HEMISPHERX BIOPHARMA INC
Form 8-K
September 01, 2005

UNITED 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) September 1,
2005 (September 1, 2005)

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

Delaware 0-27072 52-0845822
(state or other juris- (Commission (I.R.S. Employer
diction of incorporation) File 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 Exchange Act (17 CFR 240.14a-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 (17 CFR 240.13e-4(c))

Section 8 - Other Events

Item 8.01 Other Events.

On September 1, 2005, we posted on our website a letter to our Stockholders. This letter is filed herewith as Exhibit 99.1.

Section 9 - Financial Statements and Exhibits Item 9.01

Financial Statements and Exhibits.

(c) Exhibits

The following Exhibit is filed as part of this report:

Exhibit No.	Description
99.1	Letter to Stockholders dated September 1, 2005
99.2	Press Release dated September 1, 2005

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.

September 1, 2005

By: /s/William A Carter

William A. Carter M.D., President

Exhibit 99.1

HEMISPHERX BIOPHARMA, INC.

September 1, 2005

Dear Stockholders,

The purpose of this letter is to provide an update to our Stockholders regarding the status of the various endeavors that are currently being pursued by Hemispherx. We are very excited about where the company stands today.

After many years of clinical testing, we are close to filing the New Drug Application for our experimental drug Ampligen(R) to treat Chronic Fatigue Syndrome. We feel very secure in the comprehensiveness of our data, which has been compiled from our clinical trials involving over 700 participants.

We are currently accelerating the implementation of our manufacturing strategy for Ampligen(R). The first part of the strategy consists of establishing production of Ampligen(R) raw material, or polymer, in our own GMP facility in New Brunswick, New Jersey, which was acquired in 2003 as part of our transaction with Interferon Sciences, Inc. Creation of this polymer production capability has been initiated and we expect to start equipment validation in New Brunswick

in late September.

The second part of the strategy involves the formation of a partnership with a qualified contract manufacturer. We have identified several suitable manufacturing partners this year and we are currently in the process of selecting from the qualified candidates. One early candidate was Mayne Pharmaceuticals, which had prior experience manufacturing Ampligen(R) in Australia. Mayne is no longer a viable candidate since it is in the process of terminating its contract manufacturing business. This termination will not have an effect on our strategy or our timetable.

For the past 14 years Ampligen(R) has been successfully produced for our clinical trials and for use in our Treatment IND program. The management team responsible for that manufacturing remains in place and has been augmented by the experienced GMP manufacturing team we acquired at the time of the Interferon Sciences Inc. transaction. We are confident that our expanded manufacturing management team will enable the successful production of Ampligen(R) in the future. We have devoted and, assisted by the twenty million dollar equity credit facility we recently established, will continue to devote substantial resources to our manufacturing process and feel very strongly that it will be completed in a timely and successful manner.

We are also very exited about the developments relating to the oral form of our Alferon N product (Low Dose Oral Interferon Alfa-N3, Human Leukocyte Derived), which is a new delivery form of our FDA approved drug, Alferon N. Alferon N is the only natural interferon currently FDA approved and available in the marketplace. We were pleased to announce last quarter that clinical trials in human volunteers are being conducted in Philadelphia and that a clinical study will shortly commence at the Princess Margaret Hospital in Hong Kong. We are preparing more than 300,000 doses of Alferon LDO for appropriate clinical programs. Pending the outcome of the ongoing clinical studies and based on existing laboratory studies, we expect these trials to demonstrate that Alferon LDO given orally can activate the relevant immune defense pathways in the human body. This would potentially make Alferon LDO the first orally active interferon drug candidate and would open an opportunity leading to a wide range of potential new indications.

One such potential indication is Avian Flu. As widely covered in the media, Avian Flu is a devastating and contagious disease. Health officials are concerned that Avian Flu could mutate to a highly contagious form for humans. This scenario is considered by experts in the field as highly probable. Should this mutation occur it will be the genesis of the next pandemic and would render vaccines presently under development ineffective. The threat of a highly lethal pandemic has caused Governments around the world to search for a treatment that they could potentially stockpile.

