



Sales, Marketing, Distribution, and Supply Agreement {***}

WHEREAS HEMISPHERX is a biopharmaceutical company with headquarters at One Penn Center, 1617 JFK Boulevard, Suite 500, Philadelphia, PA 19103, U.S. ("HEMISPHERX") and Scientific Products Pharmaceutical Co. LTD is a pharmaceutical company with its primary offices located at Tahlia Street, P.O Box 10485, Riyadh 11433 Saudi Arabia ("SCIEN"), each a "Party" together, "Parties", and

WHEREAS HEMISPHERX owns intellectual proprietary rights relating to Interferon alfa-n3 (human leukocyte derived), and

WHEREAS HEMISPHERX desires to have Interferon alfa-n3 (human leukocyte derived) provided to physicians to treat genital warts and other infections and diseases, including MERS, in the GCC (Gulf Cooperation Council) states, as appropriate, prior to regulatory approval in such countries and to have Interferon alfa-n3 (human leukocyte derived) approved by the regulatory authorities in each GCC country (Kingdom of Saudi Arabia, Bahrain, Qatar, Kuwait, United Arab emirates (UAE) and Sultanate of Oman)), and

WHEREAS SCIEN has sales, marketing, distribution capabilities in the GCC states, and

WHEREAS, AFTER A SUCCESSFUL CLINICAL TRIAL IN MERS, SCIEN affirms it has the ability to supply Interferon alfa-n3 (human leukocyte derived) in the GCC States prior to regulatory approval and simultaneously seek to gain regulatory approval in each of the GCC States. After the clinical trial in MERS has been conducted, in the event it is successful and the Hemispherx manufacturing site requires approved by the GCC / SFDA, the cost of any post-clinical trial inspection of the facility to be the responsibility of Scien or the regulatory authority, and subsequently to market, sell and distribute Interferon alfa-n3 (human leukocyte derived) in the GCC, and

WHEREAS, SCIEN desires to supply Interferon alfa-n3 (human leukocyte derived) under special approval from the Saudi Ministry of Health and for other GCC states where applicable, and

WHEREAS, HEMISPHERX desires to supply and sell Interferon alfa-n3 (human leukocyte derived) to SCIEN, and SCIEN is willing to purchase Interferon alfa-n3 (human leukocyte derived) from HEMISPHERX for the purposes described in this agreement.

NOW THEREFORE, in consideration of the mutual covenants and agreements made herein, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the Parties agree as follows:

I. DEFINITIONS

"Affiliate" means any corporation or other business entity, which controls, is controlled by, or is under the common control of a Party.

"End User" means a physician, medical facility or institution, or government agency that purchases Product with the intent of administering it to a patient.

"Field" means refractory/recurrent genital warts, recombinant interferon refractory patients and patients with other infectious diseases, e.g., MERS, influenza, West Nile Virus, and cancer, etc.

"HEMISPHERX Intellectual Property" means all HEMISPHERX patents, patent applications, know-how, and trademarks owned or controlled by HEMISPHERX up to the termination or expiration of this Agreement.

"List Price" means \$***}/Product Unit.

"Product" means an injectable formulation of clinical grade Interferon alfa-n3 (human leukocyte derived).

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"Product Data" means all data possessed by HEMISPHERX relating to the use of Interferon alfa-n3 (human leukocyte derived) to treat patients in the Field and which is needed to obtain regulatory approval in the Territory.

"Product Unit" means 1 x1ml vial containing 5 million international units (I.U.) of Interferon alfa-n3 (human leukocyte derived)

"Sales Price" means the price SCIEN and/or its Affiliates charge an End User for a Product Unit.

"Territory" means the GCC States

"Transfer Price" means a discounted price of \${{***}}/ Product Unit.

II. LICENSE

CONDITION PRECEDENT: THE GRANTING OF ANY AND ALL LICENSES OR PRIVILEGES HEREIN IS SUBJECT THE THE SUCCESSFUL COMPLETION OF A FIVE PERSON MINIMUM CLINICAL TRIAL IN THE KINGDOM OF SAUDI ARABIA TREATING EARLY ONSET PATIENTS INFECTED WITH MERS.

A. Subject to the condition above, HEMISPHERX hereby grants SCIEN the exclusive license to sell, market, and distribute Product for use in the Field in the Territory for Direct Access/EAP and Regulatory Agency-Approved (RAA) purposes.

B. SCIEN shall not use HEMISPHERX Intellectual Property nor sell nor permit the sale of any products that use the HEMISPHERX Intellectual Property outside the Territory or knowingly sell or have sold any products that use the HEMISPHERX Intellectual Property to any party in or outside the Territory for export or sale outside the Territory, without HEMISPHERX's prior written consent.

C. SCIEN will have six 6) months after the date of this Agreement to Purchase at least 50 vials to be used by the MOH in treating patients with MERS. Scien will thereafter, based on the outcome of the initial treatment for MERS by the MOH trial, aggressively promote to all stakeholders in Saudi Arabia and the other GCC states("First Performance Milestone").

III. COMMERCIAL DEVELOPMENT

A. HEMISPHERX has or will provide SCIEN:

- 1.** As an Integral Part of this Agreement and in order for HEMISPHERX to ship Product to SCIEN, the letter with attachments (Exhibit 1) must be signed by an officer of SCIEN. A protocol is also provided (Exhibit 2).
- 2.** All the appropriate information about Products that will assist with the education of physicians about the Product in the Territory.
- 3.** Ongoing scientific and medical support.
- 4.** Product Units in quantities sufficient for SCIEN's Direct Access/EAP and RAA commercial needs in the Territory, subject to availability from HEMISPHERX.

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B. SCIEN will:

1. Within 60 days after this Agreement becomes effective, prepare and provide a Business Plan, to be attached to this Agreement as Exhibit 3, to make aware and educate physicians and patients about Product both prior to and following approval of Product.
2. Assist in determining reimbursable End User pricing of Product and gain reimbursement for Product under Direct Access/EAP program and RAA sales of the Product in the Territory.
3. Assist physicians who desire to administer Product with the required paperwork under any Direct Access/EAP program.
4. Manage the logistics within the Territory from arrival to End User supply.
6. Assist HEMISPHERX to gain regulatory approval of Product in the Field in the Territory
7. Prepare and provide a 3-year post regulatory approval Sales, Marketing, and Distribution Plan including a 3-year minimum sale forecast and a committed-dollar field sales force, product manager and marketing budget to be agreed by both Parties and a non-binding 12 month Product forecast no later than six (6) months prior to the anticipated registration and subsequent launch date for each Product, also to be agreed by both parties,
8. Pay for all the above Sales Marketing and Distribution activities and related expenses.
9. Hold 3 months inventory of the forecasted sales once the product is registered.
10. If needed, assist in recruiting clinical trial sites and principal investigators in the Field in the Territory.
11. Provide HEMISPHERX a monthly written report of SCIEN's efforts and status thereof under this Agreement.

