

HEMISPHERX BIOPHARMA INC  
Form 10-K  
March 19, 2007

**FORM 10-K**

**SECURITIES AND EXCHANGE COMMISSION**

**x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2006**

**OR**

**o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File No. 1-13441**

**DRAFT #7A 3/16/07**

**HEMISPHERX BIOPHARMA, INC.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or  
organization)

52-0845822

(I.R.S. Employer Identification Number)

1617 JFK Boulevard Philadelphia, Pennsylvania

(Address of principal executive offices)

19103

(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, \$.001 par value

Securities registered pursuant to Section 12(g) of the Act:

(Title of Each Class)

NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  
Yes  No

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The aggregate market value of Common Stock held by non-affiliates at June 30, 2006, the last business day of the registrant's most recently completed second fiscal quarter, was \$155,317,988.

The number of shares of the registrant's Common Stock outstanding as of March 8, 2007 was 69,640,036.

**DOCUMENTS INCORPORATED BY REFERENCE:** None.

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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Certain statements in this Annual Report on Form 10-K (the “Form 10-K”), including statements under “Item 1. Business,” “Item 1A. Risk Factors,” “Item 3. Legal Proceedings” and “Item 7. Management’s Discussion and Analysis of Financial Condition and Result of Operations,” constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995 (collectively, the “Reform Act”). Certain, but not necessarily all, of such forward-looking statements can be identified by the use of forward-looking terminology such as “believes,” “expects,” “may,” “will,” “should,” or “anticipates” or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. All statements other than statements of historical fact included in this Form 10-K regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note that statements regarding potential drugs, their potential therapeutic effect, the possibility of obtaining regulatory approval, our ability to manufacture and sell any products, market acceptance or our ability to earn a profit from sales or licenses of any drugs or our ability to discover new drugs in the future are all forward-looking in nature.

Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Hemispherx Biopharma, Inc. and its subsidiaries (collectively, the “Hemispherx”, “we or “us”) to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements and other factors referenced in this Form 10-K. We do not undertake and specifically decline any obligation to publicly release the results of any revisions which may be made to any forward-looking statement to reflect events or circumstances after the date of such statements or to reflect the occurrence of anticipated or unanticipated events.

**PART I**

**ITEM 1. Business.**

**GENERAL**

We are a biopharmaceutical company engaged in the clinical development, manufacture, marketing and distribution of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. The Company was founded in the early 1970s doing contract research for the National Institutes of Health. Since that time, we have established a strong foundation of laboratory, pre-clinical, and clinical data with respect to the development of nucleic acids to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of certain chronic diseases.

Our flagship products include Ampligen® and Alferon N Injection®. Ampligen® is an experimental drug currently undergoing clinical development for the treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (“ME/CFS” or “CFS”), and HIV. In August 2004, we completed a Phase III clinical trial (“AMP 516”) treating over 230 ME/CFS patients with Ampligen® and are presently in the registration process for a new drug application (“NDA”) with the Food and Drug Administration (“FDA”). Over its developmental history, Ampligen® has received various designations, including Orphan Drug Product Designation (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and “promising” clinical outcome recognition based on the evaluation of certain summary clinical reports (AHRQ, Agency Health Research Quality).

Based on the results of published, peer reviewed pre-clinical studies and clinical trials, we believe that Ampligen® may have broad-spectrum anti-viral and anti-cancer properties. Approximately 750 patients have participated in Ampligen® clinical trials authorized by the FDA at over twenty clinical trial sites across the U.S., representing the administration of more than 75,000 doses of this drug.

Alferon N Injection® is the registered trademark for our injectable formulation of natural alpha interferon, which is approved by the FDA for the treatment of genital warts. Alferon N Injection® is also in pre-clinical development for treating Multiple Sclerosis, West Nile Virus and SARS.

We are actively engaged in broad-based ongoing experimental studies assessing the efficacy of our products Ampligen®, Alferon N Injection® and Alferon LDO® against influenza viruses as an adjuvant and/or single agent antiviral with the Defence R&D Canada, the National Institute of Infectious Diseases in Tokyo, the Princess Margaret Hospital in Hong Kong and various research affiliates of the National Institutes of Health in the United States.

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ primarily designed to produce Alferon N. In 2006, we completed the installation of a polymer production line to produce Ampligen® raw materials on a more reliable and consistent basis.

We outsource certain components of our research and development, manufacturing, marketing and distribution while maintaining control over the entire process through our quality assurance group and our clinical monitoring group.

Our principal executive offices are located at One Penn Center, 1617 JFK Boulevard, Philadelphia, Pennsylvania 19103, and our telephone number is 215-988-0080.

#### **AVAILABLE INFORMATION**

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 electronically with the Securities and Exchange Commission, or SEC. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is <http://www.sec.gov>.

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports on the day of filing with the SEC on our website on the World Wide Web at <http://www.hemispherx.net> or by contacting the Investor Relations Department by calling (518) 398-6222 or sending an e-mail message to [dwill@willstar.net](mailto:dwill@willstar.net).

## **OUR PRODUCTS**

Our primary products consist of our experimental compound, Ampligen®, our FDA approved natural interferon product, Alferon N Injection® and Alferon LDO (low dose oral) our experimental liquid natural interferon for oral administration.

### **Ampligen®**

Nucleic acid compounds represent a potential new class of pharmaceutical products that are designed to act at the molecular level for treatment of human diseases. There are two forms of nucleic acids, DNA and RNA. DNA is a group of naturally occurring molecules found in chromosomes, the cell's genetic machinery. RNA is a group of naturally occurring informational molecules which orchestrate a cell's behavior which regulates the action of groups of cells, including the cells which compromise the body's immune system. RNA directs the production of proteins and regulates certain cell activities including the activation of an otherwise dormant cellular defense against viruses and tumors. Our drug technology utilizes specifically-configured RNA. Our double-stranded RNA drug product, trademarked Ampligen®, an experimental, unapproved drug, which is administered intravenously, is in human clinical development for various therapeutically oriented studies, including treatment for Chronic Fatigue Syndrome/Myalgic Encephalomyelitis ("CFS/ME"), HIV, renal cell carcinoma and malignant melanoma.

Based on the results of pre-clinical studies and clinical trials, we believe that Ampligen®, an experimental agent, may have broad-spectrum anti-viral and anti-cancer properties. Approximately 750 patients have received Ampligen® in clinical trials authorized by the Food and Drug Administration ("FDA") at over twenty clinical trial sites across the U.S., representing the administration of more than 75,000 doses of this drug. Ampligen® is available only through clinical trials for limited indications.

Clinical trials already conducted by us include treatments of ME/CFS, Hepatitis B, HIV, and cancer patients with renal cell carcinoma and malignant melanoma. Certain of these will require additional clinical trials to support regulatory approval.

We believe that Ampligen® has been generally well tolerated with a low incidence of clinical toxicity, particularly given the severely debilitating or life threatening diseases that have been treated. A mild flushing reaction has been observed in approximately 15% of patients treated in our various studies. This reaction is occasionally accompanied by erythema, a tightness of the chest, tachycardia, anxiety, shortness of breath, subjective reports of "feeling hot," sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by slowing the infusion rate. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, urticaria (swelling of the skin), bronchospasm, hypotension, photophobia, rash, bradycardia, transient visual disturbances, arrhythmias, decreased platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months.

The FDA has approved the use of Ampligen® in treating ME/CFS on an emergency basis (i.e. those with immediate life threatening illnesses). This is known as a treatment IND, or Treatment Investigational New Drug. Furthermore, the FDA has granted Hemispherx Orphan Drug Status in the United States. Orphan drugs get seven years of market exclusivity upon FDA approval.



We are in the process of completing our registration of an NDA with the FDA for the use of Ampligen® in the treatment of patients with ME/CFS.

### **Alferon N Injection®**

Interferons are a group of proteins produced and secreted by cells to combat diseases. Researchers have identified four major classes of human interferon: alpha, beta, gamma and omega. The Alferon N Injection® product contains a multi-species form of alpha interferon. The worldwide market for injectable alpha interferon-based products has experienced rapid growth and various alpha interferon injectable products are approved for many major medical uses worldwide. Alpha interferons are manufactured commercially in three ways: by genetic engineering, by cell culture, and from human white blood cells. All three of these types of alpha interferon are or were approved for commercial sale in the U.S. Our natural alpha interferon is produced from human white blood cells.

The potential advantages of natural alpha interferon over recombinant (synthetic) interferon produced and marketed by other pharmaceutical firms may be based upon their respective molecular compositions. Natural alpha interferon is composed of a family of proteins containing many molecular species of interferon. In contrast, recombinant alpha interferon each contain only a single species. Researchers have reported that the various species of interferons may have differing antiviral activity depending upon the type of virus. Natural alpha interferon presents a broad complement of species, which we believe may account for its higher activity in laboratory studies. Natural alpha interferon is also glycosylated (partially covered with sugar molecules). Such glycosylation is not present on the currently U.S. marketed recombinant alpha interferons. We believe that the absence of glycosylation may be, in part, responsible for the production of interferon-neutralizing antibodies seen in patients treated with recombinant alpha interferon. Although cell culture-derived interferon is also composed of multiple glycosylated alpha interferon species, the types and relative quantity of these species are different from our natural alpha interferon.

The FDA approved Alferon N Injection® in 1989 for the intralesional (within lesions) treatment of refractory (resistant to other treatment) or recurring external genital warts in patients 18 years of age or older. Certain types of human papillomaviruses (“HPV”) cause genital warts, a sexually transmitted disease (“STD”). A published report estimates that approximately eight million new and recurrent causes of genital warts occur annually in the United States alone.

Alferon N Injection® [Interferon alfa-n3 (human leukocyte derived)] is a highly purified, natural-source, glycosylated, multi-species alpha interferon product. There are essentially no antibodies observed against natural interferon to date and the product has a relatively low side-effect profile. Alferon® is the only natural-source, multi-species alpha interferon currently sold in the U.S.

The recombinant DNA derived alpha interferon are now reported to have decreased effectiveness after one year, probably due to antibody formation and other severe toxicities. These detrimental effects have not been reported with the use of Alferon N Injection® which could allow this product to assume a much larger market share.

It is our belief that the use of Alferon® N in combination with Ampligen® has the potential to increase the positive therapeutic responses in chronic life threatening viral diseases. Combinational therapy is evolving to the standard of acceptable medical care as demonstrated by the antiviral responses achieved by HAART (Highly Active Antiviral Therapy) in the multi-drug treatment of HIV.

The broad spectrum activity of Alferon N is evidenced by clinical trials currently underway for the treatment of multiple viral disorders including Hepatitis C, HIV/HCV co-infection and West Nile Virus.

### **Alferon® Low Dose Oral (LDO)**

Alferon® LDO is an experimental low-dose, oral liquid formulation of Natural Alpha Interferon and like Alferon N Injection® should not cause antibody formation, which is a problem with recombinant interferon. It is an experimental immunotherapeutic believed to work by stimulating an immune cascade response in the cells of the mouth and throat, enabling it to bolster systemic immune response through the entire body by absorption through the oral mucosa. Oral interferon would be much more economically feasible for patients and logistically manageable in development programs in third-world countries primarily affected by HIV and other emerging viruses (SARS, Ebola, bird flu, etc.). Oral administration of Alferon® N, with its affordability, low toxicity, no production of antibodies, and broad range of potential bio activity, could be a breakthrough treatment for viral diseases.

We have initiated clinical trials as part of an accelerated evaluation of the experimental bio-therapeutic Alferon LDO® (Low Dose Oral Interferon Alfa-n3 (Human Leukocyte Derived)) as a potential new experimental therapy for Avian Flu and other lethal viral diseases, which have high acute death rates. Clinical trials in human volunteers (being conducted in both the US at Drexel University, Philadelphia and shortly to commence in Hong Kong at the Princess Margaret Hospital) are designed to determine whether Alferon N, delivered in a new, experimental oral drug delivery format, can resuscitate the broad-spectrum antiviral and immunostimulatory genes. These human genes are shut down by acute lethal viral infections such as avian flu and smallpox.

### **Oragens**

We acquired a series of patents on Oragens, potentially a set of oral broad spectrum antivirals and immunological enhancers, through a licensing agreement with Temple University in Philadelphia, PA. We were granted an exclusive worldwide license from Temple for the Oragens products. These compounds have been evaluated in various academic laboratories for application to chronic viral and immunological disorders.

The 2', 5' oligoadenylate synthetase/RNase L system is an important and widely distributed pathway for the inhibition of viral replication and tumor growth. The 2', 5' oligoadenylate synthetase, up activation by double-stranded RNA, synthesizes 2', 5' oligoadenylates (2-5A) from ATP. These bioactive 2-5As directly activate RNase L, which degrades viral and cellular RNAs resulting in the inhibition of protein synthesis.

The bioactive 2-5A molecules can be degraded by various hydrolytic enzymes, resulting in a short half life. Analogues of these bioactive 2-5As, termed Oragen RNA compounds, have been produced to increase stability and maintain or increase biological activity without demonstrable toxicity. Additional pre-clinical tests will be conducted prior to pursuing clinical trials (See "Research, Consulting, Licensing and Supply Agreements" section of Item I for more details on this license).

## **PATENTS**

We have over 100 patents worldwide with 20 additional patents pending comprising our intellectual property. In 2006, we obtained the global patent rights for a compound that enhances DNA vaccination by the efficient intracellular delivery of immunogenic DNA (i.e.- DNA that can produce antigenic proteins that simulate an acute viral infection with a resultant umoral and cell-mediated immune response). See “Research, Consulting, Licensing and Supply Agreements” section within Item I for more information on the acquisition of these patents.

We continually review our patents rights to determine whether they have continuing value. Such review includes an analysis of the patent’s ultimate revenue and profitability potential. In addition, management’s review addresses whether each patent continues to fit into our strategic business plans for both Ampligen, Alferon N and other intellectual property.

We have been issued certain patents on the use of Ampligen® alone and Ampligen® in combination with certain other drugs including AZT, ddI, ddC, interferon and/or IL-2, for the treatment of HIV.

Our experimental compounds, which have yet to be determined "safe and effective" by regulatory authorities, are accordingly only available legally in certain authorized trials and tests; in vitro (outside the body) tests are also not necessarily indicative of any evidence of clinical benefits or advantages. But the focus of Hemispherx is on Ampligen® as a treatment for CFS/ME and HIV.

The main U.S. ME/CFS treatment patent (#6130206) expires October 10, 2017. Our main patents covering HIV treatment (#4820696, #5063209, and #5091374) expired or expire on April 11, 2006, November 5, 2008, and February 25, 2009, respectively; Hepatitis treatment coverage is conveyed by U.S. patent #5593973 which expires on January 14, 2014. The U.S. Ampligen® Trademark (#1,515,099) expires on December 6, 2008 and can be renewed thereafter for an additional 10 years. The FDA has granted us “orphan drug status” for our nucleic acid-derived therapeutics for ME/CFS, HIV, and renal cell carcinoma and malignant melanoma. Orphan drug status grants us protection against competition for a period of seven years following FDA approval, as well as certain federal tax incentives, and other regulatory benefits. Patent coverage for the HIV indication following the expiration of patents #4820696, #5063209 and #5091374 is planned to be obtained from patent pending application #PCT/US 0239890. In the event that this patent application is not approved, we still have the marketing protection provided by the orphan drug designation for using Ampligen® to treat HIV.

The U.S. Alferon® Patents expire February 10, 2012 (5,503,828 and 5,676,942) and December 22, 2017 (5,989,441).

## **RESEARCH AND DEVELOPMENT (“R&D”)**

Our focus is on developing drugs for use in treating viral and immune based chronic disorders and diseases including ME/CFS, HIV, HPV, SARS and West Nile Virus. Our current R&D projects target treatment therapies for ME/CFS, HIV, HPV and other viral diseases, i.e.; SARS and Avian/Seasonal Influenza.

### **Myalgic Encephalomyelitis/Chronic Fatigue Syndrome ("ME/CFS")**

Chronic Fatigue Syndrome (“CFS”), also known as Chronic Immune Dysfunction Syndrome (“CFIDS”) and, myalgic encephalomyelitis (“ME”) is a serious and debilitating chronic illness and a major public health problem. Long misunderstood, under-recognized, and under-diagnosed, ME/CFS is now recognized by both the government and private sector as a major health problem, including the National Institutes of Health, U.S. Centers for Disease Control and Prevention (“CDC”), FDA and Social Security Administration, recognizes ME/CFS as one of the most common chronic illnesses of our time. The CDC listed ME/CFS as a priority disease, causing severe health and financial problems for the patients, their family, and the community. ME/CFS is endemic in the population, but occasionally

seen in clusters suggesting an infectious basis. A variety of immunological, endocrine, autonomic nervous system, and metabolic abnormalities have been documented. A groundbreaking, community-based study of ME/CFS by Dr. Leonard Jason was published in the Archives of Internal Medicine in 1999 and showed a prevalence rate of 422 of every 100,000 Americans. As many as 1,000,000 people nationwide suffer from CFS, significantly more than previously estimated by the CDC. Furthermore, 90% of the patients with the illness are struggling without the benefit of medical diagnosis or treatment. While ME/CFS strikes people of all age, racial, ethnic, and socioeconomic groups, it is most prevalent amongst women. Research has shown that ME/CFS is about three times as common in women as men, a rate similar to that of many autoimmune diseases, such as multiple sclerosis and lupus. To put this into perspective, ME/CFS is over four times more common than HIV infection in women, and the rate of ME/CFS in women is considerably higher than a woman's lifetime risk of getting lung cancer as published by the CFIDS Association of America.

The most common symptom of ME/CFS is incapacitating fatigue, which does not subside with rest. Many severe ME/CFS patients become completely disabled or totally bedridden and are afflicted with severe pain and mental confusion even at rest. This debilitating tiredness is associated with flu-like symptoms such as chills, fever, headache, sore throat, painful lymph nodes, muscle aches, weakness and joint pain. Diagnosis of ME/CFS is a time-consuming and difficult process which is generally arrived at by excluding other illnesses with similar symptoms and comparing a patient's symptoms with the case definition. Overlapping symptoms can occur with several diseases, such as fibromyalgia, Gulf War Illnesses, and multiple chemical sensitivities. Many diseases have similar symptoms including Lupus and Lyme disease which so closely mimic ME/CFS that they need to be considered when making a diagnosis to rule them out.

The case definition for ME/CFS criteria calls for certain symptoms to be present along with fatigue that interferes with physical, mental, social, and educational activities. Both the fatigue and symptoms must have occurred for (at least) a six month period. People with ME/CFS may experience many more than the symptoms named in the case definition, so knowledgeable physicians will take this fact into consideration when making a diagnosis (after other possible reasons for symptoms have been ruled out).

The leading model of ME/CFS pathogenesis is thought to be rooted in abnormalities in the immune system and brain (central nervous system), both of which affects and alters the function of the other. Because some cases of chronic fatigue begin with a flu-like infection, several viruses have been studied as possible causes because all are relatively common in the general population, including Human Herpesvirus ("HHV") 6 and 7, Retroviruses, Epstein-Barr Virus, Enteroviruses, as well as, Mycoplasmas, etc. Whilst, the etiology is likely to be caused by a collection of factors, including viral, hormonal, stress, and other triggers for the illness in genetically, environmentally or otherwise susceptible individuals and continues to be a subject of discussion.

Most ME/CFS patients are treated symptomatically with traditional treatments geared toward treating symptoms of the disease, such as improving quality of sleep, reducing pain and treatment of depression. Clinically, a number of different therapeutic approaches have been pursued, but with no significant clinical success.

In 1998, we were authorized by the FDA to initiate a Phase III multicenter, placebo-controlled, randomized, double blind clinical trial to treat 230 patients with ME/CFS in the U.S. The objective of this Phase III, clinical study, denoted as Amp 516, was to evaluate the safety and efficacy of Ampligen® as a treatment for ME/CFS. Over the course of the study, we engaged the services of 12 clinical investigators at Medical Centers in California, New Jersey, Florida, North Carolina, Wisconsin, Pennsylvania, Nevada, Illinois, Utah and Connecticut. These clinical investigators were medical doctors with special knowledge of ME/CFS who have recruited, prescreened and enrolled ME/CFS patients for inclusion in the Phase III Amp 516 ME/CFS clinical trial. This clinical trial enrolled and randomized over 230 ME/CFS patients. We completed drug dosing in this trial in August 2004. A preliminary review of the data collected during this trial indicated that Ampligen® improved exercise treadmill performance by 19.0% versus 4.2% in the placebo group, or more than twice the minimum considered medically significant (6.5%), a statistically significant increase ( $p=0.025$ ). The major significance is the ability to safely obtain medical benefits (increased physical performance) which have largely eluded others. Also, Ampligen® significantly improved important secondary endpoints associated with Quality of Life. There was no significant difference in the number of serious adverse events, suggesting that the drug was generally well tolerated. Given that the FDA has already granted Ampligen® Treatment Protocol Status and Orphan Drug Status based on earlier studies, we believe these medically and statistically significant results, when finalized, will facilitate FDA review and approval of Ampligen® as a therapy to treat ME/CFS. We are in the process of completing a NDA requesting FDA approval for using Ampligen® to treat ME/CFS.

#### **Human Immunodeficiency Virus (“HIV”)**

Over fifteen antiviral drugs are currently approved by the FDA for the treatment of HIV infection. Most target the specific HIV enzymes, reverse transcriptase (“RT”) and protease. The use of various combinations of three or more of these drugs is often referred to as Highly Active Anti-Retroviral Therapy (“HAART”). HAART involves the utilization of several antiretrovirals with different mechanisms of action to decrease viral loads in HIV-infected patients. The goal of these combination treatments is to reduce the amount of HIV in the body (“viral load”) to as low as possible. Experience has shown that using combinations of drugs from different classes is a more effective strategy than using only one or two drugs. HAART has provided dramatic decreases in morbidity and mortality of HIV infection. Subsequent experience has provided a more realistic view of HAART and the realization that chronic HIV suppression using HAART, as currently practiced, would require treatment for life with resulting significant cumulative toxicities. The various reverse transcriptase and protease inhibitor drugs that go into HAART have significantly reduced the morbidity and mortality connected with HIV; however there has been a significant morbidity due to drug toxicity. It was estimated that 50% of HIV deaths were from the toxicity of the drugs in HAART. Some estimates suggest that it would require as many as 60 years of HAART for elimination of HIV in the infected patient. Thus the toxicity of HAART drugs and the enormous cost of treatment make this goal impractical.

We believe that the concept of Strategic Therapeutic Interruption (“STI”) of HAART provides a unique opportunity to minimize the current deficiencies of HAART while retaining the HIV suppression capacities of HAART. STI is the cessation of HAART until HIV again becomes detectable (i.e., rebounds) followed by resumption of HAART with subsequent suppression of HIV. By re-institution of HAART, HIV may be suppressed before it can inflict damage to the immune system of the patient. We believe that Ampligen® combined with the STI approach may offer a unique opportunity to retain HAART’s superb ability to suppress HIV while potentially minimizing its deficiencies. All present approved drugs block certain steps in the life cycles of HIV. None of these drugs address the immune system, as Ampligen® potentially does, although HIV is an immune-based disease.

By using Ampligen® in combination with STI of HAART, we will undertake to boost the patients’ own immune system’s response to help them control their HIV when they are off of HAART. Our minimum expectation is that Ampligen® has potential to lengthen the HAART-free time interval with a resultant decrease in HAART-induced toxicities. The ultimate potential, which of course requires full clinical testing to accept or reject the hypothesis, is that Ampligen® may potentiate STI of HAART to the point that the cell mediated immune system will be sufficient to eliminate the requirement for HAART. Clinical results of using our technology has been presented at several International AIDS Scientific Forums.

Our Amp 720 HIV study is a treatment using a Strategic Treatment Interruption (“STI”). The patients’ antiviral HAART regimens are interrupted and Ampligen® is substituted as mono-immunotherapy. Patients who have completed at least nine months of Ampligen® therapy, were able to stay off HAART for a total STI duration with a mean time of 29.0 weeks where as the control group, which was also taken off HAART, but not given Ampligen®, had earlier HIV rebound with a mean duration of 18.7 weeks. Thus, on average, Ampligen® Therapy spared the patients excessive exposure to HAART, with its inherent toxicities, for more than 11 weeks. Enrollment in this study has been temporarily suspended pending the completion of our Ampligen NDA Registration process with the FDA. At this time, forty-one HIV patients have participated in this 64 week study. The rate of enrollment depends on patient availability and on other products being in clinical trials for the treatment of HIV, causing competition for the same patient population. At present, more than 18 FDA approved drugs for HIV treatment may compete for available patients. The length, and subsequently the expense of these studies, will also be determined by an analysis of the interim data, which will determine when completion of the ongoing Phase IIb is appropriate and whether a Phase III trial will be conducted or not. In case a Phase III study is required; the FDA might require a patient population exceeding the current one which will influence the cost and time of the trial. Accordingly, the number of “unknowns” is sufficiently great to be unable to predict when, or whether, we may obtain revenues from our HIV treatment indications.

### **Human Papilloma Virus (HPV)**

Human papilloma virus (“HPV”) is one of the most common causes of sexually transmitted infection in the world. Experts estimate that there are more cases of genital HPV infection than of any other sexually transmitted disease (“STD”) in the United States. Overall, in the United States, an estimated 20 million people are currently infected with HPV. Roughly, six million people are infected every year. It has been estimated that at least 50% of sexually active men and women acquire genital HPV infection at some point in their lives. Genital warts are the most recognized sign of a genital HPV infection.

Treating genital warts does not cure a HPV infection. The virus remains in the body in an inactive state after warts are removed. A person treated for genital warts may still be able to transmit the infection. Common methods for removing genital warts involve surgically removing them. Cryotherapy is a method that entails freezing off the wart with liquid nitrogen and is relatively inexpensive, safe and effective. The downside to this procedure beyond the pain factor is it must be performed by a trained health care provider. Laser therapy (using an intense light to destroy the warts) or surgery (cutting off the warts) has the advantage of getting rid of warts in a single office visit. However, treatment can be expensive and the operator must be well-trained in these methods. In addition, surgery will most likely cause scarring over the afflicted area.

There are a number of topical creams and solutions available to treat genital warts. Bloodroot paste is made from naturally occurring substances, but its effects on treating genital warts are not conclusively supportive. Condylox (also called podophyllin) is a brown liquid that causes a burning sensation as it dries, but it must be washed off within four to six hours to reduce the risk of adverse reactions. Condylox can be quite expensive as well. Condysil is a cream that may be applied. It consists of “all natural” ingredients and its manufacturer claims it produces no scarring. The current leading treatment of genital warts is the topical cream Aldara, however the reoccurrence rate may be as high as 40% when this drug is used.

Treatment for genital warts may also come in the form of injections. Intron A is a substance that must be injected 3 times weekly and Alferon® N, which is the only natural source, multi-species alpha interferon currently sold in the US for HPV treatment, is injected twice weekly.

### **Hepatitis C Virus (“HCV”)**

Hepatitis C infection is typically mild in its early stages, and is often not diagnosed until a late state when it has caused severe liver disease. A typical cycle of disease from infection to symptomatic liver disease can take 20 years; therefore, the true impact of HCV may not be fully apparent. Hepatitis C is believed to be transmitted only by blood. However, unlike many other blood borne viruses (like HIV), virtually any source of blood products seems to be capable of carrying the virus, even if the source is indirect like a used razor, for example. This makes Hepatitis C far more transmittable than most other blood borne viruses including HIV.

Hepatitis C is an RNA virus. Once an infection has begun, Hepatitis C creates different genetic variations of itself within the body of the host. The mutated forms are frequently different enough from their ancestor that the immune system cannot recognize them. Thus, even if the immune system begins to succeed against one variation, the mutant strains quickly take over and become new, predominant strains. Thus, the development of antibodies against HCV may not produce an immunity against the disease like it does with most other viruses. More than 80% of individuals infected with HCV will progress to a chronic form of the disease.

