

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

HEMISPHERX BIOPHARMA INC

Form 8-K

December 14, 2007

STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)  
December 13, 2007

HEMISPHERX BIOPHARMA, INC.  
(Exact name of registrant as specified in its charter)

Delaware 0-27072 52-0845822  
(state or other jurisdiction (Commission File (I.R.S. Employer  
of incorporation) Number) Identification No.)

1617 JFK Boulevard, Philadelphia, Pennsylvania 19103  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (215) 988-0080

-----  
(former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to  
simultaneously satisfy the filing obligation of the registrant under any of the  
following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Securities Act (17 CFR 230.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240-14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240-13e-4(c))

Section 1 - Registrant's Business and Operations.

Item 1.01 Entry into a Material Definitive Agreement

On December 13, 2007 we entered into a licensing/research agreement with BIKEN (the non-profit operational arm of the Foundation for Microbial Diseases of Osaka University), to use our experimental drug Ampligen(R) as an immune enhancer in influenza vaccine. Refer to the attached exhibits for more information.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits

10.1 Biken Activating Agreement.

10.2 Biken Material Evaluation Agreement.

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.

HEMISPHERX BIOPHARMA, INC.

December 14, 2007

By: /s/ William A. Carter

-----  
William A. Carter, M.D.  
Chief Executive Officer

Exhibit 10.1

Activating Agreement

This Agreement is made by and between Hemispherx Biopharma, Inc. (hereinafter referred to as "Hemispherx") and The Research Foundation for Microbial Diseases of Osaka University (hereinafter referred to as "Biken").

RECITALS

WHEREAS, Hemispherx owns intellectual property rights relating to poly I: poly C12U, with the trade name of Ampligen(R) and possesses proprietary rights and know-how relating to the manufacture and production of Ampligen(R); and

WHEREAS, Biken is a manufacturer of biologicals in Japan, and has been engaged for many years mainly in the research and development and manufacture of a variety of infection-prophylactic vaccine products for human use. As part of the work activities relating to a research project entitled "The Research Project on Clinical Application of the Influenza Virus Vaccine in the Intranasal Dosage Form for Mucosal Administration" (hereinafter referred to as the "Research Project"), which is subsidized by the Japanese Ministry of Health, Labor and Welfare (hereinafter referred to as the MHLW") and in which the National Institute of Infectious Diseases of Japan (hereinafter referred to as the "NIID") plays a main part and Biken also participates as one of the researchers and during and in the course of which, at the end of each fiscal year research results obtained thereby are to be compiled by the NIID into an annual research report that will be submitted to the MHLW and subsequently placed, for public view, Biken has an intention to evaluate the functional capability of Ampligen(R) in serving as an adjuvant to induce mucosal immune response. In addition, Biken owns jointly with the NIID the intellectual property rights relating to the "Novel Vaccine Containing Adjuvant Capable of Inducing Mucosal Immunity", which is the object substance of the Research Project, and possesses the technical know-how to prepare prototypes of such adjuvanted vaccine preparation for experimental and research purposes, and

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

WHEREAS, Hemispherx and Biken have entered into a Material Evaluation Agreement of even date herewith ("MEA") which provides for an Evaluation Program as defined and described therein.

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

1. The Collaboration Agreement attached hereto as Exhibit 1, together with all of its terms and provisions, shall, without further act by the parties or either of them, become activated, operative and effective upon completion of the Evaluation Program as defined in the MEA with the Evaluation Program's designated success end points having been achieved.
2. The Parties may at any time by agreement in writing amend the Collaboration Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the day and year set forth below.

HEMISPHERX BIOPHARMA, INC.

THE RESEARCH FOUNDATION FOR  
MICROBIAL DISEASES OF OSAKA UNIVERSITY

/s/ William A. Carter

/s/ Yasushi Higashi

-----  
-----  
Represented by:

-----  
-----  
Represented by:

Name: William A. Carter, MD  
Title: Chairman of the Board,  
Chief Executive Officer

Name: Yasushi Higashi, M.D., D.M. Sc.  
Title: Chairman , Board of Directors

Address:  
One Penn Center  
1617 JFK Blvd.  
Philadelphia, PA 19103  
U.S.A.

Address:  
3-1, Yamada-Oka, Suita,  
Osaka 565-0871  
Japan

Date: Dec. 13, 2007

Date: Dec. 12, 2007

Exhibit 1

Collaboration Agreement

This Collaboration Agreement is made as of the Effective Date by and between The Research Foundation for Microbial Diseases of Osaka University ("Biken") and Hemispherx Biopharma, Inc. ("Hemispherx").

WHEREAS, Hemispherx owns intellectual property rights relating to poly I: poly C12U, with the trade name Ampligen(R) and possesses proprietary rights and know-how relating to the manufacture and production of Ampligen(R), and

WHEREAS, Hemispherx and Biken wish to develop and obtain appropriate regulatory approvals for the commercial sale of "Combined Product(s)" as defined in Clause 1.5, and following the awarding of appropriate regulatory approvals, wish to cause the Combined Product(s) to be manufactured, produced and marketed for administration to patients.

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

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:

### 1. Definitions

1.1 "Affiliate" shall mean any entity in whatever country organized which directly or indirectly owns, is owned by or is under common ownership with a party to this Collaboration Agreement or any entity actually controlled by, controlling or under common control of a party to this Collaboration Agreement. For the purpose of this definition, "ownership" or "control" shall mean where such entity owns or controls fifty percent (50%) or more of the equity conferring voting rights and/or otherwise has the ability to direct the business affairs of another entity.

