HEMISPHERX BIOPHARMA INC
Form 8-K
December 07, 2007

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)
December 3, 2007

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 December 3, 2007 we received notice from the U.S. Food and Drug

Administration (FDA) that our NDA submission for Ampligen(R) in Chronic Fatigue Syndrome (CFS) had been determined to be insufficiently complete to permit a substantive review under 21 CFR 314.101 (d). Specifically eleven deficiencies were noted in the Clinical Section and three in the Pre-Clinical Section. No deficiencies were cited in the Chemistry, Manufacturing and Controls Section (CMC).

We believe that several factors may influence the pace of the regulatory path: (1) Ampligen(R) (Poly I : Poly C12U) has a relatively long regulatory history (approximately twenty years) and regulatory guidelines suggest that longer clinical development histories may require more review; (2) Ampligen(R) is also the first drug of its class to apply for NDA review status; and (3) in some circumstances, clinical data reporting guidelines have changed since the initial studies on Ampligen(R), an experimental therapeutic, were executed in the late 1980s and early 1990s.

The Company will respond promptly in writing to all of the filing issues raised by the FDA and will request a guidance meeting to clarify any items outstanding.

For more information, please see the December 7, 2007 press release attached hereto 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 December 7, 2007.

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 7, 2007 By: /s/ William A. Carter

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

Exhibit 99.1

Company/Investor Contact:
Dianne Will Sean Collins, Sr. Partner

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CCG Investor Relations
310-477-9800

HEMISPHERX BIOPHARMA RECEIVES NOTICE OF
INCOMPLETE NEW DRUG APPLICATION (NDA)

Company Expects to Respond Promptly while Moving Forward
on Planned Filings outside the US

Philadelphia, PA, December 7, 2007---Hemispherx Biopharma, Inc. (AMEX, HEB) announced that it has received notice from the U.S. Food and Drug Administration (FDA) that its NDA submission for Ampligen(R) in Chronic Fatigue Syndrome (CFS), after preliminary review, had been determined to be insufficiently complete to permit a substantive review under 21 CFR 314.101 (d). Specifically eleven deficiencies were noted in the Clinical Section and three in the Pre-Clinical Section. No deficiencies were cited in the Chemistry, Manufacturing and Controls Section (CMC).

Hemispherx believes several factors may influence the pace of the regulatory path: (1) Ampligen(R) (Poly I : Poly C12U) has a relatively long regulatory history (approximately twenty years) and regulatory guidelines suggest that longer clinical development histories may require more review; (2) Ampligen(R) is also the first drug of its class to apply for NDA review status; and (3) in some circumstances, clinical data reporting guidelines have changed since the initial studies on Ampligen(R), an experimental therapeutic, were executed in the late 1980s and early 1990s.

The Company will respond promptly in writing to all of the filing issues raised by the FDA and will request a guidance meeting to clarify any items outstanding.

In October, 2007, the Company's New Brunswick facility passed a biannual FDA inspection relating to its fully commercialized interferon product (Alferon N Injection) with no infractions or citations.

The Company will continue to move forward, as originally planned, with its regulatory filings in various countries outside the United States, while continuing its efforts to meet all the FDA requirements. The NDA filing rate does not affect ongoing vaccine enhancement programs with Ampligen(R), an experimental TLR3 agonist, or ongoing Treatment IND programs for CFS in the U.S.

About Hemispherx Biopharma Hemispherx Biopharma, Inc. is a 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) and the experimental therapeutics Ampligen(R), Alferon LDO and Oragens(R). Alferon N Injection(R) is approved for a category of STD infection, and Ampligen(R) and Oragens(R) represent a large portfolio of experimental RNA nucleic acids being developed for globally important viral diseases, severely debilitating disorders and biodefense applications. 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 issued patents comprising its core intellectual property estate, a fully commercialized product (Alferon N Injection(R)) and a GMP certified manufacturing facility for its novel pharma products. The Company is actively engaged in further expansion of its intellectual property on a world wide basis to reflect the global distribution of the various disorders which its platform technology addresses. 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.