HEMISPHERX BIOPHARMA INC
Form 8-K
February 19, 2009

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)
February 19, 2009

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.

We have been notified by the Food and Drug Administration indicating that the originally scheduled Prescription Drug User Fee Act goal date of February 25, 2009 for our Ampligen(R) (Poly I Poly C12U) New Drug Application has be extended by three months to May 25, 2009 "in order to provide time for a full review of the submission." Please see the February 18, 2009 press release filed as an exhibit hereto for more information.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits:

99.1 Press Release dated February 18, 2009.

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.

February 19, 2009 By: /s/ William A. Carter

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

Exhibit 99.1

Company/Investor Contact:
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FDA EXTENDS HEMISPHERX'S NDA REVIEW DATE FOR AMPLIGEN(R)AS POTENTIAL TREATMENT FOR CFS

Extended User Fee Goal is now May 25, 2009

Philadelphia, PA, February 18, 2009 - Hemispherx Biopharma, Inc. (AMEX - HEB) has received a letter from the Food and Drug Agency ("FDA") indicating that the originally scheduled Prescription Drug User Fee Act ("PDUFA") date on the Ampligen(R) (Poly I:Poly C12U) New Drug Application (NDA) would be extended by three months "in order to provide time for a full review of the submission."

Additional data were received by the FDA within 3 months of the user fee goal date.

Due to constraints at the FDA, specifically and including the increased workload related to the recently enacted and implemented FDA Amendments Act ("FDAAA") and FDA's Safety First/Safe Use initiatives, work priorities may change resulting in the Agency going past the customary PDUFA goal set for reviews of an application.

A decision was originally expected by February 25, 2009, for the Company's submission of its Ampligen(R) NDA, which is designated as an Orphan Drug for the treatment of Chronic Fatigue Syndrome, which has no FDA approved treatments on the market. Ampligen(R) is also authorized for Emergency (compassionate) Cost Recovery Sales Authorization by the FDA and has a "promising" designation by the Agency on Health Research Quality (AHRQ): "Ampligen(R), an investigational drug that is not approved by the FDA, given intravenously to severely debilitated patients, yielded the most promising results." The extended user fee goal date is now May 25th, 2009.

Extensions of NDA reviews are a separate category of FDA response, distinct from a complete response letter or approval by the PDUFA date, and have always existed. Prior to the recent new FDA initiatives (cited above) and resultant increased workload, "on time" action by the Agency has generally ranged between 68 and 100 percent for the standard NDA reviews between FY 1999 and FY 2006 (source: Annual FDA PDUFA Performance Reports (www.FDA.gov).

About Hemispherx Biopharma

Hemispherx Biopharma, Inc. is a specialty pharma 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 50 issued 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

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(R) 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.