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FORM 10-K  
SECURITIES AND EXCHANGE COMMISSION  
 ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2004  
OR  
 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

HEMISPHERX BIOPHARMA, INC.  
(Exact name of registrant as specified in its charter)

Delaware 52-0845822

-----  
(State or other jurisdiction of (I.R.S. Employer Identification  
incorporation or organization) Number)

1617 JFK Boulevard Philadelphia, Pennsylvania 19103  
-----  
(Address of principal executive offices) (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 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 (X) 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. ( )

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes (X) No ( )

The aggregate market value of Common Stock held by non-affiliates at June 30, 2004, the last business day of the registrant's most recently completed second fiscal quarter, was \$171,234,810. For purposes of this calculation, it was assumed that all Common Stock is valued at the closing price as of such date of \$3.44 per share.

The number of shares of the registrant's Common Stock outstanding as of March 11, 2005 was 49,849,325.

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 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, 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 "Company", "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 declines 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 manufacture and clinical development of new drugs for the treatment of viral and immune based chronic disorders. We were founded in the early 1970s, as a contract researcher for the National Institutes of Health. After almost 30 years, 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 chronic diseases. We own a manufacturing facility in New Jersey, and have corporate offices in Philadelphia, PA.

Our flagship products include Ampligen and Alferon. Ampligen is an experimental drug undergoing clinical trials for the treatment of: Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), HIV, and HIV/Hepatitis C co-infection. In August 2004, we completed a Phase III clinical trial treating

over 230 ME/CFS patients with Ampligen and are in the process of preparing a new drug application to be filed with the FDA. Alferon N Injection is the registered trademark for our injectable formulation of Natural Alpha Interferon, which is <PAGE> 2 approved by the U.S. Food and Drug Administration ("FDA") for the treatment of genital warts. Alferon N is also in clinical development for treating Hepatitis C ("HEP-C"), Multiple Sclerosis, Human Immunodeficiency Virus (HIV), West Nile Virus ("WNV") and Severe Acute Respiratory Syndrome (SARS).

We have over 170 patents worldwide with 14 additional patents pending comprising our core intellectual property, a fully commercialized product (Alferon), and a GMP (good manufacturing practice) certified manufacturing facility.

In March 2003, we began the step by step acquisition from Interferon Sciences, Inc. ("ISI") of ISI's commercial assets, inventory concerning Alferon N, including a limited license for the production, manufacture, use, marketing and sale of Alferon N. Alferon N is a natural alpha interferon that has been approved by the FDA for commercial sale for the intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. The acquisition was completed in Spring 2004 with the acquisition of all world wide commercial rights, the FDA approval, acquisition of 43,000 square feet of manufacturing space in New Jersey and acquisition of all intellectual property related to Alferon.

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.

Since the completion of our AMP 516 ME/CFS Phase III clinical trial for use of Ampligen(R) in the treatment of ME/CFS we have received inquiries from and, under confidentiality agreements, are having dialogue with other companies regarding marketing opportunities. No proposal or agreements have resulted from the dialogue, nor can we be assured that any proposals or agreements will result from these inquiries.

#### OUR PRODUCTS

Our primary products consist of our experimental compound, Ampligen, our FDA approved natural interferon product, Alferon N Injection and our experimental liquid natural interferon LDO.

#### Ampligen(R)

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 and which regulate the action of groups of cells, including the cells, which comprise 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 virus and tumors. Our drug technology utilizes specially configured RNA. Our double-stranded RNA drug product, trademarked Ampligen(R), which is administered intravenously, is (or has been) in human clinical development for various disease indications, including treatment for ME/CFS, HIV, renal cell carcinoma and malignant melanoma. Further studies are planned in cancer treatment but initiation dates have not been set.

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Our proprietary development drug technology Ampligen(R) utilizes specially configured ribonucleic acid ("RNA") and currently is protected by more than 170 patents worldwide with 14 additional patent applications pending to provide further proprietary protection in various international markets. Certain patents apply to the use of Ampligen(R) alone and certain patents apply to the use of Ampligen(R) in combination with certain other drugs. Some composition of matter patents pertain to other new medications which have a similar mechanism of action. During 2004, we reviewed our patents and patent applications. As a result, various patents and patent applications were elected not to be renewed. The non-renewed patents consisted mostly of international origin or were not conducive to oral application.

The main U.S. ME/CFS treatment patent (#6130206) expires October 10, 2017. Our main patents covering HIV treatment (#4795744, #4820696, #5063209, and #5091374) expire on January 3, 2006, 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(R) Trademark (#1,515,099) expires on December 6, 2008 and can be renewed thereafter for an additional 10 years. The U.S. 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.

Based on the results of published, peer reviewed pre-clinical studies and clinical trials, we believe that Ampligen(R) may have broad-spectrum anti-viral and anti-cancer properties. Over 500 patients have received Ampligen(R) in clinical trials authorized by the FDA at over twenty clinical trial sites across the U.S., representing the administration of more than 45,000 doses of this drug.

## Alferon N Injection(R)

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(R) 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 interferon 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 <PAGE> 4 interferon species, the types and relative quantity of these species are different from our natural alpha interferon.

The FDA approved ALFERON N Injection(R) 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.

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

Alferon N Injection(R) [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(R) 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(R) 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 based on a detailed examination of the Biochemistry of the body's natural antiviral response.

## Alferon LDO

ALFERON LDO is an experimental low-dose, oral liquid formulation of Natural Alpha 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 an immune response through the entire body orally. 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(R), with its affordability, low toxicity, no production of antibodies, and broad range of potential bio activity, could be a breakthrough treatment for viral diseases.

## RESEARCH AND DEVELOPMENT

Our focus is on developing drugs for use in treating viral and immune based chronic disorders and diseases including ME/CFS, HIV, HEP-C, HPV, SARS and West Nile Virus. Our current clinical trial projects target treatment therapies for ME/CFS, HIV, HPV and HEP-C and other diseases.

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## 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), Food and Drug Administration and Social Security Administration, which recognizes 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 800,000 people nationwide suffer from CFS, twice the number previously estimated by the Centers for Disease Control and Prevention. 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 (522/100,000) 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 (125/100,000), and the rate of ME/CFS in women is considerably higher than a woman's lifetime risk of getting lung cancer (63/100,000) 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 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

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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(R) 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 19.3% versus 4.1% in the placebo group, or more than twice the minimum considered medically significant (6.5%), a statistically significant increase (p=0.037). 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.

Human Immunodeficiency Virus (HIV)

The Human Immunodeficiency Virus (HIV) is the cause of Acquired Immune Deficiency Syndrome (AIDS). HIV has high rates of viral replication and mutation, thereby developing drug resistance. Resistance is least likely to develop if treatment is based on a combination of drugs. With this approach, resistance takes longer to develop because a virus strain resistant to one drug could still be sensitive to another. To overcome the action of two or more drugs simultaneously, the virus has to acquire multiple mutations. Its chances of getting multiple mutations in the right combination to resist a number of drugs are much smaller than its chance of acquiring a single mutation that enables it to resist just one drug. Therefore, properly sequencing HIV drug treatment allows for the maximum number of options and alternatives to be available for long term.

Over fifteen antiviral drugs are currently approved by the FDA for the treatment of HIV infection. Most target the specific HIV enzymes, reverse

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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. Treatments include different classes of drugs, but they all work by stopping parts of the virus so the virus cannot reproduce. 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. Reduction of the viral load to undetectable levels in patients with wild type virus (i.e., non-drug-resistant virus) is routinely possible with the appropriate application of HAART. HIV mainly infects important immune system cells called CD4 cells. After HIV has infected a CD4 cell, the CD4 cell becomes damaged and is eventually destroyed. Fewer CD4 cells means more damage to the immune system and, ultimately, results in AIDS. Originally, reduction of HIV loads was seen as possibly allowing the reconstitution of the immune system and led to early speculation that HIV might be eliminated by HAART.

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 cost due to drug toxicity. It is estimated that 50% of HIV deaths are 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.

Although more potent second generation drugs are under development, which target the reverse transcriptase and protease genes as well as new HIV targets, such as, HIV integrase and HIV fusion inhibitors, the problem of drug toxicities, the complex interactions between these drug classes and the likelihood of life-long therapy will remain a serious drawback to their usage.

Failure of antiretroviral therapies over time and the demonstration of resistance have stimulated intensive searches for appropriate combinations of agents, or sequential use of different agents, that act upon the same or different viral targets. This situation has created interest in our drug technology, which operates by a different mechanism.

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. Based on recent publications (AIDS 2001,15: F19-27 and AIDS 2001, 15:1359-1368) in peer reviewed medical literature, it is expected that in just 30 days after stopping HAART approximately 80% to 90%, of the patients will suffer a relapse evidencing detectable levels of HIV. We believe that Ampligen(R) 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(R) potentially does, although HIV is an immune-based disease.

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By using Ampligen(R) 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(R) 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(R) may potentiate STI of HAART to the point that the cell mediated immune system will be sufficient to eliminate requirement for HAART. Clinical results of using our technology has been presented at several International AIDS Scientific Forums in 2003, including the XVI International Conference on Antiviral Research in Savannah, Georgia in April 2003 and the 2nd IAS Conference on HIV Pathogenesis and Treatment in Paris, France in July 2003.

Our AMP 720 HIV clinical trial is being conducted by treating

individuals infected with HIV who are responding well to HAART at the moment. Patients in this study are required to meet minimum immune system requirements of CD4 cell levels greater than 400, maximum HIV infection levels of less than 50 copies/ml, and a HAART regimen containing at least one anti-viral drug showing therapeutic synergy with Ampligen(R) based on recently reported ex vivo study in a peer-reviewed scientific journal (Reference: Robinson W. McDougall B and Essay R. Mixed Dose Effect Analysis of a Biological Response Modifier (Ampligen) with 14 FDA-approved anti-HIV Agents. Antiviral Res, 46:A48, No. 46, 2000). All patients are chronically HIV infected and will have been receiving the indicated HAART regimen prior to starting the STI. The trial applies strategic treatment interruption of HAART based on the hypothesis that careful management of HIV rebound following STI may have potential to result in the development of protective immune responses to HIV in order to achieve control of HIV replication. We believe that the addition of Ampligen(R), with its potential immunomodulatory properties, may reasonably achieve this outcome. Half of the participants in the trial are given 400 mg of Ampligen(R) twice a week and once they start the STI will remain off of HAART until such time as their HIV rebounds. The other half of the participants (the control group) are on STI, but they are given no Ampligen(R) during the "control" portion of the clinical test.

The targeted enrollment in the AMP 720 Clinical Trial is 120 HIV-infected persons who meet the criteria. We expect to enroll 60 people on STI with Ampligen(R) and 60 people on STI without Ampligen(R). Presently, this study is approximately 35% enrolled at approximately ten medical centers around the U.S.

#### Human Papilloma Virus (HPV)

Human papillomavirus (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 (15% of the population) are currently infected with HPV, 50-75% of which is with high-risk types, and about 5.5 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: a recent estimate suggests that 80% of women will have acquired genital HPV by age 50. An estimated 9.2 million sexually active adolescents and young adults 15 to 24 years of age are currently infected with HPV.

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 <PAGE> 9 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 additionally 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 by 4 to 6 hours otherwise it may be dangerous. Condylox can be quite expensive as well. Condylil is an additional cream that may be applied. It consists of "all natural" ingredients and its producers claim it produces no scarring. The current leading treatment of genital warts is the topical cream Aldara, but in fact there may be a reoccurrence rate of up to 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

We are evaluating potential novel clinical programs which would involve using Ampligen(R) to treat both HCV and HIV when they coexist on the same patient. We expect to commence these studies in collaboration with one or more prospective corporate partners. A collaborative Clinical study in Europe, in conjunction with Laboratorios Del Dr. Esteve S.A., was initiated in December 2004.

This clinical program is a randomized pilot study in Phase II to evaluate the antiretroviral effect of Ampligen in the treatment of HIV infected patients co-infected with HCV. At present, no single drug or biological product has been deemed by internationally recognized regulatory agencies as being effective against both viruses when coexisting in patients.

#### Severe Acute Respiratory Syndrome (SARS)

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(R) 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 Severe Acute Respiratory Syndrome (SARS).

SARS (Severe Acute Respiratory Syndrome) is one of a group of "emerging" infectious disease that recently attracted the intense scrutiny of public health officials due to the severity of disease in epidemics based in Asia, but also involving Europe and North America as well. An international effort to limit its spread and to identify the infectious agent has been spectacularly successful and of major significance in the prevention of a pandemic. A replicating virus of classic coronavirus morphology was identified initially by electron microscopy. This identification of the virus family

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allowed the rapid identification of a new human coronavirus (SARS-CoV) as the etiological agent of SARS. Recently it has been observed that the US FDA approved antiviral drug, Alferon(R) (i.e.-natural interferon) has significant activity against SARS-CoV in vitro as indicated by reduction in cytopathic effect (CPE). This protocol is designed to respond to the anticipated reemergence of SARS with a prophylaxis trial at epidemic sites to be conducted to evaluate the activity of Alferon LDO (low dose oral) to prevent symptomatic infection by SARS-CoV. Gene microarray analysis of infection by SARS-CoV and the effect of Alferon LDO are used in the design and conduct of this clinical trial. Differential cellular gene responses to infection and the response to Alferon may predict clinical outcomes.

The 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 (WHO) 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. We have prepared more than 300,000 doses of Alferon LDO for appropriate clinical programs.

#### Other Diseases

In June 2004 we initiated a clinical trial in collaboration with the infectious disease section, New York Hospital at Queens and The Medical College of Cornell University to conduct a clinical trial for treating West Nile Virus (WNV) infected patients with Alferon N injection. The approved clinical protocol is entitled "Double Blinded, Placebo Controlled Trial of Alpha-Interferon (Alferon) Therapy for West Nile Meningo Encephalitis (Protocol WN-102). As of December 31, 2004 three patients have been enrolled in this protocol. While the population of patients affected by WNV is relatively small, there is an ever increasing rate of new infections each year. Forty states reported over 2,000 WNV infected people in 2004.

An FDA authorized Phase I/II study of Ampligen(R) in cancer, including patients with renal cell carcinoma was completed in 1994. The results of this study indicated that patients receiving high doses (200-500mg) twice weekly experienced an increase in medium survival compared to the low dose group and as compared to an historical control group. We received authorization from the FDA to initiate a Phase II study using Ampligen(R) to treat patients with metastatic renal cell carcinoma. Patients with metastatic melanoma were included in the Phase I/II study of Ampligen(R) in cancer. The FDA has authorized us to conduct a Phase II clinical trial using Ampligen(R) in melanoma. We do not expect to devote any significant resources to funding these studies in the near future.

We have acquired a series of patents on Oragen(TM), potentially a set of oral broad spectrum antivirals, immunological enhancers through a licensing agreement with Temple University in Philadelphia, PA. We were granted an exclusive worldwide license from Temple for the Oragen(TM) products. Pursuant to the arrangement, we are obligated to pay royalties of 2% to 4% on sales of Oragen(TM), depending on how much technological assistance is required of Temple. We currently pay minimum royalties of \$30,000 per year to Temple. These compounds have been evaluated in various academic laboratories for application to chronic viral and immunological disorders.

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#### EUROPEAN OPERATIONS

We executed a Memorandum of Understanding (MOU) in January 2004 with Fujisawa Deutschland GmbH, ("Fuji") a major pharmaceutical corporation, granting them an exclusive option for a limited number of months to enter a Sales and Distribution Agreement with exclusive rights to market Ampligen(R) for ME/CFS in Germany, Austria and Switzerland. The MOU required us to file the full report on the results of our AMP 516 Clinical Trial with Fuji by May 31, 2004. If the full report was not provided to Fuji by May 31, 2004 and Fuji did not wish to exercise its option, we would have been required to refund one half of the 400,000 Euro fee. We submitted our initial report to Fuji on May 28, 2004 and responded to subsequent inquiries for additional information. The option period was to end 12 weeks after the later of Fuji's review of the full report on the results of our Amp 516 clinical trial and Fuji's meeting with three of the trial's principal investigators. We received an initial fee of 400,000 Euros (approximately \$497,000 US). If we did not provide them with the full report by December 31, 2004 and Fuji did not wish to exercise its option, we would be required to refund the entire fee. On November 9, 2004, we and Fuji terminated the MOU by mutual agreement. We did not agree on the process to be utilized in certain European Territories for obtaining commercial approval for the sale of Ampligen(R) in the treatment of patients suffering from Chronic Fatigue Syndrome (CFS). Instead of a centralized procedure, and in order to obtain an earlier

commercial approval of Ampligen(R) in Europe, we have determined to follow a decentralized filing procedure which was not anticipated in the MOU. We believe that it now is in the best interest of our stockholders to potentially accelerate entry into selected European markets whereas the original MOU specified a centralized registration procedure. Pursuant to mutual agreement of the parties we refunded 200,000 Euros to Fuji in 2004.

In April 2004 we entered into an agreement with the World Foundation AIDS Research and Prevention headquarters in Paris, France to provide Alferon LDO and some funding in support of a clinical trial to be conducted in the Ivory Coast area of Africa. The purpose of this clinical trial was to test the use of Alferon N LDO (low dose oral) in treating young children of HIV infected mothers. Unfortunately, the political unrest in that country has caused the World Foundation to postpone the clinical trial. Efforts are underway by the World Foundation to locate another African country in which to initiate and conduct this trial. Dr. Luc Montagnier is President of the World Foundation AIDS Research and Prevention and also serves as a member of our Scientific Advisory Board.

In December 2004, Laboratorios Del Dr. Esteve S.A. ("Esteve") initiated clinical trials in Spain to evaluate the use of Ampligen in the treatment of patients infected by HIV/HEP-C ("co-infection"). This trial plans to recruit and treat patients in a double-blind, randomized, Phase II B study. Patients affected with HIV/HEP-C suffer disproportionately high death rates and, currently, there is limited treatment available.

We continue to contact the EMEA, keeping the agency aware of our activities, as well as the health ministries in numerous countries in the European Union. Although no applications are on file currently with the EEU, we are exploring various ways to accelerate the commercial availability of our products in the various nations of the EEU, including potential appreciation of the "foreign import" rule for accepting products already approved in the U.S.

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MANUFACTURING

Historically, we outsourced the manufacturing of Ampligen(R) 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(R). We had 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. In order to obtain Ampligen(R) raw materials of higher quality (GMP certified) and on a more regular production basis, we are implementing the consolidation and transfer of manufacturing operations into our New Brunswick facility, as well as continuing to search for additional contract manufacturers for the manufacture of the polymers. This consolidation and transfer of manufacturing operations has been implemented in response to a recent inspection of the Ribotech facility in South Africa, our previous supplier of polymers. This facility is not, at present, suitable for the commercial manufacture of polymers used to make Ampligen(R). This transfer of polymer manufacturing to our own facilities, and/or to another contract manufacturer may delay certain steps in commercialization process, specifically, an NDA filing.

Until 1999, we distributed Ampligen(R) 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(R) in a dosage form, which will mainly be used upon commercial approval of Ampligen(R). We had engaged the services of Schering-Plough ("Schering") to mass produce ready-to-use Ampligen(R) 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(R) (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(R) in this facility at the end of the applicable term (which was 4th quarter, 2004) and would assist us in an orderly transfer of said activities to other non Schering facilities. Accordingly, we have entered into a Confidentiality Agreement with Mayne Pharma Pty, Ltd ("Mayne") to lead to reinitiation and expansion of its Ampligen(R) manufacturing program. We are currently in discussion with Mayne to provide us with proposals on manufacturing Ampligen(R) at their facility. Mayne (formerly known as Faulding Pharma) has already successfully manufactured Ampligen(R) several times for research and development conducted by Bioclones, and maintains a fully GMP compliant facility. Simultaneously, we expect to qualify at least one other GMP facility to maintain a minimum of two independent production sites. If we are unable to engage Mayne and/or additional manufacturers in a timely manner, our plans to file an NDA for Ampligen(R) and, eventually, to market and sell Ampligen(R) will be delayed. There are other pharmaceutical processing companies that can supply our production needs.

Bioclones (PTY) Ltd. is the majority owner in Ribotech, Ltd. (we own 24.9%) which produced most of the polymers used to date in manufacturing Ampligen(R). The licensing agreement with Bioclones presently includes South Africa, South America, Ireland, Australia, New Zealand and the United Kingdom. The agreement imposes certain clinical trial requirements on Ribotech, as well as, certain GMP standards on their facilities. Bioclones has conducted limited

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clinical studies in patients with ME/CFS in Australia and South Africa. On December 27, 2004, we initiated a lawsuit in Federal Court identifying a conspiratorial group seeking to illegally manipulate our stock for purposes of bringing about a hostile takeover of Hemispherx. This conspiratorial group includes Bioclones. This legal action may adversely affect our relationship and collaborative agreement with Bioclones.

We currently occupy and use the New Brunswick, New Jersey laboratory and production facility that we acquired from ISI. This facility is approved by the FDA for the manufacture of Alferon N Injection(R).

#### MARKETING/DISTRIBUTION

Our marketing strategy for Ampligen(R) 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(R) will be utilized in four medical arenas: physicians' offices, clinics, hospitals and the home treatment setting. We currently plan to use a service provided in the home infusion (non-hospital) segment of the U.S. market to execute direct marketing activities, conduct physical distribution of the product and handle billing and collections. Accordingly, we are developing marketing plans to facilitate the product distribution and medical support for indication, if and when they are approved, in each arena. We believe that this approach will facilitate the generation of revenue without incurring the substantial costs associated with a sales force. Furthermore, management believes that the approach will enable us to retain many options for future marketing strategies. In February 1998, we and Accredo Health Services (formerly Gentiva Health Services) entered into a Distribution/Specialty Agreement for the distribution of Ampligen(R) for the treatment of ME/CFS patients under the U.S. treatment protocols.

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(R) varies significantly by geographic region, and we intend to adjust our clinical and marketing planning to reflect the specialty of each area. We have a marketing arrangement with Bioclones that covers South America, the United Kingdom, Ireland, Africa, Australia, Tasmania, New Zealand, and certain other countries and territories. In Spain, Portugal and Andorra we have entered into a Sales Distribution Agreement with Esteve.

On December 27, 2004 we initiated a lawsuit in Federal Court identifying a conspiratorial group seeking to illegally manipulate our stock for purposes of bringing about a hostile takeover of Hemispherx. This conspiratorial group includes Bioclones. This legal action may adversely affect our relationship and collaborative agreement with Bioclones.

Our sales and marketing agreement with Engitech, LLC. to distribute Alferon N on a nationwide basis did not produce the desired result. Sales have not increased as planned and we are currently expanding our in house sales and marketing effort. After much consideration, we are establishing an internal marketing and sales infrastructure to support the sales of Alferon N Injection in the United States, including marketing and sales support professionals based at our headquarters in Philadelphia, Pennsylvania. We have hired and trained our

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regional sales managers and are aggressively hiring and training more expertise in this field. We are targeting sales representatives with an average of 6-8 years of experience. Our sales force will promote Alferon to OB GYN's, dermatologists, physicians and particularly STD Clinics, who are involved in the treatment of patients with indications of refractory or reoccurring external genital warts, as well as educate physicians about the growing problem and the risks of HPV. In addition to marketing and sales personnel, we have hired The Schwartz Group, a telemarketing group.

The Schwartz Group is a marketing partner organization that works exclusively with companies selling products or services to Physicians, Hospitals, and Retail Pharmacies. They perform telemarketing campaigns that are designed to assist their clients and expand their reach and market share. We expect to use their leads to assist our sales force in making sales calls.

#### 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. ("Schering"). ALFERON N Injection(R) currently competes with a product produced by Schering for treating genital warts. 3M Pharmaceutical also has received FDA approval for its immune response modifier product for the 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(R) 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

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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(R) is only approved for use in intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection(R) 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 will continue to present data from time to time in support of obtaining accelerated review. We have not yet submitted any New Drug Application (NDA) for Ampligen(R) or any other drug to a North American regulatory authority. In 2000 we submitted an emergency treatment protocol for clinically-resistant HIV patients, which was withdrawn by us during the statutory 30 day regulatory review period in favor of a set of individual physician-generated applications. There are no assurances that authorizations to commence such treatments will be granted by any regulatory authority or that the resultant treatments, if any, will support drug efficacy and safety. In 2001, we did receive FDA authorization for two separate Phase IIB HIV treatment protocols in which our drug is combined with certain presently available antiretroviral agents. Interim results were presented in 2002 and 2003 at various international scientific meetings.