IV. SUPPLY

- A. Subject to the terms and conditions of this Agreement, HEMISPHERX agrees to exclusively supply Product to SCIEN in the Territory with a minimum expiry of 6 months from the date of shipment.
- B. The price that SCIEN will pay for Product under this Agreement is the Transfer Price, CIF. Taxes, duties, and other expenses to be paid by SCIEN.
- C. SCIEN shall pay HEMISPHERX for each order of Product within 75 days after receipt of the goods except for the for first purchase order which will be for 50 vials of Interferon alfa-n3 (human leukocyte derived) ("First Order") and paid once the MOH approves the use for Interferon alfa-n3 (human leukocyte derived) on 5 MERS patients. All purchase orders are final.
- D. SCIEN will ensure all necessary QA testing / approval for use occurs in the Territory and that each Product is stored under the conditions stipulated in a Quality Agreement (QA) to be executed and appended to this Agreement as Exhibit 4.
- E. Forecasts, Orders, Payment, and Delivery.

Direct Access/EAP Distribution

Following the signing of this Agreement, SCIEN will start a full and comprehensive market analysis of the potential of each Product for Direct Access/ EAP distribution. This will be from a market potential and willingness to pay point of view and will be completed within 3 months of the signature of this Agreement. A forecast will then be provided for Product for Direct Access/ EAP distribution and this will be added as a supplement to the Business Plan (Exhibit 3).

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RAA Distribution

Six (6) months prior to the estimated regulatory approval for commercial sale of Product in each country in the Territory:

1. SCIEN will provide HEMISPHERX a rolling 12-month forecast of the estimated sales of Product Units, the first 3 months of which will be firm and the second three (3) months of which cannot vary by more than 25% when these become the first three (3) months. This forecast will be updated at 3-month intervals thereafter.
 2. In accordance with this forecast, SCIEN agrees to order Product from HEMISPHERX under this Agreement by submitting to HEMISPHERX written purchase orders specifying the quantity, packaging, delivery dates, and delivery location.
 3. HEMISPHERX shall manufacture Product as described in the purchase order from SCIEN and HEMISPHERX shall make all shipments to the location specified on SCIEN's purchase order as follows:
 4. Hemispherx shall pack, mark and ship Products in accordance with temperature thermometer specifications for the drug product. Hemispherx shall package Products so as to prevent damage or deterioration and shall comply with all applicable temperature and packaging laws. Unless otherwise stipulated, Products shall be packaged, marked, crated and otherwise prepared in accordance with HEMISPHERX's current packaging and crating practices, and good commercial practices.
 5. SCIEN will prominently display on all Product that the Product is a product of HEMISPHERX and be so noted and on a visible surface thereof and/or on tags, labels, manuals, and other materials with which Product is sold, the fact that the Product is manufactured and supplied to SCIEN by HEMISPHERX for use and/or sale in the Territory shall be clearly displayed.
- F.** If, for any reason, at any time, HEMISPHERX shall be unable, or should reasonably anticipate being unable to deliver any part or all of the ordered Product in accordance with the terms hereof or the accompanying purchase order, HEMISPHERX shall notify SCIEN of such inability at the earliest possible time (but no later than five (5) workings after HEMISPHERX becomes aware of this their inability to supply Product, whereupon HEMISPHERX and SCIEN will devise a plan to manage the situation.
- G.** HEMISPHERX warrants that the Product (i) shall conform to the specifications set out in the SCIEN purchase order for Product and (ii) shall meet all, if any, reasonably applicable regulatory requirements in the Territory once Product is approved. In the Direct Access/ EAP setting, the Product that HEMISPHERX supplies must confirm with all manufacturing and regulatory requirements (including labelling) for the country in which said Product is intended to be sold. SCIEN's acceptance of the Product shall relieve HEMISPHERX from the obligations arising from this warranty
- H.** SCIEN shall have the right to return and demand replacement of any Product which violates this warranty.
- I.** HEMISPHERX and/or SCIEN shall have the right to cancel, without further obligation to the other party, one or more orders for Product(s) if HEMISPHERX's or SCIEN's business is interrupted because of an event of force majeure beyond the control of HEMISPHERX or SCIEN.
- J.** HEMISPHERX shall permit SCIEN or its agent, at SCIENs' expense, to conduct periodic audits of HEMISPHERX's Quality System and Manufacturing records relating to HEMISPHERX's performance under this Agreement. The audits shall be conducted upon reasonable advance notice during regular business hours at HEMISPHERX's principal office and in such a manner as not to unduly interfere with HEMISPHERX's operations.

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- K.** SCIEN will provide HEMISPHERX with copies of Product specification sheets, Product inserts, user manuals, user bulletins, and user Product updates and any other customer materials such as brochures, educational materials, web pages or other electronic information relating to SCIEN's efforts to sell, market and distribute Product under this Agreement at least 10 (ten) days prior to the public release or use of such information.

V. REPORTS AND PAYMENTS

- A.** Within 30 days following the end of each calendar quarter after execution of the Agreement, SCIEN will provide HEMISPHERX with quarterly reports on the number of Product Units sold and the Sales Price during the preceding three months, key market place issues and successes, regulatory and reimbursement subjects and revisions to the sales and marketing plans.
- B.** Product (s) will be considered sold by SCIEN on the date it is shipped or invoiced to an End User, whichever is earlier. All shipping, taxes, duties and other expenses in the Territory is the responsibility of SCIEN.
- C.** Price Increase: Beginning on the second year anniversary of the signing of this Agreement ("Effective Date") and on each succeeding anniversary of the Effective Date during the term of this agreement and in consideration of a varies of economic factors such as for example, costs of labour, costs of material and costs the price paid by SCIEN for Product(s) shall be renegotiated. Any price increase will need to be justified by HEMISPHERX. Both parties shall, in good faith, attempt to agree upon a reasonable price increase. In the event agreement cannot be reached the Agreement shall terminate.
- D.** All payments hereunder will be made by SCIEN in United States Dollars by wire transfer of immediately available funds to an account designated by HEMISPHERX. The following is wire transfer information:

Domestic (U.S.):
{***}

International:
{***}

VI. TERM/TERMINATION

- A.** The Term will be 3 years from Effective Date with an automatic 2 year term extensions unless otherwise advised by one of the Parties.
- B.** Termination for breach will include:
1. Failure to purchase Product and distribute to End Users as called for in II D.
 2. Failure of SCIEN achieving less than 50% achievement of the minimum Purchases as in III B.7. for two (2) consecutive years,
 3. Insolvency, or the filing for protection under either Party's bankruptcy laws. Upon the filing of a petition in bankruptcy, insolvency or reorganization against or by either Party, or either Party becoming subject to a composition for creditors, whether by law or agreement, or either party going into receivership or otherwise becoming insolvent (such party hereinafter referred to as the "insolvent party"), this Agreement may be terminated by the other Party by giving written notice of termination to the insolvent Party, such termination immediately effective upon the giving of such notice of termination.

