HEMISPHERX BIOPHARMA INC
Form 8-K
February 04, 2005

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)
February 4, 2005 (February 1, 2005)

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 February 1, 2005, we sent 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 andExhibits.

(c) Exhibits

The following Exhibit is filed as part of this report:

Exhibit No.	Description
99.1	Letter to Shareholders dated January 26, 2005

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.

February 4, 2005 By:/s/William A Carter

William A. Carter M.D., President

Exhibit 99.1

HEMISPHERX BIOPHARMA, INC.

January 26, 2005

Dear Fellow Shareholders,

As 2005 begins and management takes a look back at the company's achievements during the past year, it is evident that we accomplished a great deal and that the company is positioned to succeed. There is much for us to look forward to in the coming year. Multiple events took place in this past year that have laid the groundwork for years to come and will allow us to capitalize on the hard work that the company has already undertaken.

Management would now like to help our fellow shareholders understand Hemispherx current status, our vision for tomorrow and how we plan to build for a profitable future.

Culminating many years of research and testing, in October 2004, Hemispherx successfully completed the phase III clinical trial of its drug Ampligen(R) for the treatment of Chronic Fatigue Syndrome (CFS). As most of you are aware, CFS is a debilitating disease that, according to the Center for Disease Control, affects between 400,000 and 800,000 people in the United States alone, with total annual value of lost productivity, excluding the costs for healthcare, estimated at $9.1 billion. Currently there is no approved treatment for CFS, and Ampligen(R) is the only drug in this late stage of the approval process for this disease. Given these circumstances, it is apparent that the opportunity before us is considerable. Today, the management team is focused on,

and giving priority to, preparing the final new drug application (NDA) to be filed with the Food and Drug Administration(FDA).

At this point it is crucial that we be meticulous in the preparation of our NDA filing so that we may clear this final hurdle in the approval process. While the NDA filing process certainly has many concrete requisite steps, it is truly an organic process requiring skill and good judgment to successfully complete. Our clinical research monitors and clinical research assistants have already visited all of the multiple clinical study sites around the country and have collected all of the appropriate data generated at each of the clinical study sites. The data must be reviewed and checked for gaps, inconsistencies and inaccuracies, which, due to the human factor, occur in all clinical trials. Gaps, inconsistencies and inaccuracies in the data must be resolved with the respective clinical investigators, all while maintaining a clear trail and record of events which permits the FDA and other international regulatory agencies to conduct a meaningful audit and confirmation of these events. To accelerate and optimize the accuracy of this process, management increased the company's staff by employing additional medical doctors, a PhD and other highly trained individuals. We are pleased to report to shareholders that we have completed this step in the process.

We are now moving forward with the intricate and time consuming phase of having the data put into proper format, having an independent statistical analysis of the data performed and preparation of a narrative report for the clinical study. In addition to our increased staff, to assist us with this next phase the company plans to contract with Octagon, a company with known expertise and a proven track record of success in assisting companies in the completion and electronic filing of NDAs. Needless to say the company has and will continue to diligently pursue the successful completion of the NDA filing process and is looking forward to moving on to the rewarding next phase of marketing Ampligen(R) and providing a much needed treatment for patients suffering from CFS.

As previously reported, in March 2004 we diversified our product portfolio by finalizing the acquisition of the worldwide rights to the Alferon(R) program, which include Alferon N Injection(R), a natural interferon approved by the FDA for treatment of Human Papilloma Virus (HPV), and Alferon(R) LDO, an experimental low dose, oral form of natural interferon. The company's Alferon N Injection(R) product continues to demonstrate superior efficacy as well as an outstanding safety profile in its FDA approved indication in HPV. Alferon N Injection(R) is the only natural interferon available to treat HPV and, because of the higher recurrence rates of HPV with medications other than Alferon N Injection(R), we are confident it is the most effective treatment in the marketplace and provides us with an excellent marketing opportunity. To reap this opportunity our challenge is to educate physicians with respect to Alferon N Injection(R) being the most effective treatment for HPV. During the last quarter of 2004 we implemented a multi-faceted program to convey this message to physicians and anticipate increasing sales with the increasing awareness of physicians. Your management has also undertaken to leverage the potency and safety of this outstanding product in two ways: first, identifying new therapeutic indications which take advantage of its superior efficacy and safety, and secondly devising new drug delivery formats which are leveraged out of the outstanding potency and safety of the natural Alferon(R) cocktail.

At the time of the Alferon(R) program acquisition we also acquired an FDA approved 44,000 square foot manufacturing facility and office spaces in New Brunswick, New Jersey. In addition to its significant value to the company as a manufacturing facility, currently for our Alferon N Injection(R) and Alferon(R) LDO and potentially for Ampligen(R) components, the New Brunswick facility is allowing us to gain both efficiency and economy of operation by moving our quality control operation from the leased Rockville, Maryland location to the wholly owned New Brunswick facility. The move of the quality

control operation to the New Brunswick facility is underway and should be completed during the first quarter of this year.