1.2 "Confidential Information" shall mean and include all present and future techniques, inventions, practices, knowledge, know-how, skill, experience, test data, analytical data, pre-clinical and clinical development data, clinical trial protocols, reports including case report forms, any applications to any regulatory authority including registration dossiers, marketing and sales data and descriptions (whether in electronic, documentary, eye readable or any other form) generated or obtained by either party or obtained through agreement with a third party with regard to Ampligen(R) and/or the Prototype Vaccine Preparation and/or Combined Product(s) or disclosed by either party to the other party and identified as being confidential and including any reports prepared by either party for the other, excluding, however, information which:

1.2.1 is or comes into the public domain through no fault of the receiving party; 1.2.2 is known to the receiving party prior to the date of disclosure, as evidenced by written records of that party; or

1.2.3 is lawfully disclosed to the receiving party by a third party rightfully in possession of it; or

1.2.4 is independently and subsequently developed by an employee or agent of the receiving party who had no knowledge of the Confidential Information disclosed under this Collaboration Agreement or of any Confidential Information derived by the receiving party therefrom.

1.3 "Ampligen(R)" shall mean poly I: poly C12U.

1.4 "Prototype Vaccine Preparation" shall mean the prototype of influenza virus vaccine preparation described in Clause (6) of Article 2 of the Material Evaluation Agreement dated December 13, 2007 by and between Hemispherx and Biken (hereinafter referred to as "Material Evaluation Agreement").

1.5 "Combined Product(s)" shall mean any influenza virus vaccine in the form of spray administration, using in any manner Ampligen(R) (either with or without the addition of other substance(s)) and manufactured, produced, tested and/or marketed for administration to patients. Of these Combined Products, "Biken Combined Product(s)" shall mean Combined Product(s) using vaccine antigens that Biken manufactures by propagating and purifying influenza viral antigens which Biken produces and that contain inactivated whole virus or HA antigens (hereinafter referred to as "Biken Vaccine Antigens").

1.6 "Biken Non-Exclusive Licensed Territory" shall mean Japan.

1.7 "Hemispherx Licensed Patents" shall mean:

1.7.1 all Hemispherx patents issued or pending in the Biken Non-Exclusive Licensed Territory as listed on Exhibit A attached hereto and made a part hereof.

1.7.2 any division, continuation, or continuation-in-part of any such application and any patent which shall issue based on such application, division, continuation or continuation-in-part;

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

1.7.3 any patent which is a re-issue or extension of, or patent of addition or any application maturing into a patent defined in Clauses 1.7.1 and 1.7.2;

1.7.4 any patent application or patent corresponding to any patent application or patent defined in Clause 1.7.1, 1.7.2 or 1.7.3 which is hereafter filed or issued in the Biken Non-Exclusive Licensed Territory.

1.8 "Hemispherx Licensed Know-How" shall mean and be limited to the information possessed by Hemispherx relating to Ampligen(R) specifications and its testing in animals and man and the result thereof.

1.9 "Entity" shall mean, and include, any person, firm or company or group of persons or unincorporated body.

1.10 "Person(s)" include any person, firm or company or group of persons or unincorporated body.

1.11 Effective Date. "Effective Date" shall mean the date upon which this Collaboration Agreement is activated and becomes operative and effective in accordance with the provisions of the Activating Agreement by and between Hemispherx and Biken.

### 2. Grant of License

2.1 Hemispherx hereby grants to Biken and Biken hereby accepts a non-exclusive, non-transferable license to use Hemispherx Licensed Know-How and the Hemispherx Licensed Patents in order to test, manufacture, have manufactured, market, have marketed, use and sell Biken Combined Product(s) in the Biken Non-Exclusive Licensed Territory solely in relation to research for prevention/treatment of influenza and in relation to prevention/treatment of influenza.

2.2 Biken may, with prior written notice to and with the written approval of Hemispherx, which approval shall not be unreasonably withheld, sub-license the Hemispherx Licensed Know-How and Hemispherx Licensed Patents under this Collaboration Agreement to any third party in the Biken Non-Exclusive Licensed Territory for making, using and selling Biken Combined Product(s) or sub-license the manufacture or marketing thereof, for research for the prevention/treatment of influenza, and for the prevention/treatment of influenza in the Biken Non-Exclusive Licensed Territory.

2.3 In the event of sub-licensing as provided for in clauses 2.2, Biken shall ensure that such third party sub-licensee undertakes in writing to comply with the terms of this Collaboration Agreement to the extent that such terms are applicable to it upon the granting of any such sub-license.

2.4 Biken shall guarantee the due and punctual performance of any and all responsibilities under this Collaboration Agreement as applied to such third party sub-licensee.

2.5 Hemispherx warrants that Exhibit A attached hereto contains a full disclosure of the Hemispherx Licensed Patents and all reasonably relevant information relating thereto and that this disclosure is material to the execution of this Collaboration Agreement by Biken.

2.6 Hemispherx hereby warrants and represents that it has full right and power to grant the license set forth in clause 2.1 and that there are no outstanding agreements, assignments or encumbrances in existence inconsistent with the provisions of this Collaboration Agreement including without limitation to generality any obligations to governmental agencies, private foundations, companies, corporations, individuals or the like resulting from acceptance of research grant or other monies, or otherwise.

2.7 Hemispherx warrants and undertakes to Biken that it does not know of any present or proposed litigation in the Biken Non-Exclusive Licensed Territory concerning Ampligen(R) but it does not warrant that Ampligen(R) will not infringe the rights of third parties.

2.8 Nothing in this Collaboration Agreement or any Hemispherx license granted hereunder to Biken is to be construed as a representation or warranty that Hemispherx Licensed Patents are valid or that use, sale or other dealing or disposition of Ampligen(R) is not an infringement of any intellectual property rights in the Biken Non-Exclusive Licensed Territory not owned or controlled by

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

Hemispherx.

### 3.0 Know-how

3.1 Hemispherx shall, during the term of this Collaboration Agreement, supply Biken without any payment by Biken other than the consideration referred to in Article 5 hereof, all such documents, records, computerized records and/or other data constituting the Hemispherx Licensed Know-How and Hemispherx hereby warrants that such Hemispherx Licensed Know-How will be fully disclosed to Biken.