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- C. Upon the occurrence of a breach or default as to any obligation hereunder by either Party and the failure of the breaching Party to cure (within thirty (30) days after receiving written notice thereof from the non-breaching Party) such breach or default, this Agreement may be terminated by the non-breaching Party by giving written notice of termination to the breaching Party, such termination being immediately effective upon the giving of such notice of termination.
- D. In the event this Agreement is terminated by either Party for any reason whatsoever, HEMISPHERX agrees to reasonable efforts to make Product available to SCIEN for a period of three (3) months after the termination date at the same Transfer Price and under the same terms of payment.
- E. In the event of termination of this Agreement, SCIEN will have the right to complete all contracts for the sale or disposition of Product) under which SCIEN is obligated on the date of termination, provided SCIEN pays the associated Transfer Price and provided all such sales or dispositions are completed within three (3) months after the date of termination. Thereafter, HEMISPHERX shall purchase from the SCIEN all remaining stock of Product that is of merchantable quality at the same price as was paid by SCIEN.

VII. ASSIGNMENT

Neither this Agreement nor any rights or obligations or licenses hereunder may be assigned, pledged, transferred or encumbered by either party without the express prior written approval of the other party, except that either HEMISPHERX or SCIEN may assign this Agreement to any successor by merger or sale of substantially all of its business or assets to which this Agreement pertains, without any such consent. Any assignment in violation hereof is void.

VIII. AUTHORITY

SCIEN and HEMISPHERX each warrant and represent that it has the full right and power to make the promises set forth in this Agreement and that there are no outstanding agreements, assignments, or encumbrances inconsistent with the provisions of this Agreement.

IX. EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION IX, HEMISPHERX MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, REGARDING THE DEVELOPMENT, VIABILITY, COMMERCIAL OR OTHER USEFULNESS OR SUCCESS OF PRODUCT) AND THAT NO WARRANTY OR REPRESENTATION THAT ANYTHING MADE, USED, SOLD OR OTHERWISE PRACTICED OR ANY SERVICE PROVIDED UNDER THIS AGREEMENT WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADE SECRET, OR OTHER PROPRIETARY RIGHT, FOREIGN OR DOMESTIC, OF ANY THIRD PARTY AND MAKES NO WARRANTIES OR REPRESENTATIONS AS TO THE VALIDITY, ENFORCEABILITY OR SCOPE OF ANY HEMISPHERX INTELLECTUAL PROPERTY.

X. INDEMNIFICATION AND WARRANTIES

A. INDEMNIFICATION

SCIEN and HEMISPHERX (each an "Indemnifying Party") shall indemnify, defend and hold harmless and the other Party's subsidiaries or affiliates, their agents, directors, officers, employees and assigns (the "Indemnified Parties") from and against all losses, liabilities, damages, demands and expenses (including reasonable attorneys' fees and expenses) arising out of, as a result of, or in connection with (i) the negligent actions of the Indemnifying Party, its employees or any third party acting on behalf of or under authority of the Indemnifying Party in the performance of this Agreement and/or (ii) the violation of any representation or warranty of Indemnifying Party in this Agreement. Each Party's obligations under this provision shall be subject to the other Party providing reasonable notice of any such claim. Each Party shall defend with competent counsel and pay all costs of defence, including attorneys' fees, and any and all damages and court costs awarded in respect to such claim, action or proceeding regarding the claim of infringement. The Indemnified Parties agree to permit the Indemnifying Party to defend, compromise, or settle any such claim, action or proceeding and further agree to provide all available information, and reasonable assistance to enable the other Indemnifying Party to do so. However, neither party will be liable under this indemnity for any losses, liabilities, damages, demands or expenses arising out of the gross negligence or wilful misconduct of the other party or any of its affiliates, agents, directors, officers, employees or assigns. Limitation of Liability. IN NO EVENT WILL EITHER PARTY BE LIABLE FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE LICENSE GRANTED PURSUANT TO THIS AGREEMENT OR THE USE OR COMMERCIAL DEVELOPMENT OF PRODUCT.

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B. WARRANTIES

Subject as herein provided HEMISPHERX warrants to SCIEN that:

- All Product(s) supplied hereunder will comply with the Dossier and with any specification agreed for them in the Quality Agreement;
- It is not aware of any rights of any third party in the Territory which would or might render the sale of the Product, or the use of any of the Trademarks on or in relation to the Products, unlawful;
- It is the owner or the permitted licensee of all Intellectual Property Rights and it is not aware of any claims of any third party in the Territory or worldwide related to the fact that the Products infringes any intellectual property of such third party.
- Nothing in this Agreement shall exclude either party's liability for death or personal injury.

Subject to the above WARRANTIES, HEMISPHERX shall indemnify and hold harmless SCIEN and its respective employees from any loss, damage or claim made by a third party in respect of (i) the death or personal injury arising from the manufacture or use of the Products in the Territory or (ii) infringement of third party intellectual property, if and to the extent such loss, damage or claim is caused by any act or omission of HEMISPHERX and is not attributable directly or indirectly to the breach of any of the material terms of this Agreement by SCIEN or by any wilful default or negligent act or omission of SCIEN, its employees or its agents.

1. The indemnity given by HEMISPHERX shall be subject to the following conditions:

- No indemnity shall be claimed unless notice is given by SCIEN claiming the indemnity to HEMISPHERX together with details of the claim promptly on notice of such claim being received by the SCIEN;
- No admissions of liability or compromise or offer of settlement of any claim shall be made by SCIEN without the prior written consent of HEMISPHERX; and
- HEMISPHERX shall have full control over any claim, proceedings or settlement negotiations in respect of which it is providing the indemnity.

Subject to clause X.B 1.), SCIEN shall defend and indemnify HEMISPHERX and its Affiliates and hold each of them harmless against all claims, demands, actions, losses, expenses, damages, liabilities, costs (including interest, penalties and reasonable attorneys' fees) and judgements suffered by each of them, which arise out of SCIEN's negligent or wilful acts or omissions or which otherwise arise out of SCIEN's breach of the Agreement.

Survivability. The obligations set forth in this Section X. shall survive the termination of this Agreement for the legal periods of limitation provided by US law.

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XI. CONFIDENTIALITY

- A.** SCIEN and HEMISPHERX agree to keep secret and confidential all confidential, proprietary or non-public information ("Confidential Information") of the other Party .This provision shall survive termination or expiration of this Agreement.
- B.** Such Confidential Information will be kept confidential until 5 years after the expiration of termination of this Agreement. Notwithstanding the foregoing , Confidential Information of a Party shall not include information which the other Party can establish by written documentation was (a) to have been publicly known prior to disclosure of such information by the disclosing Party to the other Party, (b) to have become publicly known, without fault on the part of the other Party, subsequent to disclosure of such information by the disclosing Party to the other Party, (c) to have been received by the other Party at any time from a source , other than the disclosing Party, rightfully having possession of and the right to disclose such information, (d) to have been otherwise known by the other Party prior to disclosure of such information by the disclosing Party to the other Party, or (e) to have been independently developed by employees or agents of the other Party without access to or use of such information disclosed by the disclosing Party to the other Party.
- C.** The confidentiality obligations contained in this section XI shall not apply to the extent that the receiving Party (the "Recipient") is required (a) to disclose information by law, order or regulation of a governmental agency or a court of competent jurisdiction , or (b) to disclose information to any governmental agency for purposes of obtaining approval to test or market a Product , provided in either case that the Recipient shall provide written notice thereof to the other Party and sufficient opportunity to object to any such disclosure or to request confidential treatment thereof.

