HEMISPHERX BIOPHARMA INC
Form 8-K
January 03, 2006

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)
January 3, 2006 (January 3, 2006)

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 January 3, 2006, we posted on our website a letter to our Shareholders. This

letter is filed herewith as Exhibit 99.1.

Section 9 - Financial Statements and Exhibits Item 9.01 Financial Statements and Exhibits.

(c) Exhibits

The following Exhibit is filed as part of this report:

Exhibit No.	Description
99.1	Letter to Shareholders dated January 3, 2006

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.

January 3, 2006

By: /s/ William A. Carter

William A. Carter M.D., President

Exhibit 99.1

[GRAPHIC OMITTED]

January 3, 2006

Dear Shareholders,

2005 has been an excellent year for Hemispherx. Years of research, development, clinical trials and perseverance have led to growing recognition of the value of our scientific approach and product portfolio and have facilitated important collaborations, acquisitions and financings, all key steps on the path to successful commercialization. Our strategy going forward is to focus all efforts on regulatory approval and advantageous alliances, with the ultimate goal being increased shareholder value. Every clinical trial initiated, alliance struck and investment made in the past year was undertaken with these objectives in mind. We have enhanced our asset base and enriched our professional resources to provide us with the resources, relationships and expertise to achieve our objectives.

The twenty million dollar equity credit line established with Fusion Capital has provided us the means to build out our manufacturing capability, strengthen our balance sheet and secure future growth with minimum dilution to our shareholders.

The expansion of our manufacturing facilities and staff in New Brunswick, New Jersey and the collaborative manufacturing relationship with HollisterStier Laboratories LLC for the production of Ampligen(R) are both ahead of schedule

and due for completion and certification late in the 2nd quarter 2006. These efforts will significantly add to our production capacity and conclude the last steps necessary for the filing of a consolidated NDA for Ampligen(R) for the treatment of CFS.

The single shortfall of our 2005 objectives was the delay in the filing of our NDA for Ampligen(R) for the treatment of CFS. Our targeted filing by 2005 year-end was based on an anticipated grant of FDA permission to submit a rolling or staged NDA application, which would allow us to file the safety and clinical sections of the NDA application in advance of the manufacturing section. Even though FDA permission to submit a rolling or staged NDA application has yet to be received, since we are scheduled to complete our manufacturing certifications late in the 2nd quarter of 2006, we should, in any event, file our NDA for Ampligen(R) for the treatment of CFS no later than the first part of the 3rd quarter of 2006.

The disturbing threats of an influenza pandemic and bio-terror attacks have pushed researchers and government institutions to pursue creative alternatives to established vaccines and antivirals. This pursuit has led to a growing recognition of the value of our scientific approach and product portfolio as investigators have identified Hemispherx products as potentially adequate options as a broad-spectrum, first line of defense approach to combat deadly pathogens, such as the H5N1 influenza virus. Investigators, with whom we are now collaborating, have sought and are utilizing Hemispherx products in ongoing clinical trials in this vital area.

Our clinical trials and those of our collaborators in the United States, Canada, Hong Kong and Japan, if successful, will allow for NDA filings of our drugs as experimental stand-alone antivirals or as adjuvants (boosters) under the proposed new emergency guidelines whereby drugs may be licensed for sale based on successful studies in two recognized animal models. While we are committed to and are actively pursuing commercial approval of Ampligen(R) for the treatment of CFS, we are aware of, and believe we are uniquely positioned to take advantage of, the fact that the avian flu (prevention / treatment) market opportunity is far larger at present, rapidly growing and encompasses areas of the market opportunity (Europe and Asia) where CFS recognition and treatment is still in its infancy.

Our strategy now is to obtain regulatory approval and to leverage our laboratory successes in aggressively pursuing advantageous relationships. We are committed to these objectives and determined to deliver. The next two years will be significant in Hemispherx's transition to a developer, manufacturer and distributor of value-added immune enhancing drugs.

At the Biodefense Research Meeting sponsored by the American Society of Microbiology in February 2006 (Washington, DC) we will unveil exciting new results in both the avian flu vaccine augmentation and the potential broad-spectrum antiviral activities of Alferon N(TM) and Ampligen(R). Mark these dates on your calendar as important milestones for our Company.

It is critical to our success that our investors understand the path that we are taking and our progress down this path. In an effort to improve upon communication to the investor community we will commence quarterly investor conference calls in line with the filing of the first 10Q of 2006.

We thank you for your on-going support.

Sincerely,

/s/ William A. Carter

Dr. William Carter

Chairman and Chief Executive Officer

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) and Oragens(TM)) 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(R) do not imply that the product will ever be specifically approved commercially for these other treatment indications.