HEMISPHERX BIOPHARMA INC
Form 8-K
March 10, 2008

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)
March 6, 2008

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

Delaware	0-27072	52-0845822
(state or other juris- diction of incorporation)	(Commission File Number)	(I.R.S. Employer 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.

Following our submission of a clarifying amendment on January 9, 2008, to our NDA application and a subsequent face-to-face meeting with the Agency, the number of items necessary to accomplish a complete NDA for filing purposes has been reduced from an original fourteen (14) to five (5). Specifically, for NDA filing purposes, 9/14 of the original incomplete items noted in the FDA letter received December 5, 2007 are no longer considered filing - related issues. The remaining open items are being promptly addressed by us thru a series of five (5) additional Amendments to the NDA.

For more information, please see the March 6, 2008 press release attached hereti as exhibit 99.1

Section 9 - Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following Exhibit is filed as part of this report:

Exhibit No.	Description
Exhibit 99.1	Press Release dated March 6, 2008

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.

March 10, 2008 By: /s/ William A. Carter

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

Exhibit 99.1

Company/Investor Contact:
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Sean Collins, Sr. Partner
CCG Investor Relations
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HEMISPHERX BIOPHARMA REACHES AGREEMENT WITH FDA ON SPECIFIC STEPS TO ACHIEVE COMPLETE NDA ON PROPOSED CFS TREATMENT

... No Additional Studies Indicated

Philadelphia, PA, March 6, 2008---Hemispherx Biopharma, Inc. (AMEX, HEB) announced today that, following its submission of a clarifying amendment on January 9, 2008, to its NDA application and a subsequent face-to-face meeting with the Agency, the number of items necessary to accomplish a complete NDA for filing purposes has been reduced from an original fourteen (14) to five (5). Specifically, for NDA filing purposes, 9/14 of the original incomplete items noted in FDA letter received December 5, 2007 are no longer considered filing - related issues. The remaining open items are being promptly addressed by the Company thru a series of five (5) additional Amendments to its NDA as described below.

Specifically, the open items-requisite for a complete NDA filing status - may be grouped into one of two categories: Category (1) Administrative items (four) include: (a) transfers of additional clinical records (termed "CRF's"), (b) transfer of several documents previously submitted to the FDA, (c) additional clinical data reconciliations (compiled from the CRF records) and (d) additional computer generated charts which summarize specific parts of the CRFs. Transfer of these records will thereby allow the Agency reviewers to evaluate independently the statistical efficacy /safety conclusions of the Company's existing NDA. Category (2) (One item): a reformatting and enlarged analysis of the existing pharmacokinetics ("PK") report to more closely align with current International Committee on Harmonization ("ICH") guidelines.

Importantly, the company believes no further studies are required to achieve a complete NDA filing status for purposes of regulatory review of the entire document.

As part of the agreement reached with the Agency, the additional files/data may be submitted sequentially as separate NDA Amendments to the existing NDA to accelerate the review process. Submission of these Amendments to the FDA is expected to begin this week with all Amendments expected to be completed and filed shortly. A collaboration with Octagon Research Solutions, a major provider of electronic filings of regulatory documents, will facilitate and accelerate the overall filing process. These Amendments will add to the overall data base of the existing NDA (submitted October 10, 2007) and the company's pre-submission of non-clinical information (submitted December 29, 2006), which was assigned the original NDA number.

While the company is optimistic as to the progress of the NDA filing, there are no assurances that the FDA will accept the amended NDA for review, and if accepted there are no assurances that the NDA will be approved.

About CFS and Ampligen(R)(poly I: Poly C12U), an Experimental Therapeutic
A recent independent study enumerated three primary causes of early death in CFS populations at large (without administration of Ampligen(R)) that may be attributable to the disease: 1) cardiovascular events, 2) suicide and 3) untreatable life-threatening malignancies/tumors. Within the NDA, Hemispherx addresses how Ampligen(R), an experimental therapeutic, may address these and other high risk aspects of CFS.

Over its developmental history, the experimental therapeutic Ampligen(R) has received various designations, including Orphan Drug Product Designation (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and "promising" designation by the Agency on Health Research Quality (AHRQ). Four well controlled, or pivotal, trials are now being reported in their entirety within Hemispherx Biopharma's NDA submission, which covers more than 1,200 subjects evaluated with more than 90,000 dose administrations. The experimental therapeutic was originally discovered and developed at The Johns Hopkins University and thereafter licensed to Hemispherx.

Chronic Fatigue Syndrome (CFS) has a top priority status at the Centers for Disease Control and Prevention ("CDC"), the governmental agency responsible for disease surveillance, as a serious and debilitating disease in the U.S. The disorder reflects a major unmet medical need. There are currently no approved therapies for CFS. The Agency for Research and Quality, a health service arm of the U.S. Department of Health and Human Services, reported that Ampligen(R), an experimental therapeutic, yielded the most promising clinical results to date related to CFS. Only regulatory agencies can determine whether any experimental therapeutic, including Poly I: Poly C12U (Ampligen(R)) is "safe and effective." At this time, Ampligen(R), an experimental therapeutic, is only available in specific clinical trial settings conducted under specific governmental authorizations. It has not been determined to be "safe and effective" by any governmental body. Ampligen(R) represents an entirely new class of RNA-based drug therapies. The Company's prompt response to the questions posed by the FDA was made possible by the broad-based team of clinical and scientific experts assembled during 2007, with experience in successful global development of NDAs for new molecular entities ("NMEs"), such as Ampligen(R).

About Hemispherx Biopharma
Hemispherx Biopharma, Inc. is an advanced biopharmaceutical company engaged in the manufacture and clinical development of new drug entities for treatment of seriously debilitating disorders. Hemispherx's flagship products include Alferon N Injection(R) (FDA approved for a category of sexually transmitted diseases) and the experimental therapeutics Ampligen(R) and Oragens(R). Ampligen(R) and Oragens(R) represent experimental RNA nucleic acids being developed for globally important debilitating diseases and disorders of the immune system. Hemispherx's platform technology includes large and small agent components for potential treatment of various severely debilitating and life threatening diseases. Hemispherx has in excess of 90 patents comprising its core intellectual property estate and a fully commercialized product (Alferon N Injection(R)). The Company wholly owns and exclusively operates a GMP certified manufacturing facility in the United States for commercial products. For more information please visit www.hemispherx.net

Contact:
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HEB's Web Site: www.hemispherx.net

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), Alferon LDO and Oragens) 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 N Injection(R) do not imply that the product will ever be specifically approved commercially for these other treatment indications; Similarly, the completion of NDA filing process with Ampligen(R) does not imply that the product will ever be approved commercially.