XII. PROSECUTION, INFRINGEMENT, AND DEFENSE OF HEMISPHERX INTELLECTUAL PROPERTY

- A.** HEMISPHERX will be responsible for and shall control, at its expense, the preparation, filing, prosecution and maintenance of HEMISPHERX Intellectual Property.
- B.** SCIEN will cooperate in all reasonable ways to establish and protect HEMISPHERX Intellectual Property in the Territory.
- C.** HEMISPHERX, at its expense, will have the right to determine the appropriate course of action to enforce its HEMISPHERX Intellectual Property against infringement or otherwise abate the infringement thereof , to take (or refrain from taking) appropriate action to enforce its HEMISPHERX Intellectual Property, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to its Intellectual Property .
- D.** Each Party shall promptly notify the other Party in writing if any claim, action, demand or other proceeding (a "Claim") is brought against or is threatened to be brought against such Party alleging that the sale of Product violates another party's intellectual property.
- E.** SCIEN will promptly notify HEMISPHERX of any Third party SCIEN knows or believes may be infringing HEMISPHERX Intellectual Property and will, to the greatest extent reasonably possible, provide to HEMISPHERX any information SCIEN has in support of such belief. HEMISPHERX will have the right, but not the obligation, to use such information in an infringement action against such third Party. SCIEN agrees to cooperate with HEMISPHERX in any action for infringement of HEMISPHERX, and HEMISPHERX will reimburse SCIEN for all reasonable costs incurred by it in providing cooperation requested by HEMISPHERX.

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- F.** HEMISPHERX is and shall remain the sole legal and registered owner for any trademark or trade name of "Interferon alfa-n3 (human leukocyte derived)". The parties shall work together, upon commercial approval in the Territory to secure a trade name in the Territory.
- G.** HEMISPHERX hereby grants to SCIEN and SCIEN hereby accepts the right, privilege and exclusive license to use of "Interferon alfa-n3 (human leukocyte derived)" solely in connection with the terms of the Sales, Marketing, Distribution and Supply Agreement of Product in the Territory for the Term of this Agreement. Should the Agreement expire or terminate, the right to use the trademark shall also terminate. SCIEN shall use "Interferon alfa-n3 (human leukocyte derived)" at all times for the sole purpose of marketing of Product for no other purpose.
- H.** The terms of the intellectual property license hereby granted shall be effective upon the Effective Date of this Agreement and during the term of this Agreement, unless sooner terminated in accordance with the provisions of the Sales, Marketing, Distribution and Supply Agreement between the parties.
- 1.** Good Will. SCIEN recognizes that there exists great value and good will associated with the Intellectual Property of Interferon alfa-n3 (human leukocyte derived)"
- 2.** SCIEN agrees that it will not during the term of this Agreement, or thereafter, attack the title or any rights of HEMISPHERX in and to Interferon alfa-n3 (human leukocyte derived) or attack the validity of the license granted herein by HEMISPHERX and solely owned by HEMISPHERX.
- I.** SCIEN agrees to assist HEMISPHERX to the extent necessary in the procurement of any protection or to protect any of HEMISPHERX's right to Interferon alfa-n3 (human leukocyte derived) and HEMISPHERX, if it so desires, may commence or prosecute any claims or suits in its own name or in the name of SCIEN or join SCIEN as a party thereto. SCIEN shall notify HEMISPHERX in writing of any infringements or imitations by others of "Interferon alfa-n3 (human leukocyte derived)" which may come to SCIEN 's attention, and HEMISPHERX shall have the sole right to determine whether or not any action shall be taken on account of any such infringements or imitations. SCIEN shall not institute any suit or take any action on account of any such infringements or imitation without first obtaining the written consent of the HEMISPHERX so to do.
- J.** SCIEN agrees to cooperate fully and in good faith with HEMISPHERX for the purpose of securing and preserving HEMISPHERX's rights.
- K.** It is agreed that nothing contained in this Sales, Marketing, Distribution, and Supply Agreement shall be construed as an assignment or grant to the SCIEN of any rights, title or interest in or to "Interferon alfa-n3 (human leukocyte derived)".
- L.** It is further understood that all rights relating thereto are reserved by HEMISPHERX, except for the license hereunder to SCIEN of the right to use and utilize the name Interferon alfa-n3 (human leukocyte derived) only as specifically and expressly provided in this Agreement.
- M.** In the event of termination of this license for any reason, SCIEN shall within 6months (as described in the Termination clause), cease all use of the "Interferon alfa-n3 (human leukocyte derived)". SCIEN shall not thereafter use any names, mark or trade name similar thereto belonging to HEMISPHERX. Termination of the license under the provisions of this Agreement shall be without prejudice to any rights which HEMISPHERX may otherwise have against SCIEN.
- N.** SCIEN shall, and shall cause its shareholders, officers, directors, and managing personnel to, comply with all laws, rules and government regulations pertaining to its business and shall not violate any laws which would create an adverse effect on "Interferon alfa-n3 (human leukocyte derived)" in the U.S. and/or the Territory.
- O.** Relationship of Parties. SCIEN shall not in any manner or respect be the legal representative or agent of HEMISPHERX and shall not enter into or create any contracts, Agreements, or obligations on the part of HEMISPHERX, either expressed or implied, nor bind HEMISPHERX in any manner or respect whatsoever regarding its intellectual property; it being understood that this Agreement is only a contract for the licensed use of the product names in connection with the terms in this Agreement.

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XIII. BUYOUT

HEMISPHERX will have the option at any time to buy out this Agreement. If exercised within the first two (2) years HEMISPHERX will pay SCIEN three (3) times the Product sales for the preceding 12 months. If exercised after year 3, HEMISPHERX will pay SCIEN two (2) times the Product sales for the preceding 12 months.

XIV. MISCELLANEOUS.

- A.** Notices. Notices sent pursuant to this Agreement are valid if in writing and addressed to the parties at the respective addresses given below or at such other addresses as either party shall notify the other in writing and sent by registered or certified mail, postage prepaid and return receipt requested, or by Federal Express or other comparable courier providing proof of delivery, and shall be deemed duly given and received (i) if mailed, on the third business day following the mailing thereof, or (ii) if sent by courier, the date of its receipt (or if not on a business day, the next succeeding business day).