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(R) 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 AND DEVELOPMENT/COLLABORATIVE AGREEMENTS

In 1994, we entered into a licensing agreement with Bioclones (Proprietary) limited ("Bioclones") for manufacturing and international market development in Africa, Australia, New Zealand, Tasmania, the United Kingdom, Ireland and certain countries in South Africa, of Ampligen(R) and Oragen(TM). Bioclones is to pursue regulatory approval in the areas of its franchise and is required to conduct Hepatitis clinical trials, based on international GMP and GLP standards. Thus far, these Hepatitis studies have not yet commenced to a meaningful level. Bioclones has been given the first right of refusal, subject to pricing, to manufacture that amount of polymers utilized in the production of Ampligen(R) sufficient to satisfy at least one-third of the worldwide sales

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requirement of Ampligen(R) and other nucleic acid-derived drugs. Pursuant to this arrangement, we received: 1) access to worldwide markets, 2) commercial-scale manufacturing resources, 3) a \$3 million cash payment in 1995

from Bioclones, 4) a 24.9% ownership in Ribotech, Ltd., a company set up by Bioclones to develop and manufacture RNA drug compounds, and 5) royalties of 6% to 8% on Bioclones nucleic acid-derived drug sales in the licensed territories, after the first \$50 million of sales. The agreement with Bioclones terminates three years after the expiration of the last of the patents supporting the license granted to Bioclones, subject to earlier termination by the parties for uncured defaults under the agreement, or bankruptcy or insolvency of either party. The last patent expires on December 22, 2012. On December 27, 2004, we initiated a lawsuit in Federal Court identifying a conspiratorial group seeking to illegally manipulate our stock for purposes of bringing about a hostile takeover of Hemispherx. This conspiratorial group includes Bioclones. This legal action may adversely affect our relationship and collaborative agreement with Bioclones.

In 1998, we entered into a strategic alliance with Accredo to develop certain marketing and distribution capacities for Ampligen(R) 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(R) for which they received a fee. Through this arrangement, Hemispherx 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(R) from the FDA, at which time, a new agreement will need to be negotiated with Accredo or another major drug distributor. There were no initial fees.

We have acquired a series of patents on Oragen(TM), potentially an oral broad spectrum antiviral, immunological enhancer through a licensing agreement with Temple University. We were granted an exclusive worldwide license from Temple for the Oragen(TM) products. Pursuant to the arrangement, we are obligated to pay royalties of 2% to 4% on sales of Oragen(TM), depending on how much technological assistance is required of Temple. There were no initial fees and we currently pay minimum royalties of \$30,000 per year to Temple. These compounds have been evaluated in various academic laboratories for application to chronic viral and immunological disorders. 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(TM) patent expires on June 1, 2018.

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

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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(R) 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 to conduct research in an effort to develop intellectual property on potential new products for diagnosing and treating various chronic illnesses such as ME/CFS. 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. During the quarter ended December 31, 2002 and September 30, 2004 we recorded a noncash charge of \$292,000 and \$373,000, respectively, with respect to our investment in Chronix. This impairment reduces our carrying value to reflect a permanent decline in Chronix's market value based on its then proposed equity offerings.

In 1998, we invested \$1,074,000 for a 3.3% equity interest in R.E.D. Laboratory ("R.E.D."). R.E.D. is a privately held biotechnology company for the development of diagnostic markers for Chronic Fatigue Syndrome and other chronic immune diseases. Primarily, R.E.D.'s research and development is based on certain technology owned by Temple University and licensed to R.E.D. We have an informal collaboration arrangement with R.E.D. to assist in this development. We have supplied scientific data with respect to ME/CFS and engaged R.E.D. to conduct certain blood tests for our ME/CFS clinical trials. We have no other obligations to R.E.D. R.E.D. is headquartered in Belgium. The investment was recorded at cost in 1998. During the three months ended June 2002 and December 2002 respectively, we recorded a non-cash charge of \$678,000 and \$396,000, respectively, to operations with respect to our investment in R.E.D. These charges were the result of our determination that R.E.D.'s business and financial position had deteriorated to the point that our investment had been permanently impaired.

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In April, 1999 we acquired a 30% equity position in the California Institute of Molecular Medicine ("CIMM") for \$750,000. CIMM'S research is focused on developing therapies for use in treating patients affected by Hepatitis C ("HCV"). We use the equity method of accounting with respect to this investment. During the fourth quarter of 2001 we recorded a non-cash charge of \$485,000 with respect to our investment in CIMM. This was a result of our determination that CIMM's operations have not yet evolved to the point where the full carrying value of our investment could be supported based on that company's financial position and operating results. During 2002, CIMM continued to suffer significant losses resulting in a deterioration of its financial condition. The \$485,000 written off during 2001 represented the unamortized balance of goodwill included as part of our investment. Additionally, during 2001 we reduced our investment in CIMM based on our percentage interest in CIMM's continued operating losses. Our remaining investment at December 31, 2001 in CIMM, representing our 30% interest in CIMM's equity at such date, was not deemed to be permanently impaired, but was completely written off during 2002. Such amount was not material. These charges are reflected in the Consolidated Statements of Operations under the caption "Equity loss in unconsolidated affiliate". We still believe CIMM will succeed in their efforts to advance therapeutic treatment of HCV. We believe that CIMM's Hepatitis C diagnostic technology has great promise and will fill a long-standing global void in the collective abilities to diagnose and treat Hepatitis C infection at an early stage of the disorder.

In March 2002, our European subsidiary Hemispherx S.A. entered into a Sales and Distribution agreement with Esteve. Pursuant to the terms of the Agreement, Esteve was granted the exclusive right to market Ampligen(R) 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(R) 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(R) in the applicable territory. Pursuant to the terms of the agreement Esteve is to conduct clinical trials using Ampligen(R) to treat patients with both HCV and HIV and is required to purchase certain minimum annual amounts of Ampligen(R) following regulatory approval. Esteve initiated the HIV/HCV clinical trials in Spain in late 2004. The agreement is terminable by either party if Ampligen(R) 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(R) 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.

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 \$11,938,000 in research and development, of which approximately \$3,842,000 was expended in the year ended December 31, 2004. These direct costs do not include the overhead and administrative costs necessary to support the research and development effort. Our European subsidiary has an exclusive license on all the technology and support from us concerning

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Ampligen(R) for the use of ME/CFS and other applications for all countries of the European Union (excluding the UK where Bioclones has a marketing license) and Norway, Switzerland, Hungary, Poland, the Balkans, Russia, Ukraine, Romania, Bulgaria, Slovakia, Turkey, Iceland and Liechtenstein. As mentioned above, Hemispherx S.A. entered into a Sales and Distribution Agreement with Esteve. Pursuant to the terms of this agreement, Esteve has been granted the exclusive right in Spain, Portugal and Andorra to market Ampligen(R) for the treatment of ME/CFS. See "European Operations", above for more detailed information.

## HUMAN RESOURCES

As of January 31, 2005, we had 54 personnel consisting of 37 full time employees, 17 regulatory/research medical personnel on a part-time basis. Part time personnel are paid on a per diem or monthly basis. 35 personnel are engaged in our research, development, clinical, and manufacturing effort. 19 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.

We believe that the combination of Hemispherx and ISI Scientific employees has 1) significantly strengthened our overall organization, 2) added expertise to monitor and complete our ongoing clinical trials and 3) improved our data management and system administration.

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. In addition, individual Scientific Advisory Board Members sometimes will 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.

In January 2004 a meeting was held in Philadelphia where certain Scientific Advisory Board members from Cornell University, University of Virginia and the Pasteur Institute gathered to review and make suggestions pertaining to our clinical and research programs in 2004. A member of our Board of Directors, Dr. William Mitchell of Vanderbilt University, also attended the meeting.

## RECENT FINANCING AND ASSET ACQUISITIONS

On March 12, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due January 2005 (the "March Debentures") and an aggregate of 743,288 warrants to two investors in a private placement for aggregate gross proceeds of \$4,650,000. The March Debentures were to mature on January 31, 2005 and bore interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest

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were valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Pursuant to the terms and conditions of the March Debentures, we pledged all of our assets, other than our intellectual property, as collateral and were subject to comply with certain financial and negative covenants, which include but were not limited to the repayment of principal balances upon achieving certain revenue milestones.

The March Debentures were convertible at the option of the investors at any time through January 31, 2005 into shares of our common stock. The conversion price under the March Debentures was fixed at \$1.46 per share, subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect.

The investors also received Warrants to acquire at any time through March 12, 2008 an aggregate of 743,288 shares of common stock at a price of \$1.68 per share.

We entered into a Registration Rights Agreement with the investors in connection with the issuance of the March Debentures and the Warrants. The Registration Rights Agreement requires that we register the shares of common stock issuable upon conversion of the Debentures, as interest shares under the Debentures and upon exercise of the Warrants. In accordance with this agreement, we have registered these shares for public sale.

As of December 31, 2003, the investors had converted the total \$5,426,000 principal of the March Debentures into 3,716,438 shares of our common stock. The total interest on these debenture was \$111,711 of which \$17,290 was paid in cash and \$94,421 was paid by the issuance of shares of our common stock. The investor exercised all 743,288 warrants in July 2003 which produced proceeds in the amount of \$1,248,724.

On July 10, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due July 31, 2005 (the "July 2003 Debentures") and an aggregate of 507,102 Warrants (the "July 2003 Warrants") to the same investors who purchased the March Debentures, in a private placement for aggregate proceeds of \$4,650,000. Pursuant to the terms of the July 2003 Debentures, \$1,550,000 of the proceeds from the sale of the July 2003 Debentures were to have been held back and released to us if, and only if, we acquired

ISI's facility with in a set timeframe. These funds were released to us in October 2003 although we had not acquired ISI's facility at that time. The July 2003 Debentures mature on July 31, 2005 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date.

The July 2003 Debentures are convertible at the option of the investors at any time through July 31, 2005 into shares of our common stock. The conversion price under the July 2003 Debentures was fixed at \$2.14 per share; however, as part of the subsequent debenture placement closed on October 29, 2003 (see below), the conversion price under the July 2003 Debentures was lowered to \$1.89 per share. The conversion price is subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then

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in effect. In addition, in the event that we do not pay the redemption price at maturity, the Debenture holders, at their option, may convert the balance due at the lower of (a) the conversion price then in effect and (b) 95% of the lowest closing sale price of our common stock during the three trading days ending on and including the conversion date.

The July 2008 Warrants received by the investors, as amended, were an aggregate of 507,102 shares of common stock at a price of \$2.46 per share. These Warrants were exercised in July 2004 which produced gross proceeds in the amount of \$1,247,470.

On June 25, 2003, we issued to each of the March 12, 2003 Debenture holders warrants to acquire at any time through June 25, 2008 an aggregate of 1,000,000 shares of common stock at a price of \$2.40 per share (the "June 2008 Warrants"). These warrants were issued as incentive for the Debenture holders to exercise prior warrant issuances. This issuance resulted in an additional debt discount to the March debentures of \$2,640,000. Pursuant to our agreement with the Debenture holders, we have registered the shares issuable upon exercise of these June 2008 Warrants for public sale. These warrants were exercised in May 2004 and we received gross proceeds of \$2,400,000.

As of December 31, 2004, the investors had converted all of the \$5,426,000 principal of the July Debentures into 2,870,900 shares of common stock.

On October 29, 2003, we issued an aggregate of \$4,142,357 in principal amount of 6% Senior Convertible Debentures due October 31, 2005 (the "October 2003 Debentures") and an aggregate of 410,134 Warrants (the "October 2008 Warrants") in a private placement for aggregate gross proceeds of \$3,550,000. Pursuant to the terms of the October 2003 Debentures, \$1,550,000 of the proceeds from the sale of the October 2003 Debentures were held back and were to be released to us if, and only if, we acquired ISI's facility within 90 days of January 26, 2004 and provide a mortgage on the facility as further security for the October 2003 Debentures. In March 2004, we acquired the facility and we subsequently provided the mortgage of the facility to the Debenture holders. The October 2003 Debentures mature on October 31, 2005 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date.

Upon completing the sale of the October 2003 Debentures, we received \$3,275,000 in net proceeds consisting of \$1,725,000 from the October 2003 Debentures and \$1,550,000 that had been withheld from the July 2003 Debentures. As noted above, pursuant to the terms of the October 2003 Debentures, \$1,550,000 of the proceeds from the sale of the October 2003 Debentures had been held back. However, these proceeds were released to us in April 2004. As required by the Debentures, we have provided a mortgage on the ISI facility as further security for the Debentures.

The October 2003 Debentures are convertible at the option of the investors at any time through October 31, 2005 into shares of our common stock. The conversion price under the October 2003 Debentures is fixed at \$2.02 per share, subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect. In addition, in the event that we

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do not pay the redemption price at maturity, the Debenture holders, at their option, may convert the balance due at the lower of (a) the conversion price then in effect and (b) 95% of the lowest closing sale price of our common stock during the three trading days ending on and including the conversion date.

The October 2008 Warrants, as amended, received by the investors were to acquire an aggregate of 410,134 shares of common stock at a price of \$2.32 per share. These Warrants were exercised in July 2004 which produced gross proceeds in the amount of \$951,510.

As of December 31, 2004, the investors had converted \$2,071,178 principal amount of the Debenture into 1,025,336 shares of common stock.

On January 26, 2004, we issued an aggregate of \$4,000,000 in principal amount of 6% Senior Convertible Debentures due January 31, 2006 (the "January

2004 Debentures"), an aggregate of 790,514 warrants (the "July 2009 Warrants") and 158,103 shares of common stock, and Additional Investment Rights (to purchase up to an additional \$2,000,000 principal amount of January 2004 Debentures commencing in six months) in a private placement for aggregate net proceeds of \$3,695,000. The January 2004 Debentures mature on January 31, 2006 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Commencing July 26, 2004, we are required to start repaying the then outstanding principal amount under the January 2004 Debentures in monthly installments amortized over 18 months in cash or, at our option, in shares of common stock. After one installment payment of \$111,111 in our common stock, one debenture holder exercised their right to waive further installment payments on their note. Any shares of common stock issued to the investors as installment payments shall be valued at 95% of the average closing price of the common stock during the 10-day trading period commencing on and including the eleventh trading day immediately preceding the date that the installment is due.

The January 2004 Debentures are convertible at the option of the investors at any time through January 31, 2006 into shares of our common stock. The conversion price under the January 2004 Debentures was fixed at \$2.53 per share, subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect. In addition, in the event that we do not pay the redemption price at maturity, the Debenture holders, at their option, may convert the balance due at the lower of (a) the conversion price then in effect and (b) 95% of the lowest closing sale price of our common stock during the three trading days ending on and including the conversion date. Upon completion of the August 2004 Private Placement (see below), the conversion price was lowered to \$2.08 per share. As of December 31, 2004, the remaining principal on these debentures was \$3,083,073. The investors converted \$139,150 principal amount of the January 2004 Debenture into 55,000 shares of our common stock. In addition, installment payments of \$777,777 were made to our investors amounting to 358,932 shares of our common stock.

There are two classes of July 2009 Warrants received by the Investors: Class A and Class B. The Class A warrants are to acquire any time from July 26, 2004 through July 26, 2009 an aggregate of up to 395,257 shares of common stock at a price of \$3.29 per share. The Class B warrants are to acquire any time from July 26, 2004 through July 26, 2009 an aggregate of up to 395,257 shares of

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common stock at a price of \$5.06 per share. On January 27, 2005, the exercise price of these July 2009 Class A and Class B Warrants was to reset to the lesser of their respective exercise price then in effect or a price equal to the average of the daily price of the common stock between January 27, 2004 and January 26, 2005. The exercise price (and the reset price) under the July 2009 Warrants also is subject to similar adjustments for anti-dilution protection. Notwithstanding the foregoing, the exercise prices as reset or adjusted for anti-dilution, will in no event be less than \$2.58 per share. Upon completion of the August 2004 Private Placement (see below), the exercise price was lowered to \$2.58 per share.

We also issued to the investors Additional Investment Rights pursuant to which the investors have the right to acquire up to an additional \$2,000,000 principal amount of January 2004 Debentures (the July 2004 Debentures") from us. The July 2004 Debentures are identical to the January 2004 Debentures except that the conversion price is \$2.58. The investors exercised the Additional Investment Rights on July 13, 2004 and we received net proceeds of 1,860,000. Upon completion of the August 2004 Private Placement (see below), the conversion price was lowered to \$2.08 per share. As of December 31, 2004, the Debenture holders had not converted any portion of this debenture.

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

On May 14, 2004, in consideration for the Debenture holders' exercise of all of the June 2008 Warrants, we issued to the holders warrants (the "May 2009 Warrants") to purchase an aggregate of 1,300,000 shares of our common stock. As a result, the warrants were valued at \$2,355,000 which was recorded as additional debt discount. We issued 1,000,000 shares of common stock and received gross proceeds of \$2,400,000 from the exercise of the June 2008 Warrants.

The May 2009 Warrants are to acquire at any time commencing on November 14, 2004 through April 30, 2009 an aggregate of 1,300,000 shares of common stock at a price of \$4.50 per share. On May 14, 2005, the exercise price of these May 2009 Warrants will reset to the lesser of the exercise price then in effect or a price equal to the average of the daily price of the common stock between May 15, 2004 and May 13, 2005. The exercise price (and the reset price) under the May 2009 Warrants also is subject to adjustments for anti-dilution protection similar to those in the other Warrants. Notwithstanding the foregoing, the exercise price as reset or adjusted for anti-dilution, will in no event be less than \$4.008 per share. This transaction generated a non-cash charge of about \$2,300,000 financing costs in the second quarter of 2004. Upon completion of the August 2004 Private Placement (see below), the exercise price was lowered to \$4.008 per share.

We entered into Registration Rights Agreements with the investors in connection with the issuance of (i) the Debentures; (ii) the June 2008, July 2008, October 2008, July 2009, and May 2009 Warrants (collectively, the "Warrants"); and (iii) the shares issued in January 2004. Pursuant to the Registration Rights Agreements we have registered on behalf of the investors the shares issued to them in January 2004 and 135% of the shares issuable upon conversion of the Debentures and upon exercise of all of the Warrants. If, subject to certain exceptions, sales of all shares so registered cannot be made pursuant to the registration statements, then we will be required to pay to the

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investors their pro rata share of \$.00067 times the outstanding principal amount of the relevant Debentures for each day the above condition exists.

Section 713 of the American Stock Exchange ("AMEX") Company Guide provides that we must obtain stockholder approval before issuance, at a price per share below market value, of common stock, or securities convertible into common stock, equal to 20% or more of our outstanding common stock (the "Exchange Cap"). The Debentures (including the July 2004 Debentures) and Warrants have provisions that require us to pay cash in lieu of issuing shares upon conversion of the Debentures or exercise of the Warrants if we are prevented from issuing such shares because of the Exchange Cap. In May 2004, the Debenture holders agreed to amend the provisions of these Debentures and Warrants to limit the maximum amount of funds that the holders could receive in lieu of shares upon conversion of the Debentures and/or exercise of the Warrants in the event that the Exchange Cap was reached to 119.9% of the conversion price of the relevant Debentures and 19.9% of the relevant Warrant exercise price.

As of December 31, 2004, the investors have converted \$13,062,329 principal amount of debt from the Debentures issued in March, July and October 2003 and January 2004 into 8,026,606 shares of our common stock. \$777,777 of principal was repaid with the issuance of 358,932 shares of stock. The March and July Debentures have been fully converted. The remaining principal balance on the outstanding Debentures is convertible into shares of our stock at the option of the investors at any time, through the maturity date. In addition, we have paid \$1,300,000 into the debenture cash collateral account as required by the terms of the October 2003 Debentures. The amounts paid through December 31, 2004 have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of December 31, 2004. The cash collateral account provides partial security for repayment of the outstanding Debentures in the event of default.

By agreement with Cardinal Securities, LLC, for general financial advisory services and in conjunction with the private debenture placements in July and October 2003 and in January, May and July 2004, we paid Cardinal Securities, LLC an investment banking fee equal to 7% of the investments made by the two Debenture holders and issued to Cardinal the following common stock purchase warrants: (i) 112,500 exercisable at \$2.57 per share; (ii) 87,500 exercisable at \$2.42 per share; and (iii) 100,000 exercisable at \$3.04 per share. The \$2.57 warrants expire on July 10, 2008, the \$2.42 warrants expire on October 29, 2008 and the \$3.04 warrants expire on January 5, 2009. With regard to the exercise of the June 2008 Warrants and issuance of the May 2009 Warrants, Cardinal received an investment banking fee of 7%, half in cash and half in shares. With regard to the exercise of the Additional Investment Rights, the July 2008 and October 2008 Warrants and issuance of the July 2009 Warrants, Cardinal received an investment banking fee of 7%, 146,980 in cash and 22,703 in shares as well as 50,000 warrants exercisable at \$4.07 expiring on July 12, 2009. By agreement with Cardinal, we have registered all of the foregoing shares and shares issuable upon exercise of the above mentioned warrants for public sale and we have agreed to register the balance. As a result of all of the transactions discussed above, we recorded \$1,430,000 as additional debt discount.

Section 713 of the American Stock Exchange ("AMEX") Company Guide provides that we must obtain stockholder approval before issuance, at a price per share below market value, of common stock, or securities convertible into common stock, equal to 20% or more of our outstanding common stock (the "Exchange Cap"). Taken separately, the July 2003, October 2003 and January 2004 Debenture transactions do not trigger Section 713. However, the AMEX took the

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position that the three transactions should be aggregated and, as such, stockholder approval was required for the issuance of common stock for a portion of the potential exercise of the warrants and conversion of the Debentures in connection with the January 2004 Debentures. The amount of potential shares that we could exceed the Exchange Cap amounted to approximately 1,299,000. In accordance with EITF 00-19, Accounting For Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock, we recorded on January 26, 2004, a redemption obligation of approximately \$1,244,000. This liability represented the fair market value of the warrants and beneficial conversion feature related to the 1,299,000 shares.

In addition, in accordance with EITF 00-19, we revalued this redemption obligation associated with the beneficial conversion feature and warrants as of March 31, 2004. We recorded an additional redemption obligation and finance charge of \$947,000 as a result of this revaluation. Upon stockholder approval, our redemption obligation was recorded as additional paid in capital as of the date approval was received.

The requisite stockholder approval was obtained at our Annual Meeting of Stockholders on June 23, 2004. In accordance with EITF 00-19, we revalued this redemption obligation associated with the beneficial conversion feature and warrants as of June 23, 2004. We recorded a reduction in the value of the

redemption obligation and financing charge of \$260,000 as a result of this revaluation. In addition, upon receiving the requisite stockholder approval, this redemption obligation was reclassified as additional paid in capital as of the date the approval was received or June 23, 2004.

On July 13, 2004, the Debenture holders exercised all of the July 2003 and October 2003 Warrants and the Additional Investment Rights amounting to approximately \$4,198,980 in gross proceeds to us. We issued to these holders warrants (the "June 2009 Warrants") to purchase an aggregate of 1,300,000 shares of common stock. The issuance of these warrants resulted in an additional debt discount to the note of 1,320,000 as explained below and a financing charge of \$2,351,000.

The June 2009 Warrants are to acquire at any time commencing on January 13, 2005 through June 30, 2009 an aggregate of 1,300,000 shares of common stock at a price of \$3.75 per share. On July 13, 2005, the exercise price of these June 2009 Warrants will reset to the lesser of the exercise price then in effect or a price equal to the average of the daily price of the common stock between July 14, 2004 and July 12, 2005. The exercise price (and the reset price) under the June 2009 Warrants also is subject to adjustments for anti-dilution protection similar to those in the other Warrants. Notwithstanding the foregoing, the exercise price as reset or adjusted for anti-dilution, will in no event be less than \$3.33 per share. Upon completion of the August 2004 Private Placement (see below), the exercise price was lowered to \$3.33 per share. This transaction was subject to a non-cash financing charge of \$1,320,000 to be amortized over the remaining life of the October 2003 Debentures. We agreed to register the shares issuable upon exercise of the June 2009 Warrants pursuant to substantially the same terms as the registration rights agreements between us and the holders. Pursuant to this obligation, we have registered the shares.

On August 5, 2004, we closed a private placement with select institutional investors of approximately 3,617,300 shares of our Common Stock and warrants to purchase an aggregate of up to approximately 1,085,200 shares of its Common Stock. Jefferies & Company, Inc. acted as Placement Agent for which <PAGE> 26 it received a fee and Common Stock Purchase Warrants. We raised approximately \$7,524,000 (\$6,984,000, net) in gross cash proceeds from this private offering.