3.2 The Hemispherx Licensed Know-How supplied by Hemispherx shall be used by Biken or its sub-licensee solely for the manufacture, use, marketing and sale of Biken Combined Product(s) in the Biken Non-Exclusive Licensed Territory, for research for the prevention/treatment of influenza and for the prevention/treatment of influenza.

3.3 Ownership of the Hemispherx Licensed Know-How supplied by Hemispherx shall at all times vest in Hemispherx. At Hemispherx's request and expense, Biken shall either assist Hemispherx in bringing actions against third parties for an infringement or unlawful appropriation, use or disclosure of the Hemispherx Licensed Know-How and otherwise in maintaining Hemispherx's rights in the Hemispherx Licensed Know-How or bring and pursue in its own name all such actions against the relevant third parties immediately, in the event of its becoming aware of any such infringement or unlawful appropriation, use or disclosure, as elected by Biken.

### 4. Commercial Development and Supply

4.1 Biken shall perform with due diligence its efforts to develop, gain regulatory approval for commercial sale, commercialize and continue the commercialization of the Biken Combined Product(s) in the Biken Non-Exclusive Licensed Territory.

4.2 For a period of three years immediately following the effective date of this Collaboration Agreement, if reasonably requested in writing by Biken, Hemispherx shall supply to Biken and/or its sub-licensee at Hemispherx's cost all Ampligen(R) required by Biken for the development of Biken Combined Product(s) in the Biken Non-Exclusive Licensed Territory.

### 5. Consideration

5.1 As consideration for the license hereby granted by Hemispherx to Biken, Biken shall pay Hemispherx a royalty of two percent (2%) of the amount received by Biken and any Affiliate of Biken for all sales and/or usage of Biken Combined Product(s) in the Biken Non-Exclusive Licensed Territory.

5.2 The royalty hereunder shall accrue and be payable to Hemispherx's designated bank quarterly in arrear, within thirty (30) days after the close of each calendar quarter following the date of first commercial sales of Biken Combined Product(s) in the Biken Non-Exclusive Licensed Territory.

5.3 At the same time as payment of any royalties due Biken shall submit or cause to be submitted to Hemispherx a statement in writing recording the sales and/or usage of Biken Combined Product(s) within the Biken Non-Exclusive Licensed Territory during the period to which such royalties relate, the net invoiced price or value of such sales and/or usages, the direct cost of production and marketing of such sales and the amount of royalties payable thereon. In the event that no sales or usage of Biken Combined Product(s) have been made during any such period in the Biken Non-Exclusive Licensed Territory Biken shall submit a nil statement.

5.4 Biken shall procure that any sub-licensee shall keep at its usual place of business, proper detailed records and books of account as may be necessary to determine the royalties payable hereunder.

5.5 Hemispherx shall have the right, after Biken has received seven (7) days notice in writing, to instruct a mutually acceptable accountant at any reasonable time during normal business hours to make such examination of the books and records of Biken as shall be deemed necessary to verify such records and books of account pertaining to the sale or use of Biken Combined Product(s) provided however, that this right may not be exercised twice in any twelve (12)

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

month period. Said inspection shall disclose to Hemispherx only such information concerning Biken as pertains to sales of Combined Product(s) and payments or royalties. Said inspection shall be conducted at the expense of Hemispherx unless when conducting such an inspection the accountant discovers an error of more than three percent (3%) in the returns made by Biken since the commencement of this agreement or the date of the last inspection in which event the cost of such inspection shall be met by Biken.

5.5.1 Any tax paid or required to be paid or held by Biken for the account of Hemispherx due to royalty payments to Hemispherx under this agreement shall be deducted from the amount of royalty otherwise due. Biken shall secure and send to Hemispherx proof of any such taxes withheld and paid by Biken or its sub-licensees for the benefit or on behalf of Hemispherx.

### 6. Confidentiality

6.1 Each party undertakes to the other that it shall keep secret and confidential all Confidential Information communicated to it by the other under this Collaboration Agreement and shall not disclose the same or any part thereof to any person whatsoever except as provided in clauses 6.2, 6.3 and 6.4

6.2 Each party may disclose Confidential Information to its directors or employees or consultants directly or indirectly concerned with Prototype Vaccine Preparation and Combined Product(s) providing that before any such disclosure the disclosing party shall procure that each of its directors, employees and consultants shall execute a confidentiality undertaking in such form as the other party may reasonably require.

6.3 Biken may disclose Confidential Information to a sub-licensee properly appointed in accordance with this Collaboration Agreement, provided that before any such disclosure Biken shall have entered into a confidentiality undertaking with its sub-licensee on terms no less onerous than the confidentiality conditions of this Clause 6.

6.4 Biken may disclose to Regulatory Authorities such Confidential Information as is required to effect the registration of Biken Combined Product(s).

6.5 In the event that the obligation of confidence imposed by this Collaboration Agreement is breached by a party to this Collaboration Agreement either willfully or negligently or carelessly, then the party at fault shall be responsible to the injured party for all the damages arising from the breach and communication to the third party of the Confidential Information excluding indirect, consequential damages and loss of profits.

6.6 Each party shall take all reasonable steps to minimize the risk of disclosure of Confidential Information and a breach of clause 6:

6.6.1 by ensuring that only employees and representatives whose duties require them to possess Confidential Information have access thereto and by instructing such employees and representatives to treat the same as confidential;

6.6.2 by providing proper and secure storage for papers, drawings and other confidential material and forbidding unauthorized persons access to the place or places where these are stored.

6.7 The provisions in this clause shall remain in force without limit in time and notwithstanding termination or cancellation of this Collaboration Agreement.

### 7. Territorial Restraint

7.1 Biken shall not use the Hemispherx Licensed Know-How or Hemispherx Licensed Patents, nor sell nor permit the sale of Biken Combined Product(s) outside the Biken Non-Exclusive Licensed Territory or knowingly sell or have sold any Biken Combined Product(s) to any party in or outside the Biken Non-Exclusive Licensed Territory for export or sale outside the Biken Non-Exclusive Licensed Territory, without Hemispherx's prior written consent.

