSED THE MERITS OF THE OFFERING OR THE ACCURACY OR ADEQUACY OF THIS CONFIDENTIAL MEMORANDUM. ANY REPRESENTATION TO THE CONTRARY IS UNLAWFUL.

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SIGNATURE PAGE

IN WITNESS WHEREOF, the undersigned has executed this Agreement on the ___ day of June, 1998.

INPHARZAM INTERNATIONAL, S.A.

BY: _____

NAME: _____

TITLE: _____

Address

ACCEPTED this ____ day of June, 1998 on behalf of the Company.

SHEFFIELD PHARMACEUTICALS, INC.

BY: _____

Name:

Title:

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CONFIDENTIAL

APPENDIX C

RESOLUTION OF SHEFFIELD BOARD OF DIRECTORS

(To be attached after July 15, 1998 Board meeting)

CONFIDENTIAL

APPENDIX D

DEVELOPMENT PLAN

[TEXT OMITTED]

CONFIDENTIAL

APPENDIX E

PROMISSORY NOTE

FOR VALUE RECEIVED the undersigned, Sheffield Pharmaceuticals, Inc., a Delaware corporation with offices at 37 South Main Street, Pittsford, New York 14534, promises to pay, in lawful money of the United States of America, to the order of Inpharzam International, S.A., at Via Industria 1, 6814 Cadempino, Switzerland, the principal sum of [TEXT OMITTED] without interest according to the following schedule:

[TEXT OMITTED]

[TEXT OMITTED]

[TEXT OMITTED]

[TEXT OMITTED]

or earlier as may be provided in subsection 4.2(g) of the Sublicense and Development Agreement between Sheffield Pharmaceuticals, Inc. and Inpharzam International, S.A. ("Agreement") dated .

In the event of any default in payments as herein agreed or in the event of a filing for bankruptcy or insolvency or any other act of default as provided in said Agreement, the entire balance of this note shall become immediately due and payable at the election of the holder hereof, and a lien and security interest shall be created in accordance with Title 11 of the United States Code upon the intellectual property that is the subject of this Agreement in favor of Inpharzam International, S.A upon notice delivered to the undersigned of such election.

The undersigned further agrees, in the event suit is instituted to collect this note or any portion thereof, to pay all costs of collection, other costs and reasonable attorneys' fees incurred by Inpharzam International, S.A. in connection therewith.

This Promissory Note may be prepaid in whole or in part by the

undersigned without premium or penalty.

This Promissory Note may not be assigned or otherwise transferred by Inpharzam International, S.A. without the prior written consent of the undersigned, except that no such consent shall be required for the assignment of this Promissory Note to an Affiliate (as the term is defined in subsection 1.1 of the Agreement) of Inpharzam International, S.A.

I hereby certify that this is one of the notes described in Section 4.2 of said Agreement between Sheffield Pharmaceuticals, Inc. and Inpharzam International, S.A. dated June , 1998, and the execution of same by the undersigned has been duly authorized by the Board of Directors of Sheffield Pharmaceuticals, Inc. on June , 1998.

Dated this day of , 19 .

SHEFFIELD PHARMACEUTICALS, INC.

BY: _____

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CONFIDENTIAL

APPENDIX F

REPORT RE: ALBUTEROL

[TEXT OMITTED]

CONFIDENTIAL

APPENDIX G

REPORT RE: BECLOMETHASONE

[TEXT OMITTED]

CONFIDENTIAL

APPENDIX H

CO-PROMOTION PRINCIPLES

The following principles shall apply to the terms of the Co-promotion Rights:

1. Co-promotion shall mean the direct promotion of Licensed Products under a single brandname to healthcare professionals and distribution channels in the United States by a Sheffield salesforce and Zambon salesforce.
2. A "Profit Contribution" from Licensed Products sales in the U.S. will be negotiated by the parties based on promotion efforts measured by each party's percentage of total audited details for Licensed Products and other relevant commercial considerations.
3. Specific call coverage assignments for each salesforce by specialty and/or geography will be agreed to by the parties.
4. There will be a minimum of [TEXT OMITTED] field sales representatives to qualify for profit sharing.
5. The parties will agree upon one unified system for coordination of adverse event reporting.
6. The parties agree to appoint a Co-Marketing Committee as part of the Commercialization Plan to oversee the ongoing relationship between the parties regarding all co-promotion activities.

-----END PRIVACY-ENHANCED MESSAGE-----