The World Health Organization estimates that more than 4.5 million people in the United States are infected with Hepatitis C and more than 200 million worldwide. A vaccine against Hepatitis C is not available and there are many times more people infected with HCV than HIV (the virus that causes AIDS). It is anticipated that without prompt intervention to treat infected populations, the death rate from Hepatitis C could surpass that from AIDS.

Alferon N Injection® has been studied for the potential treatment of HIV, Hepatitis C and other indications. ISI, the company from which Hemispherx obtained rights to Alferon N Injection®, has conducted clinical trials with regard to the use of Alferon N Injection® in the treatment of HIV and Hepatitis C. While ISI found the results to be encouraging, in both instances the FDA determined that additional trials were necessary.



Our plans for additional clinical HCV clinical trials are on hold at this time.

### **Other Viral Diseases**

We are actively engaged in broad-based ongoing experimental studies assessing the efficacy of our products Ampligen®, Alferon N Injection® and Alferon LDO® against influenza viruses as an adjuvant and/or single agent antiviral with the Defence R&D Canada, the National Institute of Infectious Diseases in Tokyo, the Princess Margaret Hospital in Hong Kong and various research affiliates of the National Institutes of Health in the United States.

A preclinical study was initiated in June 2005, to determine if Ampligen® enhances the effectiveness of different drug combinations on avian influenza. The preclinical study suggests a new, and potentially pivotal role of double-stranded RNA (“dsRNA”) therapeutics in improving the efficacy of the present standards in care in both influenza prevention and treatment of acute disease. The preclinical study is being conducted by research affiliates of the National Institutes of Health at Utah State University to examine potential therapeutic synergies with different drug combinations. The ongoing research is comparing the relative protection conveyed by Tamiflu (oseltamivir, Roche) and Relenza (Zanamivir, GlaxoSmithKline) with Ampligen® (dsRNA), alone and in combination, against the avian flu virus (H5N1). Cell destruction was measured in vitro using different drug combinations. Both drugs, given alone, were effective in inhibiting cell destruction by avian influenza, but viral suppression with the combination was greater than either drug alone. The overall assessment is that there was improvement in cell protection when Ampligen® was combined with oseltamivir carboxylate (Tamiflu) and Zanamivir (Relenza). Further immediate experimental tests are planned.

Japanese researchers (Journal of Virology page 2910, 2005) found that dsRNAs increase the effectiveness of influenza vaccine by more than 300% and may also convey “cross-protection ability against variant viruses” (mutated strains of influenza virus). In October 2005, we signed a research agreement with the National Institute of Infectious Diseases, in Tokyo, Japan. The collaboration, by Hideki Hasegawa, M.D., Ph.D., Chief of the Laboratory of Infectious Disease Pathology, assesses our experimental therapeutic Ampligen® as a co-administered immunotherapeutic to the Institution's nasal flu vaccine. On October 20, 2006 Dr. Hideki Hasegawa, of Japan's National Institute of Infectious Diseases (JNIID), presented the results of his studies co-administering Hemispherx's double-stranded RNA (dsRNA) Ampligen® (polyI:polyC<sub>12</sub>U) experimental therapeutic with a highly pathogenic avian influenza virus (HPAIV) vaccine. Dr. Hasegawa's studies, presented at the Second International Conference on Influenza Vaccines for the World in Vienna, Austria, examined the protective efficacy of intranasal co-administration of inactivated whole-virion H5N1 vaccine with Ampligen® in mice and non-human primates. Intranasal administration of a candidate influenza vaccine with Ampligen® resulted in secretion of IgA, also known as immunoglobulin A, the basis of mucosal immunity, and successfully protected experimental animals that were subsequently challenged with homologous A/Vietnam/1194/04(H5N1), heterologous A/HK/483/97(H5N1) and A/Indonesia/6/05(H5N1) viruses. Dr. Hasegawa's data demonstrates: 1) that the intranasal administration of Ampligen® combined with H5N1 vaccine induced cross-protective mucosal immunity against homologous and heterologous H5N1 influenza virus infection in mice; 2) intranasal administration of Ampligen® combined with H5N1 vaccine provided protection in the macaque monkey, a non-human primate which has a complex immune system, similar to that of humans, from H5N1 infection; 3) seasonal human influenza vaccine plus Ampligen administered intranasally in mice provided protective immune responses with apparent cross-protection against avian influenza virus challenge; 4) Nasal administration of influenza virus vaccines in conjunction with a TLR3 agonist is an effective method of vaccination; and 5) Ampligen®, a TLR3 agonist, is the only human-applicable dsRNA which has a well-documented safety profile in humans. Dr. Hasegawa and his colleagues at the JNIID intend to pursue human trials as soon as possible.

Pre-clinical research indicates that Ampligen® can provide cross-protection against avian flu viral mutations as well as boost the effectiveness of Tamiflu and Relenza, the only two drugs formally recognized for combating bird flu, up to 100 times. Other lab tests, in healthy human volunteers, indicate that Alferon® LDO (Low Dose Oral), a new delivery form of an anti-viral with prior regulatory approval for a category of sexually transmitted diseases, can stimulate a broad immune and antiviral gene modulation induce key components in the body's defense system. The studies were conducted in conjunction with Utah State University and Drexel University.

Defence R&D Canada, Suffield ("DRDC Suffield"), an agency of the Canadian Department of National Defence, is evaluating the antiviral efficacy of our experimental therapeutic Ampligen® and Alferon® for protection against human respiratory influenza virus infection in well validated animal models. DRDC Suffield is conducting research and development of new drugs that could potentially become part of the arsenal of existing antiviral weapons to combat the bird flu. The initial study focused on the testing of potential drugs against the respiratory influenza virus infection on a mouse-adapted strain of human influenza. DRDC Suffield had previously conducted extensive research in the use of liposome delivery technology to enhance the antiviral activity of a closely-allied Ampligen® analogue, Poly ICLC (an immunomodulating dsRNA) which is very similar to Ampligen®. Results suggest that ribo nucleic acid-based drugs have the ability to elicit protective broad-spectrum antiviral immunity against various pathogenic viruses. Hence, there is the potential for efficacy to be maintained against mutating strains of an influenza virus. Liposomes, a carrier system for nucleic acid-based drugs, have shown an ability to protect these drugs against in vivo degradation, delivering them to intracellular sites of infection, thereby reducing any toxicity and prolonging their therapeutic effectiveness. Protection can be afforded for 21 days with two doses of dsRNA. Initial studies reported by DRDC Suffield indicated that Ampligen® was effective in a mouse model of avian H5N1 infection by decreasing death rates.

A clinical study conducted at the Princess Margaret Hospital in Hong Kong evaluated the use of Alferon LDO (Low Dose Oral Interferon Alfa-N3, Human Leukocyte Derived) to determine the affect on genes associated with anti-viral and immunological functions in normal volunteers. This study completed the dosing of ten patients. The initial analysis of data from this study is complete. A more definitive evaluation protocol is being developed to further validate the results. The initial results, conducted in collaboration with the Cleveland Clinic, did indicate that the Alferon LDO stimulated gene banks associated with an antiviral immune response in these otherwise healthy volunteers.

A paneled clinical study to evaluate the use of Alferon LDO in HIV infected volunteers was conducted in Philadelphia, PA. The study was conducted at two sites, Drexel University and Philadelphia FIGHT, a comprehensive AIDS service organization providing primary care, consumer education, advocacy and research on potential treatments and vaccines. The study was designed to determine whether Alferon LDO can resuscitate the broad-spectrum antiviral and immunostimulatory genes. As of January 2007, twenty-two (22) patients have enrolled and completed dosing. We are currently receiving data from this study and we are in the process of analyzing the results along with the results from the Alferon LDO study conducted in Hong Kong. This methodology may have implications for treating other emerging viruses such as avian influenza (bird flu). The Philadelphia results collaborated the findings of the Hong Kong study. Present production methods for vaccines involve the use of millions of chicken eggs and would be slow to respond to an outbreak according to various World Health Organization expert panels. Health officials are also concerned that bird flu could mutate to cause the next pandemic and render present vaccines under development ineffective. We have initiated a collaboration with a research organization in the Netherlands (ViroClinics) to study the activity of Alferon LDO against avian influenza in a primate model.

Two toxicology studies have been completed at the Lovelace clinic in Albuquerque, New Mexico to support new methods of Ampligen® administration. These studies involved the use of Ampligen as a vaccine immunostimulant. We plan to conduct a study in Australia to study the immunostimulant effect of Ampligen® on influenza vaccination in the elderly. This study is expected to start in the second quarter of 2007.

These important studies show that Ampligen® can be safely administered intranasally and intramucosally, as well as intravenously.

## **MANUFACTURING**

Historically, we have outsourced the manufacturing of Ampligen® to certain contractor facilities in the United States and South Africa while maintaining full quality control and supervision of the process. Nucleic Acid polymers constitute the raw material used in the production of Ampligen®. We previously acquired our raw materials from Ribotech, Ltd. (“Ribotech”) located in South Africa. Ribotech, is jointly owned by us (24.9%) and Bioclones (Proprietary), Ltd. (75.1%). Bioclones manages and operates Ribotech. There are a limited number of manufacturers in the United States available to provide the polymers. At present, we do not have any agreements with third parties for the supply of any of such materials. Ribotech’s facility in South Africa, our previous supplier of raw materials, was determined not to be suitable for the commercial manufacture of polymers/raw material used to make Ampligen®. In response to this, we completed the set up of a polymer/raw material manufacturing operation in 2006 in our New Brunswick, NJ facility. The transfer of Ampligen® raw materials production to our own facilities has obvious advantages with respect to overall control of the manufacturing process, keeping costs down, controlling regulatory compliance issues and allows us to obtain Ampligen® raw materials on a more consistent manufacturing basis. The first lot of Ampligen® raw material was produced in the second quarter of 2006. We have continued to produce Ampligen® raw material for the purpose of conducting pilot manufacturing runs at our contract manufacture of Ampligen®, Hollister-Stier (see below). The total approximate cost of establishing this production line in 2005 and 2006 was \$2,200,000, including modifications to our New Brunswick facility. We anticipate that this polymer production line will have the capacity to produce up to two kilograms per week, or approximately 100 kilograms per year which should allow us to manufacture up to 250,000 400 mg doses per year. We have also identified three contract manufacturers to expand polymer manufacture and obtained preliminary proposals from two and initiated discussions with the third. This would provide a backup to our New Jersey facility and additional production capacity, if necessary. This transfer of polymer manufacturing to our own facilities, and/or to another contract manufacturer may delay certain steps in commercialization process, specifically, our Ampligen NDA Registration process now underway.

In the past, we distributed Ampligen® in the form of a freeze-dried powder to be formulated by pharmacists at the site of use. We perfected a production process to produce ready to use liquid Ampligen® in a dosage form, which will mainly be used upon commercial approval of Ampligen®. We had engaged the services of Schering-Plough (“Schering”) to mass produce ready-to-use Ampligen® doses; however, in connection with settling various manufacturing infractions previously noted by the FDA, Schering entered into a “Consent Decree” with the FDA whereby, among other things, it agreed to discontinue various contract (third party) manufacturing activities at various facilities including its San Juan, Puerto Rico, plant. Ampligen® (which was not involved in any of the cited infractions) was produced at this Puerto Rico plant from year 2000-2004. Operating under instructions from the Consent Decree, Schering advised us that it would no longer manufacture Ampligen® in this facility beyond 2004 and assisted us in an orderly transfer of said activities to other non-Schering facilities.

On December 9, 2005, we executed a Supply Agreement with Hollister-Stier Laboratories LLC of Spokane, Washington (“Hollister-Stier”), for the contract manufacturing of Ampligen® for a five year term. Pursuant to the agreement we will supply the key raw materials and Hollister-Stier will formulate and bottle Ampligen®. We executed a confidentiality agreement with Hollister-Stier; in conjunction with the above Supply Agreement, and commenced the transfer of our manufacturing technology to Hollister-Stier. Currently, Hollister-Stier has completed five (5) pilot manufacturing runs of Ampligen® for stability testing with one additional manufacturing run scheduled to be completed mid-March 2007. The first three pilot runs were completed during the period December 2005 through January 2006 utilizing polymer/raw material from Ribotech (our previous supplier of raw material). The six month accelerated stability data on these three lots support a two year expiration period with additional test results forthcoming. Having successfully completed these manufacturing runs, the scale up of Ampligen® manufacturing to commercial batch size and the validation of the manufacturing at Hollister-Stier was initiated. The remaining two lots were run in January and February 2007 with the aforementioned third lot planned for mid-March 2007 utilizing polymer/raw material from our NJ facility. Based on the available information from the completion of the first two commercial size manufacturing validation lots, we anticipate placing these three process validation lots in stability studies to monitor and confirm the product quality and stability.

Alferon N Injection®, the purified drug concentrate utilized in the formulation of Alferon N Injection®, was manufactured in our New Brunswick, New Jersey facility and was formulated and packaged at a production facility formerly owned and operated by Abbott Laboratories located in Kansas. Abbott Laboratories sold the facility to Hospira. Hospira ceased the labeling and packaging of Alferon N Injection® as they sought larger production runs for cost efficiency purposes. On February 8, 2006, we executed a Manufacturing and Safety Agreement with Hyaluron, Inc. (“Hyaluron”) of Burlington, Massachusetts, for the formulation, packaging and labeling of Alferon N Injection®. Pursuant to the Agreement, we will supply raw materials in sufficient quantity and provide any pertinent information to the project. Hyaluron is in the process of preparing their facility to produce Alferon N. At this time we have scheduled additional production.

## **MARKETING/DISTRIBUTION**

We continue our efforts to establish an internal marketing and sales infrastructure to facilitate and refine our commercialization initiatives.

In 1998, we entered into a strategic alliance with Accredo to develop certain marketing and distribution capacities for Ampligen® in the United States. Accredo is one of the nation's largest home health care companies with over 400 offices and sixty thousand caregivers nationwide. Pursuant to the agreement, Accredo assumed certain responsibilities for distribution of Ampligen® for which they received a fee. Through this arrangement, we may mitigate the necessity of incurring certain up-front costs. Accredo has also worked with us in connection with the Amp 511 ME/CFS cost recovery treatment program, Amp 516 ME/CFS Phase III clinical trial and the Amp 719 (combining Ampligen® with other antiviral drugs in HIV-salvage therapy and Amp 720 HIV Phase IIb clinical trials now under way). There can be no assurances that this alliance will develop a significant commercial position in any of its targeted chronic disease markets. The agreement had an initial one year term from February 9, 1998 with successive additional one year terms unless either party notifies the other not less than 180 days prior to the anniversary date of its intent to terminate the agreement. Also, the agreement may be terminated for uncured defaults, or bankruptcy, or insolvency of either party and will automatically terminate upon our receiving an NDA for Ampligen® from the FDA, at which time, a new agreement will need to be negotiated with Accredo or another major drug distributor. This agreement offers the potential to provide some marketing and distribution capacity in the United States.

Our marketing strategy for Ampligen® reflects the differing health care systems around the world, and the different marketing and distribution systems that are used to supply pharmaceutical products to those systems. In the U.S., we expect that, subject to receipt of regulatory approval, Ampligen® may be utilized in four medical arenas: physicians' offices, clinics, hospitals and the home treatment setting. We are in the process of developing pre-launch and launch driven marketing plans focusing on those audience development, medical support and payor reimbursement initiatives which will facilitate product acceptance and utilization at the time of regulatory approval. Similarly, we are developing distribution scenarios for the Specialty Pharmacy/Infusion channel which will insure market access, offer accounts receivable capabilities and provide the requisite risk management control mechanisms. It is our intent to utilize third party service providers to execute elements of both the marketing/sales and distribution plans. We currently plan to utilize a small group of Managed Market account managers to introduce the product payor, employer and government account audiences. We believe that this approach will establish a market presence and facilitate the generation of revenue without incurring the substantial costs associated with a traditional sales force. Furthermore, management believes that the approach will enable us to retain many options for future marketing strategies.

In Europe, we plan to adopt a country-by-country and, in certain cases, an indication-by-indication marketing strategy due to the heterogeneity regulation and alternative distribution systems in these areas. We also plan to adopt an indication-by-indication strategy in Japan. Subject to receipt of regulatory approval, we plan to seek strategic partnering arrangements with pharmaceutical companies to facilitate introductions in these areas. The relative prevalence of people from target indications for Ampligen® varies significantly by geographic region, and we intend to adjust our clinical and marketing planning to reflect the specialty of each area. In Spain, Portugal and Andorra we have entered into a Sales Distribution Agreement with Laboratorios del Dr. Esteve, S. A., a major pharmaceutical firm headquartered in Spain.

Plans to increase revenues of Alferon N Injection® are intended to focus on direct, non-personal selling efforts to targeted physician audiences. It is our intent to promote Alferon to those dermatologists, OB GYNs and Family practice/IMs who are involved in the treatment of patients with refractory or recurring external genital warts and who currently utilize both injectable interferons as well as topical therapeutic agents. We also intend to expand our marketing/sales programs on an international basis with our primary focus on Europe. This program is being designed to engage European pharmaceutical distributors to market and distribute Alferon N Injection®.

## **COMPETITION**

Our potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have.

These companies and their competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments will offer competition to our products. Furthermore, our competitors have significantly greater experience than we do in pre-clinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, EMEA Health Protection Branch ("HPB") and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, EMEA and HPB product approvals more rapidly than us. If any of our products receive regulatory approvals and we commence commercial sales of our products, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have no experience. Our competitors may possess or obtain patent protection or other intellectual property rights that prevent, limit or otherwise adversely affect our ability to develop or exploit our products.

The major competitors with drugs to treat HIV diseases include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs, Glaxo Smithkline, Merck and Schering-Plough Corp. Alferon N Injection® currently competes with a product produced by Schering for treating genital warts. 3M Pharmaceutical also markets its immune response modifier product, Aldera, for the treatment of genital and perianal warts. We believe the approval and marketing of this product is the main reason that sales of Alferon N Injection® have not met our expectations in the current year. In November, 2006 the botanical drug, Veregen (to be marketed by Bradley Pharmaceuticals) was also approved for the topical treatment of genital and perianal warts.

## **GOVERNMENT REGULATION**

Regulation by governmental authorities in the U.S. and foreign countries is and will be a significant factor in the manufacture and marketing of Alferon N products and our ongoing research and product development activities. Ampligen® and the products developed from the ongoing research and product development activities will require regulatory clearances prior to commercialization. In particular, new human drug products for humans are subject to rigorous preclinical and clinical testing as a condition for clearance by the FDA and by similar authorities in foreign countries. The lengthy process of seeking these approvals, and the ongoing process of compliance with applicable statutes and regulations, has required, and will continue to require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect the marketing of any products developed by us and our ability to receive product or royalty revenue. We have received orphan drug designation for certain therapeutic indications, which might, under certain conditions, accelerate the process of drug commercialization. Alferon N Injection® is only approved for use in intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection® for other applications requires regulatory approval.

A “Fast Track” designation by the FDA, while not affecting any clinical development time per se, has the potential effect of reducing the regulatory review time by fifty percent (50%) from the time that a commercial drug application is actually submitted for final regulatory review. Regulatory agencies may apply a “Fast Track” designation to a potential new drug to accelerate the approval and commercialization process. Criteria for “Fast Track” include: a) a devastating disease without adequate therapy and b) laboratory or clinical evidence that the candidate drug may address the unmet medical need. As of this date, we have not received a Fast Track designation for any of our potential therapeutic indications although we have received “Orphan Drug Designation” for both ME/CFS and HIV/AIDS in the U.S. We continue to present data from time to time in support of obtaining some form of accelerated review. We have not yet completed our NDA filing for Ampligen® which is in process.

We are subject to various federal, state and local laws, regulations and recommendations relating to such matters as safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use of and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. The laboratory and production facility in New Brunswick, New Jersey, which we acquired from ISI, is approved for the manufacture of Alferon N Injection® and we believe it is in substantial compliance with all material regulations. However, we cannot give assurances that facilities owned and operated by third parties that are utilized in the manufacture of our products, are in substantial compliance, or if presently in substantial compliance, will remain so.

#### **RESEARCH, CONSULTING, LICENSING AND SUPPLY AGREEMENTS**

As previously discussed in Item I, we acquired a series of patents on Oragens, potentially a set of oral broad spectrum antivirals and immunological enhancers, through a licensing agreement with Temple University in Philadelphia, PA. We were granted an exclusive worldwide license from Temple for the Oragens products. These compounds have been evaluated in various academic laboratories for application to chronic viral and immunological disorders. Pursuant to the terms of our agreement with Temple, we are obligated to pay royalties of 2% to 4% of sales depending on the amount of technical assistance required. We currently pay a royalty of \$30,000 per year to Temple. This agreement is to remain in effect until the date that the last licensed patent expires unless terminated sooner by mutual consent or default due to royalties not being paid. The last Oragen™ patent expires on June 1, 2018. We recorded the payment of the royalty as research and development cost for the period incurred.

In December 1999, we entered into an agreement with Biovail Corporation International (“Biovail”). Biovail is an international full service pharmaceutical company engaged in the formulation, clinical testing, registration and manufacture of drug products utilizing advanced drug delivery systems. Biovail is headquartered in Toronto, Canada. The agreement grants Biovail the exclusive distributorship of our product in the Canadian territories subject to certain terms and conditions. In return, Biovail agrees to conduct certain pre-marketing clinical studies and market development programs, including without limitation, expansion of the Emergency Drug Release Program in Canada with respect to our products. In addition, Biovail agrees to work with us in preparing and filing a New Drug Submission with Canadian Regulatory Authorities at the appropriate time. Biovail invested \$2,250,000 in Hemispherx equity at prices above the then current market price and agreed to make an additional investment of \$1,750,000 based on receiving approval to market Ampligen® in Canada from the appropriate regulatory authorities in Canada. The agreement requires Biovail to buy exclusively from us and penetrate certain market segments at specific rates in order to maintain market exclusivity. The agreement terminates on December 15, 2009, subject to successive two-year extensions by the parties and subject to earlier termination by the parties for uncured defaults under the agreement, bankruptcy or insolvency of either party, or withdrawal of our product from Canada for a period of more than ninety days for serious adverse health or safety reasons.

In May 2000, we acquired an interest in Chronix Biomedical Corp. (“CHRONIX”). Chronix focuses upon the development of diagnostics for chronic diseases. We issued 100,000 shares of common stock to Chronix toward a total equity investment of \$700,000. Pursuant to a strategic alliance agreement, we provided Chronix with \$250,000 for research and development in an effort to develop intellectual property on potential new products for diagnosing and treating various chronic illnesses such as ME/CFS. These costs were expensed as incurred. The strategic alliance agreement provides us certain royalty rights with respect to certain diagnostic technology developed from this research and a right of first refusal to license certain therapeutic technology developed from this research. The strategic alliance agreement provides us with a royalty payment of 10% of all net sales of diagnostic technology developed by Chronix for diagnosing Chronic Fatigue Syndrome, Gulf War Syndrome and Human Herpes Virus-6 associated diseases. The royalty continues for the longer of 12 years from September 15, 2000 or the life of any patent(s) issued with regard to the diagnostic technology. The strategic alliance agreement also provides us with the right of first refusal to acquire an exclusive worldwide license for any and all therapeutic technology developed by Chronix on or before September 14, 2012 for treating Chronic Fatigue Syndrome, Gulf War Syndrome and Human Herpes Virus-6 associated diseases. The carrying value of this investment as of December 31, 2006 was \$35,000.

To facilitate a financing undertaken by Chronix Biomedical, Inc. (“Chronix”) on October 5, 2006 we terminated a Shareholders’ Agreement, Investor Rights Agreement and a Co-Sale Agreement between us, Chronix and certain Chronix Investors, each dated as of August 25, 2000 (the “Chronix Agreements”). As consideration for terminating the Chronix Agreements, we received 250,000 shares of restricted Chronix common stock and entered into a Voting Agreement, Investor Rights Agreement and Co-Sale and Right of First Refusal Agreement with Chronix and certain Chronix investors. This transaction did not have a material effect on our financial statements. The Company did not assign a value for the receipt of these shares pursuant to this termination.

In March 2002, our European subsidiary Hemispherx S.A. entered into a Sales and Distribution agreement with Esteve. In December 2006 Hemispherx S.A. assigned all of its rights and obligations under the Sales and Distribution agreement to us. Pursuant to the terms of the Agreement, Esteve was granted the exclusive right to market Ampligen® in Spain, Portugal and Andorra for the treatment of ME/CFS. In addition to other terms and other projected payments, Esteve agreed to conduct certain clinical trials using Ampligen® in the patient population coinfecting with HCV and HIV viruses. The Agreement runs for the longer of ten years from the date of first arms-length sale in the Territory, the expiration of the last Hemispherx patent exploited by Esteve or the period of regulatory data protection for Ampligen® in the applicable territory. Pursuant to the terms of the agreement Esteve is to conduct clinical trials using Ampligen® to treat patients with both HCV and HIV and is required to purchase certain minimum annual amounts of Ampligen® following regulatory approval. Esteve initiated the HIV/HCV clinical trials in Spain in late 2004, but did not proceed with the trials due to an inability to enroll a sufficient number of patients. We are discussing with Esteve their initiation of another clinical trial utilizing Ampligen® in another indication. The agreement is terminable by either party if Ampligen® is withdrawn from the territory for a specified period due to serious adverse health or safety reasons; bankruptcy, insolvency or related issues of one of the parties; or material breach of the agreement. Hemispherx may transform the agreement into a non-exclusive agreement or terminate the agreement in the event that Esteve does not meet specified percentages of its annual minimum purchase requirements under the agreement. Esteve may terminate the agreement in the event that Hemispherx fails to supply Ampligen® to the territory for a specified period of time or certain clinical trials being conducted by Hemispherx are not successful. The last patent with respect to this agreement expires on June 5, 2012.



Recently, Japanese researchers (Journal of Virology page 2910, 2005) have found that dsRNAs increase the effectiveness of influenza vaccine by more than 300% and may also convey “cross-protection ability against variant viruses” (mutated strains of influenza virus). In October 2005, we signed a research agreement with the National Institute of Infectious Diseases, in Tokyo, Japan. The collaboration, by Hideki Hasegawa, M.D., Ph.D., Chief of the Laboratory of Infectious Disease Pathology, will assess our experimental therapeutic Ampligen® as a co-administered immunotherapeutic to the Institution's nasal flu vaccine.

In October 2005, we also engaged the Sage Group, Inc., a health care, technology oriented, strategy and transaction advisory firm, to assist us in obtaining a strategic alliance in Japan for the use of Ampligen® in treating Chronic Fatigue Syndrome or CFS. In the past year leaders in the Japanese medical community have established the Japanese Society of the Fatigue Science and the Osaka City University Hospital opened the Fatigue Clinical Center as the initial step in their Fatigue Research Project. We are in discussions with the Sage Group, Inc. to expand its engagement to assist us in obtaining a strategic alliance in Japan for the use of Ampligen® in treating Avian Flu.

In November 2005, we entered into an agreement with Defence R&D Canada, Suffield (“DRDC Suffield”), an agency of the Canadian Department of National Defence, to evaluate the antiviral efficacy of our experimental therapeutic Ampligen® and Alferon® for protection against human respiratory influenza virus infection in well validated animal models. DRDC Suffield is conducting research and development of new drugs that could potentially become part of the arsenal of existing antiviral weapons to combat the bird flu. The initial study will focus on the testing of potential drugs against the respiratory influenza virus infection on a mouse-adapted strain of human influenza.

We entered into an agreement with Paul Griffin and The Asclepius Trust (“Asclepius”) whereby we acquired the right, title and interest in certain awarded patents and pending patent applications (“patents”). Consideration given by us for the acquisition of these patents amounted to \$150,000 paid with shares of our common stock to Paul Griffin valued at the closing price on the date of the agreement or July 3, 2006. The value of our common stock was \$2.43 on this date and equated to consideration of 61,728 shares. We registered these shares on behalf of Mr. Griffin for public resale. Asclepius will receive in consideration a 2% royalty of the gross sums received from all sales utilizing or relying upon the patents. We recorded the acquisition of these patents as an intangible asset to be amortized over an average remaining life of 13 years.