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

### 8. Patents

8.1 Hemispherx agrees to maintain faithfully the licensed patents in the Biken Non-Exclusive Licensed Territory as reflected in Exhibits A and pay all taxes, annuities, maintenance fees and the like to ensure that the licensed patents are legally maintained.

8.2 Biken shall promptly notify Hemispherx of any infringement of the Hemispherx Licensed Patents, within the Biken Non-Exclusive Licensed Territory, misappropriation of a trade secret or declaration of an interference proceeding relating to the Hemispherx Licensed Patents or Hemispherx Licensed Know-How and shall provide Hemispherx with all available evidence relating thereto.

8.2.1 Biken and Hemispherx will immediately consult with each other as to the best manner to proceed.

8.2.2 Hemispherx shall have the right, but not the obligation, to bring, defend and maintain any appropriate suit or action. If Hemispherx requests Biken to join in such suit or action and Biken agrees to do so, Biken shall execute all papers and perform such acts as may be reasonably required and may, at its option be represented by counsel of its choice. Hemispherx and Biken shall each be responsible for their own expenses (including legal fees) in connection with any such suit or action. Should Hemispherx lack standing to bring any such action, then Hemispherx may cause Biken to do so upon first undertaking to indemnify and hold Biken harmless (to the extent permissible by law) from all consequent liability and promptly to reimburse all reasonable expenses (including legal fees) stemming therefrom.

8.2.3 If Hemispherx fails to take action with respect to such matters within a reasonable period, but in any event, not more than one hundred and twenty (120) days following receipt of such notice and evidence, Biken shall have the right, but not the obligation, to bring, defend and maintain any appropriate suit or action. If Biken finds it necessary to join Hemispherx in such suit or actions, Hemispherx shall execute all papers and perform such acts as may be reasonably required and may, at its option, be represented by counsel of its choice. Biken shall pay Hemispherx the reasonable expenses of Hemispherx (including its legal fees) in connection with any such suit or action.

8.2.4 In the absence of any agreement between the parties to jointly bring any action or suit hereunder and share the expenses thereof, any amount recovered in any such action or suit shall be retained by the party bearing the expenses thereof.

### 9. Improvements

9.1 Any improvement or technical advances made in or grant of further Letter Patent in respect of the Hemispherx Licensed Patents or Hemispherx Licensed Know-How by Hemispherx shall forthwith be disclosed to Biken, whether the subject of Letter Patent or not. For the avoidance of doubt, this disclosure shall not constitute the grant of a license to use or exploit such improved or advanced patents or know-how or to manufacture, use or sell improved or advanced Combined Product(s).

### 10. Force Majeure

10.1 "Force Majeure" shall be deemed to have prevented, restricted or interfered with the performance by a party hereto of any of its



## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

obligations hereunder if such event occurs by reason of flood, fire, explosion, strike, war, revolution, civic commotions, political riot, acts of public enemies, blockade or embargo or sanctions or any law, interdict, order proclamation, regulation, ordinance, demand or requirements of any government. Where the party so affected shall be excused from such of its obligations hereunder as it is unable to perform to the extent of Force Majeure, it shall be excused for so long as such prevention, restriction or interference shall remain in force plus a reasonable period thereafter. Notwithstanding the foregoing, should Force Majeure continue for an unbroken period of twelve (12) months then either party shall be entitled to terminate this Collaboration Agreement forthwith by giving written notice to the other.

10.2 Neither party shall be held responsible for damages caused by any delay or default due to force majeure.

### 11. Non Agency

Each party shall operate under this Collaboration Agreement as an independent contractor. Nothing contained in this Collaboration Agreement or done hereunder shall be construed as constituting either party the agent or partner of the other in any sense of that term or for any purpose whatsoever and neither party shall be entitled to bind the other to any third party.

### 12. Duration And Termination

12.1 This Collaboration Agreement shall come into effect on the effective date and shall remain in full force and effect, subject to the provisions of clause 12.2 hereof, for the life of the Hemispherx Licensed Patents and for three (3) years after the expiry of the last of the Hemispherx Licensed Patents in the Biken Non-Exclusive Licensed Territory.

12.2 Anything herein to the contrary notwithstanding, either party shall have the right to terminate this Collaboration Agreement by notice of termination in writing to the other party in the event that the commercial sales of Combined Product(s) prove to be unrealizable both in Biken Non-Exclusive Licensed Territory. Neither of the parties hereto shall have any responsibility or liability for or in connection with the termination of this Agreement pursuant to this clause.

12.3 In the event that Biken or Hemispherx (the "defaulting party") shall:

12.3.1 default in a material obligation hereunder including failure to make any payments, and fail to remedy such default within sixty (60) days after receipt by the defaulting party of written notice by the non-defaulting party calling upon it to remedy such default; or

12.3.2 be voluntarily or compulsorily liquidated, and whether provisionally or finally or commit any act of insolvency; or

12.3.3 suffer the appointment of a receiver for any substantial portion of its business who shall not be discharged within sixty (60) days after such receiver's appointment; or

12.3.4 have any judgment granted against it and not have such judgment set aside within fourteen (14) days after such judgment has come to its notice;

then and in such event, the non-defaulting party, at its option, may with immediate effect terminate its obligations to and the rights of the defaulting party under the license granted in this Collaboration Agreement and cancel this Collaboration Agreement by written notice to the defaulting party.

12.4 In the event of the cancellation or termination of this Collaboration Agreement under clause 12.2 or 12.3 howsoever arising.

12.4.1 Biken shall return promptly to Hemispherx all Hemispherx Licensed Know-How and shall co-operate with Hemispherx in the cancellation of all or any rights and licenses registered pursuant hereto and shall execute and do all

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

such documents, acts and things as may be necessary in such connection;

12.4.2 Hemispherx shall automatically have the right to take an absolute assignment of Biken's rights in terms of any sub-license granted hereunder and Biken hereby irrevocably appoints Hemispherx its attorney for the purpose of notifying any sub-licensee of such a change and of signing any document or doing any act to perfect such assignment.