In another development Alferon N and Ampligen(R), experimental immunotherapeutics, are among a small group of immunotherapeutic drugs being considered by the department of defense to potentially combat dreaded viral outbreaks including Avian influenza. The Department of Defense strategy will be outlined in an upcoming article entitled "Innate Immunity for Biodefense: A Strategy Whose Time Has Come" proposed for publication in Journal of Allergy and Clinical Immunology (JACI). This article states that "Ampligen(R) has already been tested against over 25 viruses and will be used in Advanced Biosystem's proposal for inhaled IFN in conjunction with Alferon... No evidence of inflammatory reactions has been observed in either Ampligen(R) or Alferon. Administration of over 50,000 doses of Ampligen(R) has not resulted in a cell-mediated autoimmune response. Alferon should be superior to single recombinant IFN types with regards to binding to receptors that are structurally altered by genetic polymorphisms" (emphasis added). This article, including the innate immunity strategy for biodefense, is one of the independent endorsements of our drug technology that energizes and encourages our present enthusiasm for

these products.

In closing, with the acceleration of our manufacturing strategy for Ampligen(R) and our advancements in the development of the Low Dose Oral Interferon program, we feel that the company is poised to make considerable progress toward bringing the Hemispherx products to commercial success.

Sincerely,

/s/ William A. Carter

William A. Carter, M.D.
Chairman and CEO

Information contained in this letter other than historical information, should be considered forward-looking and is subject to various risk factors and uncertainties. For instance, the strategies and operations of Hemispherx involve risk of competition, changing market conditions, change in laws and regulations affecting these industries and numerous other factors discussed in this letter and in the Company's filings with the Securities and Exchange Commission. Any specifically referenced investigational drugs and associated technologies of the company (including Ampligen(R) and Oragens(TM)) are experimental in nature and as such are not designated safe and effective by a regulatory authority for general use and are legally available only through clinical trials with the referenced disorders. The forward-looking statements represent the Company's judgment as of the date of this letter. The Company disclaims, however, any intent or obligation to update these forward-looking statements. Clinical trials for other potential indications of the approved biologic Alferon(R) do not imply that the product will ever be specifically approved commercially for these other treatment indications.

Exhibit 99.2

HEMISPHERX BIOPHARMA, INC.

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Hemispherx Biopharma Expands Manufacturing Facility for Production of Ampligen

Status of clinical Trial advancements for Alferon LDO and manufacturing programs updated in stockholder letter

Philadelphia, PA, September 1, 2005 - Hemispherx Biopharma, Inc. (AMEX: HEB) discloses by letter to stockholders that it has increased the capacity of its facility in New Brunswick, NJ to manufacture its experimental drug, Ampligen(R), as well as advancements in the application of Alferon LDO for the potential treatment of Avian Flu. The letter, which is being submitted as an 8-K with the SEC, highlights several key developments currently underway.

Hemispherx is implementing a three-phase strategy in its manufacturing process of Ampligen(R). The first component in this process highlighted in the stockholder letter is the establishment of production of Ampligen(R)'s raw material polymer in the Company's wholly owned New Brunswick, N.J. manufacturing facility. The creation of the polymer production capability has been initiated and Hemispherx expects to begin equipment validation in the facility in late September.

The second strategic component involves the formation of a partnership with a qualified contract manufacturer for finished product. The company is currently in the process of selecting a qualified candidate from a pool of already-identified and-pre-qualified contenders.

The third component of the manufacturing strategy is the development of the team responsible for the production of Ampligen(R) in New Brunswick, N.J.. For the past 14 years, Ampligen(R) has been successfully produced for clinical trials and used for an ongoing Treatment IND program. The original management team responsible for that manufacturing remains in tact and has been augmented by the experienced GMP manufacturing team that was acquired with the Alferon-N acquisition.