If to HEMISPHERX:

Thomas K. Equels, President and CEO
One Penn Center
1617 JFK Boulevard
Suite 500
Philadelphia, PA 19103 United States

If to SCIEN:

Abdelrhman Mofeed Zhreldin
Business Development Manager
Scientific Products Pharmaceutical Co. Ltd
Tahlia Street, P.O Box 10485,
Riyadh 11433 Saudi Arabia

- B.** This Agreement and the transactions contemplated herein shall be governed by, and construed in accordance with, the laws of the State of Delaware, USA and disputes, if not resolved by the Parties, will be settled by binding arbitration in and under the rules of arbitration in London, England.
- C.** This Agreement constitutes the entire understanding of the parties with respect to the purchase and sale of Products and supersedes all prior discussions, agreements, and understandings between HEMISPHERX and SCIEN.
- D.** Each party an independent contractor to the other and the relationship between the parties shall not be construed to be that of an employer and employee, or to constitute a partnership, joint venture, or agency of any kind.
- E.** This Agreement may only be amended in a writing signed by both parties hereto.
- F.** If any provision of this Agreement is declared invalid or unenforceable by a court having competent jurisdiction, it is mutually agreed that this Agreement shall endure except for the part declared invalid or unenforceable by order of such court.
- G.** This 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.

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H. Prior to their release, the parties must agree on press releases or market communication that utilises the other Party's name.

Counterparts; Integration; Effectiveness; Electronic Execution

This Agreement may be executed in counterparts (and by different parties hereto in different counterparts), each of which shall constitute an original, but all of which when taken together shall constitute a single contract. This Agreement constitutes the entire contract among the parties relating to the subject matter hereof and supersede any and all previous agreements and understandings, oral or written, relating to the subject matter hereof.

This Agreement shall become effective when it shall have been executed by all parties and upon receipt of all counterparts hereof that, when taken together, bear the signatures of each of the other parties hereto. Delivery of an executed counterpart of a signature page of this Agreement by e-mail and/or telecopy shall be effective as delivery of a manually executed counterpart of this Agreement.

The words "execution," "signed," "signature," and words of like shall be deemed to include electronic signatures or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, and any other similar State laws based on the Uniform Electronic Transactions Act.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the last date below and in so doing acknowledge that they have a corporate authority to bind their respective organizations to this Agreement.

SCIENTIFIC PRODUCTS PHARMACEUTICAL CO. LTD:

HEMISPHERX BIOPHARMA, INC:

S/ Saleh Al-Abdullah Al-Rasheed

Saleh Al-Abdullah Al-Rasheed

CEO & Owner

S/ Thomas K. Equels

Thomas K. Equels

President and CEO

Date:

Date:

3-29-2016

3-31-16

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*



Exhibit 1

The drug, Interferon Alfa-n3, is intended for investigational use in the countries in which it is distributed prior to receipt of RAA;

The drug, Interferon Alfa-n3, meets your specifications as reflected on the attached Certificate of Analysis;

The drug, Interferon Alfa-n3, is not in conflict with the laws of the countries in which it is distributed;

The investigation will be conducted in accordance with good clinical practices, including review and approval of the study by an independent ethics panel and informed consent of the study subjects;

The drug, Interferon Alfa-n3, does not present an imminent hazard to public health, either in the United States, if the drug were to be reimported, or in the countries in which it is distributed;

The drug, Interferon Alfa-n3, is labelled in accordance with the laws of the countries in which it is distributed.

I have reviewed the attached labels and the current Certificate of Analysis against the specifications and agree with the above statements that these meet the laws of the countries in which the product will be distributed.

Signature: _____ Date: _____

Printed Name: Saleh Al- Rashid

Title: Chairman and CEO

Company: Scientific Products Pharmaceutical Co. LTD

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Certificate of Analysis

{***}

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Label information enlarged for ease of read.

{***}

Enlarged Label:

{***}

Caution: Limited by Federal (US)

Law to Investigational Use.

Manufactured For:

Hemispherx Biopharma, Inc.

Philadelphia, PA 19103

(U.S.A.)

Actual Label:

{***}

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Exhibit 2 Study Protocol Synopsis

A Compassionate Use Protocol Using Natural Leukocyte Interferon (Alfa-n3) for Individual Treatment of Symptomatic Patients with Middle East Respiratory Syndrome (MERS)

{***}

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Exhibit 3 Business Plan

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

Exhibit 4

TECHNICAL/QUALITY AGREEMENT

1. Parties

This Quality Agreement is entered by and between Scientific Products Pharmaceutical Co. LTD., a pharmaceutical company with its primary offices located at Tahlia Street, P.O Box 10485, Riyadh 11433 Saudi Arabia (“SCIEN”) and Hemispherx Biopharma, Inc. 783 Jersey Avenue, New Brunswick, New Jersey 08901 (HEMISPHERX).

2. Purpose

The purpose of this Quality Agreement is to clearly define the quality operating procedures, duties and responsibilities to be employed by SCIEN and HEMISPHERX in the conduct of activities by SCIEN for Hemispherx Biopharma, Inc. The objective of these procedures and this Quality Agreement is assurance that services are conducted in a timely, consistent and uniform manner and in accordance with current laws, directives, regulations and guidelines, as may be applicable to the specific project(s). These requirements may include those defined by the U.S. FDA’s regulations At 21CFR314.80 (Post-marketing reporting of adverse drug experiences for drugs), 21CFR312.32 (IND safety reporting) 21CFR600.80 (Post marketing reporting of adverse experiences for biologics) 21CFR Parts 210 and 211 (“current Good Manufacturing Practices” or “cGMPs”) with particular interest in 21CFR211.1.42 (Warehousing), 21CFR211.150 (Distribution), 21CFR211.204 (Returned drug) and 21CFR211.208 (Drug product salvaging), ICH Guidance for Industry: E6 Good Clinical Practice Consolidated Guidance and/or others that may be appropriate for the particular project.

3. Scope

This Quality Agreement is to be applied to the activities performed by SCIEN, for HEMISPHERX as specifically defined by the Sales, Marketing, Distribution, and Supply Agreement January __, 2016 (“Agreement”) to which this Quality Agreement is an integral Exhibit. In the event of a conflict between the terms of the Agreement and this Quality Agreement, the terms of the Agreement shall control. Unless otherwise stated in these documents, SCIEN shall follow its Standard Operating Procedures (“SOPs”) with respect to the activities it shall carry out in accordance with the Agreement. Copies of all relevant SOPs shall be provided to HEMISPHERX for review during audits.

4. Confidentiality

The information and procedures contained in this Quality Agreement are confidential and subject to the terms and conditions of the confidentiality provisions as set forth in the Confidential Disclosure Agreement September 22, 2014 (“CDA”) executed by HEMISPHERX and SCIEN.

5. Terms

This Agreement between HEMISPHERX and SCIEN shall be in effect beginning the last date of execution set forth on the signature page to the Agreement (the “Effective Date”) to which this Quality Agreement is Exhibit 2 and remain in effect until HEMISPHERX and SCIEN terminate the Agreement or it is superseded by a revised Quality Agreement executed by both parties. This Quality Agreement should be reviewed periodically by both parties for any needed updating, revisions, amendments, and the like. Regular periodic review of this Quality Agreement should be conducted to ensure it is up-to-date.