The Warrant issued to each purchaser is exercisable for up to 30% of the number of shares of Common Stock purchased by such Purchaser, at an exercise price equal to \$2.86 per share. Each Warrant has a term of five years and is fully exercisable from the date of issuance.

Pursuant to the Registration Rights Agreement, made and entered into as of August 5, 2004 (the "Rights Agreement"), we have registered the resales of the shares issued to the Purchasers and shares issuable upon the exercise of the Warrants.

Closing of the August 2004 Private Placement triggered the anti-dilution provisions of the January 2004 Debentures and the July 2004 Debentures and the July 2009 Warrants and the June 2009 Warrants. The conversion price adjustment for the Debentures noted above resulted in an adjustment of \$1,320,000 in the third quarter 2004 to the Debenture discount and additional paid-in-capital. Any adjustment to the Debenture discount will be amortized over the remaining life of the Debentures. The exercise price adjustment for the above warrants resulted in a non-cash financing adjustment in the third quarter 2004 upon revaluing the warrants at the new anti-dilution pricing using the Black-Scholes Method.

As of December 31, 2004, the Company was in violation of one minor debt covenant contained within its debenture agreement. Subsequently, the Company obtained a letter of waiver from the debenture holders with respect with this matter.

In connection with the Debenture agreements, we have outstanding letters of credit of \$1 million as additional collateral.

Prior to our annual meeting of stockholders in September 2003, we had a limited number of shares of Common Stock authorized but not issued or reserved for issuance upon conversion or exercise or outstanding convertible and exercisable securities such as debentures, options and warrants. Prior to the meeting, to permit consummation of the sale of the July 2003 Debentures and the related warrants, Dr. Carter agreed that he would not exercise his warrants or options unless and until our stockholders approve an increase in our authorized shares of common stock. For Dr. Carter's waiver of his right to exercise certain options and warrants prior to approval of the increase in our authorized shares, and for Dr. Carter's entering into a \$250,000 letter of credit benefiting the Debenture holders in the event of a default, we agreed to compensate Dr. Carter with 1,450,000 warrants to purchase common stock at \$2.20 per share. This resulted in compensation expense of \$1,769,000 which was charged to operations.

On March 11, 2003, we acquired from ISI, ISI's inventory of ALFERON N Injection(R) and a limited license for the production, manufacture, use, marketing and sale of this product. As partial consideration, we issued 487,028 shares of our common stock to ISI Pursuant to our agreements with ISI, we registered these shares for public sale and ISI has reported that it has sold all of these shares. We also agreed to pay ISI 6% of the net sales of ALFERON N Injection(R).

On March 11, 2003, we also entered into an agreement to purchase from ISI all of its rights to the product and other assets related to the product including, but not limited to, real estate and machinery. For these assets, we agreed to issue to ISI an additional 487,028 shares and to issue 314,465 shares and 267,296 shares, respectively to the American National Red Cross and GP

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Strategies Corporation, two creditors of ISI. We guaranteed the market value of all but 62,500 of these shares to be \$1.59 per share on the termination date. As discussed below, we issued all of these shares and ISI, GP Strategies and the American National Red Cross have reported that they have sold all of their shares.

We also agreed to satisfy other liabilities of ISI which were past due and secured by a lien on ISI's real estate and to pay ISI 6% of the net sales of products containing natural alpha interferon.

On May 30, 2003, we issued the shares to GP Strategies and the American National Red Cross. Pursuant to our agreements with ISI and these two creditors, we registered the foregoing shares for public sale. We guaranteed the market value all but 62,500 of these shares to be \$1.59 per share. As a result at December 31, 2003 the guaranteed value of these shares (\$491,000), which had not been sold by these two creditors, were reclassified to redeemable common stock. At December 31, 2004 all shares had been sold by these two creditors and the redeemable common stock was reclassified to equity.

On November 6, 2003, we acquired, and subsequently paid the outstanding ISI property tax lien certificates in the aggregate amount of \$457,000 from certain investors. These tax liens were issued for property taxes and utilities due for 2000, 2001 and 2002.

In March 2004, we issued 487,028 shares to ISI to complete the acquisition of the balance of ISI's rights to market its product as well its production facility in New Brunswick, New Jersey. ISI has sold all of its shares.

The aggregated cost of the land and buildings in New Brunswick, New Jersey was approximately \$3,316,000. The cost of the land and buildings was allocated as follows:

Land	\$ 423,000
Buildings	2,893,000
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Total cost	\$ 3,316,000
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We accounted for these transactions as a Business Combination under Statement of Financial Accounting Standards ("SFAS") No. 141 Accounting for Business Combinations.

On March 13, 2003, we issued 347,445 shares of our common stock to Provesan SA, an affiliate of Esteve, in exchange for 1,000,000 Euros of convertible preferred equity certificates of Hemispherx Biopharma Europe, S.A., owned by Esteve, and all dividends earned and to be earned through September 30, 2003. We agreed to register the shares issued to Provesan SA, and we have registered these shares for public sale.

As of December 31, 2004, we had approximately \$16,737,000 in cash and short term investments. These funds should be sufficient to meet our operating cash requirements including debt service for the near term. However, 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(R) products. There can be no assurances that we will raise adequate funds from

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these or other sources, 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.

Because of our long-term capital requirements, we may seek to access the public equity market whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. 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.

#### 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:

No assurance of successful product development

Ampligen(R) and related products. The development of Ampligen(R) and our other related products is subject to a number of significant risks. Ampligen(R) 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(R) 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 U.S. Food and Drug Administration ("FDA") for commercial sale.

ALFERON N Injection(R). Although ALFERON N Injection(R) is approved for marketing in the United States for the intralesional 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(R) 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(R) is only approved for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of ALFERON N Injection(R) for other indications will require regulatory approval.

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In this regard, Interferon Sciences, Inc. ("ISI"), the company from which we obtained our rights to ALFERON N Injection(R), conducted clinical trials related to use of ALFERON N Injection(R) 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(R) in the treatment of HIV and Hepatitis C diseases. We have no obligation or immediate plans to conduct these additional studies at this time.

Our products, including Ampligen(R), 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 European Medical Evaluation Agency ("EMEA") 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(R) or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen(R) will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligen(R) is authorized for use in clinical trials in the United States and other countries, 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(R) 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.

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 and expanded our efforts in Europe. As of December 31, 2004 our accumulated deficit was approximately \$137,983,000. 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, 2004, we had approximately \$16,737,000 in cash and cash equivalents and short-term investments. We believe that these funds should be sufficient to meet our operating cash requirements including debt service during the next 24 months. 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 and begin commercializing Ampligen(R) products. There can be no assurances that we will  
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raise adequate funds from these or other sources, which may have a material adverse effect on our ability to develop our products.

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(R) for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen(R) for such disease. We obtained all rights to ALFERON N Injection(R), 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(R) and Ampligen(R) in combination with certain other drugs for the treatment of HIV. We also have been issued patents on the use of Ampligen(R) 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(R) in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of Ampligen(R) as a sole treatment for any of the cancers, which we have sought to target. With regard to ALFERON N Injection(R), we have acquired from ISI its patents for natural alpha interferon produced from human peripheral blood leukocytes and its production process. 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.

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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 the potential to provide some marketing and distribution capacity in the United States while agreements with Bioclones (Proprietary), Ltd, Biovail Corporation and Laboratorios Del Dr. Esteve S.A. may provide a sales force in South America, Africa, United Kingdom, Australia and New Zealand, Canada, Spain and Portugal. On December 27, 2004, we initiated a lawsuit in Federal Court identifying a conspiratorial group seeking to illegally manipulate our stock for purposes of bringing about the hostile takeover of Hemispherx. This conspiratorial group includes Bioclones and the potential legal action may adversely effect our agreement with Bioclones and the potential for marketing and distribution capacity in South America, Africa, United Kingdom, Australia and New Zealand.

We cannot assure that our domestic 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(R).

A number of essential materials are used in the production of ALFERON N Injection(R), 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

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can enter into long-term supply agreements covering essential materials on commercially reasonable terms, if at all.

At present, we do not have any agreements with third parties for the supply of any polymers for use in manufacturing Ampligen. We are consolidating relevant manufacturing operations into our New Brunswick, New Jersey facility for the production of Ampligen raw materials. This consolidation and transfer of manufacturing operations has been implemented as an inspection of the Ribotech facility in South Africa, our previous supplier of Ampligen(R) raw materials, indicated that it did not, at present, meet the necessary GMP standards for a fully certified commercial process. The transfer of Ampligen(R) raw materials manufacture to our own facilities, while having obvious advantages with respect to regulatory compliance (other parts of the 43,000 sq. ft. wholly owned facility are already in compliance for Alferon N manufacture), may delay certain steps in the commercialization process, specifically a targeted NDA filing.

If we are unable to obtain 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(R) and the commercial production of ALFERON N Injection(R) 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 may affect the chemical structure of Ampligen(R) and other RNA drugs, as well as their safety and efficacy. Changes in methods of manufacture, including commercial scale-up may affect the chemical structure of Ampligen(R) 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(R) has been only produced in limited quantities for use in our clinical trials and we are dependent upon certain third party suppliers for key components of our products and 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

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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 and HPB

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.

In connection with settling various manufacturing infractions previously noted by the FDA, Schering-Plough ("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(R) (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(R) in this facility beyond 2004 and would assist us in an orderly transfer of said activities to other non Schering facilities. Accordingly, we have entered into a Confidentiality Agreement with Mayne Pharma Pty, Ltd ("Mayne") to lead to reinitiation and expansion of its Ampligen(R) manufacturing program. We are currently in discussions with Mayne to provide us with proposals on manufacturing Ampligen(R) at their facility. Mayne (formerly known as Faulding Pharma) has already successfully manufactured Ampligen(R) several times for ongoing clinical trials, and maintains a fully GMP compliant facility. Simultaneously, we expect to qualify at least one other GMP facility to maintain a minimum of two independent production sites. If we are unable to engage Mayne and/or additional manufacturers in a timely manner, our plans to file an NDA for Ampligen(R) and, eventually, to market and sell Ampligen(R) will be delayed.

The purified drug concentrate utilized in the formulation of ALFERON N Injection(R) is manufactured in our New Brunswick, New Jersey facility and ALFERON N Injection(R) is formulated and packaged at a production facility operated by Abbott Laboratories located in Kansas. We are dependent upon Abbott Laboratories and/or another third party for product formulation and packaging.

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

We have never produced Ampligen(R) 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(R) or enter into third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Also, each production lots of Alferon N Injection(R) 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. Alferon N Injection(R) presently has a shelf life of 18 months after having been bottled. Studies are being conducted to possibly extend the shelf life to 24 months.

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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(R) . 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 Smithkline, 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(R) on the immune system, we cannot assure that we will be able to compete.

ALFERON N Injection(R). Many 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.

ALFERON N Injection(R) currently competes with Schering's injectable recombinant alpha interferon product (INTRON(R) A) for the treatment of genital warts. 3M Pharmaceuticals also received FDA approval for its immune-response modifier, Aldara(R), a self-administered topical cream, for the treatment of external genital and perianal warts. ALFERON N Injection(R) 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(R). If and when we obtain additional approvals of uses of this product, we expect to compete primarily on the basis of product performance. Our potential 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(R) for the treatment of new indications, we will

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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(R). Currently, our wholesale price on a per unit basis of ALFERON N Injection(R) 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(R) or ALFERON N Injection(R) could adversely affect potential revenues and physician/patient acceptability of our product.

Ampligen(R). We believe that Ampligen(R) 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(R) in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

ALFERON N Injection(R). At present, ALFERON N Injection(R) is only approved for the intralesional (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(R), 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(R) which could threaten or limit such product's usefulness.

We may be subject to product liability claims from the use of Ampligen(R) 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(R) 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

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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'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(R), 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 May 8, 2008. 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 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.

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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:

- o announcements of the results of clinical trials by us or our competitors;
- o adverse reactions to products;
- o 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;
- o changes in U.S. or foreign regulatory policy during the period of product development;
- o developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- o announcements of technological innovations by us or our competitors;
- o announcements of new products or new contracts by us or our competitors;
- o actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- o changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- o conditions and trends in the pharmaceutical and other industries;
- o new accounting standards; and
- o 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, 2004, the price of our common stock has ranged from \$1.50 to \$5.40 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.

As of February 15, 2005, approximately 4,178,454 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act of 1933. 4,050,566 of these shares have been registered pursuant to agreements between us and the holders of these shares. In addition, we have registered 9,754,392 shares issuable (i) upon conversion of approximately 135% of the January 2004 Debentures, the October 2003 Debentures, the July 2003 Debentures and the July 2004 Debentures; (ii) as payment of 135% of the interest

on all of the Debentures; (iii) upon exercise of 135% of the July 2009 Warrants issued in conjunction with the January 2004 Debentures, the May 2009 Warrants and the June 2009 Warrants; and (iv) upon exercise of certain other warrants.

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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.

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 10.9% 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

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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(R) 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 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 lease space of approximately 3,850 square feet in Rockville, Maryland for research and development, our pharmacy, packaging, quality assurance and quality control laboratories, as well as additional office space. We also currently occupy and use the 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 has offices, laboratories and production space and shipping and receiving areas. Building Two has 11,670 square feet consisting of offices, laboratories and warehouse space. The property has parking space for approximately 100 vehicles.

Our lease on the Rockville facility expires in June 2005 and we are in the process of moving our laboratory and equipment to our New Brunswick facility. Consolidation of this laboratory with our existing laboratory in New Brunswick will provide economical benefit. We believe that when the

consolidation is completed the consolidated facility will enable us to meet our requirements for planned clinical trials and treatment protocols for the foreseeable future.

We also have a 24.9% interest in Ribotech, Ltd. located in South Africa. Ribotech was established by Bioclones to develop and operate a manufacturing facility. Raw materials production at the pilot facility commenced in 1996. The pilot facility was shut down in 2004 and Ribotech has started construction on a new production facility. At this time we have no assurance that this facility will be completed. We have no obligation to fund this construction. Our interest in Ribotech, is a result of the marketing and manufacturing agreement executed with Bioclones in 1994.

### 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 <PAGE> 40 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 has now petitioned the Supreme Court of Pennsylvania for allowance of an appeal. We have opposed Asensio's petition for allowance of appeal and the matter is now pending before the Supreme Court of Pennsylvania.

In June 2002, a former ME/CFS clinical trial patient and her husband filed a claim in the Superior Court of New Jersey, Middlesex County, against us, one of our clinical trial investigators and others alleging that she was harmed in the ME/CFS clinical trial as a result of negligence and breach of warranties. On June 25, 2004 all claims against us were dismissed with prejudice. The former ME/CFS clinical trial patient and her husband have now appealed the dismissal of their claims to the New Jersey Superior Court, Appellate Division, where the matter is now pending.

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 our 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 June 2004, One Penn Associates, L.P. filed a claim in the Philadelphia Municipal Court for the Commonwealth of Pennsylvania seeking \$44,242.68 for alleged unpaid rent and charges related to our offices in One Penn Center in Philadelphia. We believe this claim is without merit and are defending same pursuant to the terms of our lease as we were damaged and deprived of the use of a portion of the offices due to water from the landlord's faulty sprinkler system.

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 Donninger, R. B. Kebble, H. C. Buitendag, Bart Goemaere, and John Doe(s).

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 Hemispherx's public shareholders. 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.

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, 2004.

PART II

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

Between October 1, 2004 and March 1, 2005, we issued 524,528 shares of common stock consisting of 1) 470,807 shares for debt repayment, and interest payments related to the 6% Convertible Debentures. and 2) 53,721 shares in payment of services rendered.

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.

COMMON STOCK	High	Low
	----	---
Time Period:		
January 1, 2003 through March 31, 2003	\$2.19	\$1.33
April 1, 2003 through June 30, 2003	3.35	1.33
July 1, 2003 through September 30, 2003	2.35	1.85
October 1, 2003 through December 31, 2003	2.94	1.83
Time Period:		
January 1, 2004 through March 31, 2004	4.85	2.27
April 1, 2004 through June 30, 2004	5.40	3.30
July 1, 2004 through September 30, 2004	3.54	2.10
October 1, 2004 through December 31, 2004	2.50	1.50

As of March 11, 2005, there were approximately 258 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 11, 2005, the last sale price for our common stock on the AMEX was \$1.44 per share.

We have not paid any 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.

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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, 2004.

<TABLE>  
<CAPTION>

	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))
<S>	<C>	<C>	<C>
Plan Category	(a)	(b)	(c)
Equity compensation plans approved by security holders:	921,997	\$ 2.66	7,538,801
Equity compensation plans not approved by security holders:	-	-	-
	-----	-----	-----

Total 921,997 \$ 2.66 7,538,801

</TABLE>

In September 2003, our Board of Directors changed the non-employee Board Member compensation to be 50% cash and 50% stock. The Board's stock compensation is to be paid on the first day of each calendar quarter. 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 trading day of the preceding quarter. In no event shall the number of shares issued under this plan exceed 1,000,000 shares over a ten year period.

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

<TABLE>

<CAPTION>

<S>

	<C>	<C>	<C>	<C>	<C>
Year Ended					
December 31	2000	2001	2002	2003(2)	2004
-----	----	----	----	-----	----
Statement of Operations Data:					
Revenues and License fee Income					
	\$788	\$390	\$904	\$657	\$1,229
Total Costs and Expenses(1)					
	9,831	9,192	6,961	7,909	12,118
Interest Expense and Financing Costs(3)					
	-	-	-	7,598	12,927
Net loss					
	(8,552)	(9,083)	(7,424)	(14,770)	(24,140)
Basic and diluted net loss per share					
	(0.29)	(0.29)	(0.23)	(0.42)	(0.53)
Shares used in computing basic and diluted net loss per share					
	29,251,846	31,433,208	32,085,776	35,234,526	45,177,862
Balance Sheet Data:					
Working Capital					
	\$7,550	\$7,534	\$2,925	\$7,000	\$14,504
Total Assets					
	13,067	12,035	6,040	13,404	25,172
Common Stockholders Equity					
	11,572	10,763	3,630	9,248	20,081
Other Cash Flow Data:					
Cash used in operating activities					
	\$(8,074)	\$(7,281)	\$(6,409)	\$(7,022)	\$(7,240)
Capital expenditures					
	(171)	-	-	(19)	(1,696)

</TABLE>

(1) General and Administrative expenses include stock compensation expense totaling \$397,000, \$673,000, \$132,000, \$237,000, \$2,000,000 for the years ended December 31, 2000, 2001, 2002, 2003 and 2004, respectively.

(2) For information concerning the acquisition of certain assets of ISI and related financing see note 4 to our consolidated financial statements for the year ended December 31, 2004.

(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 \$5,426,000, \$5,426,000, \$4,142,357, and \$4,000,000 and \$2,000,000 respectively, and related embedded conversion features and

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warrant issuances, we recorded debt discounts of approximately \$17.4 million which, in effect, reduced the carrying value of the debt to \$3.6 million. For additional information refer to note 7 to our consolidated financial statements for the year ended December 31, 2004.

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, 2004. 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 Part I above, "Special Note" Regarding Forward-Looking Statements" for more information about our presentation of information.

#### Background

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

In the course of almost three decades, 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 the development of therapeutic products for the treatment of chronic diseases. Our strategy is to obtain the required regulatory approvals

which will allow the progressive introduction of Ampligen(R) (our proprietary drug) for treating Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome ("ME/CFS"), HIV, Hepatitis C ("HCV") and Hepatitis B ("HBV") in the U.S., Canada, Europe and Japan. We recently completed a phase III clinical trial in the U.S. for use of Ampligen in treatment of ME/CFS and are in the process of assembling and analyzing the obtained data preparatory to completing and filing a New Drug Application("NDA") with the U.S. Food and Drug Administration("FDA"). We are also testing Ampligen in Phase IIb Clinical Trials in the U.S. for the treatment of newly emerging multi-drug resistant HIV, and for the induction of cell mediated immunity in HIV patients that are under control using potentially toxic drug cocktails.

Our proprietary drug technology utilizes specifically configured ribonucleic acid ("RNA") and is protected by more than 170 patents worldwide, with over 14 additional patent applications pending to provide further proprietary protection in various international markets. Certain patents apply to the use of Ampligen(R) alone and certain patents apply to the use of Ampligen(R) in combination with certain other drugs. Some compositions of matter patents pertain to other new RNA compounds, which have a similar mechanism of action.

In March 2003 we obtained from Interferon Sciences, Inc. ("ISI") all of its raw materials, work-in-progress and finished product ALFERON N Injection(R), together with a limited license to sell ALFERON N Injection(R), a natural alpha interferon that has been approved for commercial sale for the intralesional treatment of refractory or recurring external condylomata acuminata ("genital warts") in patients 18 years of age or older in the United States. In March 2004, we acquired from ISI the balance of ISI's rights to its product as well as ISI's production facility. We are marketing the ALFERON N Injection(R) in the United States through sales facilitated via third party agreements. Additionally, we intend to implement studies testing the efficacy of ALFERON N Injection(R) in multiple sclerosis and other chronic viral diseases. In this regard, the FDA recently authorized a Phase II clinical study designed to investigate the activity and safety of Alferon LDO(R) in early stage HIV positive patients.

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. 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.

#### Result of Operations

Years Ended December 31, 2004 vs. 2003

During the year ended December 31, 2004, we 1) materially improved our cash position, 2) completed the acquisition of our production facility in New Brunswick, New Jersey, as well as, acquired all of ISI's rights to market Alferon N, 3) completed drug dosing in our Phase III AMP 516 ME/CFS clinical trial and 4) continued our efforts to develop Ampligen/Alferon N. Our cash position improved as a result of placing January and July 2004 6% convertible debentures with an aggregate maturity value of \$6,000,000 (gross proceeds of \$5,695,000) and the August 2004 private placement with select institutional investors of approximately 3,617,000 shares of our common stock and warrants producing \$7,524,000 in gross proceeds. Completion of the drug dosing in the AMP 516 ME/CFS clinical trial in August 2004 allows us to start the next step towards final data collection and analysis.

Progress was made on all fronts including a 100% increase in Alferon N sales. This increase in sales of Alferon was due, among other things, to the fact that we were selling for an entire year in 2004 compared to nine months in 2003. However, we were disappointed in these results as we planned to achieve much higher sales. Adjustments to our marketing strategy were made in late 2004 and we expect better results in 2005.

#### Net loss

Non-cash charges materially affected our net losses for the years ended December 31, 2004 and 2003. Our losses of \$24,140,000 for the year ended December 31, 2004, include non-cash financing charges of \$12,543,000 and non-cash charges of \$2,000,000 for stock compensation expenses. The losses for the same period in 2003 of \$14,770,000 included non-cash financing charges of \$7,345,000. This \$9,370,000 increase in net operating losses reflects an increase of \$7,198,000 in non-cash accounting charges, \$692,000 in research and development expenses and \$1,610,000 in production/cost of goods sold. The increase in our research and development costs were the result of 1) costs

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incurred in the development of a more efficient bottling manufacturing process for Alferon N Injection, 2) vials abstracted from the third lot of Alferon N Injection inventory for research and development purposes, and 3) costs associated with using Alferon N Injection in a clinical trial to treat patients infected with the West Nile Virus. Our production cost/cost of goods sold increased due to 1) higher Alferon N Injection sales, 2) costs related to preparing our New Brunswick, NJ facility for the installation of the lab now

located in Rockville, MD, and 3) expanding production at our New Brunswick facility to include Ampligen(R) raw material. The \$2,000,000 for stock compensation expense primarily consisted of \$1,769,000 resulting from warrants issued to Dr. Carter in 2003 that vested in the first quarter 2004. These warrants vested upon the second ISI asset closing which occurred on March 17, 2004. See Item 11. "Executive Compensation" for details related to how Dr. Carter has been compensated with respect to this matter.

#### Revenues

Revenues for the year ended December 31, 2004 were \$1,229,000 as compared to revenues of \$657,000 for the same period in 2003. Revenues for the year ended December 31, 2004 from sales of ALFERON N totaled \$1,050,000 versus \$509,000 for the period of March 11, 2003, the date we acquired the rights to the Alferon N business from ISI, through December 31, 2003. Sales of Alferon N are anticipated to increase as we have more product available and intend to expand our marketing/sales programs on an international basis. Revenues from our ME/CFS cost recovery treatment programs principally underway in the U.S., Canada and Europe were \$179,000 for the year ended December 31, 2004 versus \$148,000 for the year ended December 31, 2003. These clinical programs allow us to provide Ampligen(R) therapy at our cost to severely debilitated ME/CFS patients. Under this program the patients pay for the cost of Ampligen(R) doses infused. These costs total approximately \$7,200 for a 24-week treatment program.