The developments of the Alferon Low Dose Oral (LDO) trials are also highlighted in the stockholder letter. Clinical trials in human volunteers are underway in Philadelphia and will also shortly commence at the Princess Margaret Hospital in Hong Kong. Accordingly, there are currently more than 300,000 doses of Alferon LDO being prepared for these clinical programs.

Pending the outcome of the ongoing clinical studies, and based on existing laboratory studies, Hemispherx expects the trials may demonstrate that Alferon LDO, given orally, can activate the relevant immune defense pathways in the human body. This development would potentially make Alferon LDO the first orally active interferon drug candidate and would open an invaluable opportunity for a wide range of potential new indications. One such potential indication is for treating Avian Flu. As widely covered in the media, Avian Flu is a devastating, contagious disease. Worldwide health officials are concerned that Avian Flu could mutate to a highly contagious form transferable to humans from animals. This scenario is considered by experts in the field to be highly probable. Should this mutation occur, it will be the genesis of the next global pandemic and would render vaccines presently under development ineffective. The threat of a highly lethal pandemic has caused governments around the world to search for a treatment that they could potentially stockpile.

Consideration of Hemispherx's Alferon and Ampligen(R) therapeutics by the US Department of Defense, in coordination with its Bio-defense strategy, is featured in an upcoming article in the Journal of Allergy and Clinical Immunology (JACI) as stated below:

The Department of Defense strategy will be outlined in an upcoming article entitled "Innate Immunity for Biodefense: A Strategy Whose Time Has Come" accepted for publication in the Journal of Allergy and Clinical Immunology (JACI). This article states that "Ampligen(R) has already been tested against over 25 viruses and will be used in Advanced Biosystem's proposal for inhaled IFN in conjunction with Alferon.... No evidence of inflammatory reactions has been observed in either Ampligen(R) or Alferon. Administration of over 50,000 doses of Ampligen(R) has not resulted in a cell-mediated autoimmune response. Alferon should be superior to single recombinant IFN types with regards to binding to receptors that are structurally altered by genetic polymorphisms."

HEMISPHERx CEO, Dr. William A. Carter concluded the stockholder letter, " With the acceleration of our manufacturing strategy for Ampligen(R) and our advancements in the development of the Low Dose Oral Interferon program, we feel that the company is poised to make considerable progress toward bringing the

Hemispherx products to commercial success."

About Hemispherx Biopharma

Hemispherx Biopharma, based in Philadelphia, is a biopharmaceutical company engaged in the manufacture and clinical development of new drug entities for treatment of viral and immune-based chronic disorders. Hemispherx's flagship products include Alferon and the experimental immunotherapeutics/antivirals Ampligen(R) and Oragens(TM). Alferon is approved for a category of STD infection, and Ampligen(R) and Oragens(TM) represent experimental nucleic acids being developed for globally important chronic viral diseases and disorders of the immune system including HPV, HIV, CFS, Hepatitis and SARS. Hemispherx's platform technology includes large and small agent components for potential treatment of various chronic viral infections. Hemispherx has in excess of 140 patents comprising its core intellectual property estate, a fully commercialized product (Alferon N) and GMP certified manufacturing facilities for its novel pharma product. For more information please visit www.hemispherx.net

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Information contained in this news release other than historical information, should be considered forward-looking and is subject to various risk factors and uncertainties. For instance, the strategies and operations of Hemispherx involve risk of competition, changing market conditions, change in laws and regulations affecting these industries and numerous other factors discussed in this release and in the Company's filings with the Securities and Exchange Commission. Any specifically referenced investigational drugs and associated technologies of the company (including Ampligen(R) and Oragens(TM)) are experimental in nature and as such are not designated safe and effective by a regulatory authority for general use and are legally available only through clinical trials with the referenced disorders. The forward-looking statements represent the Company's judgment as of the date of this release. The Company disclaims, however, any intent or obligation to update these forward-looking statements. Clinical trials for other potential indications of the approved biologic Alferon(R) do not imply that the product will ever be specifically approved commercially for these other treatment indications.

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