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HEMISPHERX may perform audits for initial qualification of **SCIEN** as well as periodic audits and “for cause” audits. At mutually agreed upon times, HEMISPHERX may review standard operating and other quality control procedures and records and the records of **SCIEN** relating to the Agreement. Such routine and general oversight review is to be requested at least twenty (20) business days in advance, limited to two (2) persons, completed within one (1) to two (2) business days and shall be offered to HEMISPHERX one (1) time each calendar year. **SCIEN** will make every reasonable effort to accommodate the special circumstances that may arise pursuant to “for cause” audits. The following applies to all audits:

- Prior to an audit HEMISPHERX will communicate to **SCIEN** the scope of the audit.
- HEMISPHERX will prepare a written report of the results of the audit and forward a copy to **SCIEN**.

SCIEN will provide a written response to HEMISPHERX’s written audit report within twenty (20) business days of receipt of such report setting forth the corrective actions to be taken by **SCIEN**, if any, and a timeline for such implementation.

In the event of an inspection by any governmental or regulatory authority concerning the activities carried out under the Agreement, **SCIEN** shall notify HEMISPHERX promptly upon learning of such an inspection, shall supply HEMISPHERX with copies of any correspondence or portions of correspondence relating to HEMISPHERX’s materials and shall inform HEMISPHERX of the general findings and outcomes of such inspections.

SCIEN and HEMISPHERX shall cooperate with each other during any such inspection, investigation or other inquiry, including applying reasonable effort, as might be practical, at allowing, upon reasonable request, a representative of HEMISPHERX to be on site during such inspection, investigation or other inquiry, and providing copies of all documents related to the inspection. Each party acknowledges that it may not direct the manner in which the other party fulfills its obligations to permit inspection by governmental entities

6. Dispute Resolution

If a dispute arises between the parties under this Agreement, the parties agree that, prior to either pursuing other available remedies, decision-making individuals from each party will promptly meet, either in person or by telephone, to attempt in good faith to negotiate a resolution of the dispute. If, within sixty days after such meeting, the parties are unable to resolve the dispute (or such longer time as the parties may agree) either party is free to pursue its legal remedies.

7. Definitions

Adverse experience: Any adverse event associated with the use of a biological or drug product in humans, whether or not considered product related, including the following: an adverse event occurring in the course of the use of a biological or drug product in professional practice; an adverse event occurring from overdose of the product whether accidental or intentional; an adverse event occurring from abuse of the product; an adverse event occurring from withdrawal of the product; and any failure of expected pharmacological action.

Disability: A substantial disruption of a person’s ability to conduct normal life functions.

Life-threatening adverse experience: Any adverse experience that places the patient, in the view of the initial reporter, at immediate risk of death from the adverse experience as it occurred, i.e., it does not include an adverse experience that, had it occurred in a more severe form, might have caused death.

Labeled event: An adverse experience that is listed on the product insert as having been observed in patients who are receiving the drug product.

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Drug Product: A finished dosage form, for example, tablet, capsule, or solution that contains an active ingredient generally, but not necessarily, in association with inactive ingredients

Serious adverse experience: Any adverse experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Unexpected adverse experience: Any adverse experience that is not listed in the current labelling for the biological or drug product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labelling, but differ from the event because of greater severity or specificity.

For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the labeling only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the labeling only listed cerebral vascular accidents. “Unexpected,” as used in this definition, refers to an adverse experience that has not been previously observed (i.e., included in the labeling) rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product.

Call report: A list of all questions, requests for circulars, and physician/patient complaints received by **SCIEN's** Clinical Support Department is prepared monthly by **SCIEN** staff and is forwarded to HEMISPHERX RA/QA Department.

Audit: A systematic examination of processes, controls and systems, operating procedures, reports, records and/or data to assess **SCIEN's** compliance with standards, regulatory submissions, SOPs; applicable laws, regulations, directives, standards and guidelines; the terms of this Agreement and other contracts in place defining the services being provided and to verify data integrity.

Good Clinical Practices (“GCPs”): Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and wellbeing of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. ICH Guidance for Industry: E6 Good Clinical Practice Consolidated Guidance.

Good Manufacturing Practices (“GMPs”): The recognized pharmaceutical regulations and requirements of regulatory authorities such as those defined by the U.S. FDA’s regulations at 21CFR Parts 210 and 211.

Key Contacts: Persons at **SCIEN** and HEMISPHERX assigned to assure proper communication and follow-up in a timely manner within both parties’ organizations. Names, titles and full contact information for Key Contacts shall be appended to this Agreement as Attachment 1 and should be maintained up-to-date during the course of the project.

Observation: A statement of fact made during an audit that is substantiated by objective evidence. HEMISPHERX categorizes observations as follows:

- o **Critical:** May pose risk to patient or consumer or otherwise compromise the integrity or quality of the material, product, process, or service being provided. Other instances that could be defined as a critical observation include: A practice that poses an immediate safety risk to personnel; Quality System(s) missing or not in compliance with regulations, guidelines, or corporate policies.

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- o **Major:** Does not fully comply with regulations, guidelines or corporate policies and may pose unnecessary risks to the integrity or quality of material, product, process or service being provided. Other instances that could be defined as a major observation include: Likely or probable safety risk to personnel; Quality System(s) weak or needing improvement; repeated Minor deficiencies of a similar nature that indicate a systemic problem and therefore may be classified as Major.
- o **Minor:** Does not comply with regulations, guidelines, or corporate policies but does not directly impact the integrity or quality of the material, product, process, or service being provided.
- o **Comment:** Compliant with regulations, guidelines and/or corporate policies; however, the auditor comment serves as a recommendation relative to maintaining or improving a specific condition noted.

Out-of-Specification / Out-of-Trend (“OOS / “OOT”): A result that is not within the established specifications or trend, whether these are qualitative or quantitative.

Standard Operating Procedures (“SOPs”): Procedures in effect at **SCIEN** that define the processes and controls by and under which activities are to be conducted to assure compliance with the appropriate Code of Federal Regulations.

7. Communications

To assure proper communication, notification and follow-up in a timely manner by both parties, “Key” contacts are listed in Attachment 1 of this Agreement. Key contacts shall have access to project managers and technical staff and, upon reasonable notice and as required, facilitate resolution of any issues. Every effort will be made by **SCIEN** to accommodate timely communications, including face-to-face meetings, with HEMISPHERX.

8. Change of Control

SCIEN will maintain and follow change control SOP(s) to ensure that changes to equipment, procedures, processes, etc. occur in a controlled manner and in compliance with requirements defined by the U.S. FDA’s regulations (see Section 2). The implementation of any change that may directly impact the integrity of the activities conducted or data being supplied for HEMISPHERX will require prior written approval of HEMISPHERX. **SCIEN** and HEMISPHERX will advise the appropriate organization’s staff member (See Attachment 1) before implementation of a change, by either party, to equipment, procedures, specifications, processes, clinical protocols, product claims or facilities directly related to HEMISPHERX’s specific products and processes. Each party agrees to review the proposed change in a timely manner and, at its discretion, may audit and/or request an alternative or additional change prior to the implementation of the proposed change. The respective party will review the proposed change, determine if it is reasonably practicable to implement the change and can suggest alternative or additional changes prior to the implementation of the proposed change. Change control requirements should be articulated within the specific operation’s documentation practices.