Since acquiring the right to manufacture and market Alferon N on March 11, 2003, we have focused on converting the work-in-progress inventory into finished goods. 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 34,000 vials have been produced. Some 3,000 of the remaining vials within this lot were held back to be utilized in the development of a more compatible vial size for manufacturing of Alferon N Injection. We plan on initiating the process of converting the third lot of approximately 16,000 vials from work-in-progress to finished goods inventory in 2005. Approximately 2,000 vials were abstracted from the third lot for research and development purposes as well during the 4th quarter 2004. Our production and quality control personnel in our New Brunswick, NJ facility are involved in the extensive process of manufacturing and validation required by the FDA.

Our sales and marketing agreement with Engitech, LLC. to distribute ALFERON N on a nationwide basis did not produce the desired result. Sales have not increased as planned and we are expanding our in house sales and marketing efforts. We are considering the use of other sales organizations in order to meet our ALFERON N sales goals.

We executed a Memorandum of Understanding (MOU) in January 2004 with Fujisawa Deutschland GmbH, ("Fuji") a major pharmaceutical corporation, granting them an exclusive option for a limited number of months to enter a Sales and Distribution Agreement with exclusive rights to market Ampligen(R) for ME/CFS in Germany, Austria and Switzerland. The MOU required us to file the full report on the results of our AMP 516 Clinical Trial with Fuji by May 31, 2004. If the full <PAGE> 47 report was not provided to Fuji by May 31, 2004 and Fuji did not wish to exercise its option, we would have been required to refund one half of the 400,000 Euro fee. We submitted our initial report to Fuji on May 28, 2004 and responded to subsequent inquiries for additional information. The option period ends 12 weeks after the later of Fuji's review of the full report on the results of our Amp 516 clinical trial and Fuji's meeting with three of the trial's principal investigators. We received an initial fee of 400,000 Euros (approximately \$497,000 US). If we did not provide them with the full report by December 31, 2004 and Fuji did not wish to exercise its option, we would be required to refund the entire fee. On November 9, 2004, we and Fuji terminated the MOU by mutual agreement. We did not agree on the process to be utilized in certain European Territories for obtaining commercial approval for the sale of Ampligen(R) in the treatment of patients suffering from Chronic Fatigue Syndrome (CFS). Instead of a centralized procedure, and in order to obtain an earlier commercial approval of Ampligen(R) in Europe, we have determined to follow a decentralized filing procedure which was not anticipated in the MOU. We believe that it now is in the best interest of our stockholders to potentially accelerate entry into selected European markets whereas the original MOU specified a centralized registration procedure. Pursuant to mutual agreement of the parties we refunded 200,000 Euros to Fuji. We have recorded the remaining 200,000 Euros as an accrued liability as of December 31, 2004. We are currently holding the 200,000 Euros pending further developments in accordance with the mutually agreed upon termination with Fuji.

On March 17, 2004, we closed on the acquisition of all of the worldwide rights of ALFERON N as well as the FDA approved biological production facility in New Brunswick, New Jersey. We are looking to expand our marketing/sales programs on an international basis.

#### Production costs/cost of goods sold

Production costs for the year ended December 31, 2004 and 2003 were \$2,112,000 and \$502,000, respectively. These costs reflect approximately \$470,000 for the cost of sales of ALFERON N Injection(R) for the year ended December 31, 2004. In addition, costs of sales for Alferon N Injection(R) for the period March 11, 2003 (acquisition date of inventory from ISI) through December 31, 2003 amounted to \$240,000. The remaining production costs in 2004 represent expenditures associated with preparing the New Brunswick facility for the installation of the lab now located in Rockville, MD and for further

production of Alferon N Injection(R) and Ampligen(R) raw materials. In August 2004, we released most of the second lot of product (approximately 13,000 vials) to Abbott laboratories for bottling and realized approximately 12,000 vials of Alferon N. Some 3,000 of the remaining vials within this lot were held back to be utilized in the development of a more compatible vial size for manufacturing of Alferon N Injection. We plan on initiating the process of converting the third lot of approximately 16,000 vials from work-in-progress to finished goods inventory in 2005. Approximately 2,000 vials were abstracted from the third lot for research and development purposes as well during the current quarter. Our production and quality control personnel in our New Brunswick, NJ facility are involved in the extensive process of manufacturing and validation required by the FDA.

#### Research and Development costs

Overall research and development direct costs for the year ended December 31, 2004 were \$3,842,000 as compared to \$3,150,000 during the same period a year earlier. These costs primarily reflect the direct costs associated with our effort to develop our lead product, Ampligen(R), as a therapy in

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treating chronic diseases and cancers as well as on-going clinical trials involving patients with HIV. The primary reasons for the increase in research and development costs of \$692,000 for the year ended December 31, 2004 versus the same period a year ago were primarily due to 1) costs incurred in the development of a more efficient bottling manufacturing process for Alferon N Injection, 2) vials abstracted from the third lot of Alferon N Injection inventory for research and development purposes, and 3) costs associated with using Alferon N Injection in a clinical trial to treat patients infected with the West Nile Virus.

We recently completed the double-blind segment of our AMP 516 ME/CFS Phase III clinical trial for use of Ampligen(R) in the treatment of ME/CFS. Clinical data on the primary endpoint exercise treadmill duration was presented at the 17th International Conference on Anti-viral Research in Tucson, AZ on May 3, 2004. The data showed that patients receiving Ampligen for 40 weeks improved exercise treadmill performance by a medically and statistically significant amount compared to the Placebo group. New data was presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy on increases in exercise capacity with Ampligen and Placebo which were correlated with an improved ability to utilize oxygen, so called, maximum oxygen consumption or (VO2max). VO2max has been previously shown by others to be decreased with individuals with CFS. An abnormal exercise stress test, including a low VO2max, could help qualify CFS patients for disability under Social Security Administration rules. Additional data on subset analyses showed that both Stratification cohorts (those with baseline exercise treadmill duration greater than or less than nine minutes) improved exercise capacity by over 6.5%, an amount considered medically significant in other chronic diseases.

Ampligen is also currently in two Phase IIb studies for the treatment of HIV to overcome multi-drug resistance, virus mutation and toxicity associated with current HAART therapies. One study, the AMP-719, is a Salvage Therapy, conducted in the U.S. and evaluating the potential synergistic efficacy of Ampligen in multi-drug resistant HIV patients for immune enhancement. The second study, the AMP-720, is a clinical trial designed to evaluate the effect of Ampligen under Strategic Treatment Intervention and is also conducted in the U.S. Enrollment in the AMP 719 study is presently on hold as we focus our efforts on ramping up the AMP 720 study.

#### ME/CFS

Over 230 patients have participated in our ME/CFS Phase III clinical trial. In August 2004, the remaining patients completed drug dosing in the open label segment (Stage II) of this Phase III protocol. We completed the randomized placebo controlled phase (Stage I) of this study in February 2004 and have started final data collection for the data analysis. This process includes validation and quality assurance and should be completed by early 2005. As with any experimental drug being tested for use in treating human diseases, the FDA must approve the testing and clinical protocols employed and must render their decision based on the safety and efficacy of the drug being tested. Historically this is a long and costly process. Our ME/CFS AMP 516 clinical study is a Phase III study, which based on favorable results, will serve as the basis for us to file a new drug application with the FDA. The FDA review process could take 18-24 months and result in one of the following events: 1) approval to market Ampligen(R) for use in treating ME/CFS patients, 2) required more research, development, and clinical work, 3) approval to market as well as conduct more testing, or 4) reject our application. Given these variables, we are unable to project when material net cash inflows are expected to commence from the sale of Ampligen(R).

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#### HIV

We are currently focused on recruiting additional clinical investigators and HIV patients to participate in the AMP 720 HIV clinical trial. Our efforts to do this have been somewhat hampered as most of our clinical resources have been directed to completing the AMP 516 ME/CFS clinical trial. Now that the AMP 516 patients have completed the randomized segment of the clinical trial, we are devoting more resources toward the AMP 720 HIV clinical trial. Our AMP 719 HIV clinical trial has been put on hold at this time.

The Amp 720 HIV study is a treatment using a Strategic Treatment Interruption (STI). The patients' antiviral HAART regimens are interrupted and

Ampligen(R) is substituted as mono-immunotherapy. Ampligen(R) is an experimental immunotherapeutic designed to display both antiviral and immune enhancing characteristics. Prolonged use of Highly Active Antiretroviral Therapy (HAART) has been associated with long-term, potentially fatal, toxicities. The clinical study AMP 720 is designed to address these issues by evaluating the administration of our lead experimental agent, Ampligen(R), a double stranded RNA drug acting potentially both as an immunomodulator and antiviral. Patients, who have completed at least nine months of Ampligen(R) 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(R), had earlier HIV rebound with a mean duration of 18.7 weeks. Thus, on average, Ampligen(R) therapy spared the patients excessive exposure to HAART, with its inherent toxicities, for more than 11 weeks. As more patients are enrolled, the related clinical costs will continue to increase with some offset to our overall expenses due to the diminishing cost of the ME/CFS clinical trial. It is difficult to estimate the duration or projected costs of these two clinical trials due to the many variables involved, i.e.: patient drop out rate, recruitment of clinical investigators, etc. The length of the study and costs related to our clinical trials cannot be determined at this time as such will be materially influenced by (a) the number of clinical investigators needed to recruit and treat the required number of patients, (b) the rate of accrual of patients and (c) the retention of patients in the studies and their adherence to the study protocol requirements. Under optimal conditions, the cost of completing the studies could be approximately \$2.0 to \$3.0 million. The rate of enrollment depends on patient availability and on other products being in clinical trials for the treatment of HIV, as there is 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 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.

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 will be conducting this double-blinded, placebo controlled trial. During 2004, over 2,000 human cases of West Nile Virus have been reported in 40 states.

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Manufacturing

In order to obtain Ampligen(R) raw materials of higher quality (GMP certified) and on a more regular production basis, we have implemented consolidation and transfer of relevant manufacturing operations into our New Brunswick, New Jersey facility. This consolidation and transfer of manufacturing operations has been implemented as a recent inspection of the Ribotech facility in South Africa, our previous supplier of Ampligen(R) raw materials, indicated that it did not, at present, meet the necessary GMP standards for a fully certified commercial process. The transfer of Ampligen(R) raw materials manufacture to our own facilities, while having obvious advantages with respect to regulatory compliance (other parts of the 43,000 sq. ft. wholly owned facility are already in compliance for Alferon N manufacture), may delay certain steps in the commercialization process, specifically a targeted NDA filing. To facilitate the process, we are in the process of hiring a senior regulatory officer with specific expertise in global quality assurance for multinational pharmaceutical operations.

In connection with settling various manufacturing infractions previously noted by the FDA, Schering-Plough ("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(R) (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 recently advised us that it would no longer manufacture Ampligen(R) in this facility at the end of the applicable term (which is 4th quarter 2004) and would assist us in an orderly transfer of said activities to other non Schering facilities. Accordingly, we have entered into a Confidentiality Agreement with Mayne Pharma Pty, Ltd ("Mayne") to lead to reinitiation and expansion of its Ampligen(R) manufacturing program. We are currently in discussions with Mayne to provide us with proposals on manufacturing Ampligen(R) at their facility. Mayne (formerly known as Faulding Pharma) has already successfully manufactured Ampligen(R) several times for ongoing clinical trials, and maintains a fully GMP compliant facility. Simultaneously, we expect to qualify at least one other GMP facility to maintain a minimum of two independent production sites. If we are unable to engage Mayne and/or additional manufacturers in a timely manner, our plans to file an NDA for Ampligen(R) and, eventually, to market and sell Ampligen(R) will be delayed.

#### General and Administrative Expenses

General and Administrative ("G&A") expenses for the year ended December 31, 2004 and 2003 were approximately \$6,164,000 and \$4,257,000, respectively. The increase in G&A expenses of \$1,907,000 during this period is primarily due to non-cash charges of \$2,000,000 for stock compensation expenses in 2004. These stock compensation charges consisted of \$1,769,000 resulting from warrants issued to Dr. Carter in 2003 that vested in 2004 and directors' fees paid in

2004 of \$231,000. The warrants noted above vested upon the second ISI asset closing which occurred on March 17, 2004. Please see "Item 11. Executive Compensation." contained herein for more details on how Dr. Carter was compensated. In addition, investment banking fees relating to assistance in financing matters increased in 2004 as compared to a period early by approximately \$124,000. These increases were offset by a decrease in service fees in 2004 of approximately \$191,000 as compared to a year earlier. These services fees related to the acquisition of ISI.

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Impairment loss

During the year ended December 31, 2004, we recorded a non-cash charge of \$373,000 with respect to our investment in Chronix. This impairment reduces our carrying value to reflect a permanent decline in Chronix's market value based on its then proposed investment offerings.

Other Income/Expense

Interest and other income for the year ended December 31, 2004 and 2003 totaled \$49,000 and \$80,000, respectively. All funds in excess of our immediate need are invested in short-term high quality securities.

Interest Expense and Financing Costs

Interest expense and financing costs were \$12,543,000 for the year ended December 31, 2004 versus \$7,345,000 for the same period a year ago. Non-cash financing costs consist of the amortization of debenture closing costs, the amortization of Original Issue Discounts and the amortization of costs associated with beneficial conversion features of our debentures and the fair value of the warrants relating to the Debentures. These charges are reflected in the Consolidated Statements of Operations under the caption "Financing Costs."

In connection with the redemption obligation recorded in conjunction with the January 2004 Debentures, we recorded additional financing costs of approximately \$947,000 in the first quarter 2004. In the second quarter 2004, we recorded a reduction in financing costs of approximately \$260,000. Please see Note 7 in the consolidated financial statements contained herein for more details on these transactions.

Years Ended December 31, 2003 vs. 2002

-----  
During the year ended December 31, 2003, we 1) acquired certain assets and patent rights to ALFERON N Injection(R), 2) privately placed the March 2003, the July 2003, and October 2003, 6% convertible debentures with an aggregate maturity value of \$14,994,357 (gross proceeds of \$12,850,000), 3) continued our efforts to develop Ampligen(R) for the treatment of patients afflicted with ME/CFS and HIV, 4) activated the ISI New Brunswick production facility to process doses of Alferon N and 5) produced some 21,000 doses of Alferon N for sale in 2003.

Net loss

Our net loss was approximately \$14,770,000 for the year ended December 31, 2003 versus a net loss of \$7,424,000 in 2002. Per share loss in 2003 was \$0.42 cents versus a per share loss of \$0.23 in 2002. This year-to-year increase in losses of \$7,346,000 is primarily due to non-cash financing costs of \$7,345,000 relating to our March 2003, July 2003, and October 2003 6% convertible debentures. These non-cash charges account for 50% of our net losses for the year ended December 31, 2003. In addition, our losses during this period include \$957,000 in operating expenses relating to our new Alferon division. Solely for comparison purposes, excluding our 2003 losses for these two factors, our losses were \$6,468,000 in 2003 compared to \$7,424,000 in 2002 or a reduction totaling \$956,000. This was primarily due to a decrease in research and development direct costs of \$1,800,000 in 2003 due to reduced costs associated with the development of Ampligen(R) to treat ME/CFS patients. During 2002, our

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AMP 516 ME/CFS Phase III clinical trial was in full force and effect therefore increasing our manufacturing and clinical support expenses during that period (See "Research and Development Costs" below). This was offset by the recovery of certain legal expenses in 2002 of approximately \$1,050,000 related to the Asensio lawsuit and trial from our insurance carrier. This recovery produced a one-time reduction in G&A Expenses for 2002 (See "General and Administrative Expenses" below).

Revenues

Our revenues were \$657,000 in 2003 compared to revenues of \$904,000 in 2002. Our 2002 revenues included a licensing fee payment of approximately \$563,000 which was not repeated in 2003.

Revenues from our ME/CFS cost recovery treatment programs principally underway in the U.S., Canada and Europe were \$148,000 in 2003 versus \$341,000 in 2002. These clinical programs allow us to provide Ampligen(R) therapy at our cost to severely debilitated ME/CFS patients. Under this program the patients pay for the cost of Ampligen(R) doses infused. These costs total approximately \$7,200 for a 24 weeks treatment program. In addition, since the March 11, 2003, acquisition of inventory from ISI, revenues from sales of ALFERON N totaled \$509,000. Sales of Alferon N are anticipated to increase as we are producing more product and our marketing/sales programs are underway.

Revenues from the cost recovery treatment programs in 2002 were

\$341,000 or 57% higher than 2003 revenues. We expected revenues in the U.S. to decline due to our efforts to complete the AMP 516 ME/CFS Phase III trials and the focus of our clinical resources on the start up of the AMP 719 and AMP 720 HIV clinical trials. The clinical data collected from treating patients under the cost recovery treatment programs will augment and supplement the clinical data collected in the U.S. AMP 516 Phase III ME/CFS trial.

In 2002, We received a licensing fee of 625,000 Euros (\$563,000) from Laboratorios Del Dr. Esteve S.A. ("Esteve") pursuant to a sales and distribution agreement in which Esteve was granted the exclusive right to market Ampligen(R) in Spain, Portugal and Andorra for the treatment of ME/CFS in turn we provided to Esteve technical scientific and commercial information. The agreement terms require no additional performance by us.

Since acquiring the right to manufacture and market Alferon N in March 2003, we have focused on converting the work-in-progress inventory into finished goods. 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. In August 2003, we released the first lot of product to Abbott Laboratories for bottling and realized some 21,000 vials of ALFERON N. Preliminary work has started on completing the second lot of approximately 16,000 vials. Our production and quality control personnel in the New Brunswick facility are involved in the extensive process of manufacturing and validation required by the FDA. Plans are underway for completing the third lot of some 18,000 vials now in very early stages of production.

Our marketing and sales plan for ALFERON N consists of engaging sales force contract organizations and supplementing their sales efforts with marketing support. This marketing support would consist of building awareness of ALFERON N with physicians as a successful and effective treatment of refractory on recurring external genital warts in patients of age 18 or older and to assist primary prescribers in expanding their practice.

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On August 18, 2003, we entered into a sales and marketing agreement with Engitech, LLC, to distribute ALFERON N on a nationwide basis. The agreement stipulated that Engitech will deploy a sales force of 100 sales representatives within one year in the U.S. domestic market and further expand the sales team up to 250 sales representative in the second year and after that as many as it takes to continually drive market share. Engitech, Inc. is to develop and implement marketing plans including extensive scientific and educational programs for use in marketing ALFERON N.

#### Production costs

Production costs were \$502,000 for the year ended December 31, 2003. These costs reflect approximately \$240,000 for the cost of sales of ALFERON N Injection(R) during the period of April 1, 2003 through December 31, 2003. In addition, we recorded \$262,000 of production costs at the New Brunswick facility. We ramped up the facility in April 2003 and started production on three lots of Alferon N Injection(R) work in process inventory of which one lot was completed and is ready to be sold.

#### Research and Development costs

Our overall research and development direct costs in 2003 were \$3,150,000 compared to research and development direct costs in 2002 of \$4,946,000. These costs primarily reflect the direct costs associated with our effort to develop our lead product, Ampligen(R), as a therapy in treating chronic diseases and cancers. At this time, this effort consists of on-going clinical trials involving patients with HIV. Our research and development direct costs are \$1,796,000 lower in 2003 due to reduced costs associated with the development of Ampligen(R) to treat ME/CFS patients. During 2002, our AMP 516 ME/CFS Phase III clinical trial was in full force and effect, therefore, increasing our manufacturing and clinical support expenses during that period.

Our strategy is to develop our lead compound, the experimental immunotherapeutic Ampligen(R), to treat chronic diseases for which there is currently no adequate treatment available. We seek the required regulatory approval, which will allow the commercial introduction of Ampligen for ME/CFS and HIV/AIDS in the U.S., Canada, Europe and Japan.

We recently completed the double-blind segment of our AMP 516 ME/CFS Phase III clinical trial for use of Ampligen(R) in the treatment of ME/CFS. Ampligen is also currently in two Phase IIb studies for the treatment of HIV to overcome multi-drug resistance, virus mutation and toxicity associated with current HAART therapies. One study, the AMP-719, is a Salvage Therapy, conducted in the U.S. and evaluating the potential synergistic efficacy of Ampligen in multi-drug resistant HIV patients for immune enhancement. The second study, the AMP-720, is a clinical trial designed to evaluate the effect of Ampligen under Strategic Treatment Intervention and is also conducted in the U.S. The AMP 719 study is presently on hold as we devote our efforts on the AMP 720 study.

#### AMP 516

Over 230 patients have participated in our ME/CFS Phase III clinical trial. Approximately 14 patients are in the open label phase of the clinical process. We have completed the randomized placebo controlled phase of this study and expect to complete data collection and start the data analysis process with the expectation of filing an NDA (New Drug Application) with the FDA by the end of 2004. As with any experimental drug being tested for use in treating human

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diseases, the FDA must approve the testing and clinical protocols employed and must render their decision based on the safety and efficacy of the drug being tested. Historically this is a long and costly process. Our ME/CFS AMP 516 clinical study is a Phase III study, which based on favorable results, will serve as the basis for us to file a new drug application with the FDA. The FDA review process could take 18-24 months and result in one of the following events; 1) approval to market Ampligen(R) for use in treating ME/CFS patients, 2) required more research, development, and clinical work, 3) approval to market as well as conduct more testing, or 4) reject our application. Given these variables, we are unable to project when material net cash inflows are expected to commence from the sale of Ampligen(R).

#### AMP 719 and AMP 720

We are currently focused on recruiting additional clinical investigators and HIV patients to participate in the AMP 720 HIV clinical trial. Our efforts to do this have been somewhat hampered in late 2003 as most of our clinical resources have been directed to completing the AMP 516 ME/CFS clinical trial. Now that the AMP 516 patients have completed the randomized segment of the clinical trial, we expect to devote more resources toward the AMP 720 HIV clinical trial. Our AMP 719 HIV clinical trial has been put on hold at this time.

In July 2003, Dr. Blick, a principal investigator in our HIV studies, presented updated results on our Amp 720 HIV study at the 2nd IAS CONFERENCE ON HIV PATHOGENESIS AND TREATMENT in Paris France. In this study using Strategic Treatment Interruption (STI), patients' antiviral HAART regimens are interrupted and Ampligen(R) is substituted as mono-immunotherapy. Ampligen(R) is an experimental immunotherapeutic designed to display both antiviral and immune enhancing characteristics. Prolonged use of Highly Active Antiretroviral Therapy (HAART) has been associated with long-term, potentially fatal, toxicities. The clinical study AMP 720 is designed to address these issues by evaluating the administration of our lead experimental agent, Ampligen(R), a double stranded RNA drug acting potentially both as an immunomodulator and antiviral. Patients, who have completed at least nine months of Ampligen(R) 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(R), had earlier HIV rebound with a mean duration of 18.7 weeks. Thus, on average, Ampligen(R) therapy spared the patients excessive exposure to HAART, with its inherent toxicities, for more than 11 weeks. As more patients are enrolled, the related clinical costs will continue to increase with some offset to our overall expenses due to the diminishing cost of the ME/CFS clinical trial. It is difficult to estimate the duration or projected costs of these two clinical trials due to the many variables involved, i.e.: patient drop out rate, recruitment of clinical investigators, etc. The length of the study and costs related to our clinical trials cannot be determined at this time as such will be materially influenced by (a) the number of clinical investigators needed to recruit and treat the required number of patients, (b) the rate of accrual of patients and (c) the retention of patients in the studies and their adherence to the study protocol requirements. Under optimal conditions, the cost of completing the studies could be approximately \$2.0 to \$3.0 million. The rate of enrollment depends on patient availability and on other products being in clinical trials for the treatment of HIV, as there is 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 be conducted or not. In case a Phase <PAGE> 55  
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.

#### General and Administrative Expenses

General and Administrative expenses ("G&A") were \$4,257,000 during the year ended December 31, 2003, which includes \$957,000 of expenses relating to our new Alferon Division and \$237,000 for a non cash stock compensation charge. Excluding the Alferon expenses, our G&A costs were \$3,300,000 compared to \$2,015,000 of expenses in 2002. This increase of \$1,285,000 is primarily due to the recovery of certain legal expenses in 2002 of approximately \$1,050,000 related to the Asensio lawsuit and trial from our insurance carrier. This recovery produced a one time reduction in G&A Expenses for 2002. Also, we recorded non-cash stock compensation expenses of \$237,000 in 2003 as compared to \$133,000 in 2002.