On July 26, 2006, we executed an agreement with Stem Cell Innovations, Inc. (formerly Interferon Sciences, Inc.) whereby we acquired the royalty interest previously granted Interferon Sciences with respect to our sale of products containing alpha interferon in exchange for 250,000 shares of common stock. We registered these shares on behalf of Stem Cell Innovations for public resale. The total consideration paid to Stem Cell under the agreement amounted to \$620,000 and was derived by multiplying the number of shares issued by the fair market value of our common stock on the date of the agreement or \$2.48 per share. The intangible asset is amortized over the period which the asset is expected to contribute directly or indirectly to our cash flow. The estimated aggregate amortization for the next five years is \$281,000 and will be fully amortized in approximately ten years.

We have entered into agreements for consulting services, which are performed at medical research institutions and by medical and clinical research individuals. Our obligation to fund these agreements can be terminated after the initial funding period, which generally ranges from one to three years or on an as-needed monthly basis. During the year ending December 31, 2004, 2005 and 2006 we incurred approximately \$220,000, \$236,000 and \$477,000 respectively, of consulting service fees under these agreements. These costs are charged to research and development expense as incurred.

As previously discussed in the "Manufacturing" Section of Item I, we executed a Supply Agreement with Hollister-Stier Laboratories LLC of Spokane, Washington ("Hollister-Stier"), for the contract manufacturing of Ampligen® for a five year term. Pursuant to the agreement we will supply the key raw materials and Hollister-Stier will formulate and bottle the Ampligen®. In November 2005, we paid \$100,000 as a deposit in order to initiate the manufacturing project. This deposit was expensed as research and development during the 4<sup>th</sup> Quarter 2005.

As previously discussed in the "Manufacturing" Section of Item I, on February 8, 2006, we executed a Manufacturing and Safety Agreement with Hyaluron, Inc. ("Hyaluron") of Burlington, Massachusetts, for the formulation, packaging and labeling of Alferon N Injection®. Pursuant to the Agreement, we will supply raw materials in sufficient quantity and provide any pertinent information to the project.

The development of our nucleic acid based products requires the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market and to establish commercial-scale production and marketing capabilities. During our last three fiscal years, we have directly spent approximately \$19,187,0000 in research and development, of which approximately \$10,127,000 was expended in the year ended December 31, 2006. These direct costs do not include the overhead and administrative costs necessary to support the research and development effort.

## **HUMAN RESOURCES**

As of March 8, 2007, we had 71 personnel consisting of 52 full time employees, 19 regulatory/research medical personnel on a part-time basis. Part time personnel are paid on a per diem or monthly basis. 50 personnel are engaged in our research, development, clinical, and manufacturing effort. 21 of our personnel perform regulatory, general administration, data processing, including bio-statistics, financial and investor relations functions. We have no union employees and we believe our relationship with our employees is good.

While we have been successful in attracting skilled and experienced scientific personnel, there can be no assurance that we will be able to attract or retain the necessary qualified employees and/or consultants in the future.

## **SCIENTIFIC ADVISORY BOARD**

Our Scientific Advisory Board consists of individuals who we believe have particular scientific and medical expertise in Virology, Cancer, Immunology, Biochemistry and related fields. These individuals will advise us about current and long term scientific planning including research and development. The Scientific Advisory Board will hold periodic meetings as needed by the clinical studies in progress by us. No Scientific Advisory Board meetings were held in 2006. In addition, individual Scientific Advisory Board Members sometimes consult with, and meet informally with our employees. All members of the Scientific Advisory are employed by others and may have commitments to and/or consulting agreements with other entities, including our potential competitors. Members of the Scientific Advisory Board are compensated at the rate of \$1,000 per meeting attended or per day devoted to our affairs.

### **ITEM 1A. Risk Factors.**

The following cautionary statements identify important factors that could cause our actual result to differ materially from those projected in the forward-looking statements made in this Form 10-K. Among the key factors that have a direct bearing on our results of operations are:

#### **Risks Associated With Our Business**

##### *No assurance of successful product development*

Ampligen® and related products. The development of Ampligen® and our other related products is subject to a number of significant risks. Ampligen® may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale, be uneconomical to market or be precluded from commercialization by proprietary right of third parties. Our products are in various stages of clinical and pre-clinical development and, require further clinical studies and appropriate regulatory approval processes before any such products can be marketed. We do not know when, if ever, Ampligen® or our other products will be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale.

We are in the registration process for an NDA with the FDA for approval to use Ampligen in the treatment of Chronic Fatigue Syndrome. We can provide no guidance as to the tentative date at which the compilation and filing of the NDA will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the ability of Hollister-Stier facilities to interface with our own New Brunswick staff/facilities to meet the manufacturing regulatory standards. Also, the timing of the FDA review process of the NDA is subject to the control of the FDA and could result in one of the following events; 1) approval to market Ampligen® for use in treating ME/CFS patients 2) require more research, development, and clinical work, 3) approval to market as well as conduct more testing, or 4) reject our NDA application. Given these variables, we are unable to project when material net cash inflows are expected to commence from the sale of Ampligen®.

Alferon N Injection®. Although Alferon N Injection® is approved for marketing in the United States for the intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older; to date it has not been approved for other indications. We face many of the risks discussed above, with regard to developing this product for use to treat other ailments such as multiple sclerosis and cancer.

***Our drug and related technologies are investigational and subject to regulatory approval. If we are unable to obtain regulatory approval, our operations will be significantly affected.***

All of our drugs and associated technologies, other than Alferon N Injection®, are investigational and must receive prior regulatory approval by appropriate regulatory authorities for general use and are currently legally available only through clinical trials with specified disorders. At present, Alferon N Injection® is only approved for the intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection® for other indications will require regulatory approval. In this regard, ISI, the company from which we obtained our rights to Alferon N Injection®, conducted clinical trials related to use of Alferon N Injection® for treatment of HIV and Hepatitis C. In both instances, the FDA determined that additional studies were necessary in order to fully evaluate the efficacy of Alferon N Injection® in the treatment of HIV and Hepatitis C diseases. We have no immediate plans to conduct these additional studies at this time.

Our products, including Ampligen®, are subject to extensive regulation by numerous governmental authorities in the U.S. and other countries, including, but not limited to, the FDA in the U.S., the Health Protection Branch (“HPB”) of Canada, and the Agency for the Evaluation of Medicinal Products (“EMA”) in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen® or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen® will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligen® is authorized for use in clinical trials in the United States, we cannot assure you that additional clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials. If Ampligen® or one of our other products does not receive regulatory approval in the U.S. or elsewhere, our operations most likely will be materially adversely affected.

***Although preliminary in vitro testing indicates that Ampligen® enhances the effectiveness of different drug combinations on avian influenza, preliminary testing in the laboratory is not necessarily predictive of successful results in clinical testing or human treatment.***

Ampligen® is undergoing pre-clinical testing for possible treatment of avian flu. Although preliminary in vitro testing indicates that Ampligen® enhances the effectiveness of different drug combinations on avian flu, preliminary testing in the laboratory is not necessarily predictive of successful results in clinical testing or human treatment. No assurance can be given that similar results will be observed in clinical trials. Use of Ampligen® in the treatment of avian flu requires prior regulatory approval. Only the FDA can determine whether a drug is safe, effective or promising for treating a specific application. As discussed in the prior risk factor, obtaining regulatory approvals is a rigorous and lengthy process.

In addition, Ampligen® is being tested on two strains of avian flu. There are a number of strains and strains mutata. No assurance can be given that Ampligen® will be effective on any strains that might infect humans.

***We may continue to incur substantial losses and our future profitability is uncertain.***

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses, as we pursued our clinical trial effort to get our experimental drug, Ampligen, approved. As of December 31, 2006 our accumulated deficit was approximately \$167,051,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

***We may require additional financing which may not be available.***

The development of our products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of December 31, 2006, we had approximately \$22,021,000 in cash and cash equivalents and short-term investments. These funds should be sufficient to meet our operating cash requirements, including debt service, for at least the next 18 months.

On April 12, 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC, pursuant to which Fusion Capital has agreed, under certain conditions and with certain limitations, to purchase on each trading day \$100,000 of our common stock up to an aggregate of \$50,000,000 over a 25 month period. See Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity And Capital Resources."

We only have the right to receive \$100,000 per trading day under the agreement with Fusion Capital unless our stock price exceeds \$1.90 by at least \$0.10, in which case the daily amount may be increased under certain conditions as the price of our common stock increases. Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than \$1.00. We have registered 12,386,723 shares purchasable by Fusion Capital pursuant to the common stock purchase agreement (inclusive of up to 643,502 additional Commitment Shares), the selling price of our common stock to Fusion Capital will have to average at least about \$4.26 per share for us to receive the maximum proceeds of \$50,000,000 without registering additional shares of common stock. As of March 8, 2007, Fusion Capital has purchased 6,839,521 shares for proceeds of \$13,689,128. Assuming a purchase price of \$1.75 per share (the closing sale price of the common stock on March 8, 2007) and the purchase by Fusion Capital of the remaining 5,225,451 shares which excludes up to 643,502 Commitment Shares) under the common stock purchase agreement, proceeds to us would only be \$22,833,667. We are planning to register an additional 15,000,000 shares which, if sold pursuant to this agreement would produce additional funds In order to be in compliance with the American Stock Exchange rules, our stockholders on September 20, 2006 approved the issuance of up to 27,386,723 shares to accommodate this agreement, if needed. In addition, Fusion Capital cannot purchase more than 27,386,723 shares, inclusive of Commitment Shares under the common stock purchase agreement. Accordingly, depending upon the future market price of our common stock, we may realize less than the maximum \$50,000,000 proceeds from the sale of stock under the Purchase Agreement. \_

The extent to which we rely on Fusion Capital as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources.

If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive and if we are unable to commercialize and sell Ampligen® and/or increase sales of Alferon N Injection® or our other products, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full \$50,000,000 under the common stock purchase agreement with Fusion Capital, we may need to raise additional funds through additional equity or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes including the commercializing of Ampligen® products. There can be no assurances that we will raise adequate funds which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

***We may not be profitable unless we can protect our patents and/or receive approval for additional pending patents.***

We need to preserve and acquire enforceable patents covering the use of Ampligen® for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen® for such disease. We obtained all rights to Alferon N Injection®, and we plan to preserve and acquire enforceable patents covering its use for existing and potentially new diseases. Our success depends, in large part, on our ability to preserve and obtain patent protection for our products and to obtain and preserve our trade secrets and expertise. Certain of our know-how and technology is not patentable, particularly the procedures for the manufacture of our drug product which are carried out according to standard operating procedure manuals. We have been issued certain patents including those on the use of Ampligen® and Ampligen® in combination with certain other drugs for the treatment of HIV. We also have been issued patents on the use of Ampligen® in combination with certain other drugs for the treatment of chronic Hepatitis B virus, chronic Hepatitis C virus, and a patent which affords protection on the use of Ampligen® in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of Ampligen® as a sole treatment for any of the cancers, which we have sought to target. With regard to Alferon N Injection®, we have acquired from ISI its patents for natural alpha interferon produced from human peripheral blood leukocytes and its production process and we have filed a patent application for the use of Alferon LDO in treating viral diseases including avian influenza. We cannot assure that our competitors will not seek and obtain patents regarding the use of similar products in combination with various other agents, for a particular target indication prior to our doing such. If we cannot protect our patents covering the use of our products for a particular disease, or obtain additional patents, we may not be able to successfully market our products.

***The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves complex legal and factual questions.***

To date, no consistent policy has emerged regarding the breadth of protection afforded by pharmaceutical and biotechnology patents. There can be no assurance that new patent applications relating to our products or technology will result in patents being issued or that, if issued, such patents will afford meaningful protection against competitors with similar technology. It is generally anticipated that there may be significant litigation in the industry regarding patent and intellectual property rights. Such litigation could require substantial resources from us and we may not have the financial resources necessary to enforce the patent rights that we hold. No assurance can be made that our patents will provide competitive advantages for our products or will not be successfully challenged by competitors. No assurance can be given that patents do not exist or could not be filed which would have a materially adverse effect on our ability to develop or market our products or to obtain or maintain any competitive position that we may achieve with respect to our products. Our patents also may not prevent others from developing competitive products using related technology.

***There can be no assurance that we will be able to obtain necessary licenses if we cannot enforce patent rights we may hold. In addition, the failure of third parties from whom we currently license certain proprietary information or from whom we may be required to obtain such licenses in the future, to adequately enforce their rights to such proprietary information, could adversely affect the value of such licenses to us.***

If we cannot enforce the patent rights we currently hold we may be required to obtain licenses from others to develop, manufacture or market our products. There can be no assurance that we would be able to obtain any such licenses on commercially reasonable terms, if at all. We currently license certain proprietary information from third parties, some of which may have been developed with government grants under circumstances where the government maintained certain rights with respect to the proprietary information developed. No assurances can be given that such third parties will adequately enforce any rights they may have or that the rights, if any, retained by the government will not adversely affect the value of our license.

***There is no guarantee that our trade secrets will not be disclosed or known by our competitors.***

To protect our rights, we require certain employees and consultants to enter into confidentiality agreements with us. There can be no assurance that these agreements will not be breached, that we would have adequate and enforceable remedies for any breach, or that any trade secrets of ours will not otherwise become known or be independently developed by competitors.

***If our distributors do not market our products successfully, we may not generate significant revenues or become profitable.***

We have limited marketing and sales capability. We are dependent upon existing and, possibly future, marketing agreements and third party distribution agreements for our products in order to generate significant revenues and become profitable. As a result, any revenues received by us will be dependent on the efforts of third parties, and there is no assurance that these efforts will be successful. Our agreement with Accredo offers potential to provide some marketing and distribution capacity in the United States while agreements with Biovail Corporation and Laboratorios Del Dr. Esteve S.A. may provide a sales force in Canada, Spain and Portugal.

We cannot assure that our United States or foreign marketing partners will be able to successfully distribute our products, or that we will be able to establish future marketing or third party distribution agreements on terms acceptable to us, or that the cost of establishing these arrangements will not exceed any product revenues-. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a materially adverse effect on us.

***There are no long-term agreements with suppliers of required materials. If we are unable to obtain the required raw materials, we may be required to scale back our operations or stop manufacturing Alferon N Injection® and/or Ampligen®.***

A number of essential materials are used in the production of Alferon N Injection®, including human white blood cells. We do not have long-term agreements for the supply of any of such materials. There can be no assurance we can enter into long-term supply agreements covering essential materials on commercially reasonable terms, if at all.

There are a limited number of manufacturers in the United States available to provide the polymers for use in manufacturing Ampligen®. At present, we do not have any agreements with third parties for the supply of any of these polymers. We have established relevant manufacturing operations within our New Brunswick, New Jersey facility for the production of Ampligen® raw materials in order to obtain polymers on a more consistent manufacturing basis. The establishment of an Ampligen® raw materials production line within our own facilities, while having obvious advantages with respect to regulatory compliance (other parts of our 43,000 sq. ft. wholly owned FDA approved facility are already in compliance for the manufacture of Alferon N Injection®), may delay certain steps in the commercialization process, specifically our Ampligen NDA Registration process with the FDA.

If we are unable to obtain or manufacture the required raw materials, we may be required to scale back our operations or stop manufacturing. The costs and availability of products and materials we need for the production of Ampligen® and the commercial production of Alferon N Injection® and other products which we may commercially produce are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, and FDA and other governmental regulations and there can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all.

***There is no assurance that successful manufacture of a drug on a limited scale basis for investigational use will lead to a successful transition to commercial, large-scale production.***

Small changes in methods of manufacturing, including commercial scale-up, may affect the chemical structure of Ampligen® and other RNA drugs, as well as their safety and efficacy, and can, among other things, require new clinical studies and affect orphan drug status, particularly, market exclusivity rights, if any, under the Orphan Drug Act. The transition from limited production of pre-clinical and clinical research quantities to production of commercial quantities of our products will involve distinct management and technical challenges and will require additional management and technical personnel and capital to the extent such manufacturing is not handled by third parties. There can be no assurance that our manufacturing will be successful or that any given product will be determined to be safe and effective, capable of being manufactured economically in commercial quantities or successfully marketed.



***We have limited manufacturing experience and capacity.***

Ampligen® has been only produced in limited quantities for use in our clinical trials and we are dependent upon third party suppliers for substantially all of the production process. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a material adverse affect on us. Also, to be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. To the extent we are involved in the production process, our current facilities are not adequate for the production of our proposed products for large-scale commercialization, and we currently do not have adequate personnel to conduct commercial-scale manufacturing. We intend to utilize third-party facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. We will need to comply with regulatory requirements for such facilities, including those of the FDA pertaining to current Good Manufacturing Practices (“cGMP”) regulations. There can be no assurance that such facilities can be used, built, or acquired on commercially acceptable terms, or that such facilities, if used, built, or acquired, will be adequate for our long-term needs.

***We may not be profitable unless we can produce Ampligen® or other products in commercial quantities at costs acceptable to us.***

We have never produced Ampligen® or any other products in large commercial quantities. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen® or enter into third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Also, each production lot of Alferon N Injection® is subject to FDA review and approval prior to releasing the lots to be sold. This review and approval process could take considerable time, which would delay our having product in inventory to sell.

***Rapid technological change may render our products obsolete or non-competitive.***

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Most of these entities have significantly greater research and development capabilities than us, as well as substantial marketing, financial and managerial resources, and represent significant competition for us. There can be no assurance that developments by others will not render our products or technologies obsolete or noncompetitive or that we will be able to keep pace with technological developments.

***Our products may be subject to substantial competition.***

Ampligen®. Competitors may be developing technologies that are, or in the future may be, the basis for competitive products. Some of these potential products may have an entirely different approach or means of accomplishing similar therapeutic effects to products being developed by us. These competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments may offer competition to our products. Furthermore, many of our competitors have significantly greater experience than us in pre-clinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, HPB or other regulatory product approvals more rapidly than us. There are no drugs approved for commercial sale with respect to treating ME/CFS in the United States. The dominant competitors with drugs to treat HIV diseases include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs, Glaxo Smith Kline, Merck and Schering-Plough Corp. These potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Although we believe our principal advantage is the unique mechanism of action of Ampligen® on the immune system, we cannot assure that we will be able to compete.

ALFERON N Injection®. Many competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Alferon N Injection® currently competes with Schering's injectable recombinant alpha interferon product (INTRON® A) for the treatment of genital warts. 3M Pharmaceuticals also received FDA approval for its immune-response modifier, Aldara<sup>®</sup>, a self-administered topical cream, for the treatment of external genital and perianal warts. In addition, Medigene recently received FDA approval for a self-administered ointment, Veregen<sup>™</sup>, which is indicated for the topical treatment of external genital and perianal warts. Alferon N Injection® also competes with surgical, chemical, and other methods of treating genital warts. We cannot assess the impact products developed by our competitors, or advances in other methods of the treatment of genital warts, will have on the commercial viability of Alferon N Injection®. If and when we obtain additional approvals of uses of this product, we expect to compete primarily on the basis of product performance. Our competitors have developed or may develop products (containing either alpha or beta interferon or other therapeutic compounds) or other treatment modalities for those uses. In the United States, three recombinant forms of beta interferon have been approved for the treatment of relapsing-remitting multiple sclerosis. There can be no assurance that, if we are able to obtain regulatory approval of Alferon N Injection® for the treatment of new indications, we will be able to achieve any significant penetration into those markets. In addition, because certain competitive products are not dependent on a source of human blood cells, such products may be able to be produced in greater volume and at a lower cost than Alferon N Injection®. Currently, our wholesale price on a per unit basis of Alferon N Injection® is higher than that of the competitive recombinant alpha and beta interferon products.

General. Other companies may succeed in developing products earlier than we do, obtaining approvals for such products from the FDA more rapidly than we do, or developing products that are more effective than those we may develop. While we will attempt to expand our technological capabilities in order to remain competitive, there can be no assurance that research and development by others or other medical advances will not render our technology or products obsolete or non-competitive or result in treatments or cures superior to any therapy we develop.

***Possible side effects from the use of Ampligen® or Alferon N Injection® could adversely affect potential revenues and physician/patient acceptability of our product.***

Ampligen®. We believe that Ampligen® has been generally well tolerated with a low incidence of clinical toxicity, particularly given the severely debilitating or life threatening diseases that have been treated. A mild flushing reaction has been observed in approximately 15% of patients treated in our various studies. This reaction is occasionally accompanied by a rapid heart beat, a tightness of the chest, urticaria (swelling of the skin), anxiety, shortness of breath, subjective reports of “feeling hot”, sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by slowing the infusion rate. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, transient visual disturbances, slow or irregular heart rate, decreases in platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills, fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months. One or more of the potential side effects might deter usage of Ampligen® in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

Alferon N Injection®. At present, Alferon N Injection® is only approved for the intra-lesional (within the lesion) treatment of refractory or recurring external genital warts in adults. In clinical trials conducted for the treatment of genital warts with Alferon N Injection®, patients did not experience serious side effects; however, there can be no assurance that unexpected or unacceptable side effects will not be found in the future for this use or other potential uses of Alferon N Injection® which could threaten or limit such product’s usefulness.

***We may be subject to product liability claims from the use of Ampligen®, Alferon N Injection®, or other of our products which could negatively affect our future operations.***

We face an inherent business risk of exposure to product liability claims in the event that the use of Ampligen® or other of our products results in adverse effects. This liability might result from claims made directly by patients, hospitals, clinics or other consumers, or by pharmaceutical companies or others manufacturing these products on our behalf. Our future operations may be negatively affected from the litigation costs, settlement expenses and lost product sales inherent to these claims. While we will continue to attempt to take appropriate precautions, we cannot assure that we will avoid significant product liability exposure. Although we currently maintain product liability insurance coverage, there can be no assurance that this insurance will provide adequate coverage against Ampligen® and/or Alferon N Injection® product liability claims. A successful product liability claim against us in excess of Ampligen®’s \$1,000,000 in insurance coverage; \$3,000,000 in aggregate, or in excess of Alferon N Injection®’s \$5,000,000 in insurance coverage; \$5,000,000 in aggregate; or for which coverage is not provided could have a negative effect on our business and financial condition.

***The loss of Dr. William A. Carter's services could hurt our chances for success.***

Our success is dependent on the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen®, and his knowledge of our overall activities, including patents and clinical trials. The loss of Dr. Carter's services could have a material adverse effect on our operations and chances for success. We have secured key man life insurance in the amount of \$2,000,000 on the life of Dr. Carter and we have an employment agreement with Dr. Carter that, as amended, runs until December 31, 2010. However, Dr. Carter has the right to terminate his employment upon not less than 30 days prior written notice. The loss of Dr. Carter or other personnel, or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

***Uncertainty of health care reimbursement for our products.***

Our ability to successfully commercialize our products will depend, in part, on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and from time to time legislation is proposed, which, if adopted, could further restrict the prices charged by and/or amounts reimbursable to manufacturers of pharmaceutical products. We cannot predict what, if any, legislation will ultimately be adopted or the impact of such legislation on us. There can be no assurance that third party insurance companies will allow us to charge and receive payments for products sufficient to realize an appropriate return on our investment in product development.

***There are risks of liabilities associated with handling and disposing of hazardous materials.***

Our business involves the controlled use of hazardous materials, carcinogenic chemicals, flammable solvents and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with the standards prescribed by applicable regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident or the failure to comply with applicable regulations, we could be held liable for any damages that result, and any such liability could be significant. We do not maintain insurance coverage against such liabilities.

***The market price of our stock may be adversely affected by market volatility.***

The market price of our common stock has been and is likely to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in U.S. or foreign regulatory policy during the period of product development;

- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries; new accounting standards; and
- the occurrence of any of the risks described in these "Risk Factors."

Our common stock is listed for quotation on the American Stock Exchange. For the 12-month period ended December 31, 2006, the closing price of our common stock has ranged from \$1.80 to \$4.23 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if without merit or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

***Our stock price may be adversely affected if a significant amount of shares are sold in the public market.***

We have registered 12,386,723 shares for sale by Fusion Capital and 530,617 shares by others, and may, in the future, register additional shares for sale by Fusion under the common stock purchase agreement. As of March 8, 2007, approximately 1,061,713 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act, 396,669 of which have been registered in prior registration statements. Also, we have registered 10,084,996 shares issuable (i) upon conversion of approximately 135% of Debentures that we issued in 2003 and 2004; (ii) as payment of 135% of the interest on all of the Debentures; (iii) upon exercise of 135% of certain Warrants; and (iv) upon exercise of certain other warrants. Registration of the shares permits the sale of the shares in the open market or in privately negotiated transactions without compliance with the requirements of Rule 144. To the extent the exercise price of the warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the conversion price and exercise price of these securities are adjusted pursuant to anti-dilution protection, the securities could be exercisable or convertible for even more shares of common stock. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock. Sales of substantial amounts of our common stock in the public market could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.



***The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by Fusion Capital and other shares registered for selling stockholders could cause the price of our common stock to decline.***

The sale by Fusion Capital and other selling stockholders of our common stock will increase the number of our publicly traded shares, which could depress the market price of our common stock. Moreover, the mere prospect of resales by Fusion Capital and other selling stockholders as contemplated in this prospectus could depress the market price for our common stock. The issuance of shares to Fusion Capital under the common stock purchase agreement, will dilute the equity interest of existing stockholders and could have an adverse effect on the market price of our common stock.

The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement will fluctuate based on the price of our common stock. All shares sold to Fusion Capital are to be freely tradable. Fusion Capital may sell none, some or all of the shares of common stock purchased from us at any time. We expect that the shares offered by this prospectus will be sold over a period of in excess of 25 months. Depending upon market liquidity at the time, a sale of shares under this offering at any given time could cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock to Fusion Capital pursuant to the purchase agreement, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

***Provisions of our Certificate of Incorporation and Delaware law could defer a change of our management which could discourage or delay offers to acquire us.***

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November 2002, we adopted a stockholder rights plan and, under the Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one unit of preferred stock for \$30.00. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Dr. Carter, our chief executive officer, who already beneficially owns 8.3% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at \$.01 per Right under certain circumstances.

Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Our research in clinical

efforts may continue for the next several years and we may continue to incur losses due to clinical costs incurred in the development of Ampligen® for commercial application. Possible losses may fluctuate from quarter to quarter as a result of differences in the timing of significant expenses incurred and receipt of licensing fees and/or cost recovery treatment revenues in Europe, Canada and in the United States.



**ITEM 1B. Unresolved Staff Comments.**

None.

**ITEM 2. Properties.**

We currently lease our headquarters located in Philadelphia, Pennsylvania consisting of a suite of offices of approximately 15,000 square feet. We also currently own, occupy and use our New Brunswick, New Jersey laboratory and production facility that we acquired from ISI. These facilities consist of two buildings located on 2.8 acres. One building is a two story facility consisting of a total of 31,300 square feet. This facility contains offices, laboratories, production space and shipping and receiving areas. It is also contains space designated for research and development, our pharmacy, packaging, quality assurance and quality control laboratories. Building Two has 11,670 square feet consisting of offices, laboratories and warehouse space. The property has parking space for approximately 100 vehicles.

We have completed the set up of a polymer/raw material manufacturing operation in 2006 in the New Brunswick, NJ facility that we own.

Our lease on the Rockville facility expired in June 2005 and we completed the move of our laboratory and equipment to our New Brunswick facility. Consolidation of this laboratory with our existing laboratory in New Brunswick will provide economical benefit. With the consolidation complete, it is our belief that the consolidated facility will enable us to meet our requirements for planned clinical trials and treatment protocols for the foreseeable future.