HEMISPHERX is responsible for assuring changes are in accordance with and/or reported to the investigational, marketing and/or any other filing with regulatory agencies (IND, IMPD, CTA, NDA, MA, etc.) and for informing **SCIEN** of any changes requested by regulatory agencies. **SCIEN** agrees to keep HEMISPHERX fully informed of any and all communications with regulatory agencies that may affect the services being provided to HEMISPHERX by **SCIEN**.

This Agreement is not meant to supersede or replace controlled documents typically used to define and record the work to be conducted by **SCIEN** for HEMISPHERX. Specific requirements of this Agreement and/or any service contracts shall be articulated within **SCIEN**’s current operating procedures and documentation systems.

9. Responsibilities

SCIEN is responsible for:

- 1) case management support services to patients and maintain a 24-hour/365-day a year telephone service for assistance of prescription drug-related medical emergencies to patients
- 2) the distribution of product, including the shipping, handling and storage and all rules and regulations of every governmental authority having jurisdiction over the shipping, handling, storage, distribution, and dispensing of Product

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- 3) confirming the product labelling requirements in the territory
- 4) conforming to all labeled specifications concerning the shipping, handling and storage of Product
- 5) notifying HEMISPHERX of any unacceptable storage or handling deviation within one (1) business day
- 6) inspecting all product shipments received by SCIEN from HEMISPHERX and reporting any damage, defect, loss in transit, or other shipping errors to HEMISPHERX within one (1) business days of receipt by SCIEN
- 7) administering recalls, field alerts, warning letters, quarantines or withdrawals in accordance with HEMISPHERX instructions (See Attachment 2)
- 8) administering HEMISPHERX's Returned Goods Policy (See Attachment 3)
- 9) immediately (within 24 hours of becoming aware of event) notifying HEMISPHERX of any serious and unexpected side effects (Adverse Experiences reported to SCIEN, as defined by 21CFR 314.80 and 21CFR 312.32))
- 10) providing HEMISPHERX with written Adverse Experience Reports (at the latest day 4 after becoming aware of event)
- 11) notifying the Regulatory Authorities within the Territory of any reportable adverse experiences
- 12) notifying the Regulatory Authorities within the Territory of any suspected counterfeiting or tampering except as required different by law
- 13) obtaining program approval from appropriate regulatory agencies in the Territory
- 14) keeping HEMISPHERX fully informed of any and all communications with regulatory agencies that may affect the services being provided to HEMISPHERX by SCIEN
- 15) receiving and processing complaints
- 16) notifying HEMISPHERX of complaints and actions taken or to be taken to address the complaints
- 17) the performance of all services provided by SCIEN's subcontractors
- 18) communicating to HEMISPHERX any events of non-conformance that impact the quality of HEMISPHERX's product. Examples of non-conformances may include, but are not limited to: equipment failure, shipping error or documentation error, labeling error, improper storage, facilities system error, and unplanned study protocol deviations. When a non-conformance event occurs that is specific to HEMISPHERX's product, SCIEN will conduct an investigation and provide copies of all investigation documentation to HEMISPHERX for review and input
- 19) for initiating, monitoring and completing CAPA tasks related to discrepancies, errors and incidents involving services that are under SCIEN's control

HEMISPHERX is responsible for:

- 1) release of product following review of all manufacturing and quality control testing requirements to confirm the batch has been manufactured according to approved processes and specifications
- 2) supply all necessary quality documentation with shipments to allow product importation and release
- 3) ensuring product intended for supply in territory is labelled accordingly
- 4) assuring changes to the established operations are in accordance with and/or reported to the investigational, marketing and/or any other filing with regulatory agencies (IND, IMPD, CTA, NDA, MA, etc.).
- 5) informing SCIEN of any changes requested by regulatory agencies
- 6) assist with/address any Agencies requests relating to manufacture of product
- 7) providing SCIEN any information that could result in a field alert or recall of a product under a HEMISPHERX NDA or ANDA immediately, but no more than one (1) business day after discovery. HEMISPHERX interprets FDA 21 CFR 314.81, "Other Post-Marketing Reports," to require a Field Alert Report to be made within three (3) days of an occurrence of an OOS result, whether that result is confirmed or not. The only exception to this would be where the original result was invalidated within the three (3) days. In that case, no field alert would be required
- 8) making the proper reports to the FDA regarding a field alert or recall

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- 9) making the proper reports to the FDA regarding any serious and unexpected side effects
- 10) communicating to SCIEN any events of non-conformance that impact the quality of HEMISPHERX's product. Examples of non-conformances may include, but are not limited to: contamination, calculation or documentation error, labeling error. When a non-conformance event occurs HEMISPHERX will conduct an investigation and inform SCIEN of any appropriate action to be taken
- 11) for initiating, monitoring and completing CAPA tasks related to discrepancies, errors and incidents involving services that are under HEMISPHERX's control
- 12) contribute to customer complaint investigations where possible issues due to manufacturing process may have contributed to complaint

HEMISPHERX and SCIEN are separately responsible for securing and maintaining all required licenses, permits and certificates applicable to their respective operations and each shall comply with any and all applicable federal, state and local laws, including but not limited to (i) the Federal Food Drug and Cosmetic Act; (ii) the Social Security Act; (iii) HIPAA; (iv) all federal and state health care anti-fraud and abuse laws, and (v) all state privacy, and consumer protection laws, including those relating to the use of medical and prescription information for commercial purposes.

10. Subcontractors

SCIEN may enter into agreements between SCIEN and a subcontractor. SCIEN will identify the services performed by each such subcontractor. SCIEN is responsible for the performance of all services provided on behalf HEMISPHERX and the compliance of each subcontractor to the terms of this Agreement. HEMISPHERX will be permitted to conduct periodic audits of the subcontractors to assure compliance to applicable GMP's, GLP's and federal regulations (CFR's).

11. Standard Operating Procedures (SOP's)

The following HEMISPHERX SOP's are relevant to this Quality Agreement and interactions between HEMISPHERX and SCIEN and affiliates.

- A. CLN-009 Handling Adverse Event Reports and Records
- B. RA-001 Post Marketing Adverse Experience Reporting
- C. QC-006 Investigation of Out of Specification Results

12. Laboratory Controls-N/A

13. Documentation and Record Maintenance

SCIEN shall preserve all records in accordance with any applicable federal, state or local requirements. Raw data, documentation, batch records, source documents, product disposition records and reports (collectively, "Documentation") shall be retained by SCIEN for a minimum period of two (2) years after termination or expiration of the Specialty Distributor Purchase and Service Agreement between HEMISPHERX and SCIEN. SCIEN shall, upon written receipt of a written request from HEMISPHERX, finish such Documentation in a format reasonably acceptable to HEMISPHERX with thirty (30) days of receipt of such request. In this case, the Documentation will be shipped to the Quality Assurance Manager named in this Agreement (see Key Contact List, Attachment 1). It is the responsibility of HEMISPHERX to notify SCIEN of any changes in this contact. During the retention period, documentation shall be available for inspection by HEMISPHERX, its authorized agents and authorized government agencies.