#### Equity Loss-Unconsolidated Affiliates

In the year ended December 31, 2002, we recorded a non-cash charge of \$1,470,000 to operations with respect to our investments in unconsolidated affiliates. \$1,074,000 of these charges were related to our investment in R.E.D. These charges were the result of our determination that R.E.D.'s business and financial position had deteriorated to the point that our investment had been permanently impaired.

We also recorded a non-cash charge of \$292,000 with respect to our investment in Chronix Biomedical. This impairment reduced our carrying value in this investment to reflect a permanent decline in Chronix's market value based on its then proposed investment offering.

These charges are reflected in the Consolidated Statements of Operations under the caption "Equity loss in unconsolidated affiliate." Please see "RESEARCH AND DEVELOPMENT/COLLABORATIVE AGREEMENTS" in Item 1. Business for more details on these transactions.

Other Income/Expense

Interest and other income totaled \$80,000 in 2003 compared to \$103,000 recorded in 2002. Lower cash available for investment basically accounted for the difference as interest rates remained relatively low in 2003. All funds in excess of our immediate need are invested in short-term high quality securities.

Interest Expense and Financing Costs

Interest expense and financing costs were \$7,598,000 in 2003. Non-cash financing costs consist of \$581,000 for the amortization of debenture closing costs, \$1,066,000 for the amortization of Original Issue Discounts and \$5,698,000 for the amortization of costs associated with beneficial conversion features of the debentures and the fair value of the warrants relating to the March 2003, July 2003 and October 2003 6% convertible debentures. These charges are reflected in the Consolidated Statements of Operations under the caption "Financing Costs." Please see Note 16 in the consolidated financial statements contained herein for more details on these transactions.

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Liquidity And Capital Resources

Cash used in operating activities for the year ended December 31, 2004 was \$7,240,000. Cash provided by financing activities for the year ended December 31, 2004 amounted to \$19,085,000, substantially from proceeds from debenture offerings, the sale of common stock and the exercising of common stock warrants. As of December 31, 2004, we had approximately \$16,737,000 million in cash and short-term investments. These funds should be sufficient to meet our operating cash requirements including debt service for the near term. However, 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(R) 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. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

Please see "Recent Financing And Asset Acquisitions" in Item 1. Business and Note 4 - "Acquisition of Assets of Interferon Sciences, Inc." and Note 7 - "Debenture Financing" in the consolidated financial statements contained herein for more details on our acquisition of assets and debenture and stock financings.

Because of our long-term capital requirements, we may seek to access the public equity market whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. 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.

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<TABLE>  
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Contractual Cash Obligations (Including Interest)	(dollars in thousands) Obligations Expiring by Period			
	Total	2005	2006	2007-2008
<S>	<C>	<C>	<C>	<C>
Operating Leases	\$445	\$187	\$193	\$65
Convertible Debentures				
October 29, 2003 \$4,142,000 6% Senior Convertible Debenture	2,175	2,175	-	-
January 26, 2004 \$4,000,000 6% Senior Convertible Debenture	3,268	3,268	-	-
July 26, 2004 \$2,000,000 6% Senior Convertible Debenture	2,120	1,413	707	-
<b>Total</b>	<b>\$8,000</b>	<b>\$7,043</b>	<b>\$900</b>	<b>\$65</b>

</TABLE>

#### New Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 123 (revised 2004) (FASB 123R), Share-Based Payment. FASB 123R will require the Corporation to expense share-based payments, including employee stock options, based on their fair value. The Corporation is required to adopt the provisions of FASB 123R effective as of the beginning of its third quarter in 2005. FASB 123R provides alternative methods of adoption, which include prospective application and a modified retroactive application. The Corporation is currently evaluating the financial impact, including the available alternative of adoption of FASB 123R.

#### Disclosure About Off-Balance Sheet Arrangements

Prior to our annual meeting of stockholders in September 2003, we had a limited number of shares of Common Stock authorized but not issued or reserved for issuance upon conversion or exercise of outstanding convertible and exercisable securities such as debentures, options and warrants. Prior to the meeting, to permit consummation of the sale of the July 2003 Debentures and the related warrants, Dr. Carter agreed that he would not exercise his warrants or options unless and until our stockholders approve an increase in our authorized shares of common stock. For Dr. Carter's waiver of his right to exercise certain options and warrants prior to approval of the increase in our authorized shares, we have agreed to compensate Dr. Carter.

In connection with the Debenture agreements, we have outstanding letters of credit of \$1,000,000 as additional collateral.

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#### 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 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

Revenues for non-refundable license fees are recognized under the Performance Method-Expected Revenue. This method considers the total amount of expected revenue during the performance period, but limits the amount of revenue recognized in a period to total non-refundable cash received to date. This limitation is appropriate because future milestone payments are contingent on future events.

Upon receipt, the upfront non-refundable payment is deferred. The non-refundable upfront payments plus non-refundable payments arising from the achievement of defined milestones are recognized as revenue over the performance period based on the lesser of (a) percentage of completion or (b) non-refundable cash earned (including the upfront payment).

This method requires the computation of a ratio of cost incurred to date to total expected costs and then apply that ratio to total expected revenue. The amount of revenue recognized is limited to the total non-refundable cash received to date.

Revenue from the sale of Ampligen(R) 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.

##### 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 on an undiscounted cash basis to support the realizability of our respective capitalized cost. In addition, management's review addresses whether each patent continues to fit into our strategic business plans.

##### Concentration of Credit Risk

Financial instruments that potentially subject us to credit risks consist of cash equivalents and accounts receivable.

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 <PAGE> 59 exposed to minimal interest rate and credit risks. At times, we have 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, 2004.

Item 7A. Quantitative And Qualitative Disclosures About Market Risk

Excluding obligations to pay us for various licensing related fees, we had approximately \$16,737,000 in cash and cash equivalents and short-term investments at December 31, 2004. To the extent that our cash and cash equivalents exceed our near term funding needs, we invest the excess cash in three to six month high quality 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, 2003, and 2004, 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, 2004, together with the report of BDO Seidman, 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.

None.

ITEM 9A. Controls and Procedures.

Effectiveness of Control Procedures

Our Chairman of the Board (serving as the principal executive officer) and the Chief Financial Officer performed an evaluation of our disclosure controls and procedures, which have been designed to permit us to effectively identify and timely disclose important information. They concluded that the controls and procedures were effective as of December 31, 2004 to ensure that material information was accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. During the quarter ended December 31, 2004, we have made no change in our internal controls over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Internal Controls Over Financial Reporting

Our management, including the Chief Executive Officer and the Chief Financial Officer, is responsible for establishing and maintaining adequate

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internal controls over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Securities Exchange Act of 1934. Our internal controls were designed to provide reasonable assurance as to the reliability of our financial reporting and the preparation and presentation of the consolidated financial statements for external purposes in accordance with accounting principles generally accepted in the United States, as well as to safeguard assets from unauthorized use or disposition.

We conducted an evaluation of the effectiveness of our internal controls over financial reporting based on the framework in Internal Control -- Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. This evaluation included review of the documentation of controls, evaluation of the design effectiveness of controls, testing of the operating effectiveness of controls and a conclusion on this evaluation. Through this evaluation, we did not identify any material weaknesses in our internal controls. There are inherent limitations in the effectiveness of any system of internal controls over financial reporting; however, based on our evaluation, we have concluded that our internal controls over financial reporting were effective as of December 31, 2004.

BDO Seidman, LLP, an independent registered public accounting firm, has issued an attestation report on management's assessment of internal control over financial reporting, which is included in ITEM 9A.

Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting

To The Board of Directors and Stockholders:

We have audited management's assessment, included in Management's Report on Internal Control Over Financial Reporting, that Hemispherx Biopharma, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control'Integrated Framework

issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). 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

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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, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Hemispherx Biopharma, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We have also audited, in accordance with standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Hemispherx Biopharma, Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, changes in stockholders' equity and comprehensive loss, and cash flows for each of the three years in the period ended December 31, 2004, and our report dated February 4, 2005 expressed an unqualified opinion thereon.

/s/ BDO SEIDMAN LLP

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Philadelphia, PA  
February 4, 2005

ITEM 9B. Other Information.

None.  
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### 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:

<TABLE>  
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Name <S>	Age <C>	Position <C>
William A. Carter, M.D.	67	Chairman, Chief Executive Officer, and
R. Douglas Hulse	61	President
Robert E. Peterson	68	Chief Financial Officer
David R. Strayer, M.D.	59	Medical Director, Regulatory Affairs
Mei-June Liao, Ph.D.	54	Vice President of Regulatory Affairs, Quality Control and Research and Development
Robert Hansen	61	Vice President of Manufacturing

Carol A. Smith, Ph.D.	55	Director of Process Development
Richard C. Piani	78	Director
William M. Mitchell, M.D.	70	Director
Ransom W. Etheridge	66	Director, Secretary and General Counsel
Iraj Egbhal Kiani, Ph.D.	59	Director

</TABLE>

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.

R. DOUGLAS HULSE was appointed our President and Chief Operating Officer in February 2005. Mr. Hulse has been an executive director at Sage Group, Inc., an international organization providing senior level strategic management services to the biotechnology and pharmaceutical sector, since 1995. Mr. Hulse is a Phi Beta Kappa graduate of Princeton University with a cum laude degree in chemistry and the holder of S.M. Degrees in both management and Chemical Engineering from M.I.T., previously served as our Chief Operating Officer in 1996 and 1997. Mr. Hulse devotes approximately 40 to 50% of his time to our business.

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(R). 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(R). 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.

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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(R). 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 and anti-viral drugs. 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.

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.

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#### 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 believe that, during the fiscal year ended December 31, 2004, all of our officers, directors and ten percent stockholders complied with all applicable Section 16(a) filing requirements on a timely basis, except that Dr. Esteve, a former director, and Mr. Kiani did not file a Form 3.

#### Audit Committee and Audit Committee Expert

Audit Committee. Our Audit Committee of the Board of Directors consists of Richard Piani, Committee Chairman, William Mitchell, M.D. and Iraj-Eghbal Kiani. Mr. Piani, Dr. Mitchell and Iraj-Eghbal Kiani are Independent Directors. We do not have a financial expert as defined in Securities and Exchange Commission rules on the committee in the true sense of the description. However, Mr. Piani is a Businessman and has 40 years of experience of working with budgets, analyzing financials and dealing with financial institutions. We believe Mr. Piani, Dr. Mitchell and Iraj-Eghbal Kiani to be independent of management and free of any relationship that would interfere with their exercise of independent judgment as members of this committee. Our audit committee is responsible for annually recommending independent accountants, preparing the reports or statements as may be required by AMEX or the securities laws, and reviewing: (i) the adequacy of our system of internal accounting controls; (ii) our audited financial statements and reports and discussing the statements and reports with management, including any significant adjustments, management judgments and estimates, new accounting policies and disagreements with management; and (iii) disclosures by independent accountants concerning relationships with our company 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 and reviewed by each officer, director and employee. You may obtain a copy of this code by visiting our web site at

Item 11. Executive Compensation.

The summary compensation table below sets forth the aggregate compensation paid or accrued by us for the fiscal years ended December 31, 2004, 2003 and 2002 to (i) our Chief Executive Officer and (ii) our five most highly paid executive officers other than the CEO who were serving as executive officers at the end of the last completed fiscal year and whose total annual salary and bonus exceeded \$100,000 (collectively, the "Named Executives").

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EXECUTIVE COMPENSATION  
SUMMARY COMPENSATION TABLE

<TABLE>  
<CAPTION>

Name and Principal Position	Year	Salary (\$)	Restricted Stock Awards	Warrants & Options Awards	All Other Compensation(1)
<S>	<C>	<C>	<C>	<C>	<C>
William A. Carter	2004	(2)605,175	-	(3) 320,000	\$32,003
Chairman of	2003	(2)582,461	-	(4)1,450,000	28,375
the Board and CEO	2002	(2)565,514	-	(5)1,000,000	24,747
Robert E. Peterson	2004	(6) 221,242	-	(7) 63,824	-
Chief	2003	(6) 193,816(6)	-	-	-
Financial Officer	2002	187,689	-	(5) 200,000	-
David R. Strayer, M.D.	2004	180,394	-	(8) 10,000	-
Medical Director	2003	190,096	-	-	-
	2002	178,594	-	(5) 50,000	-
Carol A. Smith, Ph.D.	2004	134,658	-	(8) 10,000	-
Director	2003	140,576	-	-	-
of Process Development	2002	128,346	-	(5) 20,000	-
Mei-June Liao, Ph.D., V.P.	2004	149,000	-	(8) 10,000	-
of Quality Control	2003	(9) 100,575	-	-	-
	2002	-	-	-	-
Robert Hansen	2004	132,000	-	(8) 10,000	-
V.P. of Manufacturing	2003	(9)104,500	-	-	-
	2002	-	-	-	-

</TABLE>

- (1) Consists of insurance premiums paid by us with respect to term life and disability insurance for the benefit of the named executive officer.
  - (2) Includes bonuses of \$96,684, \$99,481 and \$121,035 in 2002, 2003 and 2004, respectively.
  - (3) Consist of a stock option grant of 320,000 shares exercisable at \$2.60 per share.
  - (4) Represents warrants to purchase 1,450,000 shares of common stock exercisable at \$2.20 per share.
  - (5) Represents number of options to purchase shares of common stock at \$2 per share.
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- (6) 2002 includes a bonus of \$36,634 and 2003 includes a bonus of \$37,830 both paid in 2004, 2004 includes a bonus of \$44,248 paid in 2005.
  - (7) Consist of stock option grant of 50,000 shares exercisable at \$3.44 per share and 13,824 stock options to purchase common stock at \$2.60 per share.
  - (8) Consists of stock option grant exercisable at \$1.90 per share.
  - (9) Compensation since March 2003. Employed by ISI prior to that.

The following table sets forth certain information regarding stock options granted during 2004 to the executive officers named in the Summary Compensation Table.

<TABLE>  
<CAPTION>

-----  
Individual Grants

Name	Number Of Securities Underlying Warrants Granted	Percentage Of Total Options Granted To Employees In Fiscal Year 2004(1)	Exercise Price Per Share (2)	Expiration Date	Potential Realizable Value At Assumed Rates Of Stock Price Appreciation For Options Term	
<S>	<C>	<C>	<C>	<C>	<C>	<C>
					5% (3)	10%(3)
Carter, W.A.	320,000	50.5	\$2.60	9/7/14	\$1,357,130	\$2,161,355
Peterson, R.	50,000 13,864	10.1	3.44 2.60	6/22/14 9/7/14	280,170 58,627	446,123 93,369
Strayer, D.	10,000	1.6	1.90	12/7/14	30,949	49,498
Smith, C.	10,000	1.6	1.90	12/7/14	30,949	49,498
Liao, M.	10,000	1.6	1.90	12/7/14	30,949	49,498
Hansen, R.	10,000	1.6	1.90	12/7/14	30,949	49,498

</TABLE>

- (1) Total stock options issued to employees in 2004 were 633,080.
- (2) The exercise price is equal to the closing price of our common stock at the date of issuance.
- (3) Potential realizable value is based on an assumption that the market price of the common stock appreciates at the stated rates compounded annually, from the date of grant until the end of the respective option term. These values are calculated based on requirements promulgated by the Securities and Exchange Commission and do not reflect our estimate of future stock price appreciation.

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The following table sets forth certain information regarding the stock options held as of December 31, 2004 by the individuals named in the above Summary Compensation Table.

AGGREGATED OPTION EXERCISES IN LAST FISCAL YEAR  
AND FISCAL YEAR-END OPTION VALUE

<TABLE>  
<CAPTION>

Name	Shares Acquired on Exercise (#)	Value Realized (\$)	Securities Underlying Warrants/Options at Fiscal Year Exercisable	Unexercised End Numbers	Value of Unexercised In-the-Money-Options At Fiscal Year End (1) Dollars	Unexercisable
<S>	<C>	<C>	<C>	<C>	<C>	<C>
William Carter	-	-	5,325,378(2)	250,000(3)	\$69,750	
Robert Peterson	-	-	453,750(4)	0	0	
David Strayer	-	-	130,000(5)	10,000(7)	0	
Carol Smith	-	-	41,791(6)	10,000(7)	0	
Mei-June Liao	-	-	-	10,000(7)	0	
Robert Hansen	-	-	-	10,000(7)	0	

</TABLE>

- (1) Computation based on \$1.90, the December 31, 2004 closing bid price for the common stock on the American Stock Exchange.
- (2) Consist of (i) 750,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007 (ii) 188,325 warrants exercisable at \$6.00 per share expiring on February 22, 2006 (iii) 188,325 warrants exercisable at \$9.00 per share expiring on February 22, 2006 (iv) 1,450,000 warrants to purchase common stock at \$2.20 per share expiring on September 8, 2008, (v) 320,000 stock option exercisable at \$2.60 per share expiring

on September 7, 2014 and (vi) 73,728 stock options exercisable at \$2.71 per share until exercised. Also includes 2,355,000 warrants and options held in the name of Carter Investments, L.C. of which W.A. Carter is the principal beneficiary. These securities consist of (i) 170,000 warrants exercisable at \$4.00 per share expiring on January 1, 2008, (ii) 300,000 warrants exercisable at \$6.00 per share expiring on January 1, 2006 (iii) 20,000 warrants exercisable at \$4.00 per share expiring on 2008, (iv) 465,000 warrants exercisable at \$1.75 expiring on January 1, 2008, and 1,400,000 warrants exercisable at \$3.50 per share expiring on September 30, 2007.

- (3) Consists of (i) 250,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007.
- (4) Consists of (i) 10,000 stock options exercisable at \$4.03 per share expiring on January 3, 2011 (ii) 13,750 stock options exercisable at \$3.50 per share expiring on January 22, 2007, (iii) 200,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007, (iv) 50,000 warrants exercisable at \$3.50 expiring on March 1, 2006, (v) 100,000 warrants exercisable at \$5.00 per share expiring on April 14, 2006, (vi) 30,000 warrants exercisable at \$5.00 per share expiring on February 28, 2009 and 50,000 options to purchase common stock at \$3.44 per share expiring June 22, 2014.
- (5) Consists of (i) 50,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007, (ii) 50,000 warrants exercisable at \$4.00 per share expiring on February 28, 2008, (iii) 10,000 stock options exercisable at \$4.03 expiring on January 3, 2011 and (iv) 20,000 stock options exercisable at \$3.50 per share expiring on January 22, 2007.
- (6) Consists of (i) 20,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007, (ii) 5,000 warrants exercisable at \$4.00 per share expiring on June 7, 2008, (iii) 10,000 stock options exercisable at \$4.03 per share expiring on January 3, 2016, and (iv) 6,791 stock options exercisable at \$3.50 per share expiring on January 22, 2007.
- (7) Consists of options to purchase common stock at \$1.90 per share expiring on December 7, 2014.

In September 2003, our Board of Directors changed the non-employee Board Member compensation to be 50% cash and 50% stock. The Board's stock compensation is to be paid on the first day of each calendar quarter. 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 trading day of the preceding quarter. In no event shall the number of shares issued under this plan exceed 1,000,000 shares over a ten year period.

#### Employment and Change in Control Agreements

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.

The amended and restated employment agreement 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 we 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 initial base salary retroactive to January 1, 2005 is \$290,888, 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 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.

The amended and restated engagement agreement, retroactive to January 1, 2005, 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 initial base fee as of January 1, 2004 is \$207,777, 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 our 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 include 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 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

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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, 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 initial annual fee for services is \$202,680 and is annually 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 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 our company 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 our 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.

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Etheridge, respectively, to change of control benefits, as defined in the agreements and summarized below, upon their respective termination of employment/engagement with our company 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:

- o A lump sum cash payment of three times his base salary and annual bonus amounts; and
- o 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:

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

#### Compensation of Directors

The compensation package for Members of the Board of Directors was changed on September 9, 2003. Board member compensation consists of an annual retainer of \$100,000 to be paid 50% in cash and 50% in Company 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. In addition, all non-employee directors received some compensation in 2003 for special project work performed on our behalf. This project work ceased as of September 30, 2003. 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.

#### 2004 Equity Incentive Plan

Our 2004 Equity Incentive Plan ("2004 Plan") provides for the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards to our employees, directors, officers, consultants and advisors for the purchase of up to an aggregate of 8,000,000 shares of common stock. The 2004 plan is administered by the board of directors, which has complete discretion to select eligible individuals to receive and to establish the terms of grants under the plan. Stock options awarded under the Equity Incentive Plan may be exercisable at such times (not later than 10 years after the date of grant) and at such exercise prices (not less than fair market value at the date of grant) as the Board may determine. The Board may provide for options to become immediately exercisable upon a "change in control" as defined in the plan. The number of shares of common stock available for grant under the 2004 Plan is subject to adjustment for changes in capitalization. As of December

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31, 2004, 7,366,920 shares were available for grants under the 2004 Plan. Unless sooner terminated, the Equity Incentive Plan will continue in effect for a period of 10 years from its effective date

#### 1990 Stock Option Plan

Our 1990 Stock Option Plan, as amended ("1990 Plan"), provides for the grant of options to our employees, directors, officers, consultants and advisors for the purchase of up to an aggregate of 460,798 shares of common stock. The 1990 plan is administered by the Compensation Committee of the board of directors, which has complete discretion to select eligible individuals to receive and to establish the terms of option grants. The number of shares of common stock available for grant under the 1990 Plan is subject to adjustment for changes in capitalization. As of December 31, 2004, no options were available for grants under the 1990 plan. This plan remains in effect until terminated by the Board of Directors or until all options are issued.

#### 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. In 2004 we provided matching contributions to each employee for up to 6% of annual pay for a total of \$76,886 for all eligible employees.

#### Compensation Committee Interlocks and Insider Participation

During the fiscal year ended December 31, 2004, the members of our Compensation Committee were William Mitchell and Richard Piani. Dr. Mitchell and Mr. Piani received fees for certain consulting work performed on our behalf in 2003. Refer to Item 13. "Certain Relationships and Related Transactions" for more information.

#### Compensation Committee Report on Compensation

The Compensation Committee makes recommendations concerning salaries and compensation for our employees and consultants.

The following report of the compensation committee discusses our executive compensation policies and the basis of the compensation paid to our executive officers in 2004.

In general, the compensation committee seeks to link the compensation paid to each executive officer to the experience and performance of such executive officer. Within these parameters, the executive compensation program attempts to provide an overall level of executive compensation that is competitive with companies of comparable size and with similar market and operating characteristics.

There are three elements in our executive total compensation program, all determined by individual and corporate performance as specified in the various employment agreements; base salary, annual incentive, and long-term incentives.  
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#### Base Salary

The Summary Compensation Table shows amounts earned during 2004 by our executive officers. The base compensation of such executive officers is set by terms of the employment agreement entered into with each such executive officer. We established the base salaries for Chief Executive Officer, Dr. William A. Carter under an employment agreement in December 3, 1998 (as amended and restated on March 11, 2005), which provides for a base salary of \$290,887.68. In addition, we entered into an agreement with Dr. Carter for his services as a consultant related to patient development, development of patents and as a member of our Board of Directors. This agreement establishes a base annual fee of \$207,776.88. Both agreements are subject to annual cost of living adjustments. Dr. Carter is entitled to an annual performance bonus of up to 25% of the base salary of each agreement at the discretion of the compensation committee of the Board of Directors.

On March 11, 2005, we entered into an extended engagement agreement with Robert E. Peterson, Chief Financial Officer retroactive to January 1, 2005 for a base annual fee of \$202,680 until December 31, 2010. Mr. Peterson's agreement all ows for an nual cost of living increases and a performance bonus.

On March 11, 2005, we entered into an engagement agreement with Ransom W. Etheridge, Corporate General Counsel, retroactive to January 1, 2005 for an annual fee of \$96,000 until December 31, 2009.

#### Annual Incentive

Our Chief Executive Officer and our Chief Financial Officer are entitled to an annual incentive bonus as determined by the compensation committee based on such executive officers' performance during the previous calendar year. The cash bonus awarded to our Chief Executive Officer in 2004 and the cash bonus awarded to the Chief Financial Officer in 2004 were determined based on this provision in their employment agreements.