**ITEM 3. Legal Proceedings.**

On September 30, 1998, we filed a multi-count complaint against Manuel P. Asensio, Asensio & Company, Inc. (“Asensio”). The action included claims of defamation, disparagement, tortious interference with existing and prospective business relations and conspiracy, arising out of Asensio’s false and defamatory statements. The complaint further alleged that Asensio defamed and disparaged us in furtherance of a manipulative, deceptive and unlawful short-selling scheme in August and September, 1998. In 1999, Asensio filed an answer and counterclaim alleging that in response to Asensio’s strong sell recommendation and other press releases, we made defamatory statements about Asensio. We denied the material allegations of the counterclaim. In July 2000, following dismissal in federal court for lack of subject matter jurisdiction, we transferred the action to the Pennsylvania State Court. In March 2001, the defendants responded to the complaints as amended and a trial commenced on January 30, 2002. A jury verdict disallowed the claims against the defendants for defamation and disparagement and the court granted us a directed verdict on the counterclaim. On July 2, 2002 the Court entered an order granting us a new trial against Asensio for defamation and disparagement. Thereafter, Asensio appealed the granting of a new trial to the Superior Court of Pennsylvania. The Superior Court of Pennsylvania has denied Asensio’s appeal. Asensio petitioned the Supreme Court of Pennsylvania for allowance of an appeal, which was denied. We now anticipate the scheduling of a new trial against Asensio for defamation and disparagement in the Philadelphia Common Pleas Court.

In June 2002, a former ME/CFS clinical trial patient in Belgium filed a claim in Belgium, against Hemispherx Biopharma Europe, NV/SA, our Belgian subsidiary, and one of its clinical trial investigators alleging that she was harmed in the Belgium ME/CFS clinical trial as a result of negligence and breach of warranties. We believe the claim is without merit and we are defending the claim against us through our product liability insurance carrier.

In December 2004, we filed a multicount complaint in federal court (Southern District of Florida) against a conspiratorial group seeking to illegally manipulate our stock for purposes of bringing about a hostile takeover of Hemispherx. The lawsuit alleges that the conspiratorial group commenced with a plan to seize control of our cash and proprietary assets by an illegal campaign to drive down our stock price and publish disparaging reports on our management and current fiduciaries. The lawsuit seeks monetary damages from each member of the conspiratorial group as well as injunctions preventing further recurrences of their misconduct. The conspiratorial group includes Bioclones, a privately held South African Biopharmaceutical company that collaborated with us, and Johannesburg Consolidated Investments, a South African corporation, Cyril Donniger, R. B. Kebble, H. C. Buitendag, Bart Goemaere, and John Doe(s). Bioclones, Johannesburg Consolidated Investments, Cyril Donniger, R. B. Kebble and H.C. Buitendag filed a motion to dismiss the complaint, which was granted by the court. The Company is in the process of appealing this decision to the 11<sup>th</sup> federal circuit court of appeals.

On January 10, 2005, we initiated a multicount lawsuit in the United States District Court for the Eastern District of Pennsylvania seeking injunctive relief and damages against a conspiratorial group, many of whom are foreign nationals or companies located outside the United States alleging that the conspiratorial group has engaged in secret meetings, market manipulations, fraudulent misrepresentations, utilization of foreign accounts and foreign secrecy laws all in furtherance of an illegal scheme to take over Hemispherx and enrich themselves at the expense of our public stockholders. On February 18, 2005, we filed an amended complaint in the same lawsuit joining Redlabs, USA, Inc. as a defendant with the existing defendants R.E.D. Laboratories, N.V./S.A., Bart Goemaere, Jan Goemaere, Dr. Kenny De Meirleir, Kenneth Schepmans, Johan Goossens, Lieven Vansacker and John Does. Pursuant to an agreement in which R.E.D. Laboratories, N.V./S.A. and Dr. Kenny DeMeirleir agreed not to participate in a hostile takeover of Hemispherx for a period of five years, R.E.D. Laboratories, N.V./S.A. and Dr. Kenny DeMeirleir have been dismissed as defendants in the litigation. The Company dismissed without prejudice the litigation against the remaining defendants.

In October 2006, litigation was initiated against us in the Court of Common Pleas, Philadelphia County, Pennsylvania between us and Hospira Worldwide, Inc. with regard to a dispute with respect to fees for services charged by Hospira Worldwide, Inc. to us. The dispute was promptly settled and the litigation dismissed.

In January 2007, arbitration proceedings were initiated by Bioclones (Proprietary), Ltd., (“Bioclones”) and are pending in South Africa to determine damages arising out of the termination of a marketing agreement we had with Bioclones. We had deemed the marketing agreement void due to numerous and long standing failures of performance by Bioclones and will present claims for damages against Bioclones in the arbitration. Bioclones has now confirmed that the marketing agreement has been terminated.

In January 2007, we filed an application in South Africa for the dissolution of Ribotech (PTY) Ltd. (“Ribotech”) on the grounds that the purpose for the existence of Ribotech, the marketing agreement between us and Bioclones, had been terminated. The application for termination is now pending.

**ITEM 4. Submission of Matters to a Vote of Security Holders.**

No matters were submitted to a vote of the security holders during the last quarter of the year ended December 31, 2006.

**PART II**

**ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

In 2006, we issued 10,552,609 shares of common stock consisting of 1) 481,366 shares for debt repayment, debt conversion and interest payments related to the October 2003, January 2004 and July 2004 Convertible Debentures; 2) 422,813 shares in payment of services rendered and the purchases of Patents and Royalty Agreements 3) 9,393,014 shares issued pursuant to the 2005 and 2006 Purchase Agreements with Fusion Capital and 4) 255,416 shares issued upon conversion of warrants.

The foregoing issuances of securities were private transactions and exempt from registration under section 4(2) of the Securities Act and/or regulation D rule 506 promulgated under the Securities Act. These securities have been or will be registered with the SEC.

Since October 1997 our common stock has been listed and traded on the American Stock Exchange (“AMEX”) under the symbol HEB. The following table sets forth the high and low list prices for our Common Stock for the last two fiscal years as reported by the AMEX. Such prices reflect inter-dealer prices, without retail markup, markdowns or commissions and may not necessarily represent actual transactions.

<b>COMMON STOCK</b>	<b>High</b>	<b>Low</b>
<u>Time Period:</u>		
January 1, 2005 through March 31, 2005	2.24	1.25
April 1, 2005 through June 30, 2005	1.96	1.30
July 1, 2005 through September 30, 2005	1.90	1.36
October 1, 2005 through December 31, 2005	3.70	1.70
January 1, 2006 through March 31, 2006	4.23	2.15
April 1, 2006 through June 30, 2006	3.57	2.21
July 1, 2006 through September 30, 2006	2.63	1.80
October 1, 2006 through December 31, 2006	2.47	1.87

As of March 8, 2007, there were approximately 273 holders of record of our Common Stock. This number was determined from records maintained by our transfer agent and does not include beneficial owners of our securities whose securities are held in the names of various dealers and/or clearing agencies.

On March 8, 2007, the last sale price for our common stock on the AMEX was \$1.75 per share.

We have not paid any cash dividends on our Common Stock in recent years. It is management's intention not to declare or pay dividends on our Common Stock, but to retain earnings, if any, for the operation and expansion of our business.

The following table gives information about our Common Stock that may be issued upon the exercise of options, warrants and rights under all of our equity compensation plans as of December 31, 2006.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average Exercise price of Outstanding options, warrants and rights	Number of securities Remaining available for future issuance under equity compensation plans(excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders:	3,729,403	\$ 2.62	4,731,395
Equity compensation plans not approved by security holders:	10,262,771	2.89	-
<b>Total</b>	<b>13,992,174</b>	<b>\$ 2.82</b>	<b>4,731,395</b>

**Performance Graph****Total Return To Shareholders  
(Includes reinvestment of dividends)****ANNUAL RETURN PERCENTAGE  
Years Ending**

Company Name / Index	Dec 02	Dec 03	Dec 04	Dec 05	Dec 06
<b>HEMISPHERX BIOPHARMA INC</b>	-52.67	6.10	-15.93	14.21	1.38
<b>S&amp;P SMALLCAP 600 INDEX</b>	-14.63	38.79	22.65	7.68	15.12
<b>PEER GROUP</b>	-45.76	5.33	-52.63	-41.59	-13.24

**INDEXED RETURNS  
Years Ending**

Company Name / Index	Base Period	Dec 02	Dec 03	Dec 04	Dec 05	Dec 06
<b>HEMISPHERX BIOPHARMA INC</b>	<b>100</b>	47.33	50.22	42.22	48.22	48.89
<b>S&amp;P SMALLCAP 600 INDEX</b>	<b>100</b>	85.37	118.48	145.32	156.48	180.14
<b>PEER GROUP</b>	<b>100</b>	54.24	57.13	27.06	15.81	13.71

**Peer Group Companies****AVI BIOPHARMA INC****IMMUNE RESPONSE CORP/DE****LA JOLLA PHARMACEUTICAL CO****MAXIM PHARMACEUTICALS INC.****(Included through 2005. Acquired by Epicept 1/2006)**

**ITEM 6. Selected Financial Data (in thousands except for share and per share data).**

The selected consolidated financial data set forth below should be read in conjunction with our consolidated financial statements, and the related notes thereto, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, included in this Annual Report. The statement of operations and balance sheet data presented below for, and as of the end of, each of the years in the five year period ended December 31, 2006 are derived from our audited consolidated financial statements. Historical results are not necessarily indicative of the results to be expected in the future.

Year Ended December 31	2002	2003 <sup>(2)</sup>	2004	2005	2006
<b>Statement of Operations Data:</b>					
Revenues and License fee Income	\$ 904	\$ 657	\$ 1,229	\$ 1,083	\$ 933
Total Costs and Expenses <sup>(1)</sup>	6,961	7,909	12,118	10,998	19,627
<b>Interest Expense and Financing Costs<sup>(3)</sup></b>					
Net loss	(7,424)	(13,895)	(16,887)	(12,446)	(19,399)
Deemed Dividend	-	(1,320)	(4,031)	-	-
Net loss applicable to common stockholder	(7,424)	(15,215)	(20,918)	(12,446)	(19,399)
Basic and diluted net loss per share	(0.23)	(0.43)	(0.46)	(0.24)	(0.31)
Shares used in computing basic and diluted net loss per share	32,085,776	35,234,526	45,177,862	51,475,192	61,815,358
<b>Balance Sheet Data:</b>					
Working Capital	\$ 2,925	\$ 7,000	\$ 13,934	\$ 16,353	\$ 16,559
Total Assets	6,040	13,638	25,293	24,654	31,431
Debt, net of discount <sup>(3)</sup>	-	3,123	4,312	4,171	3,871
Stockholders Equity	3,630	8,417	19,443	18,627	24,751
<b>Other Cash Flow Data:</b>					
Cash used in operating activities	\$ (6,409)	\$ (7,022)	\$ (7,240)	\$ (7,231)	\$ (13,746)
Capital expenditures	-	(19)	(150)	(1,002)	(1,352)

(1) General and Administrative expenses include stock compensation expense of \$132, \$237, \$2,000, \$391 and \$2,483 for the years ended December 31, 2002, 2003, 2004, 2005, and 2006, respectively.

(2) For information concerning the acquisition of certain assets of ISI and related financing see Note 4 and Note 7 to our consolidated financial statements for the year ended December 31, 2006 contained herein.

(3) In accounting for the March 12, 2003, July 10, 2003, October 29, 2003, January 26, 2004 and July 13, 2004 issuances of 6% Senior Convertible Debentures in the principal amounts of \$5,426, \$5,426, \$4,142, \$4,000, and \$2,000, respectively, and related embedded conversion features and warrant issuances, we recorded debt discounts which, in effect, reduced the carrying value of the debt. For additional information refer to Note 7 to our consolidated financial statements for the year ended December 31, 2006.

## **ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

The following discussion and analysis is related to our financial condition and results of operations for the three years ended December 31, 2006. This information should be read in conjunction with Item 6 - "Selected Financial Data" and our consolidated financial statements and related notes thereto beginning on F-1 of this Form 10-K.

### **Statement of Forward-Looking Information**

Certain statements in the section are "forward-looking statements." You should read the information before Item 1B above, "Special Note" Regarding Forward-Looking Statements" for more information about our presentation of information.

### **Background**

We are a biopharmaceutical company engaged in the manufacture and clinical development of new drug entities for treatment of seriously debilitating disorders. Our flagship products include Alferon N Injection® and the experimental therapeutics Ampligen® and Oragens®. Alferon N Injection® is approved for a category of STD infection, and Ampligen® and Oragens® represent experimental RNA nucleic acids being developed for globally important viral 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. We have in excess of 100 patents comprising its core intellectual property estate, a fully commercialized product (Alferon N Injection®) and GMP certified manufacturing facilities for its novel pharma products.

We have reported net income only from 1985 through 1987. Since 1987, we have incurred, as expected, substantial operating losses due to our conducting research and development programs.

We were incorporated in Maryland in 1996 under the name HEM research, Inc., and originally served as a supplier of research support products. Our business was redirected in the early 1980's to the development of nucleic acid pharmaceutical technology and the commercialization of RNA drugs. We were reincorporated in Delaware and changed our name to Hem Pharmaceutical Corp. in 1991 and to Hemispherx Biopharma, Inc., in June 1995. We have three domestic subsidiaries BioPro Corp., BioAegean Corp., and Core BioTech Corp., all of which are incorporated in Delaware and are dormant. Our foreign subsidiaries include Hemispherx Biopharma Europe N.V./S.A. established in Belgium in 1998 and Hemispherx Biopharma Europe S.A. incorporated in Luxembourg in 2002. Hemispherx Biopharma Europe N.V./S.A. has little or no activity. Hemispherx Biopharma Europe S. A. was dissolved as of December 2006.

## RESULTS OF OPERATIONS

### Years Ended December 31, 2005 vs. 2006

#### Net loss

Our net loss of \$19,399,000 for the year ended December 31, 2006 was up \$6,953,000 or 56% compared to the same period in 2005. This increase in loss was primarily due to: 1) Higher General and Administrative (“G&A”) expense of \$2,836,000 related primarily to the adoption of FAS 123R amounting to higher stock compensation expense of \$2,092,000 and higher accounting fees mainly related to the restatement of our financial statements of \$747,000, 2) Higher research and development costs of \$4,909,000 due to an increase in direct costs associated with developing Ampligen® and Alferon N Injection® for new and existing indications and costs associated with stability studies for Ampligen® and Alferon N Injection® related to manufacturing at our new contract manufacturer’s sites, Hollister-Stier and Hyaluron, and 3) higher production costs of approximately \$884,000 is primarily due to excess manufacturing capacity. Offsetting these increased expenditures, was a net decrease in our interest expense and financing costs of approximately \$1,862,000 as the amortization of the discounts on our convertible Debentures has been decreasing as they near maturity. Net losses per share were \$.31 for current period versus \$.24 for the same period 2005.

#### Revenues

Revenues for the years ended December 31, 2006 were \$933,000 as compared to revenues of \$1,083,000 for the same period in 2005. Ampligen® sold under the cost recovery clinical program was up \$10,000 or 6% and Alferon N Injection® sales were down \$160,000 or 18%. The decline in Alferon N Injection® sales can be attributed to increased competition from rival products. Ampligen® sold under the cost recovery clinical program is a product of physicians and ME/CFS patients applying to us to enroll in the program. This program has been in effect for several years and is offered as a treatment option to patients severely affected by CFS. As the name “cost recovery” implies, we have no gain or profit on these sales. The benefits to us include 1) physicians and patients becoming familiar with Ampligen® and 2) collection of clinical data relating to the patients’ treatment and results. We are altering our marketing strategy for Alferon N Injection®. We plan to establish an internal marketing and sales department to facilitate and refine our commercialization initiatives.

#### Production costs/cost of goods sold

Our costs for production/cost of goods sold increased \$884,000 for the year ended December 31, 2006 compared to the same period in 2005. This increase was primarily due to higher production costs representing excess production capacity during the current period amounting to \$748,000. Cost of goods sold for the year ended December 31, 2005 and 2006 were \$391,000 and \$527,000, respectively.



We executed a Manufacturing and Safety Agreement with Hyaluron, Inc. (“Hyaluron”) of Burlington, Massachusetts, for the formulation, packaging and labeling of Alferon N Injection®. During 2006, Hyaluron conducted three production runs for stability testing of Alferon N Injection®’s new vial material. The stability test results at the six month check point met the required specifications. The stability and validation testing of the new vials was successfully completed by year end 2006.

We purchased the royalty interest related to the sales of our natural alpha interferon products from Stem Cell Innovations, Inc. (previously known as Interferon Sciences, Inc.). In March 2004, we acquired the FDA approved manufacturing facility in New Brunswick, N.J. and the worldwide license for the production, manufacture, use, marketing and sale of Alferon N Injection®. The royalty interest on the interferon products was a residual of this transaction.

We outsource certain components of our overall research and development, manufacturing, marketing and distribution while maintaining control over the entire process through our quality assurance group and our clinical monitoring group.

### **Research and Development costs**

Overall research and development costs for the year ended December 31, 2006 were \$10,127,000 as compared to \$5,218,000 for the same period a year ago representing an increase of \$4,909,000 or 94%. The higher costs reflect an increase in the direct costs associated with our effort to develop our lead product, Ampligen®, as a therapy in treating acute and chronic diseases, cancers and on-going clinical trials involving patients with HIV and pre-clinical and clinical testing for possible treatment for avian and seasonal influenza viruses. Also, incremental costs were incurred for development of alternative delivery routes for Alferon N more suitable for various biodefense treatment indications.

Much of this increase in R&D cost is related to the production of raw materials at our new production lines recently installed at our New Brunswick facility. The New Brunswick facility successfully produced three lots of Poly I and three lots of Poly C<sub>12</sub>U, which have been shipped to Hollister-Stier (our contract manufacturer) for use in producing Ampligen® doses.

The initial five production lots produced by Hollister-Stier are being used for validity and stability testing and are presently considered of commercial quality. The results of these tests will be used in our Ampligen NDA submission.

We continue to focus our research and development efforts on three areas that have potential for commercialization:

- The preparation of a New Drug Application (NDA) for our experimental drug, Ampligen®, for the treatment of Chronic Fatigue Syndrome (CFS). CFS is a severe chronic disease that does not have recognized treatment therapy and is considered a serious and debilitating disease by the US Government, adversely affecting the US economy by 10’s of billions of dollars.
- The formulation of a broad-spectrum biodefense strategy built on the use of our experimental compounds consisting of Ampligen® and Alferon LDO (“Low Dose Oral”). The initial phase of this program is focused on the treatment of avian and seasonal flu and is being expanded to include other life-threatening viruses.

- The use of Ampligen® as a broad-based vaccine-enhancement compound.
- The validation of suggestions that Alferon N Injection®, already approved for treating HPV-related genital warts, may have application in treating Vulvar Vestibulitis Syndrome (VVS), an HPV related disorder affecting more than 10% of the adult US female population.

### **Ampligen NDA**

We continue our efforts with respect to completing the registration process for an NDA with the Food and Drug Administration (“FDA”) for using Ampligen® to treat patients afflicted with Chronic Fatigue Syndrome (“CFS”). CFS is a severe debilitating disease in which patients suffer complex symptoms such as fatigue, flu-like ailments, headaches and muscle pain. At this time, there are no approved treatment therapies. The Center for Disease Control (“CDC”) has added CFS to its priority list of emerging diseases. The preparation of the NDA is a time consuming and laborious process and basically involves the preparation of multiple technical documents including those covering 1) safety data results from animal and humans exposed to Ampligen®, 2) the data collection and analysis of data from several human clinical trials providing insight into the efficacy of Ampligen® and 3) the capacity and ability to produce Ampligen® on a consistent basis in commercial quantities. We have hired experienced technical teams assigned to preparing each of these three segments. When completed, these three technical documents will be consolidated into the common technical document (CTD) for submitting to the FDA. While the results of our AMP 516 Phase III clinical study is the basis for filing the NDA, we must also include the safety data collected on all patients that ever received Ampligen® (some 750 patients from clinical trials and various foreign countries for ME/CFS, plus hundreds of additional patients with HIV, Hepatitis, cancer, etc.) All of this effort is time consuming as our clinical monitors and research assistants must visit and audit the records of clinical investigators involved in our Ampligen clinical studies conducted over the last 15 years. The FDA has recently invited us to submit a proposed schedule for completing our NDA submission. We believe our ME/CFS studies are now complete. Meanwhile, we continue with our existing ongoing efforts to insure a complete and audited report of our various studies, including the well-controlled Amp 516, 516C, 502 and 502T studies. We have used our best efforts to complete the requisite reports including the hiring of additional staff and various expert medical/regulatory consultants with specific fields of expertise, many of which have held senior positions in various multi-national pharmaceutical companies, but can provide no assurance as to whether the outcome of this large data collection and filing process will be favorable or unfavorable, specifically with respect to the FDA’s perspective.

The NDA is being filed electronically to facilitate the ease of review by the FDA. We cannot yet provide guidance as to the tentative date at which the compilation and filing of the NDA will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the ability of Hollister-Stier facilities to interface with our own New Brunswick staff/facilities to meet the manufacturing regulatory standards. However, the overall process is proceeding. We started the NDA registration process on December 29, 2006 with the filing of one of the three major required sections. The timing of the FDA review process of the NDA is subject to the control of the FDA and could result in one of the following events; 1) approval to market Ampligen® for use in treating ME/CFS patients, 2) require more research, development, and clinical work, 3) approval to market as well as conduct more testing, or 4) reject our NDA application. Given these variables, we are unable to project when material net cash inflows are expected to commence from the sale of Ampligen®.

## **Biodefense**

The disturbing threats of an influenza pandemic and/or bioterror attacks have caused researchers and government institutions to pursue creative alternatives to existing vaccines and antivirals. This pursuit has led to growing recognition of our scientific approach and product portfolio. Medical researchers and clinical investigators, with whom we are collaborating, are utilizing our products in ongoing pre-clinical tests in this viral area.

Ampligen® is a nucleic acid-based molecule with potent immune stimulatory activity and we believe that it has the potential to safely enhance the effectiveness of various vaccines. Alferon LDO® is a new experimental drug delivery platform for our natural source alpha interferon. Preclinical results indicate that Alferon LDO has systemic biological activity on upregulation of Interferon related genes. Potential applications include respiratory infections including influenza. With the threat of an avian influenza pandemic rising and health officials warning that the virus could develop resistance to current flu treatments, the pursuit of a cost-effective and capable co-administered immunotherapeutic to existing antivirals and vaccines has become critical. This combination may permit the use of lower dosages and fewer injections of the antivirals and vaccines used to combat avian flu, thereby decreasing the cost of both immunization programs and treatment programs for the full-blown disease and increasing vaccine effectiveness. In antimicrobial (antibacterial) therapy, which is the best-studied clinical model, synergistic drug combinations may result in curative conditions/outcomes, often not observed when the single drugs are given alone. In the case of avian influenza where global drug supplies are presumptively in very limited supply relative to potential needs, therapeutic synergistic combinations could not only affect the disease outcome, but also the number of individuals able to access therapies.

The results of on-going preclinical studies indicate:

- That the activity of Tamiflu and Relenza, the only two drugs formally recognized for combating bird flu, can be boosted up to 100 times when co-administered with Ampligen®. Lab studies reveal that 50 to 100 times less Tamiflu may be used in conjunction with Ampligen® to achieve full inhibition with no multiplication of the virus, and no host cell damage. The ability to enhance the effectiveness of influenza vaccines would significantly enhance the supply.
- That animal studies conducted in collaboration with the National Institute of Infectious Diseases in Japan, it was found that the co-administration of our experimental immunostimulant Ampligen® may help enable substantial reductions in an H5N1 vaccine dose, as well as provide cross-protection against mutated strains of the H5N1 virus.
- New tests provided further evidence that Alferon LDO (Low Dose Oral), a new delivery for an anti-viral with prior regulatory approval for a category of sexually transmitted diseases, offers potential in resisting the spread of avian flu by stimulating genes that induce the production of immune compounds that are key building blocks in the body's defense system.

- That Alferon LDO may strengthen human immune responses via interferon activated genes, potentially staving off infection from exposure to viruses.

We expect to continue and accelerate these lines of research in 2007.

On August 29, 2006, we licensed the rights, on a worldwide exclusive basis, the international patent estate developed at Vanderbilt University for the in vivo use of DOGS, abbreviation for a chemical compound (dioctadecylamidoglycylspermine), for the efficient delivery of immunogenic DNA to the interior of cells. The acquisition of this intellectual property is expected to further enhance the position of Hemispherx in the vaccine field by providing an enabling mechanism for genetic (DNA) vaccination. Supporting and encouraging the development of DNA based vaccines has become a major initiative of the U.S. Department of Health and Human Services' biodefense programs designed to counteract lethal viral outbreaks including avian influenza. The large amounts of naked immunogenic DNA usually required to induce immune responses in animals and its application in humans has been a major impediment to the development and licensure of genetic vaccines despite distinct biological advantages provided by this new form of immunization. Use of DOGS technology increases the efficiency of DNA vaccination, therefore potentially reducing significantly the amount of DNA required to induce protective immune responses. We plan to combine the DOGS delivery of genetic immunogens with its immunostimulatory drug, AMPLIGEN®, to create a new vaccine technology platform (VACCINE ENHANCE) with wide application for human and veterinary indications as well as an easily integrated tool in biodefense.

#### **Vulvar Vestibulitis Syndrome (VVS)**

Alferon N. Injection® is our injectable formulation of Natural Alpha Interferon, and is approved by the FDA for the intralesional treatment of refractory or recurring external genital warts (condylomata acuminata) in patients. Alferon N Injection® is the first and only natural human alfa interferon product made available in the United States. It is an FDA approved treatment for human papilloma viruses (HPV) and clinical trials are planned to extend the treatment indication to other HPV related disorders, especially in the female health sector. Our strategy is to pursue a modified FDA approval for a related ailment with a large market opportunity and little competition. Vulvar vestibulitis syndrome is a perplexing and debilitating disorder involving pain limited to the vulvar vestibule. The condition impairs sexual function, social interactions and creates psychological distress and despair in millions of women. Its cause may be multi-factorial, and a number of studies have suggested vulvar vestibulitis syndrome to be linked to HPV. The market opportunity is large and represents approximately 14 million adult women in the United States alone.

We may initiate further clinical studies using Alferon N to treat VVS during 2007.

#### **General and Administrative Expenses**

General and Administrative (“G&A”) expenses for the years ended December 31, 2005 and 2006 were approximately \$5,389,000 and \$8,225,000, respectively, representing an increase of a \$2,836,000 or 53%. The increase in G&A expenses relates primarily to the adoption of FAS 123R which has increased stock compensation expense approximately \$2,092,000 during the current period versus a year ago. In addition, we have incurred higher accounting fees related to the restatement of our financial statements which has increased these fees by approximately \$747,000 from the same period a year earlier.

### **Interest and Other Income and Expense**

Interest and other income for the years ended December 31, 2005 and 2006 totaled \$590,000 and \$554,000, respectively. The decrease in interest and other income during the current period can primarily be attributed to the timing of the maturities of our marketable securities during the 2006 period versus the same period a year earlier. All funds in excess of our immediate need are invested in short-term high quality securities.

### **Interest Expense and Financing Costs**

Interest expense and non-cash financing costs were approximately \$1,259,000 for the year ended December 31, 2006 versus \$3,121,000 for the same period a year ago. The main reason for the decrease in interest expense and financing costs of \$1,862,000 can be attributed to decreased amortization charges on debt discounts during the current period versus the same period a year earlier as our convertible debentures have come closer to maturity (Please see Note 7 in the consolidated financial statements contained herein for more details on these transactions).

