HEMISPHERX BIOPHARMA INC
Form 8-K
May 26, 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)
May 22, 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 7 - Regulation FD Disclosure

Item 7.01 Regulation FD Disclosure.

On May 26, 2009, we issued a press release, in which we announced that the U.S. Food and Drug Administration has advised the Company that it may require up to 1-2 additional weeks to take action beyond the scheduled Prescription Drug User Fee Act action date of May 26, 2009 on the New Drug Application for Ampligen(R)(Poly I POly C12U), a selective TLR3 modulator, for the management of Chronic Fatigue Syndrome. The text of this press release is set forth as Exhibit 99.1

In accordance with the general instructions B.6 of form 8-K, the information in this report, including Exhibit 99.1, is furnished and shall not be deemed "filed" for the purposes of section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific references in such filing.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits:

99.1 Press Release dated May 26, 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.

May 26, 2009 By: /s/ William A. Carter

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

Exhibit 99.1

Company/Investor Contact:
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HEMISPHERX BIOPHARMA ANNOUNCES POSSIBLE BRIEF DELAY IN FDA ACTION ON AMPLIGEN(R)

NEW DRUG APPLICATION

Philadelphia, PA, May 26, 2009 - Hemispherx Biopharma, Inc. (NYSE/AMEX -HEB) today announced that the U.S. Food and Drug administration ("FDA") has advised the company that it may require up to 1-2 additional weeks to take action beyond the scheduled Prescription Drug User Fee Act action date of May 25, 2009 on the New Drug Application for Ampligen(R) (Poly I Poly C12U), a selective TLR3 modulator, for the management of Chronic Fatigue Syndrome. Reason for the possible delay was attributed by the Agency to certain staff scheduling changes which might (or might not) delay the report. Accordingly the Company's development plan for Ampligen(R) continues as described in the recently filed 10Q and 10K, as the FDA did not request additional information from the Company at this time.

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 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. # # #