12.5 Notwithstanding the termination of a party's obligations to or the rights of the defaulting party under this Collaboration Agreement in accordance with clauses 12.2 and/or 12.3, the provisions of clause 6 shall survive such termination and continue in full force and effect without limit in time.

12.6 Nothing contained herein shall limit any remedies available to either party at law or in equity for the default of the other party under clause 12.3. Termination shall not excuse the obligations of either party to pay money due to the other party.

### 13. Successors and Assigns

The rights and obligations of Biken and Hemispherx shall bind and inure to the benefit of their successors and assigns who shall be bound by the terms of this Collaboration Agreement.

### 14. Headings

The headings of the clauses of this Collaboration Agreement have been inserted only to facilitate reference and shall not be taken as being of any significance whatsoever in the construction and interpretation of this Collaboration Agreement.'

### 15. General

15.1 No waiver by either party of a provision hereof or default hereunder shall be deemed a waiver of any other provisions or default.

15.2 Any notices or communications to or from the respective parties required or permitted to be given hereunder shall be deemed to have been received:

15.2.1 if mailed by registered prepaid airmail to the recipient at the address given herein and the date of receipt shall be deemed to be fourteen (14) working days after date of mailing unless the contrary can be proved;

15.2.2 if sent by telefax to the recipient at the number given herein and evidence exists of receipt thereof on the next business day of the recipient after sending unless the contrary can be proved and provided that such telefax message is confirmed by registered prepaid post;

15.3 This Collaboration Agreement embodies the entire Collaboration Agreement between the parties. On the Effective Date hereof, it supersedes any previous agreement the parties may have in respect of the subject matter. Neither party shall assert that it had an understanding inconsistent with, or that goes beyond, or falls short of, any provision herein. No change in terms of this Collaboration Agreement or the consensual cancellation thereof shall be effective as to either party hereto unless reduced to writing and signed by all the parties hereto.

15.4 Biken and Hemispherx shall, at their own expense in the respective countries, take such steps as may be required to satisfy the laws and requirements of the respective countries with respect to declaring, recording and otherwise rendering this Collaboration Agreement valid.

15.5 If any provision of this Collaboration Agreement is found by any court of competent jurisdiction to be invalid or unenforceable for any reason whatsoever, this shall not in itself be deemed to affect the other provisions thereof and such invalid or unenforceable clause shall be severable from the remaining terms of this Collaboration Agreement.

### 16. RESOLUTION OF DISPUTE

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

16.1 Any dispute at any time between the Parties hereto arising out of or pursuant to this Agreement or its interpretation, rectification, breach or termination shall, if not resolved through negotiations between the Parties, be finally settled by arbitration. Arbitration shall be conducted in the United States pursuant to the rules of the American Arbitration Association in New York, New York, U.S.A. if Hemispherx is the respondent, and in Tokyo, Japan pursuant to the Commercial Arbitration Rules of the Japan Commercial Arbitration Association if BIKEN is the respondent.

16.2 The decision of the arbitrator shall be final and binding and shall be capable of being made an order of any court having jurisdiction over any of the Parties.

16.3 This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, United States of America without regard to the conflicts of laws, rules or principles thereof.

### 17. Domicilia

17.1 The parties hereto choose domicilia citandi et executandi for all purposes in terms of this Collaboration Agreement as follows:

17.1.1 The Research Foundation for Microbial Diseases of Osaka University

3-1, Yamada-Oka, Suita  
Osaka, 565-0871, Japan  
Telephone: +81-6-6877-4804  
Telefax: +81-6-6876-1984

17.1.2 Hemispherx Biopharma, Inc.

One Penn Center  
1617 JFK Blvd.  
Philadelphia, PA 19103, U.S.A.  
Telephone: 215-988-0080  
Telefax: 215-988-0739

Either party shall be entitled to change the domicilia citandi executandi chosen by it by giving the other party thirty (30) days notice of such change of address.

This is the last page of the Collaboration Agreement.

Exhibit 10.2

### Material Evaluation Agreement

This Agreement is made by and between Hemispherx Biopharma, Inc. (hereinafter referred to as "Hemispherx") and The Research Foundation for Microbial Diseases of Osaka University (hereinafter referred to as "Biken").

### RECITALS

WHEREAS, Hemispherx owns intellectual property rights relating to poly I: poly C12U, with the trade name of Ampligen(R) and possesses proprietary rights and know-how relating to the manufacture and production of Ampligen(R); and

WHEREAS, Biken is a manufacturer of biologicals in Japan, and has been engaged for many years mainly in the research and development and manufacture of a variety of infection-prophylactic vaccine products for human use. As part of the work activities relating to a research project entitled "The Research Project on Clinical Application of the Influenza Virus Vaccine in the Intranasal Dosage Form for Mucosal Administration" (hereinafter referred to as the "Research Project"), which is subsidized by the Japanese Ministry of Health, Labor and Welfare (hereinafter referred to as the MHLW) and in which the National Institute of Infectious Diseases of Japan (hereinafter referred to as the

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

"NIID") plays a main part and Biken also participates as one of the researchers and during and in the course of which, at the end of each fiscal year research results obtained thereby are to be compiled by the NIID into an annual research report that will be submitted to the MHLW and subsequently placed, for public view, Biken has an intention to evaluate the functional capability of Ampligen(R) in serving as an adjuvant to induce mucosal immune response. In addition, Biken owns jointly with the NIID the intellectual property rights relating to the "Novel Vaccine Containing Adjuvant Capable of Inducing Mucosal Immunity", which is the object substance of the Research Project, and possesses the technical know-how to prepare prototypes of such adjuvanted vaccine preparation for experimental and research purposes.