### **Years Ended December 31, 2005 vs. 2004**

#### **Net loss applicable to common stockholders**

Our net loss applicable to common stockholders of \$12,446,000 for the year ended December 31, 2005 was down 41% compared to the same period in 2004. This reduction of \$8,472,000 in loss was primarily due to: 1) lower costs associated with non-cash financing charges related to our convertible debentures and related warrants. These non-cash financing costs were down \$2,557,000 and represents 58% of the change in net loss from period to period, 2) production/cost of goods sold expenditures were down \$1,721,000 due to increased expenditures during 2004 associated with ramping up of the New Brunswick facility for further production of Alferon N Injection®, 3) deemed dividend of \$4,031,000 recorded upon the issuance of warrants to our debenture holders as incentive to exercise prior warrant issuances in 2004, and 4) lower non-cash stock compensation expenses of approximately \$1,609,000. These lower expenses were slightly offset by an increase in research & development (“R & D”) costs during the current period of approximately \$1,376,000 mainly due to costs associated with the future manufacture on technology at Hollister-Stier, our contract manufacturer of Ampligen®. Net loss applicable to common stockholder per share was \$(.24) for the current period versus \$(.46) in the same period in 2004.

The stock compensation expense noted above is due to a one-time, non-recurring event in that 1,450,000 warrants were granted to Dr. Carter in 2003 and fully expensed in the amount of \$1,769,000 upon vesting in 2004. These warrants were granted in exchange for Dr. Carter agreeing not to exercise his warrants/options unless, or until, stockholders approved an increase in our authorized shares. This agreement with Dr. Carter allowed us to complete the July 2003 Debenture transactions.

## Revenues

Total revenues for the year ended December 31, 2005 were \$1,083,000 as compared to \$1,229,000 for the same period in 2004. Alferon N Injection® sales of \$910,000 in 2005 were down \$140,000 or 13% while Ampligen® sold under the cost recovery clinical program was down \$6,000 or 3%. The decline in Alferon N Injection® sales can be attributed to increased competition from rival products, specifically, 3M Pharmaceutical's product Aldera. Ampligen® sold under the cost recovery clinical program is a product of physicians and ME/CFS patients applying to us to enroll in the program. After screening the patient's enrollment records, we ship Ampligen® to the physician. A typical six-month treatment therapy costs the patient about \$7,200 for Ampligen®. This program has been in effect for many years and is offered as a treatment option to patients severely affected by ME/CFS. As the name "cost recovery" implies, we have no gain or profit on these sales. The benefits to us include 1) physicians and patients becoming familiar with Ampligen® and 2) collection of clinical data relating to the patients' treatment and results.

## Production costs/cost of goods sold

Our costs for production/cost of goods sold were down \$1,721,000 for the year ended December 31, 2005 compared to the same period in 2004. \$1,642,000 of this decrease in production costs is primarily due to expenses incurred in 2004 related to preparing the New Brunswick facility for the production of Alferon N Injection®. There were no such costs in 2005. We are nearing completion of the construction of the production line within our own facility in New Brunswick for Ampligen® raw materials which was started in 2005. This installation will increase production capacity, improve efficiency and assure compliance with worldwide drug manufacturing standards and processes.

Alferon N Injection® cost of goods sold for the year ended December 31, 2005 and 2004 were \$391,000 and \$470,000, respectively. Since acquiring the right to manufacture and market Alferon N Injection® in March 2003, we have converted the work-in-progress inventory into finished goods as needed. This work-in-progress inventory included three production lots totaling the equivalent of approximately 55,000 vials (doses) at various stages of the manufacturing process. Approximately 42,000 vials have been produced. Our contractor, Hospira completed the labeling and packaging of approximately 12,000 vials of Alferon N Injection® inventory and these vials were released into finished goods inventory in November 2005. Hospira gave notice that they will no longer label and package Alferon N Injection® as they are seeking larger production runs for cost efficiency purposes. We have identified two manufacturers to replace Hospira and, on February 8, 2006, we executed a Manufacturing and Safety Agreement with Hyaluron, Inc. ("Hyaluron") of Burlington, Massachusetts, for the formulation, packaging and labeling of Alferon N Injection®. Pursuant to the Agreement, we will supply raw materials in sufficient production quantities and provide technical information to the project.

We have started preliminary work to convert the third lot of approximately 13,000 vials to finished goods inventory with an anticipated completion date for the third quarter 2006. By the first quarter 2007, we anticipate preparing new Alferon N Injection® lots from blood leukocytes at our New Jersey facility. Final formulation and packaging of Alferon N Injection® would be completed by a third party contractor as noted above.

The installation of a Ampligen® raw material production line within our New Brunswick facility has been completed and is now in production. The transfer of Ampligen® raw material production to our own facilities has obvious advantages with respect to overall control of the manufacturing process, keeping costs down and controlling regulatory compliance issues (other parts of our 43,000 sq. ft. wholly owned FDA approved facility are already in compliance for Alferon N Injection® manufacture). This will also allow us to obtain Ampligen® raw materials on a more consistent and reliable basis. As of April 30, 2006, we have capitalized approximately \$1,400,000 towards the construction and installation of this production line. The anticipated completion date for the first lot of Ampligen® raw material being produced is the second quarter 2006. We estimate the total cost of establishing this production line to be some \$1,900,000, including modifications to our New Brunswick facility. This polymer production line will have the capacity to produce up to two kilograms per week, or approximately 100 kilograms per year which should

allow us to manufacture up to one-quarter million 400 mg doses per year. We have identified three contract manufacturers to expand polymer manufacture, if necessary, and obtained preliminary proposals from two and initiated discussions with the third.

Research and Development costs

Overall research and development direct costs for the year ended December 31, 2005 and 2004 were \$5,218,000 and \$3,842,000, respectively. These costs in 2005 reflect the direct costs associated with our effort to develop our lead product, Ampligen®, as a therapy in treating chronic diseases, cancers and on-going clinical trials involving patients with HIV. In addition, these costs reflect direct costs incurred relating to the development of Alferon® LDO (low dose oral interferon alfa-N3, human leukocyte derived). We had approximately 130,000 doses on hand of Alferon® LDO which was prepared for use in clinical trials treating patients affected with the SARS, Avian Flu or other potentially emerging infectious diseases.

During 2005, we increased our clinical staff by employing several highly trained individuals to focus on the preparation of our Ampligen® NDA filing. The NDA filing is a very complex document and we are being meticulous in the preparation of the document. Our clinical monitors and research assistants completed the process of visiting the multiple clinical study sites around the country for our AMP 516 study in January 2006. Our process included collecting and auditing data generated at each of these sites. Since we incorporated a larger sample of data from our previous trials for inclusion in the NDA filing (see below for further details), our clinical monitors and research assistants visited our sites associated with our AMP 511 study in 2006 for the purpose of collecting and auditing this additional data. All data must be reviewed and checked to clarify any inconsistencies or inaccuracies are resolved. Due to the human factor, these types of problems occur in all clinical trials. These gaps and inconsistencies in data must be resolved with the respective clinical investigators, while maintaining a clear record of events which allows the FDA to conduct a meaningful audit of these records.

We believe that our AMP 516 ME/CFS Phase III clinical trial for use of Ampligen® in the treatment of ME/CFS is the most comprehensive study ever conducted in ME/CFS. This Phase III clinical trial, which was conducted over a six-year period, involved an enrollment of more than 230 severely debilitated ME/CFS patients and was conducted at twelve medical centers throughout the United States. The study is serving as the basis for us to file a new drug application with the FDA.

We had originally targeted a late 2004 filing date for this NDA for Ampligen®. In order to respond to changes in the regulatory environment that place a greater emphasis on the safety and efficacy of all new experimental drug candidates, we incorporated a larger sample of data from our previous trials. The NDA filing now includes data accumulated from 75,000 administrations of the studied drug to approximately 750 ME/CFS patients. We are in the process of completing an NDA registration process requesting FDA approval for using Ampligen® to treat ME/CFS.



The clinical development of the experimental therapeutic, Ampligen® for ME/CFS was initiated approximately 16 years ago. To date federal health agencies have yet to reach a consensus regarding various aspects of ME/CFS, including parameters of “promising therapies” for ME/CFS and which aspects of ME/CFS are anticipated to be “serious or life-threatening”.

Over its developmental history, Ampligen® has received various designations, including Orphan Drug Product Certification (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and “promising” clinical outcome recognition based on the evaluation of certain summary clinical reports (AHRQ, Agency Health Research Quality). However to date, the FDA has determined it has yet to receive sufficient information to support the potential of Ampligen® to treat a serious or life threatening aspect of ME/CFS. The definition of the “seriousness of a condition”, according to Guidance for Industry documents published in July, 2004 is “a matter of judgment, but generally based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one”. The FDA has recently requested a “complete and audited report of the Amp 516 study to determine whether Ampligen® has a clinically meaningful benefit on a serious or life threatening aspect of ME/CFS in order to evaluate whether the Amp 516 study results do or do not support a “fast track designation”. The FDA has also invited us to include a schedule for completion of all ME/CFS studies as well as a proposed schedule for our NDA submission. We are using our best efforts to complete the requisite reports including the hiring of new staff and various recognized expert medical/regulatory consultants, but can provide no assurance as to whether the outcome of this large data collection and filing process (approximately 750 patients, treated more than 75,000 times) will be favorable or unfavorable, specifically with respect to the FDA’s perspective. We plan to use an independent contractor to file the NDA electronically to facilitate the review by the FDA. Also, we can provide no guidance as to the tentative date at which the compilation and filing of such data will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the ability of Hollister-Stier facilities to interface with our own New Brunswick staff/facilities to meet the manufacturing regulatory standards.

The timing of the FDA review process of the NDA is subject to the control of the FDA and result in one of the following events; 1) approval to market Ampligen® for use in treating ME/CFS patients, 2) require more research, development, and clinical work, 3) approval to market as well as conduct more testing, or 4) reject our NDA application. Given these variables, we are unable to project when material net cash inflows are expected to commence from the sale of Ampligen®.

Our Amp 720 HIV study is a treatment using a Strategic Treatment Interruption (“STI”). The patients’ antiviral HAART regimens are interrupted and Ampligen® is substituted as mono-immunotherapy. Patients, who have completed at least nine months of Ampligen® therapy, were able to stay off HAART for a total STI duration with a mean time of 29.0 weeks whereas the control group, which was also taken off HAART, but not given Ampligen®, had earlier HIV rebound with a mean duration of 18.7 weeks. Thus, on average, Ampligen® therapy spared the patients excessive exposure to HAART, with its inherent toxicities, for more than 11 weeks.

41 HIV patients have participated in this 64 week study. The rate of enrollment depends on patient availability and on other products being in clinical trials for the treatment of HIV, causing competition for the same patient population. At present, more than 18 FDA approved drugs for HIV treatment competing for available patients. The length, and subsequently the expense of these studies, will also be determined by an analysis of the interim data, which will determine when completion of the ongoing Phase IIb is appropriate and whether a Phase III trial will be conducted or not. In case a Phase III study is required, the FDA might require a patient population exceeding the current one which will influence the cost and time of the trial. Accordingly, the number of “unknowns” is sufficiently great to be unable to predict when, or whether, we may obtain revenues from our HIV treatment indications.

With the threat of an avian influenza pandemic rising and health officials warning that the virus could develop resistance to current flu treatments, the pursuit of a cost-effective and complementary treatment to existing antivirals and vaccines has become critical. This combination may permit the use of lower dosages and fewer injections of the antivirals and vaccines used to combat avian flu, thereby decreasing the cost of both immunization programs and treatment programs for the full-blown disease.

In antimicrobial (antibacterial) therapy, which is the best-studied clinical model, synergistic drug combinations may result in curative conditions/outcomes, often not observed when the single drugs are given alone. In the case of avian influenza where global drug supplies are presumptively in very limited supply relative to potential needs, therapeutic synergistic combinations could not only affect the disease outcome, but also the number of individuals able to access therapies.

At the fourth annual Biodefense Research Meeting of the American Society of Microbiology held in Washington, D.C., we presented results of laboratory testing that showed our two investigational immunotherapeutics, Ampligen® and Alferon®, are potentially useful against H5N1, or avian flu, virus. The pre-clinical research indicates that Ampligen®, a specifically configured double-stranded RNA, can provide cross-protection against avian flu viral mutations as well as boost the effectiveness of Tamiflu and Relenza, the only two drugs formally recognized for combating bird flu, up to 100 times. Other lab tests, in healthy human volunteers, indicate that Alferon® LDO (Low Dose Oral), a new delivery form of an anti-viral with prior regulatory approval for a category of sexually transmitted diseases, can stimulate genes that induce the production of interferon and other immune compounds, key building blocks in the body’s defense system. The studies were conducted in conjunction with the National Institute of Infectious Diseases of Japan.

We entered into an agreement with Defence R&D Canada, Suffield (“DRDC Suffield”), an agency of the Canadian Department of National Defence, to evaluate the antiviral efficacy of our experimental therapeutic Ampligen® and Alferon® for protection against human respiratory influenza virus infection in well validated animal models. DRDC Suffield is conducting research and development of new drugs that could potentially become part of the arsenal of existing antiviral weapons to combat the bird flu. The initial study will focus on the testing of potential drugs against the respiratory influenza virus infection on a mouse-adapted strain of human influenza. DRDC Suffield has already conducted extensive research in the use of liposome delivery technology to enhance the antiviral activity of a closely-allied Ampligen® analogue, Poly ICLC (an immunomodulating dsRNA) which is very similar to Ampligen®. Results suggest that ribo nucleic acid-based drugs have the ability to elicit protective broad-spectrum antiviral immunity against various pathogenic viruses. Hence, there is the potential for efficacy to be maintained against mutating strains of an influenza virus. Liposomes, a carrier system for nucleic acid-based drugs, have shown an ability to protect these drugs against in vivo degradation, delivering them to intracellular sites of infection, thereby reducing any toxicity and prolonging their therapeutic effectiveness. Protection can be afforded for 21 days with two doses of dsRNA. It is believed that in humans with active flu infection, Tamiflu, given twice daily, may ameliorate symptoms.

A preclinical study was initiated in June 2005, to determine if Ampligen® enhances the effectiveness of different drug combinations on avian influenza. The preclinical study suggests a new, and potentially pivotal role of double-stranded RNA (“dsRNA”) therapeutics in improving the efficacy of the present standards in care in both influenza prevention and treatment of acute disease. The preclinical study is being conducted by research affiliates of the National Institutes of Health at Utah State University to examine potential therapeutic synergies with different drug combinations. The ongoing research is comparing the relative protection conveyed by Tamiflu (oseltamivir, Roche) and Relenza (Zanamivir, GlaxoSmithKline) with Ampligen® (dsRNA), alone and in combination, against the avian flu virus (H5N1). Cell destruction was measured in vitro using different drug combinations. Both drugs, given alone, were effective in inhibiting cell destruction by avian influenza, but viral suppression with the combination was greater than either drug alone. The overall assessment is that there was improvement in cell protection when Ampligen® was combined with oseltamivir carboxylate (Tamiflu) and Zanamivir (Relenza). Further immediate experimental tests are planned.

Japanese researchers (Journal of Virology page 2910, 2005) have found that dsRNAs increase the effectiveness of influenza vaccine by more than 300% and may also convey “cross-protection ability against variant viruses” (mutated strains of influenza virus). In October 2005, we signed a research agreement with the National Institute of Infectious Diseases, in Tokyo, Japan. The collaboration, by Hideki Hasegawa, M.D., Ph.D., Chief of the Laboratory of Infectious Disease Pathology, will assess our experimental therapeutic Ampligen® as a co-administered immunotherapeutic to the Institution's nasal flu vaccine.

In October 2005, we also engaged the Sage Group, Inc., a health care, technology oriented, strategy and transaction advisory firm, to assist us in obtaining a strategic alliance in Japan for the use of Ampligen® in treating Chronic Fatigue Syndrome or CFS. In the past year leaders in the Japanese medical community have established the Japanese Society of the Fatigue Science and the Osaka City University Hospital opened the Fatigue Clinical Center as the initial step in their Fatigue Research Project.

A clinical study has been approved by the Clinical Research Ethics Committee of the Kowloon West Cluster at the Princess Margaret Hospital in Hong Kong to evaluate the use of Alferon® LDO (Low Dose Oral Interferon Alfa-N3, Human Leukocyte Derived) in normal volunteers and/or asymptomatic subjects with exposure to a person known to have SARS. This study completed the dosing of ten patients during the fourth quarter 2005 and we expect to complete analyzing the results of this study in the coming months.

A clinical study to evaluate the use of Alferon® LDO in HIV infected volunteers was initiated during the second quarter 2005 in Philadelphia, PA. The study is currently being conducted at two sites, Drexel University and Philadelphia FIGHT, a comprehensive AIDS service organization providing primary care, consumer education, advocacy and research on potential treatments and vaccines. The study is designed to determine whether Alferon® LDO can resuscitate the broad-spectrum antiviral and immunostimulatory genes. The initial patient enrolled in this study in July 2005 and, as of December 2005, seven patients have enrolled and completed dosing. We are currently receiving data from this study and we are in the process of analyzing the results. This trial methodology may have implications for treating other emerging viruses such as avian influenza (bird flu). Present production methods for vaccines involve the use of millions of chicken eggs and would be slow to respond to an outbreak according to a recently convened World Health Organization expert panel in November 2004. Health officials are also concerned that bird flu could mutate to cause the next pandemic and render present vaccines under development ineffective.

In September 2004, we commenced a clinical trial using Alferon N Injection® to treat patients infected with the West Nile Virus. The infectious Disease section of New York Queens Hospital and the Weill Medical College of Cornell University are conducting this double-blinded, placebo controlled trial. This study plans to enroll 60 patients as they become available. As of March 1, 2006, nine patients have entered this study. The CDC reports that 2,744 cases of West Nile Virus have been reported in the US as of January 10, 2006, including 105 deaths.

We completed the transfer and consolidation of our Rockville Quality Assurance Lab and equipment into our New Brunswick facility. We believe this consolidated lab will provide more efficiencies with regard to the quality assurance needs for both Ampligen® and Alferon N Injection®.

In connection with settling various manufacturing infractions previously noted by the FDA, Schering entered into a “Consent Decree” with the FDA whereby, among other things, it agreed to discontinue various contract (third party) manufacturing activities at various facilities including its San Juan, Puerto Rico, plant. Ampligen® (which was not involved in any of the cited infractions) was produced at this Puerto Rico plant from year 2000-2004. Operating under instructions from the Consent Decree, Schering has advised us that it would no longer manufacture Ampligen® in this facility beyond 2004 and would assist us in an orderly transfer of said activities to other non Schering facilities.

On December 9, 2005, we executed a Supply Agreement with Hollister-Stier Laboratories LLC of Spokane, Washington, for the contract manufacturing of Ampligen® for a five year term. Pursuant to the agreement we will supply the key raw materials and Hollister-Stier will formulate and bottle the Ampligen®. We paid \$100,000 as a deposit in order to initiate the manufacturing project. This deposit was expended as research and development in 2005. The achievement of the initial objectives described in the agreement, in combination with our polymer production facility under construction in New Brunswick, N.J., may enable us to manufacture the raw materials for approximately 10,000 doses of Ampligen® per week. We executed a confidentiality agreement with Hollister-Stier; therefore, we completed the transfer of our manufacturing technology to Hollister-Stier. Currently, Hollister-Stier has completed two pilot manufacturing runs of Ampligen® for stability testing.

We have identified two other cGMP production facilities in the United States capable of manufacturing Ampligen®. Engagement of either of these facilities would provide back-up to Hollister-Stier and/or provide additional production capacity if needed. We are reviewing proposals from these production facilities and expect to act upon one or the other at the appropriate time.

Please see “Results of Operations” for the years ended December 31, 2006 and 2005 for further updates on research and development.

#### General and Administrative Expenses

General and Administrative (“G&A”) expenses for the years ended December 31, 2005 and 2004 were approximately \$5,389,000 and \$6,164,000, respectively. The decrease in G&A expenses of \$775,000 is primarily due to a non-cash stock compensation charge in 2004 of \$1,769,000 resulting from the issuance of 1,450,000 warrants to purchase common stock at \$2.20 per share to Dr. Carter in 2003 that vested in the first quarter 2004. Higher professional fees, specifically legal costs, during 2005, slightly offset this decrease in G&A as we initiated legal proceedings seeking injunction relief and damages against conspiratorial group engaged in illegal activities to take over Hemispherx and enrich themselves at the expense of our stockholders. Please see Item 3. “Legal Proceedings” in Part I, above for more information.

#### Interest and Other Income

Interest and other income for the years ended December 31, 2005 and 2004 totaled \$590,000 and \$49,000, respectively. The increase in interest and other income during the year can primarily be attributed to the maturing of marketable securities during the 2005 period. All funds in excess of our immediate need are invested in short-term high quality securities.

#### Interest Expense and Financing Costs

Non-cash financing costs and interest expenses were approximately \$3,121,000 for the year ended December 31, 2005 versus \$5,674,000 for the same period a year ago. Non-cash financing costs consist of the amortization of Original Issue Discounts and amortization of the costs associated with beneficial conversion features of our debentures and the relative fair value of the warrants relating to the Debentures. These charges are reflected in the Consolidated Statements of Operations under the caption “Financing Costs.” The main reason for the decrease in financing costs and interest expense of \$2,557,000 or 45% can be attributed to the aggregate total of these charges being reduced since 2004 due to decreased amortization charges as well as lower charges related to the conversion of debentures and the principal amounts decreasing. Please see Note 8 in the consolidated financial statements contained herein for more details on these transactions.

#### Deemed Dividend

Deemed dividend for the years ended December 31, 2004 and 2005, was \$4,031,000 and \$0 respectively. This represents the fair value of the warrants issued to our debenture holders as incentive to exercise prior warrant issuances.

#### **Liquidity and Capital Resources**

Cash used in operating activities for the year ended December 31, 2006 was \$13,746,000. Cash used in investing activities for the year ending December 31, 2006, amounted to \$7,206,000, primarily from the purchase of short-term investments. Cash provided by financing activities for the year ended December 31, 2006 amounted to \$20,771,000, primarily from the sale of common stock. As of February 28, 2007 we had approximately \$23,700,000 in cash and cash equivalents and short-term investments, or an increase of approximately 8% from December 31, 2006. These funds should be sufficient to meet our operating cash requirements including debt service for the next 19 months.

Over the long term, we may need to raise additional funds through additional equity or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes including the commercializing of Ampligen® products. There can be no assurances that we will raise adequate funds from these or other sources, which may have a material adverse effect on our ability to develop our products. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. We may also need additional funding earlier than anticipated, and our cash requirements, in general, may vary materially from those now planned, for reasons including, but not limited to, changes in our research and development programs, clinical trials, competitive and technological advances, the regulatory process, and higher than anticipated expenses and lower than anticipated revenues from certain of our clinical trials for which cost recovery from participants has been approved.

## Debentures

As of March 8, 2007, the Company made aggregate installment payments of \$2,389,000 and the investors converted an aggregate \$3,651,000 principal amount of debt from the debentures as noted below (in thousands):

Debenture	Original Principal Amount	Debt Conversion to Common Shares	Installment payments in Common Shares	Remaining Principal Amount	Common Shares issued for Conversion	Common Shares issued in installments
October 2003	\$ 4,142	\$ 2,071	\$ -	\$ 2,071	1,025,336	-
January 2004	4,000	1,080	1,889	1,031	507,257	1,094,149
July 2004	2,000	500	500	1,000	240,385	331,669
Totals	\$ 10,142	\$ 3,651	\$ 2,389	\$ 4,102	1,772,978	1,425,818

Pursuant to the terms and conditions of all of the outstanding Debentures, we have pledged all of our assets, other than our intellectual property, as collateral, and we are subject to comply with certain financial covenants.

In connection with the debenture agreements, we are required to have outstanding Letters of Credit of \$1,000,000 as additional collateral. These Letters of Credit expired in 2006 and were subsequently renewed during the first quarter of 2007. As of December 31, 2006, we were in violation of this provision within the agreements. We obtained a waiver letter from our debenture holders regarding the failure to meet this requirement.

See Note 7 of the consolidated financial statements for a full description of all Debentures.

## Equity Financing

On April 12, 2006, we entered into a common stock purchase agreement (the “2006 Purchase Agreement”) with Fusion Capital Fund II, LLC (“Fusion Capital”), pursuant to which Fusion Capital has agreed, under certain conditions, to purchase on each trading day \$100,000 of our common stock up to an aggregate of \$50.0 million over a period of approximately 25 months as described below. We have the right to suspend such purchases or terminate the agreement at any time. The purchase price of the shares of common stock will be equal to a price based upon the future market price of the common stock. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than \$1.00.

The purchase price per share will be equal to the lesser of (i) the lowest sale price of our common stock on the purchase date; or (ii) the average of the three lowest closing sale prices of our common stock during the twelve consecutive trading days prior to the date of a purchase by Fusion Capital.

The purchase price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction. Fusion Capital may not purchase shares of our common stock under the common stock purchase agreement if it, together with its affiliates, would beneficially own more than 9.9% of our common stock outstanding at the time of the purchase by Fusion Capital. Fusion Capital has the right at any time to sell any shares purchased under the 2006 Purchase Agreement which would allow it to avoid the 9.9% limitation. Without prior stockholder approval, we do not have the right or the obligation under the Agreement to sell shares to Fusion Capital in excess of 12,386,723 shares (i.e. 19.99% of the 61,964,598 outstanding shares of our common stock on April 12, 2006, the date the 2006 Purchase Agreement) inclusive of the commitment shares (discussed below). We would have to average a purchase price of approximately \$4.26 per share to receive the full \$50.0 million under the common stock purchase agreement if we do not receive stockholder approval. As of March 8, 2007, Fusion Capital has purchased from the Company 6,839,521 shares for aggregate gross proceeds of approximately \$13,689,127. In addition, the Company issued to Fusion Capital 88,111 shares towards the remaining commitment fee.

We also have the right to increase the daily purchase amount at any time, provided however, we may not increase the daily purchase amount above \$100,000 unless our stock price is above \$1.90 per share for five consecutive trading days. Specifically, for every \$0.10 increase in Threshold Price (as defined below) above \$1.90, we have the right to increase the daily purchase amount by up to an additional \$10,000. The "Threshold Price" is the lowest sale price of our common stock during the five trading days immediately preceding our notice to Fusion Capital to increase the daily purchase amount. If at any time during any trading day the sale price of our common stock is below the Threshold Price, the applicable increase in the daily purchase amount will be void.

In addition to the daily purchase amount, we may elect to require Fusion Capital to purchase on any single trading day the following:

- \$250,000 if our common stock trades at \$1.50 or better for five trading days.
- \$500,000 if our common stock trades at \$3.00 or better for five trading days.
- \$1,000,000 if our common stock trades at \$5.00 or better for five trading days.
- \$2,000,000 if our common stock trades at \$8.00 or better for five trading days.

The price at which such shares would be purchased will be the lesser of (i) the lowest Sale Price on the trading day that such purchase notice was received Fusion Capital or (ii) the lowest purchase price (as defined above) during the previous ten trading days prior to the date that such purchase notice was received by Fusion Capital.

Generally, Fusion Capital may terminate the common stock purchase agreement without any liability or payment to us upon the occurrence of any of the following events of default:

- the effectiveness of the registration statement covering the shares to be issued to Fusion under the Agreement lapses for any reason or is unavailable to Fusion Capital for sale of our common stock and such lapse or unavailability continues for a period of 10 consecutive trading days or for more than an aggregate of 30 trading days in any 365-day period;
- suspension by our principal market of our common stock from trading for a period of three consecutive trading days;
- the de-listing of our common stock from the American Stock Exchange, our principal market, provided our common stock is not immediately thereafter trading on the Nasdaq National Market, the Nasdaq SmallCap Market or the New York Stock Exchange or the OTC Bulletin Board;
- the transfer agent's failure for five trading days to issue to Fusion Capital shares of our common stock which Fusion Capital is entitled to under the 2006 Purchase Agreement;
- any material breach of the representations or warranties or covenants contained in the 2006 Purchase Agreement or any related agreements which has or which could have a material adverse affect on us subject to a cure period of 10 trading days;
  - any participation or threatened participation in insolvency or bankruptcy proceedings by or against us;
- a material adverse change in our business, properties, operations, financial condition or results of operations; or
- the issuance of an aggregate of 12,386,733 shares to Fusion Capital under our agreement and we fail to obtain the requisite stockholder approval.

