

HEMISPHERX BIOPHARMA INC

Form 8-K

December 21, 2012

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 20, 2012

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))

Item 8.01 Other Events.

On December 21, 2012, Hemispherx Biopharma, Inc. (the “Company”) issued a press release regarding the results of a public U.S. Food and Drug Administration (“FDA”) Arthritis Advisory Committee (the “AAC”) meeting on December 20, 2012 which considered the Company’s pending new drug application (“NDA”) for Ampligen® for the treatment of chronic fatigue syndrome (CFS), including the 8 to 5 vote of the AAC against a finding that “the applicant provided sufficient efficacy and safety data to support marketing of Ampligen for the treatment of CFS.”

The Prescription Drug User Fee Act date for completion of FDA review of the Ampligen® NDA is February 2, 2013. The AAC provides FDA with independent expert advice and recommendations, but the final decision regarding approval of a medication is made by the FDA.

For more information about the AAC hearing and the vote, please see the press release attached as Exhibit 99.1 to this Current Report on Form 8-K which is incorporated by reference herein

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits:

99.1 Press Release dated December 21, 2012

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 21, 2012 By: /s/ Charles T. Bernhardt
Charles T. Bernhardt
Chief Financial Officer