#### Long-Term Incentives

We grant long-term incentive awards periodically to align a significant portion of the executive compensation program with stockholder interest over the long-term through encouraging and facilitating executive stock ownership. Executives are eligible to participate in our incentive stock option plans. Our Chief Executive Officer and President, Dr. William Carter, received a grant of 320,000 stock options in 2004. These options are exercisable at \$2.60 per share and expire on September 7, 2014, unless previously exercised. The options vested on September 8, 2004.

On June 23, 2004, our Chief Financial Officer, Robert E. Peterson, was granted 50,000 stock options exercisable at \$3.44 per share expiring on June 22, 2014 unless previously exercised. These options were issued in connection with his renewed and extended employment agreement. On September 8, 2004 Mr. Peterson was granted 13,824 stock options exercisable at \$2.60 per share expiring on September 7, 2014.

Ransom Etheridge, our Corporate Secretary and General Counsel, was awarded 50,000 stock options on September 8, 2004 exercisable at \$2.60 per share expiring September 7, 2014, unless previously exercised.

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Performance Graph

Total Return to Shareholders  
(Includes reinvestment of dividends)

<TABLE>  
<CAPTION>

<S> Company Name / Index	<C>	ANNUAL RETURN PERCENTAGE				
		Years Ending				
		<C> Dec00	<C> Dec01	<C> Dec02	<C> Dec03	<C> Dec04
HEMISPHERX BIOPHARMA INC		-52.20	-5.26	-52.67	6.10	-15.93
S&P 600 INDEX		11.80	6.54	-14.63	38.79	22.65
PEER GROUP		-33.76	48.39	-45.76	5.33	-52.63

</TABLE>  
<TABLE>  
<CAPTION>

<S> Company Name / Index	<C> Base Period Dec99	<C> Dec00	INDEXED RETURNS		<C> Dec03	<C> Dec04
			<C> Dec01	<C> Dec02		
			Years Ending			
HEMISPHERX BIOPHARMA INC	100	47.80	45.28	21.43	22.74	19.12
S&P 600 INDEX	100	111.80	119.11	101.68	141.13	173.09
PEER GROUP	100	66.24	98.29	53.31	56.15	26.60

Peer Group Companies

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 AVI BIOPHARMA INC  
 IMMUNE RESPONSE CORP/DE  
 LA JOLLA PHARMACEUTICAL CO  
 MAXIM PHARMACEUTICALS INC

</TABLE>  
 <PAGE> 76  
 [GRAPHIC OMITTED][GRAPHIC OMITTED]

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

The following table sets forth as of March 1, 2005, the number and percentage of outstanding shares of common stock beneficially owned by:

- o 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;
- o each of our directors and the Named Executives; and
- o all of our officers and directors as a group.

As of March 1, 2005, there were no other persons, individually or as a group, known to the Hemispherx to be deemed the beneficial owners of five percent or more of the issued and outstanding common stock.

<TABLE>  
<CAPTION>

Name and Address of Beneficial Owner <S>	Shares Beneficially Owned <C>	% Of Share Beneficially Owned <C>
William A. Carter, M.D.	6,067,868 (1)	10.9
Robert E. Peterson	468,074 (2)	*
Ransom W. Etheridge 2610 Potters Rd. Virginia Beach, VA 23452	454,430(3)	*
<PAGE> 77 Richard C. Piani 97 Rue Jeans-Jaure Levaillois-Perret France 92300	241,469(4)	*
Doug Hulse Sage Group, Inc. 3322 Route 22 West Building 2, Suite 201 Branchburg, NJ 08876	339,400(10)	*
William M. Mitchell, M.D.	215,454(5)	*

Vanderbilt University  
 Department of Pathology  
 Medical Center North  
 21st and Garland  
 Nashville, TN 37232

David R. Strayer, M.D.	148,746(6)	*
Carol A. Smith, Ph.D.	51,791(7)	*
Iraj-Eqbal Kiani, Ph.D. Orange County Immune Institute 18800 Delaware Street Huntington Beach, CA 92648	12,000(8)	*
Mei-June Liao, Ph.D.	10,000(9)	*
Robert Hansen	10,000(9)	0
All directors and executive officers as a group (11 persons)	8,019,232	14.1%

\* Less than 1%

</TABLE>

(1) Includes (i) warrants to purchase 1,450,000 shares of common stock at \$2.20 per share, expiring on September 8, 2008, (ii) 1,000,000 warrants to purchase common stock at \$2.00 per share expiring on August 7, 2007, (iii) 188,325 warrants to purchase common stock at \$6.00 per share expiring on February 22, 2006, (iv) 188,325 warrants to purchase common stock at \$9.00 per share expiring on February 22, 2006, (v) 320,000 stock options to purchase common stock at \$2.60 per share expiring on September 7, 2014, (vi) 73,728 stock options exercisable at \$2.71 per share until exercised and (vii) 492,490 shares of common stock. Also includes 2,355,000 warrants and options originally issued to Dr. Carter and subsequently transferred to Carter Investments of which Dr. Carter is a majority owner. These warrants and options include 170,000 warrants to purchase common stock at \$4.00 per share expiring January 1, 2008; 300,000 warrants to purchase common stock at \$6.00 per share expiring on January 1, 2006; 20,000 warrants to purchase common stock expiring on January 1, 2008; 465,000 warrants to purchase common stock

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at \$1.75 expiring on June 30, 2005 and 1,400,000 warrants to purchase common stock at \$3.50 expiring on September 30, 2007.

(2) Includes (i) 13,750 options to purchase common stock at an exercise price of \$3.50 per share, expiring on January 7, 2007; (ii) warrants to purchase 50,000 shares of Common stock at an exercise price of \$3.50 per share, expiring on February 28, 2006; (iii) warrants to purchase 100,000 shares of common stock at \$5.00 per share, expiring on April 14, 2006; (iv) 30,000 warrants to purchase common stock at \$5.00 per share an expiring on April 30, 2006 (v) options to purchase 10,000 shares at \$4.03 per share that expire on January 3, 2011 (vi) 200,000 warrants exercised at \$2.00 per share expiring on August 13, 2007, (vii) 50,000 options to purchase common stock at \$3.44 per share expiring on June 22, 2014; (viii) 13,824 options to purchase common stock exercisable at \$2.60 per share expiring on September 7, 2014 and (ix) 500 shares of common stock.

(3) Includes (i) 100,000 warrants to purchase common stock at \$2.00 per share expiring on August 13, 2007, (ii) 20,000 warrants to purchase common stock at \$4.00 per share expiring January 2, 2008, (iii) 100,000 stock options to purchase common stock at \$2.75 per share expiring on November 13, 2013, (iv) 50,000 stock options to purchase common stock at \$2.60 per share expiring on September 7, 2014 and 84,430 shares of common stock. Also includes 100,000 stock options originally issued to Mr. Etheridge and subsequently transferred to relatives and trusts. These options to purchase common stock at \$2.75 expire on December 4, 2013.

(4) Includes (i) 20,000 warrants to purchase common stock at \$4.00 per share expiring on January 1, 2006, (ii) 54,608 stock options to purchase Common Stock at \$2.60 per share expiring on September 7, 2014, (iii) 100,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007, (iv) 48,961 shares of common stock owned by Mr. Piani (v) 12,900 shares of common stock owned jointly by Mr. and Mrs. Piani; and (vi) 5,000 shares of common stock owned by Mrs. Piani.

(5) Includes (I) warrants to purchase 12,000 shares of common stock at \$6.00 per share, expiring on August 25, 2008; (ii) 50,000 stock options to purchase common stock at \$2.60 per share expiring on September 7, 2014, (iii) 100,000 warrants exercisable at \$2.00 per share expiring in August 13, 2007 and 53,454 shares of common stock.

(6) Includes (i) stock options to purchase 20,000 shares of common stock at \$3.50 per shares expiring on February 22, 2007; (ii) 50,000 warrants to purchase common stock at \$4.00 per shares expiring on February 28, 2008; (iii) 10,000 stock options exercisable at \$4.03 per share and expiring on January 3, 2011; 50,000 warrants to purchase common stock at \$2.00 per share and expiring on August 13, 2007, 10,000 stock options to purchase common stock at \$1.90 per share expiring on December 7, 2014 and (iv) 8,746 shares of common stock.

(7) Consists of 5,000 warrants to purchase common stock at \$4.00 per share

expiring June 7, 2008; 6,791 stock options exercisable at \$3.50 expiring January 22, 2007, 20,000 warrants exercisable at \$2.00 per share expiring in August 13, 2007, options to purchase 10,000 shares of common stock at \$ 4.03 per share expiring on January 3, 2011 and 10,000 stock options to purchase common stock at \$1.90 per share expiring on December 7, 2014.

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- (8) Consist of 12,000 warrants exercisable at \$3.86 per share expiring on April 30, 2005.
- (9) Consists of options to purchase common stock at \$1.90 per share expiring on December 7, 2014.
- (10) Consists of 250,000 options to purchase common stock at \$1.55 expiring February 13, 2015. These warrants vest at the rate of 12,000 per month beginning March 14, 2005. These options are issued to Sage Healthcare, LLC, an affiliate of The Sage Group. Also includes 89,400 shares of common stock owned by The Sage Group.

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 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 \$60,000 in 2004 and options to purchase Company stock valued at \$237,000 using the Black Scholes pricing model and recorded as stock compensation expense. Richard C. Piani, another of our directors, lives in Paris, France and assisted our European subsidiaries in their dealings with medical institutions and the European Medical Evaluation Authority. Dr. William Mitchell, another of our directors, assisted us in establishing clinical trial protocols and performed other scientific work for us from time to time. The services provided by these latter two directors were terminated in September 2003. For these services, these two directors were paid an aggregate of \$144,955, \$170,150 and \$100,100 for the years ending December 31, 2001, 2002 and 2003, respectively.

Through November 2002, William A. Carter, our Chief Executive Officer, had received an aggregate of \$12,106 in short term advances which were repaid as of December 31, 2002. All advances bore interest at 6% per annum. We loaned \$60,000 to Ransom W. Etheridge in November, 2001 for the purpose of exercising 15,000 class A redeemable warrants. This loan bears interest at 6% per annum.

We paid \$33,450, \$18,800 and \$7,600 for the years ending December 31, 2002, 2003 and 2004, respectively to Carter Realty for the rent of property used at various times in years 2002, 2003 and 2004 by us. The property was owned by others, but was acquired in 2004 by Resort House, LLC of which William A. Carter has minority interest .

Antoni Esteve, one of our former directors, is 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. For more information about our activities with Laboratorios Del Dr. Esteve S.A. see "European Operations" in Item 1. Business above. 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.

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ITEM 14. Principal Accounting Fees and Services.

All audit and professional services provided by BDO Seidman, LLP are approved by the Audit Committee. The total fees billed by BDO Seidman, LLP were \$308,497 in 2003 and \$226,484 in 2004. The following table shows the aggregate fees billed to us by BDO Seidman, LLP for professional services rendered during the year ended December 31, 2004.

<TABLE>

<CAPTION>

<S>	Amount (\$)	
	<C>	<C>
Description of Fees	2003	2004
Audit Fees	\$264,917	\$149,950
Audit-Related Fees	43,580	76,534
Tax Fees	-	-
All Other Fees	-	-

Total	\$308,497 =====	\$226,484 =====
-------	--------------------	--------------------

</TABLE>

Audit Fees

Represents fees for professional services provided for the audit of our annual financial statements 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 are reasonably related to the performance of the audit or review of our financial statements, including those in 2003 and 2004 related to the acquisition of ISI.

The Audit Committee has determined that BDO Seidman, LLP's rendering of these non-audit services is compatible with maintaining auditors independence. The Board of Directors considers BDO Seidman, LLP to be well qualified to serve as our independent public accountants. The committee also approved the charges for services performed in 2004.

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.

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PART IV

ITEM 15. Exhibits and Financial Statement Schedules

(a)(1)(2) Financial Statements and Schedules - See index to financial statements on page F-1 of this Annual Report.

(a)(3) 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)
- 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.
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- 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, (11)
- 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 (11)
- 10.39 Amended and restated engagement agreement with Dr. William A. Carter (11)
- 10.40 Amended and restated engagement agreement with Robert E. Peterson (11)
- 10.41 Engagement Agreement with Ransom W. Etheridge (11)
- 10.42 Change in control agreement with Dr. William A. Carter (11)
- 10.43 Change in control agreement with Dr. William A. Carter (11)
- 10.44 Change in control agreement with Robert E. Peterson (11)
- 10.45 Change in control agreement with Ransom Etheridge (11)
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- 21 Subsidiaries of the Registrant.
- 23.1 BDO Seidman, LLP consent.(11)
- 31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer.(11)
- 31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer.(11)
- 32.1 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer.(11)

32.2 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer.(11)

(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 herewith.

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SIGNATURES

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

HEMISPHERx BIOPHARMA, INC.

By: /s/ William A. Carter

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

March 11, 2005

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

<TABLE>

<CAPTION>

<S>

<C>

<C>

/s/ William A. Carter	William A. Carter,	Chairman of the Board, Chief Executive Officer and Director	March 11, 2005
M.D.			
/s/ Richard Piani	Richard Piani	Director	March 11, 2005
/s/ Robert E. Peterson		Chief Financial Officer	March 11, 2005
Robert E. Peterson			
/s/ Ransom Etheridge	Ransom Etheridge	Secretary And Director	March 11, 2005
/s/ William Mitchell	William Mitchell,	Director	March 11, 2005
M.D., Ph.D.			
/s/ Iraj E. Kiani		Director	March 11, 2005

Iraj E. Kiani, Ph.D.

</TABLE>

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HEMISPHERx BIOPHARMA, INC AND SUBSIDIARIES  
Index to Consolidated Financial Statements

	Page
Report of Independent Registered Certified, Public Accounting Firm. . . . .	F-2
Consolidated Balance Sheets at December 31, 2003 and 2004. . .	F-3
Consolidated Statements of Operations for each of the years in the three-year period ended December 31, 2004. . . . .	F-4
Consolidated Statements of Changes in Stockholders' Equity and Comprehensive (Loss) for each of the years in the three-year period ended December 31, 2004 . . . . .	F-5
Consolidated Statements of Cash Flows for each of the years in the three-year period ended December 31, 2004 . . . . .	F-6
Notes to Consolidated Financial Statements . . . . .	F-8

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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, 2003 and 2004 the related consolidated statements of operations, changes in stockholders' equity and comprehensive loss and cash flows for each of the three years in the period ended December 31, 2004. These consolidated financial statements 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 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, 2003 and 2004 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Hemispherx Biopharma, Inc. internal control over financial reporting as of December 31, 2004, 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 February 4, 2004 expressed an unqualified opinion thereon.

/s/ BDO SEIDMAN, LLP  
Philadelphia, Pennsylvania  
February 4, 2005

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HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES  
Consolidated Balance Sheets  
December 31, 2003 and 2004  
(in thousands)

<TABLE>

<CAPTION>	2003	2004
<S>	<C>	<C>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,764	\$8,813
Short term investments (Note 5)	1,495	7,924
Inventory (Note 3)	2,896	2,148
Accounts and other receivables (Note 2)	282	139
Prepaid expenses and other current assets	170	266
	-----	-----
Total current assets	8,607	19,290
	-----	-----
Property and equipment, net	94	3,303
Patent and trademark rights, net	1,027	908
Investment	408	35
Deferred acquisition costs (Note 4)	1,546	-
Deferred financing costs	393	319
Advance receivable (Note 7)	1,300	1,300
Other assets	29	17
	-----	-----
Total assets	\$ 13,404	\$ 25,172
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 488	\$ 526
Accrued expenses (Note 6)	1,119	1,012
Current portion of long-term debt	-	3,248
	-----	-----
Total current liabilities	1,607	4,786
	-----	-----
Long-Term Debt-net of current portion (Note 7)	2,058	305
Commitments and contingencies (Notes 10, 12, 13 and 15)		
Redeemable common stock (Note 4)	491	-
Stockholders' equity (Note 8):		
Common stock	39	50
Additional paid-in capital	123,054	158,024
Accumulated other comprehensive income	-	(10)
Accumulated deficit	(113,843)	(137,983)
Treasury stock	(2)	-
	-----	-----
Total stockholders' equity	9,248	20,081
	-----	-----
Total liabilities and stockholders' equity	\$ 13,404	\$25,172
	=====	=====

</TABLE>

See accompanying notes to consolidated financial statements.

<PAGE> F-4

HEMISPHERE BIOPHARMA, INC. AND SUBSIDIARIES  
Consolidated Statements of Operations For each of the years  
in the three-year period ended December 31, 2004  
(in thousands, except share and per share data)

<TABLE>

<CAPTION>

<S>	Years ended December 31,		
	2002	2003	2004
<C>	<C>	<C>	<C>
Revenues:			
Sales of product net	\$ -	\$ 509	\$ 1,050
Clinical treatment programs	341	148	179
License fee income	563	-	-
	-----	-----	-----
Total Revenues:	904	657	1,229
Costs and expenses:			
Production/cost of goods sold	-	502	2,112
Research and development	4,946	3,150	3,842
General and administrative	2,015	4,257	6,164
	-----	-----	-----
Total costs and expenses	6,961	7,909	12,118

Equity loss and write off of investments in unconsolidated

affiliates (Note 2c)	(1,470)	-	(373)
Interest and other income	103	80	49
Interest expense		(253)	(384)
Financing costs (Note 7)		(7,345)	(12,543)
	-----	-----	-----
Net loss	\$ (7,424)	\$ (14,770)	\$ (24,140)
	=====	=====	=====
Basic and diluted loss per share	\$ (.23)	\$ (.42)	\$ (.53)
	=====	=====	=====
Weighted average shares outstanding	32,085,776	35,234,526	45,177,862
	=====	=====	=====

</TABLE>

See accompanying notes to consolidated financial statements.

<PAGE> F-5

<TABLE>

<CAPTION>

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES  
Consolidated Statements of Changes in Stockholders' Equity and Comprehensive (loss)  
For each of the years in the  
three-year period ended  
December 31, 2004  
(in thousands except share data)

<S>	<C>	<C>	<C>	<C>	<C>	<C>	<C>	<C>
	Common Stock Shares	Common Stock Par Value	Additional .001 paid-in capital	Accumulated other Comprehensive Income (loss)	Accumulated deficit	Treasury stock shares	Treasury Stock	Total stockhol equity
	-----	-----	-----	-----	-----	-----	-----	-----
Balance at December 31, 2001	32,575,986	\$ 33	\$ 106,832	\$ 17	\$ (91,649)	515,706	\$ (4,470)	\$ 10,7
Common stock issued	25,800	-	37	-	-	-	-	-
Treasury stock Purchased	-	-	-	-	-	27,500	(50)	(
Stock issued in settlement of debt	48,392	-	154	-	-	-	-	1
Stock and stock warrant compensation expense	-	-	132	-	-	-	-	1
Net comprehensive (loss)	-	-	-	18	(7,424)	-	-	(7,4
	-----	-----	-----	-----	-----	-----	-----	-----
Balance at December 31, 2002	32,650,178	33	107,155	35	(99,073)	543,206	(4,520)	3,6
Debt conversion and interest payments	4,334,916	4	6,741	-	-	-	-	6,7
Fair value ascribed to debenture beneficial conversion features and related warrants issued	-	-	9,363	-	-	-	-	9,3
Warrants exercised	790,745	1	1,234	-	-	-	-	1,2
Common stock issued in connection with ISI acquisition	1,068,789	1	1,667	-	-	-	-	1,6
Reclassification of redeemable Common Stock in connection with ISI acquisition	-	-	(491)	-	-	-	-	(4
Treasury stock purchased	-	-	-	-	-	43,000	(83)	(
Treasury Stock retired	(339,543)	-	(4,272)	-	-	(339,543)	4,144	(1
Conversion of minority interest of subsidiary into common stock	347,445	-	946	-	-	-	-	9
Stock issued in settlement of debt	215,047	-	474	-	-	(246,220)	457	9
Stock warrant compensation expense	-	-	237	-	-	-	-	2
Net comprehensive loss	-	-	-	(35)	(14,770)	-	-	(14,8
	-----	-----	-----	-----	-----	-----	-----	-----
Balance December 31, 2003	39,067,577	39	123,054	-	(113,843)	443	(2)	9,2
Treasury shares sold	-	-	-	-	-	(443)	2	-
Shares issued for:								
Payment of accounts payable	127,243	-	382	-	-	-	-	3
OID on convertible debt	158,104	-	465	-	-	-	-	4
Purchase of building	487,028	1	1,626	-	-	-	-	1,6
Conversion of debt	3,691,695	5	7,239	-	-	-	-	7,2
Interest on convertible debt	170,524	-	430	-	-	-	-	4
Private placement, net of issuance costs	3,617,306	3	6,981	-	-	-	-	6,9
Warrants exercised	2,268,586	2	5,091	-	-	-	-	5,0
Stock Issued with convertible debt	43,703	-	8,540	-	-	-	-	8,5
Conversion price adjustment	-	-	1,038	-	-	-	-	1,0
Reclassification of redeemable Common Stock in connection with ISI acquisition	-	-	491	-	-	-	-	4
Options and warrants issued for services	-	-	2,000	-	-	-	-	2,0
Adjustment in accordance with EITF 00-19	-	-	687	-	-	-	-	6
net comprehensive loss	-	-	-	(10)	(24,140)	-	-	(24,1
	-----	-----	-----	-----	-----	-----	-----	-----
Balance December 31, 2004	49,631,766	\$ 50	\$ 158,024	\$ (10)	\$ (137,983)	-	\$ -	\$ 20,0
	=====	=====	=====	=====	=====	=====	=====	=====

</TABLE>

See accompanying notes to consolidated financial statements

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES  
Consolidated Statements of Cash  
Flows for each of the years in the three-year period  
ended December 31, 2004  
(in thousands)

<TABLE>  
<CAPTION>

	Years ended December 31,		
	2002	2003	2004
<S>	<C>	<C>	<C>
Cash flows from operating activities:			
Net loss	\$(7,424)	\$(14,770)	\$(24,140)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of property and			
Equipment	91	80	113
Amortization of patent and			
Trademark rights	206	122	327
Amortization of deferred			
Financing costs	-	7,345	12,543
Equity loss and write off of			
Investments in unconsolidated			
Affiliates	1,470	-	373
Stock option and warrant			
Compensation and service			
Expense	132	237	2,000
Inventory reserve	-	-	225
Changes in assets and liabilities:			
Inventory	-	(1,429)	523
Accounts and other receivables	(1,293)	1,225	143
Prepaid expenses and other			
Current assets	104	(98)	(96)
Accounts payable	(67)	(298)	420
Accrued expenses	385	558	323
Other assets	(13)	6	6
Net cash used in operating			
Activities	(6,409)	(7,022)	(7,240)
Cash flows from investing activities:			
Purchase of property and			
Equipment, net	-	(19)	(150)
Additions to patent and trademark			
Rights	(176)	(154)	(208)
Maturity of short term			
Investments	5,293	520	1,496
Purchase of short term			
Investments	(520)	(1,496)	(7,934)
Deferred acquisition costs	-	(638)	-
Net cash (used in) provided by			
Investing Activities	4,597	(1,787)	(6,796)

(CONTINUED)

</TABLE>

<TABLE>  
<CAPTION>

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES  
Consolidated Statements of Cash Flows (Continued)  
(in thousands)

	Years ended December 31,		
	2002	2003	2004
<S>	<C>	<C>	<C>
Cash flows from financing activities:			
Proceeds from issuance of common	\$ 65	\$ -	\$ -
stock, net	-	-	6,984
Deferred financing costs	-	(835)	(542)
Proceeds from issuance of			
Preferred stock Certificates of			
Subsidiary	946	-	-
Proceeds from long-term borrowing	-	11,300	7,550
Advance receivable	-	(1,300)	-

Proceeds from exercise of stock Warrants	-	1,235	5,093
Purchase of treasury stock	(50)	(83)	-
Net cash provided by financing Activities	961	10,317	19,085
Net increase (decrease) in cash and cash equivalents	(851)	1,508	5,049
Cash and cash equivalents at beginning of year	3,107	2,256	3,764
Cash and cash equivalents at end of year	\$2,256	\$3,764	\$8,813
Supplemental disclosures of cash flow information:			
Issuance of common stock for accounts payable and accrued expenses	\$ 154	\$ 931	\$ 382
Issuance of Common Stock for Acquisition of ISI assets deferred acquisition costs Stock Options and Warrants		\$1,668	\$1,626
Issued for Compensation	\$132	\$237	\$2,000
Issuance of Common Stock for Debt Conversion Interest Payments and debt payments	-	\$6,741	\$7,669
Common Stock Issued for Conversion of Minority Interest in Subsidiary	-	\$946	-

</TABLE>

See accompanying notes to consolidated financial statements.