We have the unconditional right at any time for any reason to give notice to Fusion Capital terminating the 2006 Purchase Agreement. Such notice shall be effective one trading day after Fusion Capital receives such notice.

Under the terms of 2006 Purchase Agreement, Fusion Capital received 321,751 shares of our common stock as a partial commitment fee and is entitled to receive up to an additional 321,751 commitment shares. These additional commitment shares will be issued in an amount equal to the product of (x) 321,751 and (y) the Purchase Amount Fraction. The "Purchase Amount Fraction" means a fraction, the numerator of which is the purchase price at which the shares are being purchased by Fusion Capital and the denominator of which is \$50,000,000. Unless an event of default occurs these shares must be held by Fusion Capital until 25 months from the date of the 2006 Purchase Agreement or the date such agreement is terminated or in the event that certain conditions precedent are not met such as the registration statement not being declared effective by August 31, 2006.

We are using the proceeds from this financing for general corporate purposes.

On July 8, 2005, we entered into a common stock purchase agreement (the "2005 Agreement") with Fusion Capital, pursuant to which Fusion Capital agreed, under certain conditions, to purchase on each trading day \$40,000 of our common stock, unless our stock price equals or exceeds \$2.00 in which case the daily amount may be increased under certain conditions as the price of the common stock increases, up to an aggregate of \$20.0 million over approximately a 25 month period, subject to earlier termination at our discretion. As of April 3, 2006, Fusion Capital purchased 8,791,838 shares for gross proceeds of the full \$20.0 million. Pursuant to the Agreement, in our discretion, we could elect to sell less common stock to Fusion Capital than the daily amount or increase the daily amount as the market



price of our stock increases. The purchase price of the shares of common stock was equal to a price based upon the market price of the common stock without any fixed discount to the market price. Fusion Capital did not have the right or the obligation to purchase shares of our common stock in the event that the price of the common stock is less than \$1.00. Pursuant to our agreement with Fusion Capital, on July 31, 2005, we registered for public sale by Fusion Capital up to 10,795,597 shares of our common stock.

In connection with entering into the above agreement with Fusion Capital, in July 2005, we issued to Fusion Capital 402,798 shares of common stock. 392,798 of these shares represented 50% of the commitment fee due Fusion Capital with the remaining 10,000 shares issued as reimbursement for expenses. An additional 392,799 shares, representing the remaining balance of the commitment, are issuable in conjunction with daily purchases of common stock by Fusion Capital. These additional commitment shares were issued in an amount equal to the product of (x) 392,799 and (y) the Purchase Amount Fraction. The "Purchase Amount Fraction" means a fraction, the numerator of which is the purchase price at which the shares are being purchased by Fusion Capital and the denominator of which is \$20,000,000. As of April 5, 2006, Fusion Capital was issued 392,799 shares towards this remaining commitment fee.

Please see Note 7 - "Debenture Financing" and Note 8 "Stockholder's Equity" in the consolidated financial statements contained herein for more details on debenture and stock financings.

### Contractual Cash Obligations

	(dollars in thousands)	
	Total	2007
Minimum Lease Payments	\$ 65	\$ 65
Convertible Debentures:		
October 2003	2,071	2,071
January 2004	1,031	1,031
July 2004	1,000	1,000
Interest on 7% Convertible Notes	144	144
Total	\$ 4,311	\$ 4,311

### New Accounting Pronouncements

On July 13, 2006, the Financial Accounting Standards Board issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"). The requirements are effective for fiscal years beginning after December 15, 2006. The purpose of FIN 48 is to clarify and set forth consistent rules for accounting for uncertain tax positions in accordance with Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes". The cumulative effect of applying the provisions of this interpretation are required to be reported separately as an adjustment to the opening balance of retained earnings in the year of adoption. Management does not believe the adoption of this standard will have a material impact on the financial condition or the results of our operations.

In February 2006, the FASB issued SFAS No. 155, "Accounting for Certain Hybrid Financial Instruments" ("FAS 155") - an amendment of FASB Statements No. 133 and 140. FAS 155 amends SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"), and SFAS No. 140 ("FAS 140"), "Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities", to permit fair value re-measurement of any hybrid financial instrument that contains an embedded derivative that would otherwise require bifurcation. Additionally, FAS 155 seeks to clarify which interest-only strips and principal-only strips are not subject to the requirements of FAS 133 and to clarify that concentrations of credit risk in the form of subordination are not embedded derivatives. This Statement is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. Management does not believe the adoption of this standard will have a material impact on the financial condition or the results of our operations.

In September 2006, the FASB issued Statement No. 157, "Fair Value Measurements," This new standard provides guidance for using fair value to measure assets and liabilities. The FASB believes the standard also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. Statement 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value but does not expand the use of fair value in any new circumstances.

Currently, over 40 accounting standards within GAAP require (or permit) entities to measure assets and liabilities at fair value. Prior to Statement 157, the methods for measuring fair value were diverse and inconsistent, especially for items that are not actively traded. The standard clarifies that for items that are not actively traded, such as certain kinds of derivatives, fair value should reflect the price in a transaction with a market participant, including an adjustment for risk, not just the our mark-to-market value. Statement 157 also requires expanded disclosure of the effect on earnings for items measured using unobservable data.

Under Statement 157, fair value refers to the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. In this standard, the FASB clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability. In support of this principle, Statement 157 establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. The fair value hierarchy gives the highest priority to quoted prices in active markets and the lowest priority to unobservable data, for example, the reporting entity's own data. Under the standard, fair value measurements would be separately disclosed by level within the fair value hierarchy.

The provisions of Statement 157 are effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Earlier application is encouraged, provided that the reporting entity has not yet issued financial statements for that fiscal year, including any financial statements for an interim period within that fiscal year. Management does not believe the adoption of this standard will have a material impact in the financial condition or results of our operations.

## **Disclosure About Off-Balance Sheet Arrangements**

None

## **Critical Accounting Policies**

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our significant accounting policies are described in the Notes to the Consolidated Financial Statements. The significant accounting policies that we believe are most critical to aid in fully understanding our reported financial results are the following:

### Revenue

Revenue from the sale of Ampligen® under cost recovery clinical treatment protocols approved by the FDA is recognized when the treatment is provided to the patient.

Revenues from the sale of product are recognized when the product is shipped, as title is transferred to the customer. We have no other obligation associated with our products once shipment has occurred.

### Short-term Investments

Investments with original maturities of more than three months and less than 12 months and marketable equity securities are considered available for sale. The investments classified as available for sale include debt securities and equity securities carried at estimated fair value. The unrealized gains and losses are recorded as a component of stockholders' equity.

### Inventories

We use the lower of first-in, first-out ("FIFO") cost or market method of accounting for inventory.

### Patents and Trademarks

Patents and trademarks are stated at cost (primarily legal fees) and are amortized using the straight-line method over the estimated useful life of 17 years. We review our patents and trademark rights periodically to determine whether they have continuing value. Such review includes an analysis of the patent and trademark's ultimate revenue and profitability potential. In addition, management's review addresses whether each patent continues to fit into our strategic business plans.

### Convertible Securities with Beneficial Conversion Features

The March 2003, July 2003, October 2003, January 2004 and July 2004 Debenture issuances and related embedded conversion features and warrants issuances were accounted for in accordance with EITF 98-5 "Accounting for Convertible Securities with Beneficial Conversion Features or Contingency Adjustable Conversion" and with EITF No. 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments". We determined the fair values to be ascribed to detachable warrants issued with the convertible debentures utilizing the Black-Scholes method. Discounts derived from determining the beneficial conversion feature and fair value of the warrants based on the relative fair value of the proceeds are amortized to financing costs over the remaining life of the debenture in accordance with the effective interest method of accounting. The unamortized discount upon the conversion of the debentures is expensed to financing cost on a pro-rata basis.



### Stock Based Compensation

Under FAS 123R, share-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the requisite service period. We adopted the provisions of FAS 123R, effective January 1, 2006, using a modified prospective application. Under this method, compensation cost is recognized for all share-based payments granted, modified or settled after the date of adoption, as well as for any unvested awards that were granted prior to the date of adoption. Prior periods are not revised for comparative purposes. Because we previously adopted only the pro forma disclosure provisions of FAS 123, it will recognize compensation cost relating to the unvested portion of awards granted prior to the date of adoption, using the same estimate of the grant-date fair value and the same attribution method used to determine the pro forma disclosures under FAS 123, except that forfeiture rates will be estimated for all options, as required by FAS 123R. The cumulative effect of applying the forfeiture rates is not material.

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model. Expected volatility is based on the historical volatility of the price of our common stock. The risk-free interest rate is based on U.S. Treasury issues with a term equal to the expected life of the option. We use historical data to estimate expected dividend yield, expected life and forfeiture rates.

### Concentration of Credit Risk

Our policy is to limit the amount of credit exposure to any one financial institution and place investments with financial institutions evaluated as being credit worthy, or in short-term money markets, which are exposed to minimal interest rate and credit risks. At and since December 31, 2006, we have had bank deposits and overnight repurchase agreements that exceed federally insured limits.

Concentration of credit risk, with respect to receivables, is limited through our credit evaluation process. We do not require collateral on our receivables. Our receivables consist principally of amounts due from wholesale drug companies as of December 31, 2006.

Sales to three large wholesalers represented approximately 80% and 70% of our total sales for the years ended December 31, 2005 and 2006, respectively.

### **Item 7A. Quantitative And Qualitative Disclosures About Market Risk**

We had approximately \$22,021,000 in cash and cash equivalents and short-term investments at December 31, 2006. To the extent that our cash and cash equivalents exceed our near term funding needs, we invest the excess cash in three to twelve month interest bearing financial instruments. We employ established conservative policies and procedures to manage any risks with respect to investment exposure.

We have not entered into, and do not expect to enter into, financial instruments for trading or hedging purposes.

#### **ITEM 8. Financial Statements and Supplementary Data.**

The consolidated balance sheets as of December 31, 2005 and 2006, and our consolidated statements of operations, changes in stockholders' equity and comprehensive loss and cash flows for each of the years in the three year period ended December 31, 2006, together with the reports of BDO Seidman, LLP and McGladrey & Pullen, LLP, independent registered public accountants, are included at the end of this report. Reference is made to the "Index to Financial Statements and Financial Statement Schedule" on page F-1.

#### **ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures.**

As previously reported in our current Report on Form 8-K filed on November 9, 2006, on November 7, 2006, the Audit Committee of our Board of Directors approved the appointment of McGladrey & Pullen, LLP ("McGladrey") as our independent registered public accounting firm, effective immediately. McGladrey replaces BDO Seidman, LLP ("BDO") as our independent registered public accounting firm.

As noted in our Current Report on Form 8-K/A filed with the Commission on September 22, 2006, BDO informed us that it would resign from the client-auditor relationship with us no later than the date of our filing of our Form 10-Q report for the period ending September 30, 2006. BDO's decision to resign was not recommended or approved by our Audit Committee. On November 7, 2006, we filed our Form 10-Q report for the period ended September 30, 2006 and BDO resigned from the client-auditor relationship with us.

BDO's reports on our financial statements for the fiscal years ended December 31, 2004 and December 31, 2005 did not contain any adverse opinion or any disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles.

During the fiscal years ended December 31, 2004 and December 31, 2005, and the subsequent interim period preceding the date of BDO's resignation, there were no disagreements between us and BDO on any matter of accounting principals or practice, financial statement disclosure or auditing scope of procedure which, if not resolved to the satisfaction of BDO, would have caused BDO to make a reference to the subject matter thereof in connection with its reports and, during the same period, there were no reportable events as defined in item 304(a)(1)(v) of the Commission Regulation S-K, except as previously reported in Item 9A of our 2005 Form 10-K/A2.

#### **ITEM 9A. Controls and Procedures.**

##### Effectiveness of Control Procedures

As of December 31, 2006, the end of the period covered by this report, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Act of 1934, as amended, as of December 31, 2006. Our disclosure controls and procedures are intended to ensure that the information we are required to disclose in the reports that we file or submit under the Securities Exchange Act of 1934 is (i) recorded, processed, summarized and reported within the time periods specified in the Securities Exchange Commission's rules and forms and (ii) accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as the principal executive and financial officers, respectively, to allow final decisions regarding required disclosures. Our management has concluded that the financial statements included in this Form 10-K present fairly, in all material respects our financial position, results of operations and cash flows for the periods presented in conformity with generally accepted accounting principles.





Changes in Internal Control over Financial Reporting

We made no changes in our internal control over financial reporting during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act).

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rules 13a-15(f) or 15d-15(f), under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers and affected by our Board of Directors, management and other personnel, and to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on its financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2006. In making this assessment, management used the criteria set forth in the framework established by the Committee of Sponsoring Organizations of the Treadway Commission *Internal Control—Integrated Framework*, (COSO). Based on this assessment, management has not identified any material weaknesses as of December 31, 2006. A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

Management has concluded that we did maintain effective internal control over financial reporting as of December 31, 2006, based on the criteria set forth in “*Internal Control—Integrated Framework*” issued by the COSO.

Management’s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006 has been audited by McGladrey and Pullen, an independent registered public accounting firm, as stated in their report which appears herein.

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors  
Hemispherx Biopharma, Inc.  
Philadelphia, Pennsylvania

We have audited management's assessment, included in the accompanying Management’s Report on Internal Control Over Financial Reporting, that Hemispherx Biopharma, Inc. maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in “*Internal Control—Integrated Framework*” issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)”. Hemispherx Biopharma, Inc.’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Hemispherx Biopharma, Inc. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on criteria established in “*Internal Control—Integrated Frameworks issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)*”. Also in our opinion, Hemispherx Biopharma, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 20X3, based on criteria established in “*Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)*”.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Hemispherx Biopharma, Inc. as of December 31, 2006 and the related consolidated statements of operations, stockholders’ equity and comprehensive loss, and cash flows for the year then ended, and our report dated March 19, 2007 expressed an unqualified opinion.

Blue Bell, Pennsylvania  
March 19, 2007

/s/ McGladrey & Pullen, LLP

**ITEM 9B. Other Information.**

None.

**PART III**

**Item 10. Directors and Executive Officers of the Registrant.**

The following sets forth biographical information about each of our directors and executive officers as of the date of this report:

<b>Name</b>	<b>Age</b>	<b>Position</b>
William A. Carter, M.D.	69	Chairman, Chief Executive Officer
Anthony A. Bonelli	56	President, Chief Operating Officer
Robert E. Peterson	69	Chief Financial Officer
David R. Strayer, M.D.	60	Medical Director, Regulatory Affairs
Mei-June Liao, Ph.D.	55	Vice President of Regulatory Affairs, Quality Control and Research and Development
Robert Hansen	62	Vice President of Manufacturing

Carol A. Smith, Ph.D.	56	Director of Process Development
Richard C. Piani	79	Director
William M. Mitchell, M.D.	71	Director
Ransom W. Etheridge	67	Director, Secretary and General Counsel
Steven D. Spence	48	Director
Iraj Eqhbal Kiani, Ph.D.	60	Director

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Each director has been elected to serve until the next annual meeting of stockholders, or until his earlier resignation, removal from office, death or incapacity. Each executive officer serves at the discretion of the Board of Directors, subject to rights, if any, under contracts of employment.

**WILLIAM A. CARTER, M.D.**, the co-inventor of Ampligen®, joined us in 1978, and has served as: (a) our Chief Scientific Officer since May 1989; (b) the Chairman of our Board of Directors since January 1992; (c) our Chief Executive Officer since July 1993; (d) our President since April, 1995; and (e) a director since 1987. From 1987 to 1988, Dr. Carter served as our Chairman. Dr. Carter was a leading innovator in the development of human interferon for a variety of treatment indications including various viral diseases and cancer. Dr. Carter received the first FDA approval to initiate clinical trials on a beta interferon product manufactured in the U.S. under his supervision. From 1985 to October 1988, Dr. Carter served as our Chief Executive Officer and Chief Scientist. He received his M.D. degree from Duke University and underwent his post-doctoral training at the National Institutes of Health and Johns Hopkins University. Dr. Carter also served as Professor of Neoplastic Diseases at Hahnemann Medical University, a position he held from 1980 to 1998. Dr. Carter served as Director of Clinical Research for Hahnemann Medical University's Institute for Cancer and Blood Diseases, and as a professor at Johns Hopkins School of Medicine and the State University of New York at Buffalo. Dr. Carter is a Board certified physician and author of more than 200 scientific articles, including the editing of various textbooks on anti-viral and immune therapy.

**ANTHONY A. BONELLI** was appointed as President and Chief Operating Officer in November 2006. Mr. Bonelli is a graduate of Harvard University with a degree in Biological Sciences as well as an MBA from Rutgers University Graduate School of Business and JD from the University of San Francisco. Mr. Bonelli has over twenty-five years of diversified healthcare industry experience. Most recently, he served as President and CEO of Optigenex, an applied DNA sciences company, since October 2005, having joined that company in September 2004 as President and Chief Operating Officer. As principal of Anthony Bonelli Associates between 1999 and 2004, some of the firms he has advised include Parke-Davis, Schering-Plough Company, Aventis, Pharmacia and Pfizer. From 1998 to 1999, he was President and COO of Vitaquest International, a custom developer and manufacturer of vitamins and nutritional supplements.

**ROBERT E. PETERSON** has served as our Chief Financial Officer since April, 1993 and served as an Independent Financial Advisor to us from 1989 to April, 1993. Also, Mr. Peterson has served as Vice President of the Omni Group, Inc., a business consulting group based in Tulsa, Oklahoma since 1985. From 1971 to 1984, Mr. Peterson worked for PepsiCo, Inc. and served in various financial management positions including Vice President and Chief Financial Officer of PepsiCo Foods International and PepsiCo Transportation, Inc. Mr. Peterson is a graduate of Eastern New Mexico University.

**DAVID R. STRAYER, M.D.** who served as Professor of Medicine at the Medical College of Pennsylvania and Hahnemann University, has acted as our Medical Director since 1986. He is Board Certified in Medical Oncology and Internal Medicine with research interests in the fields of cancer and immune system disorders. Dr. Strayer has served as principal investigator in studies funded by the Leukemia Society of America, the American Cancer Society, and the National Institutes of Health. Dr. Strayer attended the School of Medicine at the University of California at Los Angeles where he received his M.D. in 1972.

**MEI-JUNE LIAO, Ph.D.** has served as Vice President of Regulatory Affairs, Quality and Research & Development since October 2003 and as Vice President of Research & Development since March 2003 with responsibilities for the regulatory, quality control and product development of Alferon®. Before the acquisition of certain assets of ISI, Dr. Liao was Vice President of Research and Development from 1995 to 2003 and held senior positions in the Research and Development Department of ISI from 1983 to 1994. Dr. Liao received her Ph.D. from Yale University in 1980 and completed a three year postdoctoral appointment at the Massachusetts Institute of Technology under the direction of Nobel Laureate in Medicine, Professor H. Gobind Khorana. Dr. Liao has authored many scientific publications and invention disclosures.

**ROBERT HANSEN** joined us as Vice President of Manufacturing in 2003 upon the acquisition of certain assets of ISI. He is responsible for the manufacture of Alferon® N. Mr. Hansen had been Vice President of Manufacturing for ISI since 1997, and served in various capacities in manufacturing since joining ISI in 1987. He has a B.S. degree in Chemical Engineering from Columbia University in 1966.

**CAROL A. SMITH, Ph.D.** is Director of Process Development and has served as our Director of Manufacturing and Process Development since April 1995, as Director of Operations since 1993 and as the Manager of Quality Control from 1991 to 1993, with responsibility for the manufacture, control and chemistry of Ampligen®. Dr. Smith was Scientist/Quality Assurance Officer for Virotech International, Inc. from 1989 to 1991 and Director of the Reverse Transcriptase and Interferon Laboratories and a Clinical Monitor for Life Sciences, Inc. from 1983 to 1989. She received her Ph.D. from the University of South Florida College of Medicine in 1980 and was an NIH post-doctoral fellow at the Pennsylvania State University College of Medicine.

**RICHARD C. PIANI** has been a director since 1995. Mr. Piani has been employed as a principal delegate for Industry to the City of Science and Industry, Paris, France, a billion dollar scientific and educational complex. Mr. Piani provided consulting to us in 1993, with respect to general business strategies for our European operations and markets. Mr. Piani served as Chairman of Industrielle du Batiment-Morin, a building materials corporation, from 1986 to 1993. Previously Mr. Piani was a Professor of International Strategy at Paris Dauphine University from 1984 to 1993. From 1979 to 1985, Mr. Piani served as Group Director in Charge of International and Commercial Affairs for Rhone-Poulenc and from 1973 to 1979 he was Chairman and Chief Executive Officer of Societe "La Cellophane", the French company which invented cellophane and several other worldwide products. Mr. Piani has a Law degree from Faculte de Droit, Paris Sorbonne and a Business Administration degree from Ecole des Hautes Etudes Commerciales, Paris.

**RANSOM W. ETHERIDGE** has been a director since October 1997, and presently serves as our secretary and general counsel. Mr. Etheridge first became associated with us in 1980 when he provided consulting services to us and participated in negotiations with respect to our initial private placement through Oppenheimer & Co., Inc. Mr. Etheridge has been practicing law since 1967, specializing in transactional law. Mr. Etheridge is a member of the Virginia State Bar, a Judicial Remedies Award Scholar, and has served as President of the Tidewater Arthritis Foundation. He is a graduate of Duke University, and received his Law degree from the University of Richmond School of Law.

**WILLIAM M. MITCHELL, M.D., Ph.D.** has been a director since July 1998. Dr. Mitchell is a Professor of Pathology at Vanderbilt University School of Medicine. Dr. Mitchell earned a M.D. from Vanderbilt and a Ph.D. from Johns Hopkins University, where he served as an Intern in Internal Medicine, followed by a Fellowship at its School of Medicine. Dr. Mitchell has published over 200 papers, reviews and abstracts dealing with viruses, anti-viral drugs and immune responses to HIV infection. Dr. Mitchell has worked for and with many professional societies, including the International Society for Interferon Research, and committees, among them the National Institutes of Health, AIDS and Related Research Review Group. Dr. Mitchell previously served as one of our directors from 1987 to 1989.

**STEVEN D. SPENCE** was appointed to the Board of Directors in March 2005. Mr. Spence is currently Managing Partner of Valued Ventures, a consultancy Mr. Spence founded in 2003 to foster the development of micro and small cap companies. For the six years prior to founding Valued Ventures, Mr. Spence performed the duties as Managing Director at Merrill Lynch. Prior to his tenure as Managing Director, Mr. Spence has held several high-ranking management positions within Merrill Lynch including Chief Operating Officer for the Security Services Division, Global Head of the Broker Dealer Security Services Division, and Global Head of Financial Futures and Options. Mr. Spence is a graduate of Columbia University in New York City.

**IRAJ EQHBAL KIANI, M.B.A., Ph.D.**, was appointed to the Board of Directors on May 1, 2002. Dr. Kiani is a citizen of England and resides in Newport, California. Dr. Kiani served in various local government position including the Governor of Yasoi, Capital of Boyerahmand, Iran. In 1980, Dr. Kiani moved to England, where he established and managed several trading companies over a period of some 20 years. Dr. Kiani is a planning and logistic specialist who is now applying his knowledge and experience to build a worldwide immunology network, which will use our proprietary technology. Dr. Kiani received his Ph.D. degree from the University of Warwick in England.

#### **Compliance with Section 16(a) of the Exchange Act**

Section 16(a) of the Exchange Act requires our officers and directors, and persons who own more than ten percent of a registered class of equity securities, to file reports with the Securities and Exchange Commission reflecting their initial position of ownership on Form 3 and changes in ownership on Form 4 or Form 5. Based solely on a review of the copies of such Forms received by us, we found that, during the fiscal year ended December 31, 2006, certain of our officers and directors had not complied with all applicable Section 16(a) filing requirements on a timely basis. This situation was rectified on January 17, 2007 upon filing the delinquent forms with the Securities and Exchange Commission. Forms 5 were filed with the Securities and Exchange Commission on January 26, 2007 for each officer and director reflecting the number of late reports, the number of transactions, and any known failure to file a required form.

### Audit Committee and Audit Committee Expert

The Audit Committee of our Board of Directors consists of Steven Spence, Committee Chairman, William Mitchell, M.D. and Richard Piani. Mr. Spence, Dr. Mitchell, and Mr. Piani are all determined by the Board of Directors to be independent directors as required under Section 121B(2)(a) of the AMEX Company Guide. Mr. Spence serves as the financial expert as defined in Securities and Exchange Commission rules on the committee. We believe Mr. Spence, Dr. Mitchell, and Mr. Piani to be independent of management and free of any relationship that would interfere with their exercise of independent judgment as members of this committee. The principal functions of the Audit Committee are to (i) assist the Board in fulfilling its oversight responsibility relating to the annual independent audit of our consolidated financial statements and internal control over financial reporting, the engagement of the independent registered public accounting firm and the evaluation of the independent registered public accounting firm's qualifications, independence and performance (ii) prepare the reports or statements as may be required by AMEX or the securities laws, (iii) assist the Board in fulfilling its oversight responsibility relating to the integrity of our financial statements and financial reporting process and our system of internal accounting and financial controls, (iv) discuss the financial statements and reports with management, including any significant adjustments, management judgments and estimates, new accounting policies and disagreements with management, and (v) review disclosures by our independent registered public accounting firm concerning relationships with us and the performance of our independent accountants.

### Code of Ethics

Our Board of Directors adopted a code of ethics and business conduct for officers, directors and employees that went into effect on May 19, 2003. This code has been presented, reviewed and signed by each officer, director and employee. You may obtain a copy of this code by visiting our web site at [www.hemispherx.net](http://www.hemispherx.net) (Corporate Info) or by written request to our office at 1617 JFK Boulevard, Suite 660, Philadelphia, PA 19103.

## **Item 11. Executive Compensation.**

### **Compensation Discussion and Analysis**

#### **Objectives and Philosophy of Executive Compensation**

The primary objectives of the compensation committee of our board of directors with respect to executive compensation are to attract and retain the most talented and dedicated executives possible, to tie annual and long-term cash and stock incentives to achievement of measurable performance objectives, and to align executives' incentives with stockholder value creation. To achieve these objectives, the compensation committee expects to implement and maintain compensation plans that tie a substantial portion of executives' overall compensation to key strategic financial and operational goals such as the establishment and maintenance of key strategic relationships, the development of our products, the identification and advancement of additional product and the performance of our common stock price. The compensation committee evaluates individual executive performance with the goal of setting compensation at levels the committee believes are comparable with executives in other companies of similar size and stage of development operating in the biotechnology industry while taking into account our relative performance and our own strategic goals.



Our compensation plans are developed by utilizing publicly available compensation data and subscription compensation survey data for national and regional companies in the biopharmaceutical industry. We believe that the practices of this group of companies provide us with appropriate compensation benchmarks, because these companies have similar organizational structures and tend to compete with us for executives and other employees. For benchmarking executive compensation, we typically review the compensation data we have collected from the complete group of companies, as well as a subset of the data from those companies that have a similar number of employees as our company. We have also engaged independent outside consultants to help us analyze this data and to compare our compensation programs with the practices of the companies represented in the compensation data we review.

### **Elements of Executive Compensation**

Executive compensation consists of the following elements:

#### **Base Salary**

Base salaries for our executives are established based on the scope of their responsibilities, taking into account competitive market compensation paid by other companies for similar positions. Generally, we believe that executive base salaries should be targeted near the median of the range of salaries for executives in similar positions with similar responsibilities at comparable companies, in line with our compensation philosophy. Base salaries are reviewed annually, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. This review normally occurs in the fourth quarter of each year.

On November 6, 2006, the Board of Directors, at the recommendation of the compensation committee and based upon an independent valuation of Executive Compensation by the compensation committee determined that: (1) Dr. Carter's annual compensation under his Employment and Engagement Agreements be increased by \$90,000 and \$60,000, respectively; and (2) Robert E. Peterson's annual compensation under his Engagement Agreement be increased by \$50,000. These annual compensation adjustments were retroactive to January 1, 2006.