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

### 1. OBJECTIVE

The objective of this Agreement is to set forth the terms and conditions under which, as described in the Evaluation Program outlined in Exhibit 1 hereof, Biken evaluates Ampligen(R) primarily from the aspects of both adjuvant-function as induction of satisfactory mucosal immune response and its safety, in collaboration with the Co-Researcher, by using the Prototype Vaccine Preparation as defined in Paragraph (6) of Article 2 hereof (hereinafter referred to as the "Evaluation"), in order to select candidates of both viral-antigens and adjuvant-auxiliaries which are identified as the most promising substances and determine the formulations of potential influenza virus vaccine candidates containing such viral-antigens as the active ingredients and such adjuvant-auxiliaries, during and in the course of the Research Project aimed at practical use of a newly developed adjuvanted-influenza virus vaccine which is capable of inducing a cross-protective immunity against seasonal influenza viruses causing annual influenza epidemics and/or the new influenza viruses with new pandemic potential.

### 2. DEFINITIONS

- (1) "Ampligen(R)" shall mean poly I: poly C12U.
- (2) "Confidential Information" shall mean and include all present and future techniques, inventions, practices, enforcement, knowledge, know-how, skill, experience, test data, analytical data, descriptions (including the explanation set forth in Paragraph (3) of Article 6 hereof), and reports (whether in electronic, documentary, eye readable or any other form) generated or obtained by either Party or obtained through agreement with a third party with regard to Ampligen(R) and/or the Evaluation to be performed by Biken in cooperation with the Co-Researchers or disclosed by either Party to the other Party pursuant to or in connection with this Agreement, and identified as being confidential, and including any reports prepared by either Party for the other, excluding, however, information which:
  - 1) is or comes into the public domain through no fault of the receiving Party;
  - 2) is known to the receiving Party prior to the date of disclosure, as evidenced by written records of that Party; 3) is lawfully disclosed to the receiving Party by a third party rightfully in possession of it; or
  - 4) is independently and subsequently developed by an employee or agent of the receiving Party who had no knowledge of the Confidential Information disclosed under this Agreement or of any Confidential Information derived by the receiving Party therefrom.
- (3) "Effective Date" means the date on which this Agreement is last executed by either Party.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

- (4) "Co-Researcher" means the following researchers, who are involved in the Research Project as set forth in Recitals Clause hereof, who will cooperate with Biken on the Evaluation:

Name	Institution/Organization to which one belongs	Title
Hideki Hasegawa	National Institute of Infectious Diseases	Chief, Laboratory Diseases Pathology, Pathology
Masato Tashiro	National Institute of Infectious Diseases	Director, Department o
Hiroshi Kida	Department of Disease Control, Hokkaido University Graduate School of Veterinary Medicine	Professor

In case of any changes in personnel composition of the aforementioned Co-Researcher, Biken shall so notify Hemispherx in writing.

- (5) "Party" shall mean either Hemispherx or Biken or both, as the case may be.
- (6) "Prototype Vaccine Preparation" shall mean the prototype of influenza virus vaccine preparation in the form of intranasal and/or injectable dosage, containing primarily of candidates of influenza viral-antigens and Ampligen(R), which is prepared by Biken for the purpose of performing the Evaluation as defined in Article 1 hereof.
- (7) "Research Adviser" shall mean any of the following specialists, who dispenses expert advice as required from Biken and/or the Co-Researcher in a position of adviser on the Research Project during and in the course of which Biken performs the Evaluation in cooperation with the Co-Researchers:

Name	Institution/Organization to which one belongs	Title
Koichi Yamanishi	National Institute of Biomedical Innovation	Director Gene
Takeshi Kurata	Toyama Institute of Health	Director

3. PROVISION OF MATERIAL AND RELATED INFORMATION

Provided that Biken agrees to the following terms, Hemispherx shall provide Biken with Ampligen(R) and the Confidential Information relating to Ampligen(R):

- (1) During the effective term of this Agreement, Hemispherx grants to Biken the

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

exclusive right to use Ampligen(R) and the Confidential Information relating to Ampligen(R) for the purpose of performing the Evaluation as provided in Article 1 hereof in Japan.

- (2) Biken shall use Ampligen(R) and the Confidential Information relating to Ampligen(R) solely for the purpose of performing the Evaluation in accordance with Paragraph (1) of this Article.
(3) Nothing contained herein shall be construed to grant to Biken any rights in technology or license of any patent, copyright or trademark now or hereafter in existence except for the purposes of the Evaluation.

4. SUPPLY OF AMPLIGEN(R) AND PAYMENT

- (1) Hemispherx shall supply to Biken, pursuant to Biken's written request, and Biken shall purchase from Hemispherx, such volume of Ampligen(R) as will be necessary for Biken in performing the Evaluation in Japan. The price of Ampligen(R) for such supply and purchase shall be as specified below:

.....
\$200.00 U.S. per 400 mg. Unit
.....

- (2) The payments of the price provided in Paragraph (1) of this Article shall be made by Biken to Hemispherx within thirty (30) days after Biken's receipt and inspection of the Ampligen(R) in the United States Dollars by means of telegraphic transfer to the following bank account, unless Hemispherx notifies otherwise to Biken in writing:

-----
Bank: Wachovia Bank
-----
Bank Address: Centre Square Branch,
15th and Market Streets,
Philadelphia, PA 19102
Phone: (215) 985-7377
-----
SWIFT No: International Swift Address: FUNB33 INT
-----
Account Number: 2000-009-652305 ABA Number 031201468
-----
Account Name: Hemispherx Biopharma, Inc.
-----

- (3) If Biken detects that the Ampligen(R) provided by Hemispherx has any defect, Biken shall notify Hemispherx of it, and Hemispherx shall recall such defective items and provide non-defective Ampligen(R) at its cost within thirty (30) days at the latest after the receipt of said notice from Biken. In this case, the period of the payment set forth in the above paragraph shall be thirty (30) days after Biken's receipt and inspection of the replacement Ampligen.(R)

5. CONFIDENTIALITY

- (1) Except as provided elsewhere herein, each Party shall keep in strict confidence and shall not disclose to any third party any Confidential Information (including the Ampligen(R) as owned by Hemispherx) provided or disclosed by the other Party hereunder during the effective period hereof without first obtaining the written consent of said other Party.