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HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) Business

Hemispherx Biopharma, Inc. and subsidiaries (the Company) is a pharmaceutical company using nucleic acid technologies to develop therapeutic products for the treatment of viral diseases and certain cancers. The Company's drug technology uses specially configured ribonucleic acid (RNA). The Company's double-stranded RNA drug product, trademarked Ampligen(R), is in human clinical development for various therapeutic indications. The potential efficacy and safety of Ampligen(R) is being evaluated clinically for three anti-viral indications: myalgic encephalomyelitis, also known as chronic fatigue syndrome ("ME/CFS"), human immunodeficiency virus ("HIV") associated disorders, and chronic hepatitis C ("HVC") virus infection. The Company also has clinical experience with Ampligen(R) used in treating patients with certain cancers including renal cell carcinoma (kidney cancer) and metastatic malignant melanoma. The Company has other compounds to be evaluated.

On March 11, 2003, we acquired from Interferon Sciences, Inc. ("ISI") ISI's inventory of ALFERON N INJECTIONS(R), a pharmaceutical product used for the treatment of certain types of genital warts, and a limited license for the production, manufacturing, use, marketing and sale of this product.

The consolidated financial statements include the financial statements of Hemispherx Biopharma, Inc. and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

(2) Summary of Significant Accounting Policies

(a) Cash and Cash Equivalents

Cash equivalents consist of money market certificates and overnight repurchase agreements collateralized by money market securities with original maturities of less than three months, with both a cost and fair value of \$3,764,000 and \$8,813,000 at December 31, 2003 and 2004, respectively.

(b) Short-term Investments

Investments with original maturities of more than three 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 of \$1,495,000 and \$7,924,000 at December 31, 2003 and 2004

respectively. The unrealized gains and losses are recorded as a component of shareholders' equity.

(c) Investments in unconsolidated affiliates

Investments in companies in which the Company owns 20% or more and not more than 50% are accounted for using the equity method of accounting.

Investments in companies in which the Company owns less than 20% of and does not exercise a significant influence are accounted for using the cost method of accounting.

In 1998, the Company invested \$1,074,000 for a 3.3% equity interest in R.E.D. Laboratory ("R.E.D."). R.E.D. is a privately held biotechnology company for the development of diagnostic markers for Chronic Fatigue Syndrome and other chronic immune diseases. We have a research collaboration agreement with R.E.D. to assist in this development. R.E.D. is headquartered in Belgium. The investment was recorded at cost. During the three months ended June 30, 2002 and December 31, 2002 we recorded non-cash charges of \$678,000 and \$396,000 respectively, to

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operations with respect to our investment in R.E.D. These charges were the result of our determination that R.E.D.'s business and financial position had deteriorated to the point that our investments had been permanently impaired.

In April, 1999 we acquired a 30% equity position in the California Institute of Molecular Medicine ("CIMM") for \$750,000 and entered into a research and development arrangement. CIMM'S research is focused on developing therapies for use in treating patients affected by Hepatitis C ("HCV"). We use the equity method of accounting with respect to this investment. During the fourth quarter of 2001 we recorded a non-cash charge of \$485,000 with respect to our investment in CIMM. This was a result of our determination that CIMM's operations have not yet evolved to the point where the full carrying value of our investment could be supported based on that company's financial position and operating results. During 2002, CIMM continued to suffer significant losses resulting in a deterioration of its financial condition. The \$485,000 written off during 2001 represented the unamortized balance of goodwill included as part of the Company's investment. Additionally, during 2001 the Company reduced its investment in CIMM based on its percentage interest in CIMM's continued operating losses. The Company's remaining investment at December 31, 2001 in CIMM, representing its 30% interest in CIMM's equity at such date, was not deemed to be permanently impaired, but was completely written off during 2002. Such amount was not material. These charges are reflected in the Consolidated Statements of Operations under the caption "Equity loss in unconsolidated affiliates".

The Company's investment in Ribotech, Ltd. is also accounted for using the equity method of accounting. The Company received 24.9% of Ribotech, Ltd. as partial compensation under the license agreement described in Note 12. Ribotech, Ltd. has incurred net losses since inception. The Company does not share in those losses in accordance with the licensing agreement and is not obligated to fund such losses. The net investment in Ribotech is zero at all year end periods presented.

Investments include an initial equity investment of \$290,625 in Chronix Biomedical ("Chronix"). Chronix focuses upon the development of diagnostics for chronic diseases. This initial investment was made in May 31, 2000 by the issuance of 50,000 shares of Company common stock from the treasury. On October 12, 2000, the Company issued an additional 50,000 shares of its common stock and on March 7, 2001 the Company issued 12,000 more shares of its common stock from the treasury to Chronix for an aggregate equity investment of \$700,000. The percentage ownership in Chronix is approximately 5.4% and is accounted for under the cost method of accounting. During the quarters ended December 31, 2002 and September 30, 2004, we recorded non cash charges of \$292,000 and \$373,000, respectively with respect to our investment in Chronix. This impairment reduces our carrying value to reflect a permanent decline in Chronix's market value based on its then proposed investment offerings.

(d) Property and Equipment

(000 omitted)

December 31,

-----

2003                      2004

-----

Land and buildings	\$ -	\$ 3,316
Furniture, fixtures, and equipment	779	786
Leasehold improvements	85	85
	-----	-----
Total property and equipment	864	4,187
Less accumulated depreciation	770	884
	-----	-----
Property and equipment, net	\$ 94	\$ 3,303
	=====	=====

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Property and equipment consists of land, building, furniture, fixtures, office equipment, and leasehold improvements and is recorded at cost. Depreciation and amortization is computed using the straight-line method over the estimated useful lives of the respective assets, ranging from five to thirty-nine years. Depreciation and amortization expense was \$91,000, \$80,000 and \$113,000 for 2002, 2003 and 2004, respectively. In 2002, fully depreciated equipment in the amount of \$418,000 and fully depreciated leasehold improvements in Europe in the amount of \$12,000 were written-off due to the closing of European offices.

(e) Patent and Trademark Rights

Patents and trademarks are stated at cost (primarily legal fees) and are amortized using the straight line method over the established useful life of 17 years. The Company reviews its 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 on an undiscounted cash flow basis to support the realizability of its respective capitalized cost. Management's review addresses whether each patent continues to fit into the Company's strategic business plans. During the years ended December 31, 2002, 2003 and 2004, the Company decided not to pursue the technology in certain countries for strategic reasons and recorded charges of \$5,000, \$5,000 and \$223,000 respectively. Amortization expense was \$201,000, \$122,000 and \$104,000 in 2002, 2003 and 2004, respectively. The accumulated amortization as of December 31, 2003 and 2004 is \$2,150,000 and \$1,807,000, respectively.

As of December 31, 2004, the weighted average remaining life of the patents and trademarks was 8.7 years. Amortization of patents and trademarks for each of the next five years is as follows: 2005 - \$87,000, 2006 - \$87,000, 2007 - \$86,000, 2008 - \$86,000 and 2009 - \$86,000.

(f) Revenue and License Fee Income

On March 20, 2002 our European Subsidiary Hemispherx Biopharma Europe, S.A. ("Hemispherx, S.A.") entered into a Sales and Distribution agreement with Laboratorios del Dr. Esteve S.A. ("Esteve"). Pursuant to the terms of the Agreement, Esteve was granted the exclusive right to market Ampligen(R) in Spain, Portugal and Andorra for the treatment of Myalgic Encephalitis/Chronic Fatigue Syndrome ("ME/CFS"). Esteve paid the initial and non refundable fee of 625,000 Euros (approximately \$563,000) to Hemispherx S.A. on April 24, 2002.

The terms of the agreement granting the licensee marketing rights for Ampligen(R) for the treatment of myalgic/chronic fatigue syndrome ("ME/CFS") in Spain, Portugal and Andorra require the Company to provide the licensee with technical, scientific and commercial information. The Company fulfilled the requirements during the first quarter of 2002. The agreement terms required no additional performance on the part of the Company.

The agreement also requires the licensee to pay of 1,000,000 Euros after FDA approval of Ampligen(R) for the treatment of ME/CFS and a fee of 1,000,000 after issuance in Spain of final marketing approval authorization for Ampligen(R) for the treatment of ME/CFS.

Revenues for non-refundable license fees are recognized under the Performance Method-Expected Revenue. This method considers the total amount of expected revenue during the performance period, but limits the amount of revenue recognized in a period to total non-refundable cash received to date. This limitation is appropriate because future milestone payments are contingent on future events.

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Upon receipt, the upfront non-refundable payment is deferred. The non-refundable upfront payments plus non-refundable payments arising from the achievement of defined milestones are recognized as revenue over the performance period based on the lesser of (a) percentage of completion or (b) non-refundable cash earned (including the upfront payment).

This method requires the computation of a ratio of cost incurred to date to total expected costs and then apply that ratio to total expected revenue. The amount of revenue recognized is limited to the total non-refundable cash received to date.

The percentage of expenses incurred to date to total expected expenses in connection with the research and development project, exceed the percentage of license fees received compared to total license fees to be earned per the agreement. Therefore the amount of revenue recognized by the Company was limited to the total non-refundable cash received to date of approximately \$563,000.

We executed a Memorandum of Understanding (MOU) in January 2004 with Fujisawa Deutschland GmbH, ("Fuji") a major pharmaceutical corporation, granting them an exclusive option for a limited number of months to enter a Sales and Distribution Agreement with exclusive rights to market Ampligen(R) for ME/CFS in Germany, Austria and Switzerland. The MOU required us to file the full report on the results of our AMP 516 Clinical Trial with Fuji by May 31, 2004. If the full report was not provided to Fuji by May 31, 2004 and Fuji did not wish to exercise its option, we would have been required to refund one half of the 400,000 Euro fee. We submitted our initial report to Fuji on May 28, 2004 and responded to subsequent inquiries for additional information. The option period ends 12 weeks after the later of Fuji's review of the full report on the results of our Amp 516 clinical trial and Fuji's meeting with three of the trial's principal investigators. We received an initial fee of 400,000 Euros (approximately \$497,000 US). If we did not provide them with the full report by December 31, 2004 and Fuji did not wish to exercise its option, we would be required to refund the entire fee. On November 9, 2004, we and Fuji terminated the MOU by mutual agreement. We did not agree on the process to be utilized in certain European Territories for obtaining commercial approval for the sale of Ampligen(R) in the treatment of patients suffering from Chronic Fatigue Syndrome (CFS). Instead of a centralized procedure, and in order to obtain an earlier commercial approval of Ampligen(R) in Europe, we have determined to follow a decentralized filing procedure which was not anticipated in the MOU. We believe that it now is in the best interest of our stockholders to potentially

accelerate entry into selected European markets whereas the original MOU specified a centralized registration procedure. Pursuant to mutual agreement of the parties we refunded 200,000 Euros to Fuji. We have recorded the remaining 200,000 Euros as an accrued liability as of December 31, 2004. We are currently holding the 200,000 Euros pending further developments in accordance with the mutually agreed upon termination with Fuji.

Revenue from the sale of Ampligen(R) 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 Alferon N Injection(R) are recognized when the product is shipped, as title is transferred to the customer. The Company has no other obligation associated with its products once shipment has occurred.

(g) Net Loss Per Share

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Equivalent common shares, consisting of stock options and warrants, are excluded from the calculation of diluted net loss per share since their effect is antidilutive.

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(h) Accounting for Income taxes

Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws in effect when the differences are expected to reverse. The measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance for any tax benefits, which are not expected to be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

(i) Comprehensive (loss)

Comprehensive (loss) consists of net loss and net unrealized gains (losses) on securities and is presented in the consolidated statements of changes in stockholders' equity and comprehensive (loss).

(j) Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Actual results could differ from those estimates.

(k) Foreign currency translations

Assets and liabilities of the Company's foreign operations are generally translated into U.S. dollars at current exchange rates as of balance sheet date. Revenues and expenses are translated at average exchange rates during each period. Transaction gains and losses that arise from exchange rate fluctuations are included in the results of operations as incurred. The resulting translation adjustments are immaterial for all years presented.

(l) Recent Accounting Standard and Pronouncements:

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 123 (revised 2004) (FASB 123R), Shared-Based Payment. FASB 123R will require the Corporation to expense share-based payments, including employee stock options, based on their fair value. The Corporation is required to adopt the provisions of FASB 123R effective as of the beginning of its third quarter in 2005. FASB 123R provides alternative methods of adoption, which include prospective application and a modified retroactive application. The Corporation is currently evaluating the financial impact, including the available alternative of adoption of FASB 123R.

(m) Research and Development Costs

Research and development related to both future and present products are charged to operation as incurred.

(n) Stock Based Compensation

The Company follows Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock-Based Compensation." We chose to apply Accounting Principal Board Opinion 25 and related interpretations in accounting for stock options granted to our employees.

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The Company provides pro forma disclosures of compensation expense under the fair market value method of SFAS No. 123, "Accounting for Stock-Based Compensation," and SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure."

The weighted average assumptions used for the years presented are as follows:

<TABLE>

<CAPTION>

		December 31,		
		2002	2003	2004
		-----	-----	-----
<S>		<C>	<C>	<C>
Risk-free interest rate	5.23%	5.23%	2.25 - 3.4%	
Expected dividend yield	-	-	-	
Expected lives		2.5 yrs	2.5 yrs	5-10 yrs
Expected volatility	63.17%	98.07%	68.92-71.16%	

</TABLE>  
Had compensation cost for the Company's option plan been determined using the fair value method at the grant dates, the effect on the Company's net loss and loss per share for the years ended December 31, 2002, 2003, and 2004 would have been as follows:

(In Thousands except for per share data)

For the years ended December 31,	2002	2003	2004
-----	-----	-----	-----
Net (loss) as reported	\$(7,424)	\$(14,770)	\$(24,140)
Add: Stock based compensation included in net loss as reported, net of related tax effects	-	-	1,769
Deduct: Stock based compensation determined under fair value based method for all awards, net of related tax effects	(1,085)	(1,825)	(638)
Pro forma - net loss	\$(8,509)	\$(16,594)	\$(23,009)
	=====	=====	=====
Basic and diluted loss per share - as reported	\$(.23)	\$(.42)	\$(.53)
	=====	=====	=====
Basic and diluted loss per share - pro forma	\$(.27)	\$(.47)	\$(.51)
	=====	=====	=====

For stock warrants granted to non-employees, the Company measures fair value of the equity instruments utilizing the Black-Scholes method if that value is more reliably measurable than the fair value of the consideration or service received. The Company amortizes such cost over the related period of service.

The exercise price of all stock warrants granted was equal to or greater than the fair market value of the underlying common stock as defined by APB 25 on the date of the grant.

(0) Accounts Receivable

Concentration of credit risk, with respect to accounts receivable, is limited due to the Company's credit evaluation process. The Company does not require collateral on its receivables. The Company's receivables primarily consist of amounts due from the wholesale drug companies as of December 31, 2004.

(3) Inventories

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

Inventories consist of the following:

	December 31,	
	2003	2004
	-----	-----
Raw materials and work in process	\$1,729	\$1,711
Finished goods, net of reserves of \$225,000 at December 31, 2004	1,167	437
	-----	-----
	\$2,896	\$2,148
	=====	=====

(4) ACQUISITION OF ASSETS OF INTEFERON SCIENCES, INC.

On March 11, 2003, we acquired from ISI, ISI's inventory of ALFERON N Injection(R) and a limited license for the production, manufacture, use, marketing and sale of this product. As partial consideration, we issued 487,028 shares of our common stock to ISI Pursuant to our agreements with ISI, we registered these shares for public sale and ISI has reported that it has sold all of these shares. We also agreed to pay ISI 6% of the net sales of ALFERON N Injection(R).

On March 11, 2003, we also entered into an agreement to purchase from ISI all of its rights to the product and other assets related to the product including, but not limited to, real estate and machinery. For these assets, we agreed to issue to ISI an additional 487,028 shares and to issue 314,465 shares and 267,296 shares, respectively to the American National Red Cross and GP Strategies Corporation, two creditors of ISI. We guaranteed the market value of all but 62,500 of these shares to be \$1.59 per share on the termination date. As discussed below, we issued all of these shares and ISI, GP Strategies and the American National Red Cross have reported that they have sold all of their shares.

We also agreed to satisfy other liabilities of ISI which were past due and secured by a lien on ISI's real estate and to pay ISI 6% of the net sales of products containing natural alpha interferon.

On May 30, 2003, we issued the shares to GP Strategies and the American National Red Cross. Pursuant to our agreements with ISI and these two creditors, we registered the foregoing shares for public sale. We guaranteed the market value all but 62,500 of these shares to be \$1.59 per share. As a result at December 31, 2003 the guaranteed value of these shares (\$491,000), which had not been sold by these two creditors, were reclassified to redeemable common stock. At December 31, 2004 all shares had been sold by these two creditors and the redeemable common stock was reclassified to equity.

On November 6, 2003 we acquired and subsequently paid, the outstanding ISI property tax lien certificates in the aggregate amount of \$457,000 from certain investors. These tax liens were issued for property taxes and utilities due for 2000, 2001 and 2002.

In March 2004, we issued 487,028 shares to ISI to complete the acquisition of the balance of ISI's rights to market its product as well its production

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facility in New Brunswick, New Jersey. ISI has sold all of its shares. The aggregated cost of the land and buildings was approximately \$3,316,000. The cost of the land and buildings was allocated as follows:

Land	\$ 423,000
Buildings	2,893,000
	-----
Total cost	\$ 3,316,000
	=====

We accounted for these transactions as a Business Combination under Statement of Financial Accounting Standards ("SFAS") No. 141 Accounting for Business Combinations.

The following table represents the Unaudited pro forma results of operations as though the ISI acquisitions had occurred on January 1, 2003.

Year Ended December 31, 2003  
(in thousands except for share data)

Net revenues	\$ 899
Expenses	(16,215)
5787:	
Net Loss	\$(15,316)
	=====
Basic and diluted loss per share	\$(.43)
	-----
Weighted average shares outstanding	35,326,594
	=====

(5) Short-term investments:

Securities classified as available for sale at December 31, 2003 consisted of General Motors commercial paper with a cost approximating its market value of \$1,495,000 and matures in April and May 2004, and at December 31, 2004 consisted of General Motors and Ford Motor commercial paper with a market value of \$7,924,000 which was \$10,000 less than its cost and matures in May 2005, January 2006 and February 2006 in the amount of \$1,018,000, \$3,222,000 and \$3,684,000, respectively.

(6) Accrued Expenses

Accrued expenses at December 31, 2003 and 2004 consists of the following:

	(000's omitted)	
	December 31,	
	-----	
	2003	2004
	-----	
Compensation . . . . .	\$ 366	\$ 385

Interest	158	112
Commissions and royalties	100	47
Professional fees	126	50
Other expenses . . . . .	369	418
	-----	-----
	\$ 1,119	\$ 1,012
	=====	=====

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(7) Debenture Financing

Long term debt consists of the following:

	(in thousands)	
	December	December
	31, 2003	31, 2004
	-----	-----
July 2003 Debenture	\$ 2,334	\$ -
October 2003 Debenture	4,257	2,072
January 2004 Debenture	-	3,083
July 2004 Debenture	-	2,000
	-----	-----
Total	6,591	7,155
Less Discounts	(4,533)	(3,602)
	-----	-----
Balance	2,058	3,553
Less Current Portion of long-term debt (net of discounts of \$3,239)	-	(3,248)
	-----	-----
Total long-term debt	\$ 2,058	\$ 305
	=====	=====

On March 12, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due January 2005 (the "March Debentures") and an aggregate of 743,288 warrants to two investors in a private placement for aggregate gross proceeds of \$4,650,000. The March Debentures were to mature on January 31, 2005 and bore interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest were valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Pursuant to the terms and conditions of the March Debentures, we pledged all of our assets, other than our intellectual property, as collateral and were subject to comply with certain financial and negative covenants, which include but were not limited to the repayment of principal balances upon achieving certain revenue milestones.

The March Debentures were convertible at the option of the investors at any time through January 31, 2005 into shares of our common stock. The conversion price under the March Debentures was fixed at \$1.46 per share, subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect.

The investors also received Warrants to acquire at any time through March 12, 2008 an aggregate of 743,288 shares of common stock at a price of \$1.68 per share. On March 12, 2004, the exercise price of the Warrants was to reset to the lesser of the exercise price then in effect or a price equal to the average of the daily price of the common stock between March 13, 2003 and March 11, 2004 (but in no event less than \$1.176 per share). The exercise price (and the reset price) under the Warrants also was subject to similar adjustments for anti-dilution protection. All of these warrants have been exercised.

We entered into a Registration Rights Agreement with the investors in connection with the issuance of the March Debentures and the Warrants. The Registration Rights Agreement requires that we register the shares of common stock issuable

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upon conversion of the Debentures, as interest shares under the Debentures and upon exercise of the Warrants. In accordance with this agreement, we have registered these shares for public sale.

As of December 31, 2003, the investors had converted the total \$5,426,000 principal of the March Debentures into 3,716,438 shares of our common stock. The total interest on these debentures was \$111,711 of which \$17,290 was paid in cash and \$94,421 was paid by the issuance of shares of our common stock. The investor exercised all 743,288 warrants in July 2003 which produced proceeds in the amount of \$1,248,724.

On July 10, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due July 31, 2005 (the "July 2003 Debentures") and an aggregate of 507,102 Warrants (the "July 2008 Warrants") to the same investors who purchased the March Debentures, in a private placement for aggregate proceeds of \$4,650,000. Pursuant to the terms of the July 2003 Debentures, \$1,550,000 of the proceeds from the sale of the July 2003 Debentures were to have been held back and released to us if, and only if, we acquired ISI's facility within a set timeframe. These funds were released to us in October 2003 although we had not acquired ISI's facility at that time. The July

2003 Debentures mature on July 31, 2005 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date.

The July 2003 Debentures are convertible at the option of the investors at any time through July 31, 2005 into shares of our common stock. The conversion price under the July 2003 Debentures was fixed at \$2.14 per share; however, as part of the subsequent debenture placement closed on October 29, 2003 (see below), the conversion price under the July 2003 Debentures was lowered to \$1.89 per share. The conversion price is subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect. In addition, in the event that we do not pay the redemption price at maturity, the Debenture holders, at their option, may convert the balance due at the lower of (a) the conversion price then in effect and (b) 95% of the lowest closing sale price of our common stock during the three trading days ending on and including the conversion date.

The July 2008 Warrants received by the investors, as amended, were an aggregate of 507,102 shares of common stock at a price of \$2.46 per share. The amended Warrants resulted in an additional debt discount of approximately \$335,000 in 2004. These Warrants were exercised in July 2004 which produced gross proceeds in the amount of \$1,247,470.

On June 25, 2003, we issued to each of the March 12, 2003 Debenture holders warrants to acquire at any time through June 25, 2008 an aggregate of 1,000,000 shares of common stock at a price of \$2.40 per share (the "June 2008 Warrants"). These warrants were issued as incentive for the debenture holders to exercise prior warrant issuances. This issuance resulted in an additional debt discount to the March debentures of \$2,640,000. Pursuant to our agreement with the Debenture holders, we have registered the shares issuable upon exercise of these June 2008 Warrants for public sale. These warrants were exercised in May 2004 and we received gross proceeds of \$2,400,000.

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As of December 31, 2004, the investors had converted the total \$5,426,000 principal of the July Debentures into 2,870,900 shares of common stock.

On October 29, 2003, we issued an aggregate of \$4,142,357 in principal amount of 6% Senior Convertible Debentures due October 31, 2005 (the "October 2003 Debentures") and an aggregate of 410,134 Warrants (the "October 2008 Warrants") in a private placement for aggregate gross proceeds of \$3,550,000. Pursuant to the terms of the October 2003 Debentures, \$1,550,000 of the proceeds from the sale of the October 2003 Debentures were held back and were to be released to us if, and only if, we acquired ISI's facility within 90 days of January 26, 2004 and provide a mortgage on the facility as further security for the October 2003 Debentures. In March 2004, we acquired the facility and we subsequently provided the mortgage of the facility to the Debenture holders. The October 2003 Debentures mature on October 31, 2005 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date.