#### **Annual Bonus**

Our compensation program includes eligibility for an annual performance-based cash bonus in the case of all executives and certain senior, non-executive employees. The amount of the cash bonus depends on the level of achievement of the stated corporate, department, and individual performance goals, with a target bonus generally set as a percentage of base salary. As provided in their employment agreements, our Chief Executive Officer and Chief Financial Officer are eligible for an annual performance-based bonus up to 25% of their salaries, the amount of which, if any, is determined by the board of directors in its sole discretion based on the recommendation of the compensation committee.

The compensation committee utilizes annual incentive bonuses to compensate officers for achieving financial and operational goals and for achieving individual annual performance objectives. These objectives will vary depending on the individual executive, but will relate generally to strategic factors such as establishment and maintenance of key strategic relationships, development of our product, identification and research and development of additional products, and to financial factors such as raising capital and improving our results of operations.

### Long-Term Incentive Program

We believe that long-term performance is achieved through an ownership culture that encourages such performance by our executive officers through the use of stock and stock-based awards. Our stock plans have been established to provide our employees, including our executive officers, with incentives to help align those employees' interests with the interests of stockholders. The compensation committee believes that the use of stock and stock-based awards offers the best approach to achieving our compensation goals. We have historically elected to use stock options as the primary long-term equity incentive vehicle. We have adopted stock ownership guidelines and our stock compensation plans have provided the principal method, other than through direct investment for our executive officers to acquire equity in our company. We believe that the annual aggregate value of these awards should be set near competitive median levels for comparable companies. However, in the early stage of our business, we provided a greater portion of total compensation to our executives through our stock compensation plans than through cash-based compensation.

### Stock Options

Our stock plans authorize us to grant options to purchase shares of common stock to our employees, directors and consultants. Our compensation committee oversees the administration of our stock option plan. The compensation committee reviews and recommends approval by our Board of Directors of stock option awards to executive officers based upon a review of competitive compensation data, its assessment of individual performance, a review of each executive's existing long-term incentives, and retention considerations. Periodic stock option grants are made at the discretion of the Board of Directors upon recommendation of the compensation committee to eligible employees and, in appropriate circumstances, the compensation committee considers the recommendations of members of management. In 2006, certain named executive officers were awarded stock options in the amounts indicated in the section entitled "Stock Option Grants to Executive Officers." These grants included grants made in connection with merit-based grants made by the board of directors to a large number of employees, including certain executive officers, which were intended to encourage an ownership culture among our employees. Grants were made to certain of our employees who had been employed with us for at least one year based on past performance of such employees and to encourage continued service with us. Stock options granted by us have an exercise price equal to the fair market value of our common stock on the day of grant and typically vest over a period of years based upon continued employment, and generally expire ten years after the date of grant. Incentive stock options also include certain other terms necessary to assure compliance with the Internal Revenue Code of 1986, as amended, or Internal Revenue Code.

We expect to continue to use stock options as a long-term incentive vehicle because; (1) Stock options align the interests of executives with those of the shareholders, support a pay-for-performance culture, foster employee stock ownership, and focus the management team on increasing value for the shareholders, (2) Stock options are performance based. All the value received by the recipient of a stock option is based on the growth of the stock price, (3) Stock options help to provide a balance to the overall executive compensation program as base salary and our discretionary annual bonus program focus on short-term compensation, while the vesting of stock options increases shareholder value over the longer term, and (4) The vesting period of stock options encourages executive retention and the preservation of shareholder value.

In determining the number of stock options to be granted to executives, we take into account the individual's position, scope of responsibility, ability to affect profits and shareholder value and the individual's historic and recent performance and the value of stock options in relation to other elements of the individual executive's total compensation.

As of December 31, 2006, 4,671,299 shares were available for future grants under the 2004 Plan. Options granted include 633,080 in 2004, 1,352,600 in 2005 and 1,345,742 in 2006. Unless sooner terminated, the Equity Incentive Plan will continue in effect for a period of 10 years from its effective date.

#### Restricted Stock and Restricted Stock Units

Our 2004 Equity Compensation Plan authorizes us to grant restricted stock and restricted stock units. To date, we have not granted any restricted stock or restricted stock units under our 2004 equity compensation plan. We anticipate that in order to implement the long-term incentive goals of the compensation committee we may grant restricted stock units in the future.

#### **Other Compensation**

Our Chief Executive Officer, Chief Operating Officer, Chief Financial Officer and General Counsel have employment, and/or engagement contracts that will remain in effect until they are terminated, expire, or are renegotiated. Each contract is different with respect to specific benefits or other compensation. We maintain a broad-based benefits program that is provided to all employees including vacation, sick leave and health insurance. Details of these agreements are as follows:

On March 11, 2005, our board of directors, at the recommendation of the Compensation Committee, approved an amended and restated employment agreement and an amended and restated engagement agreement with Dr. William A. Carter. On November 6, 2006, our Board of Director's, at the recommendation of the Compensation Committee adjusted the compensation within Dr. Carter's Employment and Engagement Agreement and Robert E. Peterson's Engagement Agreement based upon an independent valuation of Executive Compensation and determined that Dr. Carter's annual compensation under his Employment and Engagement Agreements be increased by \$90,000 and \$60,000, respectively. In addition, Robert E. Peterson's annual compensation under his Employment and Engagement Agreement was increased by \$50,000 as noted within the same, valuation report. These annual compensation adjustments were retroactive to January 1, 2006.

The employment agreement, as adjusted, provides for Dr. Carter's employment as our Chief Executive Officer and Chief Scientific Officer until December 31, 2010 unless sooner terminated for cause or disability. The agreement automatically renews for successive one year periods after the initial termination date unless the Company or Dr. Carter give written notice otherwise at least ninety days prior to the termination date or any renewal period. Dr. Carter has the right to terminate the agreement on 30 days' prior written notice. The base salary is subject to adjustments and the average increase or decrease in the Consumer Price Index for the prior year. In addition, Dr. Carter could receive an annual performance bonus of up to 25% of his base salary, at the sole discretion of the Compensation Committee of the board of directors, based on his performance or our operating results. Dr. Carter will not participate in any discussions concerning the determination of his annual bonus. Dr. Carter is also entitled to an incentive bonus of 0.5% of the gross proceeds received by us from any joint venture or corporate partnering arrangement. Dr. Carter's agreement also provides that he be paid a base salary and benefits through the last day of the then term of the agreement if he is terminated without "cause", as that term is defined in agreement. In addition, should Dr. Carter terminate the agreement or the agreement be terminated due to his death or disability, the agreement provides that Dr. Carter be paid a base salary and benefits through the last day of the month in which the termination occurred and for an additional twelve month period. Pursuant to his original agreement, Dr. Carter was granted options to purchase 73,728 (post split) shares in 1991. The exercise period of these options is extended through December 31, 2010 and,

should Dr. Carter's employment agreement be extended beyond that date, the option exercise period is further extended to the last day of the extended employment period. In accordance with FASB Interpretation No. 44, Accounting for Certain Transactions involving Stock Compensation, no compensation expense was recognized as the exercise price at the extension date exceeded the fair value of the underlying common stock.

The engagement agreement provides for our engagement of Dr. Carter as a consultant related to patent development, as one of our directors and as chairman of the Executive Committee of our board of directors until December 31, 2010 unless sooner terminated for cause or disability. The agreement automatically renews for successive one year periods after the initial termination date or any renewal period. Dr. Carter has the right to terminate the agreement on 30 days' prior written notice. The base fee is subject to annual adjustments equal to the percentage increase or decrease of annual dollar value of directors' fees provided to our directors during the prior year. The annual fee is further subject to adjustment based on the average increase or decrease in the Consumer Price Index for the prior year. In addition, Dr. Carter could receive an annual performance bonus of up to 25% of his base fee, at the sole direction of the Compensation Committee of the board of directors, based on his performance. Dr. Carter will not participate in any discussions concerning the determination of this annual bonus. Dr. Carter's agreement also provides that he be paid his base fee through the last day of the then term of the agreement if he is terminated without "cause", as that term is defined in the agreement. In addition, should Dr. Carter terminate the agreement or the agreement be terminated due to his death or disability, the agreement provides that Dr. Carter be paid fees due him through the last day of the month in which the termination occurred and for an additional twelve month period.

On February 14, 2005 we entered into an agreement with The Sage Group of Branchburg, New Jersey for R. Douglas Hulse, an Executive Director of The Sage Group, to serve as President and Chief Operating Officer of the Company. In addition, other Sage Group principals and Senior Directors will be made available to assist as needed. The engagement is expected to continue for a period of 18 months; however, it is terminable on 30 days written notice by either party after 12 months. Compensation for the services includes a ten year warrant to purchase 250,000 shares of our common stock at an exercise price of \$1.55. These warrants are to be issued to Sage Healthcare Advisors, LLC and are to vest at the rate of 12,500 per month of the engagement with 25,000 vesting upon completion of the eighteenth month. Vesting accelerates in the event of a merger or a purchase of a majority of our assets or equity. The Sage Group also is to receive a monthly retainer of \$10,000 for the period of the engagement. In addition, for each calendar year (or part thereof) during which the agreement is in effect, The Sage Group will be entitled to an incentive bonus in an amount equal to 0.5% of the gross proceeds received by us during such year from any joint ventures or corporate partnering arrangements. After termination of the agreement, The Sage Group will only be entitled to receive the incentive bonus based upon gross proceeds received by us during the two year period commencing on the termination of the agreement with respect to any joint ventures or corporate partnering arrangements entered into by us during the term of the agreement. Mr. Hulse will devote approximately two to two and one half days per week to our business. We used the Black-Scholes valuation model to value the shares received by the Sage Group pursuant to the agreement. We recorded a charge to earnings of approximately \$124,000 in 2005 with a related increase to additional paid in capital.

Mr. Hulse resigned during the fourth quarter of 2006. His various responsibilities to The Sage Group have grown to preclude him from dedicating his time fully to the Company. He intends to continue with us in a capacity of Senior Advisor to our Chairman and Board of Directors.

We entered into an engagement agreement, retroactive to January 1, 2005, with Ransom W. Etheridge which provides for Mr. Etheridge's engagement as our General Counsel until December 31, 2009 unless sooner terminated for cause or disability. The agreement automatically renews for successive one year periods after the initial termination date unless we or Mr. Etheridge give written notice otherwise at least ninety days prior to the termination date or any renewal period. Mr. Etheridge has the right to terminate the agreement on 30 days' prior written notice. The initial annual fee for services is \$96,000 and is annually subject to adjustment based on the average increase or decrease in the Consumer Price Index for the prior year. Mr. Etheridge's agreement also provides that he be paid all fees through the last day of then current term of the agreement if he is terminated without "cause" as that term is defined in the agreement. In addition, should Mr. Etheridge terminate the agreement or the agreement be terminated due to his death or disability, the agreement provides that Mr. Etheridge be paid the fees due him through the last day of the month in which the termination occurred and for an additional twelve month period. Mr. Etheridge will devote approximately 85% of his business time to our business.

We entered into an amended and restated engagement agreement, retroactive to January 1, 2005, as adjusted, with Robert E. Peterson which provides for Mr. Peterson's engagement as our Chief Financial Officer until December 31, 2010 unless sooner terminated for cause or disability. Mr. Peterson has the right to terminate the agreement on 30 days' prior written notice. The annual fee for services is subject to increases based on the average increase in the cost of inflation index for the prior year. Mr. Peterson shall receive an annual bonus in each year that our Chief Executive Officer is granted a bonus. The bonus shall equal a percentage of Mr. Peterson's base annual compensation comparable to the percentage bonus received by the Chief Executive Officer. In addition, Mr. Peterson shall receive bonus compensation upon Federal Drug Administration approval of commercial application of Ampligen®. Mr. Peterson's agreement also provides that he be paid all fees through the last day of then current term of the agreement if he is terminated without "cause" as that term is defined in the agreement. In addition, should Mr. Peterson terminate the agreement or the agreement be terminated due to his death or disability, the agreement provides that Mr. Peterson be paid the fees due him through the last day of the month in which the termination occurred and for an additional twelve month period. Mr. Peterson will devote approximately 85% of his business time to our business.

On November 27, 2006, we engaged Anthony A. Bonelli to serve as our full time President and Chief Operating Officer. Pursuant to this agreement, the President and Chief Operating Officer is employed for an initial term of two years. The employment automatically renews thereafter for successive one year periods unless either party gives written notice not to renew within 90 days of the termination date.

The President and Chief Operating Officer receives an annual salary at the rate of \$350,000 per year through December 31, 2007 and, thereafter, at the annual rate of \$400,000. His salary is subject to cost of living increases. He is entitled to annual bonuses in the discretion of our Chairman and Board of Directors. A \$50,000 cash bonus and 100,000 options was given upon the execution of the employment agreement and a minimum cash bonus for the year ended December 31, 2007 will be \$75,000. He was entitled to an additional 50,000 options upon his successful completion of three months of employment and an aggregate of up to an additional 950,000 options upon the happening of specific business milestones. The 50,000 options are in the process of being issued. We have the right, at its discretion, to modify the time periods within which the milestones must be met. Each option vests upon award, expires in ten years and has an exercise price equal to 110% of the closing price of our common stock on the American Stock Exchange on the date of the award. Upon the happening of certain events, such as our merger with and in to another entity or our sale or transfer of assets or earning power aggregating 50% or more of our assets or earning capacity, provided he is still employed by us, any of the foregoing options not granted to him will be granted. He is also entitled to receive fringe benefits generally available to our executive officers and we have agreed, during his employment period, to pay premiums on a term life insurance policy in the face amount of \$1,500,000 with a beneficiary of his choosing.

The employment agreement terminates upon his death or disability and is terminable by us for "cause" as defined in the agreement, or without cause. He has the right to terminate the agreement upon not less than 60 day's prior notice. In the event that the agreement terminates due to his death or disability, or by him, he will be entitled to fees due and payable through the last day of the month in which the termination occurs. If it is terminated by us for cause, he will be entitled to fees due and payable to him through the date of termination. If we terminate the agreement without cause, he is entitled to fees depending upon the amount of time he has been employed by us ranging from 12 months' of fees if he is terminated within the first 12 months of employment to three months' of fees if he is terminated in the 21st month of employment. He is subject to confidentiality and non-compete covenants.

On March 11, 2005 the Board of Directors, deeming it essential to the best interests of our shareholders to foster the continuous engagement of key management personnel and recognizing that, as is the case with many publicly held corporations, a change of control might occur and that such possibility, and the uncertainty and questions which it might raise among management, might result in the departure or distraction of management personnel to the detriment of us and our shareholders, determined to reinforce and encourage the continued attention and dedication of members of our management to their engagement without distraction in the face of potentially disturbing circumstances arising from the possibility of a change in control of the Company and entered into identical agreements regarding change in control with William A. Carter, our Chief Executive Officer and Chief Scientific Officer, Robert E. Peterson, our Chief Financial Officer and Ransom W. Etheridge, our General Counsel. Each of the agreements regarding change in control became effective March 11, 2005 and continue through December 31, 2007 and shall extend automatically to the third anniversary thereof unless we give notice to the other party prior to the date of such extension that the agreement term will not be extended. Notwithstanding the foregoing, if a change in control occurs during the term of the agreements, the term of the agreements will continue through the second anniversary of the date on which the change in control occurred. Each of the agreements entitles William A. Carter, Robert E. Peterson and Ransom W. Etheridge, respectively, to change of control benefits, as defined in the agreements and summarized below, upon their respective termination of employment/engagement with us during a potential change in control, as defined in the agreements or after a change in control, as defined in the agreements, when their respective terminations are caused (1) by us for any reason other than permanent disability or cause, as defined in the agreement (2) by William A. Carter, Robert E. Peterson and/or Ransom W. Etheridge, respectively, for good reason as defined in the agreement or, (3) by William A. Carter, Robert E. Peterson and/or Ransom W. Etheridge, respectively for any reason during the 30 day period commencing on the first date which is six months after the date of the change in control.

The benefits for each of the foregoing executives would be as follows:

- A lump sum cash payment of three times his base salary and annual bonus amounts; and
- Outplacement benefits.

Each agreement also provides that the executive is entitled to a “gross-up” payment to make him whole for any federal excise tax imposed on change of control or severance payments received by him.

Dr. Carter’s agreement also provides for the following benefits:

- Continued insurance coverage through the third anniversary of his termination; and
- Retirement benefits computed as if he had continued to work for the above period.

In order to facilitate our need to obtain financing and prior to our shareholders approving an amendment to our corporate charter to merge the number of authorized shares, Dr. Carter, our Chief Executive Officer, agreed to waive his right to exercise certain warrants and options unless and until our shareholder approved an increase in our authorized shares of Common Stock.

In October 2003, in recognition of this action as well as Dr. Carter’s prior and on-going efforts relating to product development securing critically needed financing and the acquisition of a new product line, the Compensation Committee determined that Dr. Carter be awarded bonus compensation in 2003 consisting of \$196,636 and a grant of 1,450,000 stock warrants for a value of \$1,769,000 with an exercise price of \$2.20 per share. These warrants vested upon the second ISI Asset closing during the first quarter 2004 and we recorded stock compensation of \$1,769,000.

We engaged the Sage Group, Inc., a health care, technology oriented, strategy and transaction advisory firm, to assist us in obtaining a strategic alliance in Japan for the use of Ampligen® in treating Chronic Fatigue Syndrome or CFS. R. Douglas Hulse, our former President and Chief Operating Officer, is a member and an executive director of The Sage Group, Inc.

#### **401(K) Plan**

In December 1995, we established a defined contribution plan, effective January 1, 1995, entitled the Hemispherx Biopharma employees 401(K) Plan and Trust Agreement. All of our full time employees are eligible to participate in the 401(K) plan following one year of employment. Subject to certain limitations imposed by federal tax laws, participants are eligible to contribute up to 15% of their salary (including bonuses and/or commissions) per annum. Participants' contributions to the 401(K) plan may be matched by Hemispherx at a rate determined annually by the board of directors. Each participant immediately vests in his or her deferred salary contributions, while our contributions will vest over one year. See Note 11 to the consolidated financial statements contained herein.



## **Severance**

Upon termination of employment, most executive officers are entitled to receive severance payments under their employment and/or engagement agreements. In determining whether to approve and setting the terms of such severance arrangements, the compensation committee recognizes that executives, especially highly ranked executives, often face challenges securing new employment following termination. The employment agreement with our CEO, which expires on December 31, 2010, provides that we pay him an annual salary through the terms of the agreement if terminated without cause. The engagement agreement with our CFO, which expires on December 31, 2010, provides that we pay him one year's salary. The employment agreement of our COO, which expires in November 2008, provides that he is entitled to severance pay up to 12 months depending on the time employed, if terminated without cause.

We believe that our Executive Officer's severance packages are generally in line with severance packages offered to chief executive officers of the companies of similar size to us represented in the compensation data we reviewed.

## **Compensation of Directors**

On the recommendation of the compensation committee based upon an independent survey of Directors' compensation obtained by the committee, the compensation package for non-employee members of the Board of Directors was, on November 2006, changed, retroactively to January 1, 2006. Board member compensation consists of an annual retainer of \$150,000 to be paid two thirds in cash and one third in our common stock. On September 9, 2003, the Directors approved a 10 year plan which authorizes up to 1,000,000 shares for use in supporting this compensation plan. The number of shares paid shall have a value of \$12,500 with the value of the shares being determined by the closing price of our common stock on the American Stock Exchange on the last day of the calendar quarter. All directors have been granted options to purchase common stock under our Stock Option Plans and/or Warrants to purchase common stock. We believe such compensation and payments are necessary in order for us to attract and retain qualified outside directors.

## **Conclusion**

Our compensation policies are designed to retain and motivate our senior executive officers and to ultimately reward them for outstanding individual and corporate performance.

## Summary Compensation Table - 2006

Name and Principal Position	Salary	Bonus	Stock Award	Option Award (1)	Change in Pension Value and Non-Equity Incentive		All Other Compensation	Total
					Non-qualified Deferred Compensation	Non-qualified Deferred Compensation		
W. A. Carter, CEO	\$ 655,686	\$ 166,624	-	\$ 1,236,367	-	-	\$ 118,087(2)(3)	\$ 2,186,764
A. Bonelli, COO	35,000(4)	50,000	-	122,601	-	-	3,000(2)	210,601
R. E. Peterson, CFO	259,164	64,791	-	373,043	-	-	-	696,998
D. Strayer, Medical Director	225,144	-	-	19,200	-	-	-	244,344
M. J. Liao, Director - QC	158,381	-	-	9,600	-	-	18,246(3)	186,406
C. Smith, Director - PD	143,136	-	-	9,600	-	-	17,227(3)	169,963
R. Hansen, VP of Manufact.	140,311	-	-	9,600	-	-	17,006(3)	166,917
R. D. Hulse (5)	105,000	-	-	-	-	-	-	105,000

## Notes:

- (1) Based on Black Scholes Pricing Model of valuing options. Total Fair Value of Option Awards granted in 2006 was \$1,780,011.
- (2) Consists of Healthcare premiums, life insurance premiums, 401-K matching funds, qualifying insurance premium, company car and parking cost.
- (3) Consists of healthcare premiums and 401-K matching funds.
- (4) Mr. Bonelli joined the Company on November 27, 2006. His annual salary is \$350,000.

**Outstanding Equity Awards at Year End - 2006**

Option/Warrants Awards  
 Stock Awards

Name

Number of Securities Underlying Unexercised Options (#) Exercisable  
 Number of Securities Underlying Unexercised Options (#) Unexercisable  
 Equity Incentive Plan Awards Number of Securities Underlying Unexercised Unearned Options  
 Option Exercise Price  
 Option Expiration Date  
 Number of Shares or Units of Stock That Have Not Vested (#)  
 Market Value of Shares or Unit That Have Not Vested  
 Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested  
 Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested

W.A. Carter, CEO  
 1,450,000  
 0  
 0  
 \$2.20  
 9/8/08  
 -  
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A. Bonelli, COO  
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R. Douglas Hulse

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R. Peterson, CFO  
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D. Strayer, Medical Director  
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C. Smith, Director of Process Development

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M.J. Liao, Director of QA  
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R. Hansen, VP of Manufact.

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**Options Exercised / Stock Vested - 2006**

Name (a)	Option Awards		Stock Awards	
	Number of Shares Acquired on Exercise (#) (b)	Value Realized on Exercise (\$) (c)	Number of Shares Acquired on Vesting (#) (d)	Value of Realized on Vesting (\$) (e)
W.A. Carter, CEO	none			
A. Bonelli, COO	none			
R. Peterson, CFO	none			
D. Strayer, Medical Director	none			
C. Smith, Director	none			
M.J. Liao, Director	none			
R. Hansen, VP	none			

**Compensation Committee Interlocks and Insider Participation**

Our Compensation Committee of the Board of Directors, consisting of Richard Piani, the Committee Chairman, William Mitchell, M.D. and Dr. Iraj E. Kiani, are all independent directors. There are no interlocking relationships.

**COMPENSATION COMMITTEE REPORT**

Our Committee has reviewed and discussed the Compensation Discussion and Analysis contained in this Annual Report with management. Based on our Committee's review of and the discussions with management with respect to the Compensation Discussion and Analysis, our Committee recommended to the board of directors that the Compensation Discussion and Analysis be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 for filing with the SEC.

C O M P E N S A T I O N  
C O M M I T T E E  
Richard Piani, Committee  
Chairman  
William Mitchell, M.D.  
Dr. Iraj E. Kiani

The foregoing Compensation Committee report shall not be deemed incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, and shall not otherwise be deemed filed under these acts, except to the extent we incorporate by reference into such filings.

**Director Compensation - 2006**

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$) (2)	Change in Pension Non-Equity Value and Incentive Nonqualified Plan Compensation			All Other Compensation (\$)	Total (\$)
				Deferred Earnings	Compensation	Compensation		
R. Etheridge, Director, General Counsel	100,000	50,000	113,978	0	0	99,360	(1)	363,338
W. Mitchell, Director	100,000	50,000	113,978	0	0	0	0	263,798
R. Piani, Director	100,000	50,000	113,978	0	0	0	0	263,798
S. Spence, Director	100,000	50,000	113,978	0	0	0	0	263,798
I. Kiani, Director	100,000	50,000	113,978	0	0	0	0	263,798

(1) General Counsel fees as per Engagement Agreement.

(2) The total Fair Value of Stock Options granted in 2006 to Directors was \$569,890.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The following table sets forth as of March 8, 2007, the number and percentage of outstanding shares of common stock beneficially owned by:

- Each person, individually or as a group, known to us to be deemed the beneficial owners of five percent or more of our issued and outstanding common stock;
- each of our directors and the Named Executives; and
- all of our officers and directors as a group.

As of March 8, 2007, there were no other persons, individually or as a group, known to us to be deemed the beneficial owners of five percent or more of our issued and outstanding common stock.

Name and Address of Beneficial Owner	Shares Beneficially Owned	% Of Shares Beneficially Owned
William A. Carter, M.D.	6,241,868	8.3%
Robert E. Peterson	(1)	*
Ransom W. Etheridge 2610 Potters Rd. Virginia Beach, VA 23452	540,574 (2)	*
Richard C. Piani 97 Rue Jeans-Jaures Levaillois-Perret France 92300	663,319 (3)	1.0
Anthony Bonelli	491,371 (4)	*
	152,500 (5)	*

783 Jersey Avenue New Brunswick, NJ 08901 William M. Mitchell, M.D. Vanderbilt University Department of Pathology Medical Center North 21 <sup>st</sup> and Garland Nashville, TN 37232	418,643 (6)	*
David R. Strayer, M.D.	175,746 (7)	*
Carol A. Smith, Ph.D.	69,291 (8)	*
Iraj-Eqhbali Kiani, Ph.D. Orange County Immune Institute 18800 Delaware Street Huntingdon Beach, CA 92648	125,899 (9)	*
Steven Spence	266,302 (10)	*
Mei-June Liao, Ph.D.	27,500 (11)	*
Robert Hansen	27,500 (11)	*
All directors and executive officers as a group (11 persons)	9,200,523	11.8%

\* Less than 1%

- (1) Includes shares issuable upon the exercise of (i) replacement options issued in 2006 to purchase 376,650 shares of common stock exercisable at \$3.78 per share expiring on February 22, 2016; (ii) stock options issued in 2001 to purchase 10,000 shares of common stock at \$4.03 per share expiring January 3, 2011; (iii) warrants issued in 2002 to purchase 1,000,000 shares of common stock exercisable at \$2.00 per share expiring on August 7, 2007; (iv) warrants issued in 2003 to purchase 1,450,000 shares of common stock exercisable at \$2.20 per share expiring on September 8, 2008; (v) stock options issued in 2004 to purchase 320,000 shares of common stock at \$2.60 per share expiring on September 7, 2014; (vi) Stock Options issued in 2005 to purchase 100,000 shares of common stock at \$1.75 per share expiring on April 26, 2015; (vii) Stock options issued in 2005 to purchase 465,000 shares of common stock at \$1.86 per share expiring July 1, 2011; and (viii) stock options issued in 2005 to purchase 70,000 shares of Common Stock at \$2.87 per share expiring December 9, 2015; (ix) stock options issued in 2005 to purchase 10,000 shares of Common Stock at \$2.61 per share expiring December 8, 2015; (x) 300,000 options issued in 2006 to purchase common stock at \$2.38 per share and expiring on January 3, 2016; and (xi) 476,490 shares of Common Stock. Also includes 1,868,188 warrants and options originally issued to William A. Carter and subsequently transferred to Carter Investments of which Dr. Carter is the beneficial owner. These securities consist of (a) warrants issued in 1998 to purchase 190,000 shares of common stock consisting of 190,000 exercisable at \$4.00 per share expiring on January 1, 2008, (b) stock options granted in 1991 and extended in 1998 to purchase 73,728 shares of common stock exercisable at \$2.71 per share expiring on August 8, 2008 and (c) Warrants issued in 2002 to purchase 1,400,000 shares of common stock at \$3.50 per share expiring on September 30, 2007.
- (2) Includes shares issuable upon exercise of (i) replacement options issued in 2007 to purchase 13,750 shares of common stock at \$2.37 per share and expiring on January 22, 2017; (ii) options issued in 2001 to purchase 10,000 shares of common stock at \$4.03 per share and expiring on January 3, 2011; (iii) options issued in 2005 to purchase 10,000 shares of Common Stock at \$2.61 per share expiring December 8, 2015; and (iv) 8,000 shares of Common Stock. Also includes 498,824 warrants/options originally issued to Robert E. Peterson and subsequently transferred to the Robert E. Peterson Trust of which Robert E. Peterson is owner and Trustee and to Mr. Peterson's spouse, Leslie Peterson. The trust securities include options issued in 2002 to purchase 200,000 shares at \$2.00 per share expiring August 13, 2007; options issued in 2006 to purchase 50,000 shares of common stock exercisable at \$3.85 per share expiring on February 28, 2016; replacement options issued in 2006 to purchase 100,000 shares of common stock at \$3.48 per share expiring on April 14, 2016; replacement options issued in 2006 to purchase 30,000 shares of common stock exercisable at \$3.55 per share expiring on April 30, 2016 and 63,824 stock options issued in 2004 consisting of 50,000 options to acquire common stock at \$3.44 per share expiring on June 22, 2014 and 13,824 options to acquire common stock at \$2.60 per share expiring on September 7, 2014. 55,000 options to purchase common stock at \$1.75 per share expiring on April 16, 2015 were transferred to Mrs. Peterson of which Mr. Peterson is still considered the beneficial owner.