14. Complaints

In the event SCIEN is notified of a complaint, SCIEN will receive, investigate and respond to the complaint following its internal procedures. A copy of all complaint investigation documentation will be provided to HEMISPHERX.

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15. Contact List of Key Personnel. See Attachment 1

IN WITNESS WHEREOF, the parties hereto have executed this Quality Agreement as of the Effective Date.

Hemispherx Biopharma Inc.

Quality Assurance Signature: _____

Printed Name: Victoria Scott

Title: Associate Director Quality and Regulatory

Date: _____

Management Signature: _____

Printed Name: Wayne Springate

Title: Senior Vice President Operations

Date: _____

SCIEN.

Quality Assurance Signature: _____

Printed Name: _____

Title: _____

Date: _____

Management Signature: _____

Printed Name: Abdelrhman Mofeed Zhreldin

Title: Business Development Manager

Date: _____

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**Attachment 1
List of Key Contacts**

SUBJECT	HEMISPHERX CONTACT	SCIEN CONTACT
Regulatory Compliance Requirements	Victoria Scott Associate Director/Quality and Regulatory Phone: 732-249-3250 Fax: 732-249-6895 Email: Regulatory@Hemispherx.net	
Notification of Regulatory Agencies and Regulatory Submissions	Victoria Scott Associate Director/Quality and Regulatory Phone: 732-249-3250 Fax: 732-249-6895 Email: Regulatory@Hemispherx.net	
Recall of Marketed Product	Victoria Scott Associate Director/Quality and Regulatory Phone: 732-249-3250 Fax: 732-249-6895 Email: Regulatory@Hemispherx.net	
Adverse Drug Events	David Strayer, MD Medical Director Phone: 215-988-0880 Fax: 215-988-1739 Email: SAE@Hemispherx.net	
Product Complaint	Victoria Scott Associate Director/Quality and Regulatory Phone: 732-249-3250 Fax: 732-249-6895 Email: Victoria.Scott@Hemispherx.net	
Field Alert Reports/Biological Product Deviation Reports	Victoria Scott Associate Director/Quality and Regulatory Phone: 732-249-3250 Fax: 732-249-6895 Email: Victoria.Scott@Hemispherx.net	
Change Control	Victoria Scott Associate Director/Quality and Regulatory Phone: 732-249-3250 Fax: 732-249-6895 Email: Victoria.Scott@Hemispherx.net	
Clinical Study Protocol Changes	David Strayer, MD Medical Director Phone: 215-988-0880 Fax: 215-988-1739 Email: David.Strayer@Hemispherx.net	
New or Revised Product Claims	David Strayer, MD Medical Director Phone: 215-988-0880 Fax: 215-988-1739 Email: David.Strayer@Hemispherx.net	
Documentation Quality Records Record Retention	Victoria Scott Associate Director/Quality and Regulatory Phone: 732-249-3250 Fax: 732-249-6895 Email: Victoria.Scott@Hemispherx.net	

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SUBJECT	HEMISPHERX CONTACT
Product Testing and Release	Victoria Scott Associate Director/Quality and Regulatory Phone: 732-249-3250 Fax:732-249-6895 Email:Victoria.Scott@Hemispherx.net
Control of Components, Labelling and Packaging Materials	Chris Cavalli VP Quality and Process Development Phone: 732-249-3250 Email:Chris.Cavalli@Hemispherx.net Fax:732-249-6895
Product Storage and Shipping	Victoria Scott Associate Director/Quality and Regulatory Phone: 732-249-3250 Fax:732-249-6895 Email:Victoria.Scott@Hemispherx.net
Returned Goods	Victoria Scott Associate Director/Quality and Regulatory Phone: 732-249-3250 Fax:732-249-6895 Email:Victoria.Scott@Hemispherx.net
Deviations/Investigations	Victoria Scott Associate Director/Quality and Regulatory Phone: 732-249-3250 Fax:732-249-6895 Email:Victoria.Scott@Hemispherx.net
Nonconforming or Rejected Material	Victoria Scott Associate Director/Quality and Regulatory Phone: 732-249-3250 Fax:732-249-6895 Email:Victoria.Scott@Hemispherx.net
Supplier Qualification	Victoria Scott Associate Director/Quality and Regulatory Phone: 732-249-3250 Fax:732-249-6895 Email:Victoria.Scott@Hemispherx.net
Quality Audits & Regulatory Inspections	Victoria Scott Associate Director/Quality and Regulatory Phone: 732-249-3250 Fax:732-249-6895 Email:Victoria.Scott@Hemispherx.net

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Attachment 2
QA-007-Product Recall

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Attachment 3
HEMISPHERX Return Goods Policy

This Return Goods Policy us for all HEMISPHERX product, Interferon alfa-n3 (human leukocyte derived) distributed by **SCIEN**.

The following products are eligible for return and reimbursement:

- Outdated Product: Product within two (2) months prior or six (6) months past expiration date and noted on product;
- AND
- Product in its original container and bearing its original label.
- OR
- Product which HEMISPHERX has specified be returned

The following products are not eligible for return and reimbursement:

- Product that is not outdated.
- Product in which the lot number and/or expiration date is missing, illegible, covered, and/or unreadable on original container.
- Product that has been damaged due to improper storage handling, fire, flood, or catastrophe.
- Product that has been sold expressly on a non-returnable basis.
- Product that is not in its original container and/or not bearing its original label.
- Product that is in its original container with a prescription label attached.
- Product that has been repackaged
- Partial Vials
- Product obtained illegally or via diverted means
- Product purchased on the “secondary source” market or from a distributor other than **SCIEN**.
- Product that HEMISPHERX determines, in its sole discretion, is otherwise adulterated, misbranded, or counterfeit.

HEMISPHERX will only accept returns shipped to **SCIEN**. All eligible products shall be shipped in a safe, secure, and reliable manner, and in compliance with all applicable federal, state and local laws, regulations and statutes. It is the shipper’s responsibility to securely package all return goods to prevent to prevent breakage during transit and otherwise comply with the laws and regulations applicable to the packaging, shipping, and transport of return goods shipments.

HEMISPHERX is not responsible for shipments lost and/or damaged in transit. HEMISPHERX recommends that all customers insure return goods shipments.

HEMISPHERX will audit the quantities of return goods and final reimbursement will be based on HEMISPHERX count. All products will be reimbursed based on the price paid direct purchasing customers reimbursement will be issued in the form of credit or product replacement to the appropriate party.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*

To assist in accurate credit memo processing, please include the following information:

1. Purchasers Name and Mailing Address
2. Date and Quantity

Return goods shipments which are deemed to be outside of this policy will not be returned to the customer or the third party processor and no reimbursement will be issued by HEMISPHERX. HEMISPHERX return goods policy is subject to change at any time and without prior notices to other parties.

*{***} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.*