Throughout the year we have reported on the initiation and progress of other trials involving our Ampligen(R) and Alferon(R) products. Because of the nature of our products which stimulate and modulate the human bodies own immune system we believe they will be effective in a number of diseases and should be clinically tested in a number of disease indications. To achieve broad testing of our patented drug technologies while conserving our resources to permit focus upon completion of the phase III clinical trial of Ampligen(R) for the treatment of CFS and the NDA filing, we have partnered with others, under our direction, to conduct these promising trials. Laboratorios del Dr. Esteve, S.A., pursuant to a distribution and partnering agreement with us, is now conducting in Spain an FDA compliant Phase IIb clinical trial studying Ampligen(R) in the treatment of patients co-infected with HIV and HCV. Dr. James Rahal., former president of the New York State Society of Infectious Diseases, in association with us, is conducting a multi-site phase III clinical trial studying Alferon N Injection(R) in the treatment of patients with West Nile Virus. In collaboration with Vanderbilt University and the Princess Margaret Hospital in Hong Kong, China, a clinical trial is being conducted studying Alferon(R) LDO in patients with SARS and other sudden onset viruses.

Under the direction of Dr. Luc Montagnier, the discoverer of the human immunodeficiency virus (HIV) and a member of the Hemispherx Scientific Advisory Board, the World Foundation AIDS Research and Prevention, in collaboration with the company, attempted initiation of a Phase II clinical trial in Ivory Coast, Africa utilizing Alferon(R) LDO in the treatment of patients with HIV. As Alferon(R) LDO is administered orally and has relatively low cost, the conduct of this trial in Africa, with its high HIV infection rates and relatively poor economies, is particularly apt. However, due to the political unrest in Ivory Coast, conditions there for conduct of the trial have proved unmanageable and a new location in Africa is being identified, with implementation of this important trial expected to begin shortly. Our clinical investigators continue to enroll patients in our promising clinical trial (AMP 720) studying Ampligen(R) in patients with HIV who are on the HART STI regimen. Having completed our Ampligen(R) CFS Phase III clinical trial in October 2004, we are seeking to add new clinical investigators to the AMP 720 clinical trial. Additionally we are surveying appropriate partners to undertake, under our direction, a Phase IIb clinical study pursuant to our FDA approved protocol utilizing Alferon N Injection(R) in the treatment of patients with multiple sclerosis.

Recently the company was compelled to initiate two complaints in federal court against certain individuals and entities for illegal actions damaging to the company and the company's shareholders. Both complaints allege that another entity made overtures to Hemispherx seeking a merger; that Hemispherx undertook appropriate due diligence and in each case determined that merger would not be in the best interest of Hemispherx and its shareholder, as each of these companies, in the judgment of Hemispherx' Board of Directors, substantially overvalued its assets and/or exhibited various technological deficiencies; that these entities and major shareholders of these entities, upon being informed of Hemispherx' non interest in merger, in order to save their respective enterprises and investments, undertook and are undertaking illegal acts in an effort to gain control of Hemispherx and, through Hemispherx, save their respective companies and investments. We believe that in each instance the illegal actions emanated from Belgian sources. The company regrets the occurrence of these illegal actions necessitating the litigation. Through the litigation the company is taking, and will continue to take, appropriate, firm action against those seeking, through illegal actions, to damage the company and its shareholders. At the same time management will not allow these illegal actions to divert the company from diligent pursuit of its business goals, including the preparation and filing of the NDA for Ampligen(R) for the

treatment of CFS.

Significantly validating and recognizing, we believe, the strength of our intellectual property and its value, on November 30, 2004 the company received an invitation from the Department of Defense inviting the company to submit a proposal for a collaborative undertaking with the Department of Defense with regard to the company's drug technology which stimulates the human bodies "innate immunity", which is defined as its ability to withstand a broad spectrum of viruses and noxious agents.

Interferon/Ampligen(R) is considered a major component which triggers the human bodies "innate immunity". There are very few, if any, competing products which have been clinically studied which trigger the human bodies "innate immunity". We have, in concert with Vanderbilt University, now submitted three proposals in response to the invitation, one for Alferon(R) LDO, one for an oral form of Ampligen(R) and one for Oragens. Obviously we are excited about this potential to work with the Department of Defense in the further development of our drug technology and the valuable market opportunities which accompany it.

Our overall vision has remained the fulfillment of needs of the marketplace in areas that will provide excellent returns on our investments by serving large and untapped markets. Through our extensive patent portfolio, attention to large and underserved markets, a positive cash position and recent acquisitions, Hemispherx is uniquely positioned to become a major player in the pharmaceutical marketplace. With many programs in place, the year 2005 holds great promise. The company's strong infrastructure places us in an enviable position.

Sincerely,

/s/ William A. Carter

William A. Carter
Chairman of the Board & CEO

[GRAPHIC OMITTED][GRAPHIC OMITTED]

Hemispherx New Brunswick Manufacturing Facility

****

Information contained in this shareholder letter 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 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. Only Clinical Studies under well-controlled conditions can establish efficacy and safety of any product. 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.