- (3) Includes shares issuable upon exercise of (i) 20,000 warrants issued in 1998 to purchase common stock at \$4.00 per share, originally expiring on January 1, 2003 and extended to January 1, 2008; (ii) 100,000 warrants issued in 2002 exercisable \$2.00 per share expiring on August 13, 2007; (iii) stock options issued in 2005 to purchase 100,000 shares of common stock exercisable at \$1.75 per share expiring on April 26, 2015; and (iv) stock options issued in 2004 to purchase 50,000 shares of common stock exercisable at \$2.60 per share expiring on September 7, 2014; and (v) 143,319 shares of common stock of which 40,900 are subject to security interest. Also includes 200,000 stock options originally granted to Ransom Etheridge in 2003 and 50,000 stock options originally granted to Ransom Etheridge in 2006, all of which were subsequently transferred to relatives and family trusts. 200,000 of these stock options are exercisable at \$2.75 per share and expire on December 4, 2013. 37,500 of these options were transferred to Julianne Inglima; 37,500 of these options were transferred to Thomas Inglima; 37,500 of these options were transferred to R. Etheridge-BMI Trust; 37,500 options were transferred to R. Etheridge-TCI Trust and 50,000 of these options were transferred to the Etheridge Family Trust. 50,000 of these stock options are exercisable at \$3.86 per share and expire on February 24, 2016. 12,500 of these shares were transferred to Julianne Inglima; 12,500 of these options were transferred to Thomas Inglima; 12,500 of these options were transferred to R. Etheridge - BMI Trust; and 12,500 of these options were transferred to R. Etheridge-TCI Trust. Julianne and Thomas are Mr. Etheridge's daughter and son-in-law.
- (4) Includes shares issuable upon exercise of (i) 20,000 warrants issued in 1998 to purchase common stock at \$4.00 per share originally expiring on January 1, 2005 and extended to January 1, 2008; (ii) 100,000 warrants issued in 2003 exercisable at \$2.00 per share expiring on August 13, 2007; (iii) options granted in 2004 to purchase 54,608 shares of common stock exercisable at \$2.60 per share expiring on September 17, 2014; (iv) options granted in 2005 to purchase 100,000 shares of common stock exercisable at \$1.75 per share expiring on April 26, 2015; (v) stock options issued in 2006 to purchase 50,000 shares of common stock exercisable at \$3.86 per share expiring February 24, 2006; (vi) 120,863 shares of common stock owned by Mr. Piani; (vii) 40,900 shares of common stock owned jointly by Mr. and Mrs. Piani; and (viii) and 5,000 shares of common stock owned by Mrs. Piani.

- (5) Consists of (i) 100,000 options exercisable at \$2.11 per share expiring November 27, 2016 (ii) 50,000 options exercisable at \$2.08 per share expiring February 26, 2017 and (iii) 2,500 shares of common stock.
- (6) Includes shares issuable upon exercise of (i) warrants issued in 1998 to purchase 12,000 shares of common stock at \$6.00 per share, expiring on August 25, 2008; (ii) 100,000 warrants issued in 2002 exercisable at \$2.00 per share expiring on August 13, 2007; (iii) 50,000 stock options issued in 2004 exercisable at \$2.60 per share expiring on September 7, 2014; (iv) 100,000 stock options issued in 2005 exercisable at \$1.75 per share expiring on April 26, 2015; (v) stock options issued in 2006 to purchase 50,000 shares of common stock exercisable at \$3.86 per share expiring February 24, 2006; and (vi) 106,643 shares of common stock.
- (7) (i) stock options issued in 2007 to purchase 20,000 shares of common stock at \$2.37 per share expiring on February 22, 2017; (ii) warrants issued in 1998 to purchase 50,000 shares of common stock exercisable at \$4.00 per share expiring on February 28, 2008; (iii) stock options granted in 2001 to purchase 10,000 shares of common stock exercisable at \$4.03 per share expiring on January 3, 2011; (iv) warrants issued in 2002 to purchase 50,000 shares of common stock exercisable at \$2.00 per share expiring on August 13, 2007; (v) stock options issued in 2004 to purchase 10,000 shares of common stock exercisable at \$1.90 per share expiring on December 7, 2014; (vi) stock options issued in 2005 to purchase 10,000 shares of Common Stock at \$2.61 per share expiring December 8, 2015; (vii) stock options to purchase 15,000 shares of common stock at \$2.20 per share expiring November 20, 2016 and (viii) 10,746 shares of common stock.
- (8) Consists of shares issuable upon exercise of (i) 5,000 warrants issued in 1998 to purchase common stock at \$4.00 per share expiring June 7, 2008; (ii) 20,000 warrants issued in 2002 exercisable at \$2.00 per share expiring in August 13, 2007; (iii) 6,791 stock options issued in 1997 exercisable at \$2.37 expiring January 22, 2017; (iv) 10,000 stock options issued in 2001 exercisable at \$4.03 per share expiring January 3, 2011; (v) 10,000 stock options issued in 2004 exercisable at \$1.90 expiring on December 7, 2014; (vi) 10,000 stock options issued in 2005 to purchase Common Stock at \$2.61 per share expiring December 8, 2015 and (vii) 7,500 stock options issued in 1996 to purchase common stock at \$2.20 per share expiring November 20, 2016.
- (9) Consists of shares issuable upon exercise of (i) 12,000 options issued in 2005 exercisable at \$1.63 per share expiring on June 2, 2015; (ii) 15,000 options issued in 2005 exercisable at \$1.75 per share expiring on April 26, 2015; (iii) stock options issued in 2006 to purchase 50,000 shares of common stock exercisable at \$3.86 per share expiring February 24, 2006; and (iv) 48,899 shares of common stock.
- (10) Consists of 15,000 stock options granted in 2005 exercisable at \$1.75 per share expiring on April 26, 2015; stock options issued in 2006 to purchase 50,000 shares of common stock exercisable at \$3.86 per share expiring February 24, 2006; and 201,302 shares of common stock.
- (11) Consists of (i) 10,000 stock options granted in 2004 exercisable at \$1.90 per share of common stock expiring on December 7, 2014; (ii) 10,000 stock options issued in 2005 to purchase Common Stock at \$2.61 per share expiring December 8, 2015 and (iii) 7,500 stock options issued in 1996 to purchase common stock at \$2.20 per share expiring November 20, 2016.

### **Item 13. Certain Relationships and Related Transactions.**

We have employment agreements with certain of our executive officers and have granted such officers and directors options and warrants to purchase our common stock, as discussed under the headings, “Item 11. Executive Compensation,” and “Item 12. Security Ownership of Certain Beneficial Owners and Management,” above.

Ransom W. Etheridge, our Secretary, General Counsel and one of our directors, is an attorney in private practice, who renders corporate legal services to us from time to time, for which he has received fees totaling approximately \$91,000 in 2006. In addition, Mr. Etheridge serves on the Board of Directors for which he received Director’s Fees of cash and stock valued at \$150,000 in 2006. We loaned \$60,000 to Ransom W. Etheridge in November, 2001 for the purpose of exercising 15,000 class A redeemable warrants. This loan bore interest at 6% per annum. This loan was granted prior to the enactment of the Sarbanes Oxley Act of 2002 prohibiting such transactions. In lieu of granting Mr. Etheridge a bonus for outstanding legal work performed on behalf of the Company, the Board of Directors forgave the loan and accrued interest on February 24, 2006.

Richard Piani, a Director, lives in Paris, France and assisted our European subsidiaries in their dealings with medical institutions and the European Medical Evaluation Authority. Mr. Piani assisted us in establishing clinical trial protocols as well as performed other scientific work for us. The services provided by Mr. Piani terminated in September 2003. For these services, Mr. Piani was paid an aggregate of \$100,100 for the year ended December 31, 2003.

We paid \$18,800, and \$7,600 for the years ended December 31, 2003 and 2004, respectively, to Carter Realty for the rent of property used by us at various times in years 2003 and 2004 by us. The property was owned by others, but was acquired in late 2004 by Retreat House, LLC an entity in which the children of William A. Carter have a beneficial interest. We paid Retreat House, LLC \$54,400 for the use of the property at various times in 2005 and \$102,000 in 2006.

Antoni Esteve, one of our former directors, was a Member of the Executive Committee and Director of Scientific and Commercial Operations of Laboratorios Del Dr. Esteve S.A. In March 2002, our European subsidiary Hemispherx S.A. entered into a Sales and Distribution Agreement with Laboratorios Del Dr. Esteve S.A. In addition, in March 2003, we issued 347,445 shares of our common stock to Provesan SA, an affiliate of Laboratorios Del Dr. Esteve S.A., in exchange for 1,000,000 Euros of convertible preferred equity certificates of Hemispherx S.A., owned by Laboratorios Del Dr. Esteve S.A.

We have engaged the Sage Group, Inc., a health care, technology oriented, strategy and transaction advisory firm, to assist us in obtaining a strategic alliance in Japan for the use of Ampligen® in treating Chronic Fatigue Syndrome (CFS) and Avian Flu. R. Douglas Hulse, our former President and Chief Operating Officer, is a member and an executive director of The Sage Group, Inc.

**ITEM 14. Principal Accounting Fees and Services.**

All audit and professional services are approved in advance by the Audit Committee to assure such services do not impair the auditor's independence from us. BDO Seidman, LLP ("BDO") resigned as our auditor on November 7, 2006 and, on November 9, 2006, we engaged McGladrey & Pullen, LLP ("McGladrey") as our certified public accountants. The total fees billed by McGladrey for 2006 was \$75,000 and the total fees billed by BDO were \$591,000 for 2005 and \$65,000 for 2006. The following table shows the aggregate fees for professional services rendered during the year ended December 31, 2006.

Description of Fees	Amount (\$)		
	2004	2005	2006
Audit Fees	\$ 189,475	\$ 591,000	\$ 200,000
Audit-Related Fees	37,009	-	89,700
Tax Fees	-	-	-
All Other Fees	-	-	-
Total	\$ 226,484	\$ 591,000	\$ 289,700

*Audit Fees*

Represents fees for professional services provided for the audit of our annual financial statements, audit of the effectiveness of internal control over financial reporting, services that are performed to comply with generally accepted auditing standards, and review of our financial statements included in our quarterly reports and services in connection with statutory and regulatory filings.

*Audit-Related Fees*

Represents the fees for assurance and related services that were reasonably related to the performance of the audit or review of our financial statements.

The Audit Committee has determined that BDO's rendering of these non-audit services was compatible with maintaining auditors independence. The Board of Directors considered McGladrey to be well qualified to serve as our independent public accountants. The committee also pre-approved the charges for services performed in 2006.

The Audit Committee pre-approves all auditing services and the terms thereof (which may include providing comfort letters in connection with securities underwriting) and non-audit services (other than non-audit services prohibited under Section 10A(g) of the Exchange Act or the applicable rules of the SEC or the Public Company Accounting Oversight Board) to be provided to us by the independent auditor; provided, however, the pre-approval requirement is waived with respect to the provisions of non-audit services for us if the "de minimus" provisions of Section 10A(i)(1)(B) of the Exchange Act are satisfied. This authority to pre-approve non-audit services may be delegated to one or more members of the Audit Committee, who shall present all decisions to pre-approve an activity to the full Audit Committee at its first meeting following such decision.

**PART IV**

**ITEM 15. Exhibits and Financial Statement Schedules**

(a) Financial Statements and Schedules - See index to financial statements on page F-1 of this Annual Report.

All other schedules called for under regulation S-X are not submitted because they are not applicable or not required, or because the required information is included in the financial statements or notes thereto.

(b) Exhibits - See exhibit index below.

Except as disclosed in the footnotes, the following exhibits were filed with the Securities and Exchange Commission as exhibits to our Form S-1 Registration Statement (No. 33-93314) or amendments thereto and are hereby incorporated by reference:

Exhibit No.	Description
2.1	First Asset Purchase Agreement dated March 11, 2003, by and between the Company and ISI.(1)
2.2	Second Asset Purchase Agreement dated March 11, 2003, by and between the Company and ISI.(1)
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended, along with Certificates of Designations.
3.1.1	Series E Preferred Stock.
3.2	By-laws of Registrant, as amended.
4.1	Specimen certificate representing our Common Stock.
4.2	Rights Agreement, dated as of November 19, 2002, between the Company and Continental Stock Transfer & Trust Company. The Right Agreement includes the Form of Certificate of Designation, Preferences and Rights of the Series A Junior Participating Preferred Stock, the Form of Rights Certificate and the Summary of the Right to Purchase Preferred Stock.(2)
4.3	Form of 6% Convertible Debenture of the Company issued in March 2003.(1)
4.4	Form of Warrant for Common Stock of the Company issued in March 2003.(1)
4.5	Form of Warrant for Common Stock of the Company issued in June 2003.(3)
4.6	Form of 6% Convertible Debenture of the Company issued in July 2003.(4)
4.7	Form of Warrant for Common Stock of the Company issued in July 2003.(4)
4.8	Form of 6% Convertible Debenture of the Company issued in October 2003.(5)
4.9	Form of Warrant for Common Stock of the Company issued in October 2003.(5)
4.10	Form of 6% Convertible Debenture of the Company issued in January 2004.(6)

- 4.11 Form of Warrant for Common Stock of the Company issued in January 2004.(6)
- 4.12 Form of Warrant for Common Stock of the Company. (9)
- 4.13 Amendment Agreement, effective October 6, 2005, by and among the Company and debenture holders.(11)
- 4.14 Form of Series A amended 7% Convertible Debenture of the Company (amending Debenture due October 31, 2005).(11)
- 4.15 Form of Series B amended 7% Convertible Debenture of the Company (amending Debenture issued on January 26, 2004 and due January 31, 2006).(11)

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- 4.16 Form of Series C amended 7% Convertible Debenture of the Company (amending Debenture issued on July 13, 2004 and due January 31, 2006).(11)
- 4.17 Form of Warrant issued effective October 6, 2005 for Common Stock of the Company.(11)
- 10.1 1990 Stock Option Plan.
- 10.2 1992 Stock Option Plan.
- 10.3 1993 Employee Stock Purchase Plan.
- 10.4 Form of Confidentiality, Invention and Non-Compete Agreement.
- 10.5 Form of Clinical Research Agreement.
- 10.6 Form of Collaboration Agreement.
- 10.7 Amended and Restated Employment Agreement by and between the Company and Dr. William A. Carter, dated as of July 1, 1993. (7)
- 10.8 Employment Agreement by and between the Registrant and Robert E. Peterson, dated April 1, 2001.
- 10.9 License Agreement by and between the Company and The Johns Hopkins University, dated December 31, 1980.
- 10.10 Technology Transfer, Patent License and Supply Agreement by and between the Company, Pharmacia LKB Biotechnology Inc., Pharmacia P-L Biochemicals Inc. and E.I. du Pont de Nemours and Company, dated November 24, 1987.
- 10.11 Pharmaceutical Use Agreement, by and between the Company and Temple University, dated August 3, 1988.
- 10.12 Assignment and Research Support Agreement by and between the Company, Hahnemann University and Dr. David Strayer, Dr. Isadore Brodsky and Dr. David Gillespie, dated June 30, 1989.
- 10.13 Lease Agreement between the Company and Red Gate Limited Partnership, dated November 1, 1989, relating to the Company's Rockville, Maryland facility.
- 10.14 Agreement between the Company and Bioclones (Proprietary) Limited.
- 10.15 Amendment, dated August 3, 1995, to Agreement between the Company and Bioclones (Proprietary) Limited (contained in Exhibit 10.14).
- 10.16 Licensing Agreement with Core BioTech Corp.
- 10.17 Licensing Agreement with BioPro Corp.
- 10.18 Licensing Agreement with BioAegean Corp.
- 10.19 Agreement with Esteve.
- 10.20 Agreement with Accredo (formerly Gentiva) Health Services.

- 10.21 Agreement with Biovail Corporation International.
- 10.22 Forbearance Agreement dated March 11, 2003, by and between ISI, the American National Red Cross and the Company.(1)
- 10.23 Forbearance Agreement dated March 11, 2003, by and between ISI, GP Strategies Corporation and the Company.(1)
- 10.24 Securities Purchase Agreement, dated March 12, 2003, by and among the Company and the Buyers named therein.(1)
- 10.25 Registration Rights Agreement, dated March 12, 2003, by and among the Company and the Buyers named therein.(1)
- 10.26 Securities Purchase Agreement, dated July 10, 2003, by and among the Company and the Buyers named therein.(4)
- 10.27 Registration Rights Agreement, dated July 10, 2003, by and among the Company and the Buyers named therein.(4)
- 10.28 Securities Purchase Agreement, dated October 29, 2003, by and among the Company and the Buyers named therein.(5)
- 10.29 Registration Rights Agreement, dated October 29, 2003, by and among the Company and the Buyers named therein.(5)
- 10.30 Securities Purchase Agreement, dated January 26, 2004, by and among the Company and the Buyers named therein.(6)
- 10.31 Registration Rights Agreement, dated January 26, 2004, by and among the Company and the Buyers named therein.(6)
- 10.32 Memorandum of Understanding with Fujisawa. (8)



- 10.33 Securities Purchase Agreement, dated July 30, 2004, by and among the Company and the Purchasers named therein.(9)
- 10.34 Registration Rights Agreement, dated July 30, 2004, by and among the Company and the Purchasers named therein. (9)
- 10.35 Agreement for services of R. Douglas Hulse, (12)
- 10.36 Amended and Restated Employment Agreement of Dr. William A. Carter. (10)
- 10.37 Engagement Agreement with Dr. William A. Carter. (10)
- 10.38 Amended and restated employment agreement of Dr. William A. Carter (12)
- 10.39 Amended and restated engagement agreement with Dr. William A. Carter (12)
- 10.40 Amended and restated engagement agreement with Robert E. Peterson (12)
- 10.41 Engagement Agreement with Ransom W. Etheridge (12)
- 10.42 Change in control agreement with Dr. William A. Carter (12)
- 10.43 Change in control agreement with Dr. William A. Carter (12)
- 10.44 Change in control agreement with Robert E. Peterson (12)
- 10.45 Change in control agreement with Ransom Etheridge (12)
- 10.46 Supply Agreement with Hollister-Stier Laboratories LLC
- 10.47 Manufacturing and Safety Agreement with Hyaluron, Inc.
- 10.48 Common Stock Purchase Agreement, dated July 8, 2005, by and among the Company and Fusion Capital.(13)
- 10.49 Registration Rights Agreement, dated July 8, 2005, by and among the Company and Fusion Capital.(13)
- 10.48 Common Stock Purchase Agreement, dated April 12, 2006, by and among the Company and Fusion Capital.(14)
- 10.49 Registration Rights Agreement, dated April 12, 2006, by and among the Company and Fusion Capital.(14)
- 10.50 Supply Agreement with Hollister-Stier Laboratories LLC. (15)
- 10.51 Manufacturing and Safety Agreement with Hyaluron, Inc. (15)
- 10.52 April 19, 2006 Amendment to Common Stock Purchase Agreement by and among the Company and Fusion Capital.(15)
- 10.53 July 21, 2006 Letter Amendment to Common Stock Purchase Agreement by and among the Company and Fusion Capital.(15)

- 10.54 Royalty Purchase Agreement with Stem Cell Innovations, Inc. (15)
- 21 Subsidiaries of the Registrant.
- 23.1 BDO Seidman, LLP consent.(15)
- 23.2 McGladrey & Pullen, LLP consent.(15)
- 31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer.(15)
- 31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer.(15)
- 32.1 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer.(15)
- 32.2 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer.(15)

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(1) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) dated March 12, 2003 and is hereby incorporated by reference.

(2) Filed with the Securities and Exchange Commission on November 20, 2002 as an exhibit to the Company's Registration Statement on Form 8-A (No. 0-27072) and is hereby incorporated by reference.

(3) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) dated June 27, 2003 and is hereby incorporated by reference.

(4) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) dated July 14, 2003 and is hereby incorporated by reference.

(5) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) dated October 30, 2003 and is hereby incorporated by reference.

(6) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) dated January 27, 2004 and is hereby incorporated by reference.

(7) Filed with the Securities and Exchange Commission as an exhibit to the Company's quarterly report on Form 10-Q (No. 1-13441) for the period ended September 30, 2001 and is hereby incorporated by reference.

(8) Filed with the Securities and Exchange Commission as an exhibit to the Company's Form S-1 Registration Statement (No. 333-113796) and is hereby incorporated by reference.

(9) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) dated August 6, 2004 and is hereby incorporated by reference.

(10) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) dated September 15, 2004 and is hereby incorporated by reference.

(11) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K/A-1 (No. 1-13441) filed on October 28, 2005 and is hereby incorporated by reference.

(12) Filed with the Securities and Exchange Commission as an exhibit to the Company's annual report on Form 10-K (No. 1-13441) for the year ended December 31, 2004 and is hereby incorporated by reference.

(13) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) dated September 15, 2005 and is hereby incorporated by reference.

(14) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) dated April 12, 2006 and is hereby incorporated by reference.

(15) Filed with the Securities and Exchange Commission on July 31, 2006 as an exhibit to the Company's Form S-1 Registration Statement (No. 333-136187) and is hereby incorporated by reference.

(16) Filed herewith.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this amended report to be signed on its behalf by the undersigned, thereunto duly authorized.

HEMISPHERx BIOPHARMA, INC.

By: /s/ William A. Carter

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

March 14, 2007

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange of 1934, as amended, this amended report has been signed below by the following persons on behalf of this Registrant and in the capacities and on the dates indicated.

/s/ William A. Carter	Chairman of the Board, Chief Executive Officer and Director	March 14, 2007
William A. Carter, M.D.		
/s/ Richard Piani	Director	March 14, 2007
Richard Piani		
/s/ Robert E. Peterson	Chief Financial Officer	March 14, 2007
Robert E. Peterson		
/s/ Ransom Etheridge	Secretary And Director	March 14, 2007
Ransom Etheridge		
/s/ William Mitchell	Director	March 14, 2007
William Mitchell, M.D., Ph.D.		
/s/ Steven Spence	Director	March 14, 2007
Steven Spence		
/s/ Iraj E. Kiani	Director	March 14, 2007
Iraj E. Kiani, Ph.D.		

**HEMISPHERx BIOPHARMA, INC AND SUBSIDIARIES**  
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Report of Independent Registered Public Accounting Firm

To the Board of Directors  
Hemispherx Biopharma, Inc.  
Philadelphia, PA

We have audited the consolidated balance sheet of Hemispherx Biopharma, Inc. and Subsidiaries as of December 31, 2006 and the related consolidated statements of operations, stockholders' equity and comprehensive loss and cash flows for the year ended December 31, 2006. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Hemispherx Biopharma, Inc. and Subsidiaries as of December 31, 2006, and the results of their operations and their cash flows for the year ended December 31, 2006, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 2 to the consolidated financial statements, in 2006 Hemispherx Biopharma, Inc. and Subsidiaries adopted Statement of Financial Accounting Standards No. 123R, "Share-Based Payment."

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Hemispherx Biopharma, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2006, based on criteria established in "*Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)*" and our report dated March 19, 2007, expressed an unqualified opinion on management's assessment of the effectiveness of Hemispherx Biopharma, Inc.'s internal control over financial reporting and an unqualified opinion on the effectiveness of Hemispherx Biopharma, Inc.'s internal control over financial reporting.

/s/ McGladrey & Pullen, LLP

Blue Bell, Pennsylvania  
March 19, 2007

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders  
Hemispherx Biopharma, Inc.

We have audited the accompanying consolidated balance sheets of Hemispherx Biopharma, Inc. and subsidiaries as of December 31, 2005 and the related consolidated statements of operations, changes in stockholders' equity and comprehensive loss and cash flows for each of the two years in the period ended December 31, 2005. We have also audited the financial statement schedule listed under Item 15(a). These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements and financial statement schedule are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Hemispherx Biopharma, Inc. and subsidiaries as of December 31, 2005 and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the financial statement schedule presents fairly, in all material respects, the information set forth therein for each of the two years in the period ended December 31, 2005.

/s/ BDO SEIDMAN, LLP

Philadelphia, Pennsylvania  
June 1, 2006

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**HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES****Consolidated Balance Sheets****December 31, 2005 and 2006**

(in thousands, except for share and per share amounts)

	2005	2006
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents (Notes 2 & 18)	\$ 3,827	\$ 3,646
Short term investments (Notes 2 & 5)	12,377	18,375
Inventories (Note 3)	1,767	957
Accounts and other receivables (Note 2)	96	93
Prepaid expenses and other current assets	142	168
<b>Total current assets</b>	<b>18,209</b>	<b>23,239</b>
Property and equipment, net (Note 2)	3,364	4,720
Patent and trademark rights, net (Note 2)	795	857
Investment (Notes 2 & 5)	35	35
Royalty interest, net (Note 17)	-	601
Construction in progress (Note 2)	821	624
Deferred financing costs, net (Note 2)	113	38
Advance receivable (Note 7)	1,300	1,300
Other assets	17	17
<b>Total assets</b>	<b>\$ 24,654</b>	<b>\$ 31,431</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 991	\$ 1,548
Accrued expenses (Notes 2 & 6)	865	1,261
Current portion of long-term debt (Notes 2 & 7)	-	3,871
<b>Total current liabilities</b>	<b>1,856</b>	<b>6,680</b>
Long-term debt-net of current portion (Notes 2 & 7 )	4,171	-
Commitments and contingencies (Notes 10, 12, 13, 15)		
Stockholders' equity (Note 8):		
Preferred stock, par value \$0.01 per share, authorized 5,000,000; issued and outstanding; none	-	-
Common stock, par value \$0.001 per share, authorized 200,000,000 shares; issued and outstanding 56,264,155 and 66,816,764, respectively	56	67
Additional paid-in capital	166,394	191,689
Accumulated other comprehensive income (loss)	(171)	46
Accumulated deficit	(147,652)	(167,051)
<b>Total stockholders' equity</b>	<b>18,627</b>	<b>24,751</b>



Total liabilities and stockholders' equity \$ 24,654 \$ 31,431

See accompanying notes to consolidated financial statements.

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**HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES**

**Consolidated Statements of Operations**  
(in thousands, except share and per share data)

	2004	Years ended December 31,		2006
		2005		
Revenues:				
Sales of product net	\$ 1,050	\$ 910	\$ 750	
Clinical treatment programs	179	173	183	
Total Revenues:	1,229	1,083	933	