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

- (2) Notwithstanding the provisions of the preceding Paragraph hereof, Biken may disclose the Confidential Information (including the Ampligen(R) as owned by Hemispherx) provided or disclosed by Hemispherx hereunder during the effective period hereof to the Co-Researcher and/or the Research Adviser, as defined in Paragraphs (4) and (7) of Article 2 of this Agreement, respectively, provided both are then bound and agree to all provisions of this Agreement relating to the confidentiality of Ampligen(R) and Confidential Information.
- (3) Each Party shall exercise the same degree of care and safeguards with respect to the Confidential Information (including Ampligen(R) as owned by Hemispherx) as used to maintain the confidentiality of its own information of the similar nature; provided, however, the degree of the care and safeguard shall not at any time be less than the reasonable degree.
- (4) If Biken wishes to publish research papers relating to the use of Ampligen(R) and the Confidential Information relating to Ampligen(R) provided by Hemispherx pursuant to or in connection with this Agreement for the purpose of the Evaluation, or to publicly disclose any information relating to or resulting from such use, together with the Co-Researchers, Biken shall notify Hemispherx in writing prior to the publication or disclosure. As for the research results to be compiled into annual research reports to be submitted to the MHLW and subsequently placed for public view in connection with the Research Project referred to in the Recitals hereof, it is deemed that by virtue of the execution of this Agreement by the Parties hereto that Hemispherx has consented thereto.
- (5) If either Party is required by any governmental agency, court or other quasi-judicial or regulatory authorities to provide any of the Confidential Information (including Ampligen(R) as owned by Hemispherx) provided or disclosed by the other Party hereunder during the effective period hereof, the Party shall, if possible, promptly notify the other Party in writing prior to any such disclosure so that said other Party may seek an appropriate remedy and/or waive compliance with the provisions of this Agreement.
- (6) The provisions in this Article shall remain in force for five (5) years from the Effective Date notwithstanding termination or cancellation of this Agreement; it being understood and agreed that the foregoing provisions of this Article shall not be construed as permitting either Party to voluntarily disclose any Confidential Information (including Ampligen(R) as owned by Hemispherx) provided or disclosed by the other Party to it hereunder during the effective period hereof to any third party subsequent to the expiration of the aforesaid period of confidentiality.

### 6. EVALUATION AND TERM OF AGREEMENT

- (1) Biken may, by giving prior written notice to Hemispherx, commission a part of the evaluation tests which are necessitated by the Evaluation Program outlined in Exhibit 1 hereof, to external specialized testing institutions; provided, however, that in such a case, Biken shall require said external specialized testing institutions be bound by and agree to all provision of this Agreement relating to the confidentiality of Ampligen(R) and Confidential Information.
- (2) This Agreement shall come into force and effect on the Effective Date, and shall continue to be in force and effect until the expiration of a one year period from the Effective Date, provided that this Agreement shall be terminated when any of the following events occurs, and provided further that Biken may extend the term of this Agreement for a period not exceeding three (3) months by so notifying Hemispherx in writing not later than

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

thirty (30) days before the expiration of the original term of this Agreement, if none of the following events will have occurred:

- (a) Completion of the Evaluation Program with the Evaluation Program's designated success end points having been achieved;
- (b) Cessation of funding of the Research Project by MHLW with no alternative source of such funding identified within ninety (90) days of the cessation of funding by MHLW; or
- (c) Completion of the Evaluation Program with the Evaluation Program's designated success end points not having been achieved...

- (3) Upon termination of this Agreement based on the paragraph (b) and (c) of the proviso of Clause (2) of this article, unless otherwise agreed, Biken shall return to Hemispherx or destroy, as instructed by Hemispherx, all documents and data, whatever the type or media thereof may be, concerning Ampligen(R) and the Confidential Information relating to Ampligen(R) provided and disclosed by Hemispherx to Biken pursuant to or in connection with this Agreement.
- (4) Upon termination of this Agreement pursuant to paragraph (b) or (c) of the proviso of Clause (2) of this article, unless otherwise agreed, Hemispherx shall return to Biken or destroy, as instructed by Biken, all documents and data (except for the results of the Evaluation, whatever the type or media thereof may be, concerning Ampligen(R) and the Confidential Information relating to Ampligen(R) provided and disclosed by Biken to Hemispherx pursuant to or in connection with this Agreement.
- (5) Notwithstanding paragraphs (3) and (4) of this Article, subject to compliance with this Agreement, each Party may keep one (1) copy or sample of the Confidential Information for archival purposes.

### 7. PATENT INFRINGEMENT

In the event that a third party files claims or suits against either Party, to whom the other Party has provided and/or disclosed its own Confidential Information (including Ampligen(R) as owned by Hemispherx) pursuant to this Agreement during the effective period hereof, on the basis of the alleged infringement of any patent or other intellectual property right of said third party in connection with such information, the disclosing Party shall, at its sole cost and responsibility, deal with, dispose of and settle such claims or suits brought by said third party and shall pay and bear any and all costs, damages and liabilities incurred in connection therewith.

### 8. FORCE MAJEUR

- (1) Force Majeur shall be deemed to have prevented, restricted or interfered with the performance by a Party hereto of any of its obligations hereunder if such event occurs by reason of flood, fire, explosion, strike, war, revolution, civic commotions, political riot, acts of public enemies, blockage or embargo or sanctions or any law, interdict, order proclamation, regulation, ordinance, demand or requirements of any government.
- (2) Neither Party shall be held responsible for damages caused by any delay or default due to force majeure.

### 9. SUCCESSORS AND ASSIGNS@

This Agreement and all rights and obligations arising hereunder shall not be assigned or otherwise transferred by either Party, whether by operation of law or otherwise, unless the other Party has given its written consent thereto, and any such purported assignment or transfer without such written consent shall be null and void.



## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

### 10. HEADINGS

The headings of the clauses of this Agreement have been inserted only to facilitate reference and shall not be taken as being of any significance whatsoever in the construction and interpretation of this Agreement.

### 11. GENERAL

- (1) No waiver by either Party of a provision hereof or default hereunder shall be deemed as a waiver of any other provisions or default.
- (2) Any notices or communications to or from the respective Parties required or permitted to be given hereunder shall be deemed to have been received:
  - 1) if mailed by registered prepaid airmail to the recipient at the address as set forth in Article 14 hereof and the date of receipt shall be deemed to be fourteen (14) working days after date of mailing unless the contrary can be proved;
  - 2) if sent by telefax to the recipient at the number given herein and evidence exists of receipt of thereof on the next business day of the recipient after sending unless the contrary can be proved and provided that such telefax message is confirmed by registered prepaid post.
- (3) This Agreement including the attached Exhibit hereto constitutes the entire agreement between the Parties hereof with respect to the subject matter hereof. This Agreement may only be changed or amended by writing executed by the authorized representatives of the Parties which refers to this Agreement and contains a copy thereof as an attached document.
- (4) If any provision of this Agreement is found by any court of competent jurisdiction to be invalid or unenforceable for any reason whatsoever, this shall not in itself be deemed to affect the other provisions thereof and such invalid or unenforceable clause shall be severable from the remaining terms of this Agreement.

### 12. RESOLUTION OF DISPUTE

- (1) Any dispute at any time between the Parties hereto arising out of or pursuant to this Agreement or its interpretation, rectification, breach or termination shall, if not resolved through negotiations between the Parties, be finally settled by arbitration. Arbitration shall be conducted in the United States pursuant to the rules of the American Arbitration Association in New York, New York, U.S.A. if Hemispherx is the respondent, and in Tokyo, Japan pursuant to the Commercial Arbitration Rules of the Japan Commercial Arbitration Association if BIKEN is the respondent.
- (2) The decision of the arbitrator shall be final and binding and shall be capable of being made an order of any court having jurisdiction over any of the Parties.
- (3) This Agreement shall be governed by and construed in accordance with the laws of Japan.

### 13. COUNTERPARTS OF AGREEMENT

This Agreement is prepared and made in the English language in duplicate.

### 14. DOMICILIA

The Parties hereto choose domicilia citandi et executandi for all purposes in terms of this Agreement as follows:

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

(1) Hemispherx Biopharma, Inc.  
One Penn Center  
1617 JFK Blvd.  
Philadelphia, PA 19103  
Telephone: 215-988-0080  
Telefax : 215-988-0739

(2) The Research Foundation for  
Microbial Diseases of Osaka University (Biken)  
3-1, Yamada-Oka, Suita  
Osaka, 565-0871, Japan  
Telephone: +81-6-6877-4804  
Telefax : +81-6-6876-1984

Either Party shall be entitled to change the domicilia citandi et executandi chosen by it giving the other Party thirty (30) days notice of such change of address.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the day and year set forth below.

HEMISPHERX BIOPHARMA, INC.

THE RESEARCH FOUNDATION FOR  
MICROBIAL DISEASES OF OSAKA UNIVERSITY

/s/ William A. Carter

/s/ Yasushi Higashi

-----  
-----  
Represented by:

-----  
-----  
Represented by:

Name: William A. Carter  
Title: Chairman of the Board,  
Chief Executive  
Officer

Name:: Yasushi Higashi, M.D., D.M.Sc.  
Title: Chairman, Board of Directors

Address:  
One Penn Center  
1617 JFK Blvd.  
Philadelphia, PA 19103

Address:  
3-1, Yamada-Oka, Suita,  
Osaka 565-0871  
JAPAN

Date: Dec. 13, 2007

Date: Dec. 12, 2007

Exhibit 1

Evaluation Program

The Outline of the Evaluation Program on the Ampligen(R) as a candidate for Adjuvant incorporated into Potential Influenza Virus Vaccines in the form of Intranasal Mucosal Administration

1.Evaluation of the Efficacy and Stability of Prototype Vaccines(one-year study)  
Evaluate the immunogenicity of intranasal prototype vaccines containing antigens from 3 sub-type influenza viruses, namely, H1N1, H3N2 and B.

(1) Evaluation of immunogenicity of prototype vaccines in mouse models

1) Step-1

Investigate the immunogenicity of prototype vaccines containing different-concentrated antigens in combination with the

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 8-K

Ampligen(R) of varying concentration levels.  
the needed volume of the Ampligen(R): around 140 mg

- 2) Step-2  
Evaluate antigens prepared with different culture methods for selection of candidate vaccine strain.  
the needed volume of the Ampligen(R): around 100 mg
- 3) Step-3  
Assess the efficacy of prototype vaccines on challenge experiment.  
the needed volume of the Ampligen(R): around 100 mg

- (2) Evaluation of immunogenicity of prototype vaccines in animal models other than mice

the needed volume of the Ampligen(R): around 500 mg

- (3) Evaluation of stability of prototype vaccines for formulation of candidate vaccines (preliminary tests) the  
needed volume of the Ampligen(R): around 750 mg

The total volume of Ampligen(R) as required for the above-mentioned Efficacy and Stability Evaluation Studies: around 1600 mg

2. Evaluation of the Safety Profile of the Ampligen(R) (one-year study)  
Perform the following testing items through procuring external GLP (Good Laboratory Practice) study-related services from contract research organizations:

- (1) Single dose toxicity study (FD (fatal dose) in rat models)  
the needed volume of the Ampligen(R): around 160 mg

- (2) Single dose toxicity study (Setting test for probable maximum repeat-dose in dog models)  
the needed volume of the Ampligen(R): around 160 mg

- (3) Repeated dose toxicity study (Toxicity study in rat models)  
the needed volume of the Ampligen(R): around 5 mg

The total volume of Ampligen(R) as required for the above-mentioned Safety Profile Evaluation Studies: around 325 mg