HEMISPHERX BIOPHARMA INC
Form 8-K
October 11, 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)
October 11, 2007

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.

On October 10, 2007, we filed a New Drug Application ("NDA") with the U.S. Food

and Drug Administration for our experimental therapeutic Ampligen(R) to treat Chronic Fatigue Syndrome. We are also moving forward as planned with filings in countries outside the United States. The NDA includes four well-controlled trials, more than 1,200 trial subjects and 90,000 doses.

For more information, please see the October 11, 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 October 11, 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.

October 11, 2007 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, Senior Partner
CCG Investor Relations
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Hemispherx Biopharma Files New Drug Application for Ampligen(R)
as Treatment of Chronic Fatigue Syndrome

NDA of investigational drug includes four well-controlled trials,
more than 1,200 trial subjects and 90,000 doses

Philadelphia, Pennsylvania--October 11, 2007--Hemispherx Biopharma, Inc. (AMEX: HEB) announced today that it has filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for its experimental therapeutic Ampligen(R), also known as Poly I : Poly C12U, to treat Chronic Fatigue Syndrome

("CFS"). The Company is also moving forward as planned with filings in countries outside the United States.

According to data from the Centers for Disease Control ("CDC"), Chronic Fatigue Syndrome may now affect more than 1 million people in the United States alone, causing an economic impact estimated at more than $9 billion annually. The Centers for Disease Control refers to CFS as a "... disabling disease, as disabling as other severe chronic conditions like multiple sclerosis, COPD [Chronic Obstructive Pulmonary Disease] and rheumatoid arthritis" in their ongoing public awareness campaign launched in 2006. The condition may also be associated with early death due to secondary depression/suicide and cancer.

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 approximately 90,000 dose administrations.

The experimental therapeutic was originally discovered and developed at The Johns Hopkins University and thereafter licensed to Hemispherx. On December 29, 2006, the FDA received the Company's pre-submission of pre-clinical information and assigned an NDA number. The Company will now move forward promptly with a series of scientific and medical peer-reviewed publications on the audited database contained within the NDA application.

William A. Carter, M.D., Chief Executive Officer and Chairman of Hemispherx, commented: "The comprehensive data package being submitted today has been possible because of the guidance, and scientific support, of the FDA, the CDC and CFS Advisory Committees to both the government and the private sector. Our profound gratitude goes out to the teams of independent clinical investigators around the country and especially, to the individuals afflicted with CFS who supplied the courage and will to sustain the research, clinical and regulatory communities in their continuing search for better understanding and management of CFS."

The bioactivity of the experimental therapeutic, Ampligen(R), as noted in a peer-reviewed Journal of Immunology study and reported by Hemispherx on April 30, 2007, may be based on its binding to the human toll-like receptor 3 (TLR3) and activating subsequent signaling cascades. Toll-like receptors such as TLR-3 serve as "pattern recognition" receptors in the early detection of pathogens and the establishment of early defense mechanisms (innate immunity). As such, they may be critical to the first line of immunological defense against a broad range of pathogens, such as otherwise lethal viruses and various forms of cancer.

About Chronic Fatigue Syndrome
Chronic Fatigue Syndrome (CFS) has a top priority status at the Centers for Disease Control and Prevention, 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. It should be noted that only federal regulatory agencies can determine whether any experimental therapeutic is "safe and effective" for wider distribution outside of the existing authorized clinical trials.

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 100 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.

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