HEMISPHERX BIOPHARMA INC
Form 8-K
December 01, 2009

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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 1, 2009

HEMISPHERX BIOPHARMA, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware 0-27072 52-0845822
(State or Other Jurisdiction (Commission (IRS Employer
of Incorporation) File Number) Identification No.)

1617 JFK Boulevard, Philadelphia, Pennsylvania, 19103
(Address of Principal Executive Offices, including Zip Code)

Registrant's telephone number, including area code: (215) 988-0080

Not Applicable
(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))

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Item 8.01 Other Events.

On December 1, 2009, the Company issued a press release announcing its receipt

of a Complete Response Letter from the Food and Drug Administration on its New Drug Application for Ampligen(R).

A copy of the press release, dated December 1, 2009, is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated December 1, 2009 regarding receipt of a Complete Response Letterfrom the Food and Drug Administration.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 1, 2009

HEMISPHERX BIOPHARMA, INC.

/s/ William A. Carter

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

Exhibit 99.1

Company/Investor Contact:
Dianne Will
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Hemispherx Biopharma Receives Complete Response Letter from FDA on Ampligen(R) New Drug Application for Chronic Fatigue Syndrome
...Outlines Additional Recommendations

Philadelphia, PA - December 1, 2009 - Hemispherx Biopharma, Inc. (NYSE Amex: HEB) (the "Company" or "Hemispherx"), announced that it received a Complete Response Letter from the US Food and Drug Administration ("FDA") which describes specific additional recommendations related to the Ampligen(R) NDA. In

accordance with its 2008 "Complete Response" procedure, the FDA reviewers determined that they cannot approve the application in its present form and provided specific recommendations to address the outstanding issues. Hemispherx is carefully reviewing the Complete Response letter and will seek an expedited meeting with the FDA to discuss its recommendations. Management is pleased to have received specific advice on the remaining issues and is looking forward to making a thorough but expedited response its top priority, and plans to take all appropriate steps to seek approval and commercialization of Ampligen(R).

Most notably, the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen(R) and recommends at least one additional clinical study which shows a convincing effect and confirms safety in the target population. The FDA indicated that the additional study should be of sufficient size and sufficient duration (6 months) and include appropriate monitoring to rule out the generation of autoimmune disease. In addition, patients in the study should be on more than one dose regimen, including at least 300 patients on dose regimens intended for marketing. Finally, the additional study must incorporate both a well-controlled QT interval study and pharmacokinetic evaluations.

Other items required by the FDA include certain aspects of Non-Clinical safety assessment, and Product Quality. In the Non-Clinical area, the FDA is recommending that the Company complete rodent carcinogenicity studies in two species. As part of the NDA submission, the Company had requested that these studies be waived, but the waiver has not been granted. Certain additional non-clinical studies and additional data to support non-clinical studies already submitted with the NDA are also recommended by the FDA. Prior to the receipt of the Complete Response letter, the Company had already begun many of these additional studies and the collection of the requested additional data.

Under the Product Quality section of the Complete Response letter, the FDA recommends that the Company submit additional data and complete various analytical procedures. The collection of these data and the completion of these procedures is already part of the Company's ongoing Quality Control, Quality Assurance program for Ampligen(R) manufacturing under cGMP (current Good Manufacturing Practice Guidelines) and the manufacturing enhancement program recently undertaken by the Company and announced in a news release on September 16, 2009.

Finally, the FDA commented on Ampligen(R) manufacturing noting the need to resolve outstanding inspection issues at the facilities producing Ampligen(R). These include the Company facility located in New Brunswick, NJ and one of the Company's third party manufacturing facilities (Hollister-Stier Laboratories). The Company has been working to resolve these issues.

At this time the Company's management has not determined the impact of the additional recommendations set forth in the Complete Response letter on the timelines and overall cost of the Ampligen(R) program, but the Company's management has made response to the issues and satisfaction of any additional requirements a top priority. The Company will seek to meet with the FDA to clarify any issues identified in the Complete Response letter and to work with the FDA to identify the most expeditious path to satisfaction of the requirements for approval of the Ampligen(R) NDA.

About Hemispherx Biopharma
Chronic Fatigue Syndrome is an enigmatic, profoundly debilitating and potentially life-threatening disease with which a new retrovirus was recently associated. Researchers are investigating the possible role of this virus in the symptomatology of the disease.

Hemispherx Biopharma, Inc. is an advanced specialty pharmaceutical 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) Oragens(R), and Alferon LDO. 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 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 completion of the NDA filing process with Ampligen(R) and the receipt of a Complete Response Letter from the FDA do not imply that the Company will be able to successfully comply with any or all of the requirements requested in that Letter or that the product will ever be approved for commercial sale. In addition, 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(R)) 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.