Upon completing the sale of the October 2003 Debentures, we received \$3,275,000 in net proceeds consisting of \$1,725,000 from the October 2003 Debentures and \$1,550,000 that had been withheld from the July 2003 Debentures. As noted above, pursuant to the terms of the October 2003 Debentures, \$1,550,000 of the proceeds from the sale of the October 2003 Debentures had been held back. However, these proceeds were released to us in April 2004. As required by the Debentures, we have provided a mortgage on the ISI facility as further security for the Debentures.

The October 2003 Debentures are convertible at the option of the investors at any time through October 31, 2005 into shares of our common stock. The conversion price under the October 2003 Debentures is fixed at \$2.02 per share, subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect. In addition, in the event that we do not pay the redemption price at maturity, the Debenture holders, at their option, may convert the balance due at the lower of (a) the conversion price then in effect and (b) 95% of the lowest closing sale price of our common stock during the three trading days ending on and including the conversion date.

The October 2008 Warrants, as amended, received by the investors were to acquire an aggregate of 410,134 shares of common stock at a price of \$2.32 per share. The amended Warrants resulted in a reduction in debt discount of approximately \$53,000 in 2004. These Warrants were exercised in July 2004 which produced gross proceeds in the amount of \$951,510.

As of December 31, 2004, the investors had converted \$2,071,178 principal amount of the Debenture into 1,025,336 shares of Common Stock.

On January 26, 2004, we issued an aggregate of \$4,000,000 in principal amount of 6% Senior Convertible Debentures due January 31, 2006 (the "January 2004 Debentures"), an aggregate of 790,514 warrants (the "July 2009 Warrants") and 158,103 shares of common stock, and Additional Investment Rights (to purchase up to an additional \$2,000,000 principal amount of January 2004 Debentures

commencing in six months) in a private placement for aggregate net proceeds of \$3,695,000. The January 2004 Debentures mature on January 31, 2006 and bear  
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interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Commencing July 26, 2004, we are required to start repaying the then outstanding principal amount under the January 2004 Debentures in monthly installments amortized over 18 months in cash or, at our option, in shares of common stock. After one installment payment of \$111,111 in our common stock, one debenture holder exercised its right to waive further installment payments on their note. Any shares of common stock issued to the investors as installment payments shall be valued at 95% of the average closing price of the common stock during the 10-day trading period commencing on and including the eleventh trading day immediately preceding the date that the installment is due.

The January 2004 Debentures are convertible at the option of the investors at any time through January 31, 2006 into shares of our common stock. The conversion price under the January 2004 Debentures was fixed at \$2.53 per share, subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect. In addition, in the event that we do not pay the redemption price at maturity, the Debenture holders, at their option, may convert the balance due at the lower of (a) the conversion price then in effect and (b) 95% of the lowest closing sale price of our common stock during the three trading days ending on and including the conversion date. Upon completion of the August 2004 Private Placement (see Note 8), the conversion price was lowered to \$2.08 per share. As of December 31, 2004, the remaining principal on these debentures was \$3,083,073. The investors converted \$139,150 principal amount of the January 2004 Debenture into 55,000 shares of common stock. In addition, installment payments of \$777,777 were made to our investors amounting to 358,932 shares of our common stock.

There are two classes of July 2009 Warrants received by the Investors: Class A and Class B. The Class A warrants are to acquire any time from July 26, 2004 through July 26, 2009 an aggregate of up to 395,257 shares of common stock at a price of \$3.29 per share. The Class B warrants are to acquire any time from July 26, 2004 through July 26, 2009 an aggregate of up to 395,257 shares of common stock at a price of \$5.06 per share. On January 27, 2005, the exercise price of these July 2009 Class A and Class B Warrants will reset to the lesser of their respective exercise price then in effect or a price equal to the average of the daily price of the common stock between January 27, 2004 and January 26, 2005. The exercise price (and the reset price) under the July 2009 Warrants also is subject to similar adjustments for anti-dilution protection. Notwithstanding the foregoing, the exercise prices as reset or adjusted for anti-dilution, will in no event be less than \$2.58 per share. Upon completion of the August 2004 Private Placement (see Note 8), the exercise price was lowered to \$2.58 per share.

We also issued to the investors Additional Investment Rights pursuant to which the investors have the right to acquire up to an additional \$2,000,000 principal amount of January 2004 Debentures (the July 2004 Debentures) from us. The July 2004 Debentures are identical to the January 2004 Debentures except that the conversion price is \$2.58. The investors exercised the Additional Investment Rights on July 13, 2004 and we received net proceeds of \$1,860,000. Upon completion of the August 2004 Private Placement (see below), the conversion price was lowered to \$2.08 per share. As of December 31, 2004, the Debenture holders had not converted any portion of this debenture.  
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Pursuant to the terms and conditions of all of the outstanding Debentures (collectively, the "Debentures"), we have pledged all of our assets, other than our intellectual property, as collateral, and we are subject to comply with certain financial and negative covenants.

On May 14, 2004, in consideration for the Debenture holders' exercise of all of the June 2008 Warrants, we issued to the holders warrants (the "May 2009 Warrants") to purchase an aggregate of 1,300,000 shares of our common stock. As a result the warrants were valued at \$2,355,000 which was recorded as additional debt discounts. We issued 1,000,000 shares of common stock and received gross proceeds of \$2,400,000 from the exercise of the June 2008 Warrants.

The May 2009 Warrants are to acquire at any time commencing on November 14, 2004 through April 30, 2009 an aggregate of 1,300,000 shares of common stock at a price of \$4.50 per share. On May 14, 2005, the exercise price of these May 2009 Warrants will reset to the lesser of the exercise price then in effect or a price equal to the average of the daily price of the common stock between May 15, 2004 and May 13, 2005. The exercise price (and the reset price) under the May 2009 Warrants also is subject to adjustments for anti-dilution protection similar to those in the other Warrants. Notwithstanding the foregoing, the exercise price as reset or adjusted for anti-dilution, will in no event be less than \$4.008 per share. This transaction generated a non-cash charge of about \$2,300,000 financing costs in the second quarter of 2004. Upon completion of the August 2004 Private Placement (see below), the exercise price was lowered to \$4.008 per share.

We entered into Registration Rights Agreements with the investors in connection with the issuance of (i) the Debentures; (ii) the June 2008, July 2008, October 2008, July 2009, and May 2009 Warrants (collectively, the "Warrants"); and (iii)

the shares issued in January 2004. Pursuant to the Registration Rights Agreements we have registered on behalf of the investors the shares issued to them in January 2004 and 135% of the shares issuable upon conversion of the Debentures and upon exercise of all of the Warrants. If, subject to certain exceptions, sales of all shares so registered cannot be made pursuant to the registration statements, then we will be required to pay to the investors their pro rata share of \$.00067 times the outstanding principal amount of the relevant Debentures for each day the above condition exists.

As discussed below, Section 713 of the American Stock Exchange ("AMEX") Company Guide provides that we must obtain stockholder approval before issuance, at a price per share below market value, of common stock, or securities convertible into common stock, equal to 20% or more of our outstanding common stock (the "Exchange Cap"). The Debentures (including the July 2004 Debentures) and Warrants have provisions that require us to pay cash in lieu of issuing shares upon conversion of the Debentures or exercise of the Warrants if we are prevented from issuing such shares because of the Exchange Cap. In May 2004, the Debenture holders agreed to amend the provisions of these Debentures and Warrants to limit the maximum amount of funds that the holders could receive in lieu of shares upon conversion of the Debentures and/or exercise of the Warrants in the event that the Exchange Cap was reached to 119.9% of the conversion price of the relevant Debentures and 19.9% of the relevant Warrant exercise price. See below for the accounting effect on this matter.

As of December 31, 2004, the investors have converted \$13,062,329 principal amount of debt from the Debentures issued in March, July and October 2003 and January 2004 into 8,026,606 shares of our common stock. \$777,777 of principal was repaid with the issuance of 358,932 shares of stock. The March and July

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Debentures have been fully converted. The remaining principal balance on the outstanding Debentures is convertible into shares of our stock at the option of the investors at any time, through the maturity date. In addition, we have paid \$1,300,000 into the debenture cash collateral account as required by the terms of the October 2003 Debentures. The amounts paid through December 31, 2004 have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of December 31, 2004. The cash collateral account provides partial security for repayment of the outstanding Debentures in the event of default.

By agreement with Cardinal Securities, LLC, for general financial advisory services and in conjunction with the private debenture placements in July and October 2003 and in January, May and July 2004, we paid Cardinal Securities, LLC an investment banking fee equal to 7% of the investments made by the two Debenture holders and issued to Cardinal the following common stock purchase warrants: (i) 112,500 exercisable at \$2.57 per share; (ii) 87,500 exercisable at \$2.42 per share; and (iii) 100,000 exercisable at \$3.04 per share. The \$2.57 warrants expire on July 10, 2008, the \$2.42 warrants expire on October 29, 2008 and the \$3.04 warrants expire on January 5, 2009. With regard to the exercise of the June 2008 Warrants and issuance of the May 2009 Warrants, Cardinal received an investment banking fee of 7%, half in cash and half in shares. With regard to the exercise of the Additional Investment Rights, the July 2008 and October 2008 Warrants and issuance of the July 2009 Warrants, Cardinal received an investment banking fee of 7%, 146,980 in cash and 22,703 in shares as well as 50,000 warrants exercisable at \$4.07 expiring on July 12, 2009. By agreement with Cardinal, we have registered all of the foregoing shares and shares issuable upon exercise of the above mentioned warrants for public sale and we have agreed to register the balance. As a result of all of the transactions discussed above, the Company recorded \$1,430,000 as additional debt discounts.

Section 713 of the AMEX Company Guide provides that we must obtain stockholder approval before issuance, at a price per share below market value, of common stock, or securities convertible into common stock, equal to 20% or more of our outstanding common stock (the "Exchange Cap"). Taken separately, the July 2003, October 2003 and January 2004 Debenture transactions do not trigger Section 713. However, the AMEX took the position that the three transactions should be aggregated and, as such, stockholder approval was required for the issuance of common stock for a portion of the potential exercise of the warrants and conversion of the Debentures in connection with the January 2004 Debentures. The amount of potential shares that we could exceed the Exchange Cap amounted to approximately 1,299,000. In accordance with EITF 00-19, Accounting For Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock, we recorded on January 26, 2004, a redemption obligation of approximately \$1,244,000. This liability represented the fair market value of the warrants and beneficial conversion feature related to the 1,299,000 shares.

In addition, in accordance with EITF 00-19, we revalued this redemption obligation associated with the beneficial conversion feature and warrants as of March 31, 2004. We recorded an additional redemption obligation and finance charge of \$947,000 as a result of this revaluation. Upon stockholder approval, our redemption obligation was recorded as additional paid in capital as of the date approval was received.

The requisite stockholder approval was obtained at our Annual Meeting of Stockholders on June 23, 2004. In accordance with EITF 00-19, we revalued this redemption obligation associated with the beneficial conversion feature and warrants as of June 23, 2004. We recorded a reduction in the value of the redemption obligation and financing charge of \$260,000 as a result of this revaluation. In addition, upon receiving the requisite stockholder approval,

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this redemption obligation was reclassified as additional paid in capital as of the date the approval was received or June 23, 2004.

On July 13, 2004, the Debenture holders exercised all of the July 2003 and October 2003 Warrants and the Additional Investment Rights amounting to approximately \$4,198,980 in gross proceeds to the Company. We issued to these holders warrants (the "June 2009 Warrants") to purchase an aggregate of 1,300,000 shares of common stock. The issuance of these warrants resulted in an additional debt discount to the note of \$1,320,000 as explained below and a financing charge of \$2,351,000.

The June 2009 Warrants are to acquire at any time commencing on January 13, 2005 through June 30, 2009 an aggregate of 1,300,000 shares of common stock at a price of \$3.75 per share. On July 13, 2005, the exercise price of these June 2009 Warrants will reset to the lesser of the exercise price then in effect or a price equal to the average of the daily price of the common stock between July 14, 2004 and July 12, 2005. The exercise price (and the reset price) under the June 2009 Warrants also is subject to adjustments for anti-dilution protection similar to those in the other Warrants. Notwithstanding the foregoing, the exercise price as reset or adjusted for anti-dilution, will in no event be less than \$3.33 per share. Upon completion of the August 2004 Private Placement (see below), the exercise price was lowered to \$3.33 per share. This transaction was subject to a non-cash financing charge of \$1,320,000 to be amortized over the remaining life of the October 2003 Debentures. The Company agreed to register the shares issuable upon exercise of the June 2009 Warrants pursuant to substantially the same terms as the registration rights agreements between the Company and the holders. Pursuant to this obligation, the Company has registered the shares.

The March, July, October and January 2004 issuances of 6% Senior Convertible Debentures in the principal amounts of \$5,426,000, \$4,142,357 and \$4,000,000 and \$2,000,000 respectively 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. The Company determined the fair values to be ascribed to detachable warrants issued with the convertible debentures utilizing the Black-Scholes method. We recorded debt discounts of approximately \$17.4 million which, in effect, reduced the carrying value of the debt to \$3.6 million. For additional information refer to note 7 to our consolidated financial statements for year ended December 31, 2004.

As of December 31, 2004, the Company was in violation of one minor debt covenant contained within its debenture agreement. Subsequently, the we obtained a letter of waiver from the debenture holders with respect with this matter.

In connection with the Debenture agreements, we have outstanding letters of credit of \$1 million as additional collateral.

#### (8) Stockholders' Equity

##### (a) Preferred Stock

The Company is authorized to issue 5,000,000 shares of \$.01 per value preferred stock with such designations, rights and preferences as may be determined by the board of directors. There were no preferred shares issued and outstanding at December 31, 2003 and 2004.

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##### (b) Common Stock

On July 31, 2003, we had approximately 104,000 shares of our \$.001 authorized shares of \$.001 par value Common Stock that were not issued or reserved for issuance. In order to accommodate the shares needed for the July Debenture, Dr. Carter, our Chief Executive Officer and Cardinal Capital, the placement agent, agreed that they would not exercise their warrants or options unless and until our stockholders approved an increase in our authorized shares of common stock (see note 11). This action freed up 3,206,650 shares. One of the proposals for the annual meeting of our stockholders that was held in September 2003 was an amendment to our certificate of incorporation to increase the authorized shares of common stock from 50,000,000 to 100,000,000 (the "Proposal"). We could not be assured that the Proposal would be approved.

Our stockholders approved an amendment to our corporate charter at the Annual Shareholder meeting held in Philadelphia, PA on September 10, 2003. This amendment increased our authorized shares from 50,000,000 to 100,000,000.

As of December 31, 2003 and 2004, 39,067,134 and 49,631,766 shares, net of shares held in the treasury, were outstanding, respectively.

##### (c) Minority Shareholder Interest

On March 20, 2002 our European Subsidiary Hemispherx Biopharma Europe, S.A. ("Hemispherx, S.A.") entered into a Sales and Distribution agreement with Laboratorios del Dr. Esteve S.A. ("Esteve"). Pursuant to the terms of the Agreement, Esteve was granted the exclusive right to market Ampligen(R) in Spain Portugal and Andorra for the treatment of Myalgic Encephalitis/Chronic Fatigue Syndrome ("ME/CFS"). In addition to other terms and other projected payments, Esteve paid an initial and non refundable fee of 625,000 Euros (approximately \$563,000) to Hemispherx S.A. on April 24, 2002 as the first part of a series of milestone based payments.

During March 2002, Hemispherx Biopharma Europe, S.A. (Hemispherx S.A.) was authorized to issue up to 22,000,000 Euros of seven percent (7%) convertible preferred securities. Such securities will be guaranteed by the parent company and will be converted into a specified number of shares of Hemispherx S.A. pursuant to the securities agreement. Conversion is to occur on the earlier of an initial public offering of Hemispherx S.A. on a European stock exchange or September 30, 2003.

Esteve purchased 1,000,000 Euros of Hemispherx Biopharma Europe S.A.'s convertible preferred equity certificates on May 23, 2002. During 2002, the terms and conditions of these securities were changed so that these preferred equity certificates could be converted into the common stock of Hemispherx Biopharma, Inc. (HEB) in the event that a European IPO is not completed by September 30, 2003. The conversion rate is to be 300 shares of Hemispherx Biopharma, Inc.'s common shares for each 1,000 Euro convertible preferred certificate. As a result the Company recorded approximately \$946,000 as minority interest in subsidiary on its balance sheet at December 31, 2002.

On December 18, 2002, we proposed that Esteve convert their convertible preferred equity certificates into Hemispherx common stock pursuant to the terms of the agreement and all unpaid dividends at the market price on that conversion date. On January 9, 2003, Esteve accepted our proposal and we registered these shares for public sale.

On March 13, 2003, we issued 347,445 shares of our common stock to Provesan SA, an affiliate of Esteve S.A., in exchange for 1,000,000 Euros of convertible  
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preferred equity certificates and any unpaid dividends. As a result of the exchange, the minority interest in subsidiary was transferred to stockholders' equity on such date.

The contingent conversion price was more than the then market value of the parent company's or subsidiaries' common stock at each of the respective measurement dates. As a result and in accordance with Emerging Issues Task Force (EITF) No. 00-27 "Application of Issue No. 98-5 (Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios) to Certain Convertible Instruments", the Company did not ascribe any value to any contingent conversion feature.

(d) Private Placement

On August 5, 2004, the Company closed a private placement with select institutional investors of approximately 3,617,300 shares of its Common Stock and warrants to purchase an aggregate of up to approximately 1,085,200 shares of its Common Stock. Jefferies & Company, Inc. acted as Placement Agent for which it received a fee and Common Stock Purchase Warrants. The Company raised approximately \$6,984,000 net proceeds from this private offering.

The Warrant issued to each purchaser is exercisable for up to 30% of the number of shares of Common Stock purchased by such Purchaser, at an exercise price equal to \$2.86 per share. Each Warrant has a term of five years and is fully exercisable from the date of issuance.

Pursuant to the Registration Rights Agreement, made and entered into as of August 5, 2004 (the "Rights Agreement"), the Company has registered the resales of the shares issued to the Purchasers and shares issuable upon the exercise of the Warrants.

Closing of the August 2004 Private Placement triggered the anti-dilution provisions of the January 2004 Debentures and the July 2004 Debentures and the July 2009 Warrants and the June 2009 Warrants. The conversion price adjustment for the Debentures noted above resulted in an adjustment of \$1,320,000 in the third quarter 2004 to the Debenture discount and additional paid-in-capital. Any adjustment to the Debenture discount will be amortized over the remaining life of the Debentures. The exercise price adjustment for the above warrants resulted in a non-cash financing adjustment in the third quarter 2004 upon revaluing the warrants at the new anti-dilution pricing using the Black-Scholes Method.

(e) Common Stock Options and Warrants

(i) Stock Options

The 1990 Stock Option Plan provides for the grant of options to purchase up to 460,798 shares of the Company's Common Stock to employees, directors, and officers of the Company and to consultants, advisors, and other persons whose contributions are important to the success of the Company. The recipients of options granted under the 1990 Stock Option Plan, the number of shares to be converted by each option, and the exercise price, vesting terms, if any, duration and other terms of each option shall be determined by the Company's board of directors or, if delegated by the board, its Compensation Committee. No option is exercisable more than 10 years and one month from the date as of which an option agreement is executed. These shares become vested through various periods not to exceed four years from the date of grant. The option price represents the fair market value of each underlying share of Common Stock at the date of grant, based upon the public trading price.

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Information regarding the options approved by the Board of Directors under the 1990 Stock Option Plan is summarized below:

<TABLE>  
<CAPTION>

	2002			2003			2004		
	Option		Weighted Average Exercise	Option		Weighted Average Exercise	Option		Weighted Average Exercise
	Shares	Price	Price	Shares	Price	Price	Shares	Price	Price
<S>	<C>	<C>	<C>	<C>	<C>	<C>	<C>	<C>	<C>
Outstanding, beginning of year	306,263	\$1.06-4.34	\$3.58	294,665	\$1.06-4.34	\$3.50	433,134	\$1.06-4.34	\$3.10
Granted	-	-	-	200,000	\$2.75	\$2.75	-	-	-
Canceled	(11,598)	\$3.00-4.34	\$3.71	(61,531)	\$3.80-4.03	\$3.97	(18,432)	\$4.34	\$4.34
Exercised	-	-	-	-	-	-	-	-	-
Outstanding, end of year	294,665	\$1.06-4.34	\$3.57	433,134	\$1.06-4.34	\$3.10	414,702	\$2.71-4.03	\$3.11
Exercisable	252,746	\$1.06-4.34	\$3.50	433,134	\$1.06-4.34	\$3.10	414,702	\$2.71-4.03	\$3.11
Weighted average remaining contractual life (years)	3.68			3.37			8.24		
Exercised in current and prior years	(37,791)			(37,791)			(37,791)		
Available for future grants	200,000			-0-			8,305		

</TABLE>

The following table summarizes information about these options outstanding at December 31, 2004:

<TABLE>  
<CAPTION>

<S>	Exercise Price Range			
	<C>	<C>	<C>	<C>
	\$2.71 - \$2.75	\$3.50	\$4.03	Total
Outstanding Options:				
Number Outstanding	273,728	54,974	86,000	414,702
Remaining contracted life years	9.0	4.0	3.0	7.1
Weighted average exercise price	\$2.74	\$3.50	\$4.03	\$3.1
Exercisable Options:				
Number outstanding	273,728	54,974	86,000	414,702
Weighted average exercise price	\$2.74	\$3.50	\$4.03	\$3.1

</TABLE>

In December 1992, the Board of Directors approved the 1992 Stock Option Plan (the 1992 Stock Option Plan) which provides for the grant of options to purchase up to 92,160 shares of the Company's Common Stock to employees, directors, and officers of the Company and to consultants, advisors, and other persons whose contributions are important to the success of the Company. The recipients of the options granted under the 1992 Stock Option Plan, the number of shares to be covered by each option, and the exercise price, vesting terms, if any, duration and other terms of each option shall be determined by the Company's board of directors. No option is exercisable more than 10 years and one month from the

date as of which an option agreement is executed. To date, no options have been granted under the 1992 Stock Option Plan.

The Company's 1993 Employee Stock Purchase Plan (the 1993 Purchase Plan) was approved by the board of directors in July 1993. The outline of the 1993 Purchase Plan provides for the issuance, subject to adjustment for capital changes, of an aggregate of 138,240 shares of Common Stock to employees.

The 1993 Purchase Plan is administered by the Compensation Committee of the board of directors. Under the 1993 Purchase Plan, Company employees are eligible to participate in semi-annual plan offerings in which payroll deductions may be used to purchase shares of Common Stock. The purchase price for such shares is equal to the lower of 85% of the fair market value of such shares on the date of grant or 85% of its fair market value of such shares on the date such right is exercised. There have been no offerings under the 1993 Purchase Plan to date and no shares of Common Stock have been issued thereunder.

During 2003, the Company issued options to acquire 200,000 shares to its general counsel under the 1990 plan for services rendered. As a result, the Company charged operating expenses in the amount of \$237,000.

The Equity Incentive Plan effective May 1, 2004, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 8,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan. Unless sooner terminated, the Equity Incentive Plan will continue in effect for a period of 10 years from its effective date.

The Equity Incentive Plan is administered by the Board of Directors. The Equity Incentive Plan provides for awards to be made to such officers, other key employees, non-employee directors, consultants and advisors of the Company and its subsidiaries as the Board may select.

Stock options awarded under the Equity Incentive Plan may be exercisable at such times (not later than 10 years after the date of grant) and at such exercise prices (not less than fair market value at the date of grant) as the Board may determine. The Board may provide for options to become immediately exercisable upon a "change in control," which is defined in the Equity Incentive Plan to occur upon any of the following events: (a) the acquisition by any person or group, as beneficial owner, of 20% or more of the outstanding shares or the voting power of the outstanding securities of the Company; (b) either a majority of the directors of Company at the annual stockholders meeting has been nominated other than by or at the direction of the incumbent directors of the Board, or the incumbent directors cease to constitute a majority of the Company's Board; (c) the Company's stockholders approve a merger or other business combination pursuant to which the outstanding common stock of the Company no longer represents more than 50% of the combined entity after the transaction; (d) the Company's shareholders approve a plan of complete liquidation or an agreement for the sale or disposition of all or substantially all of the Company's assets; or (e) any other event or circumstance determined by the Company's Board to affect control of the Company and designated by resolution of the Board as a change of control.

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Information regarding the options approved by the Board of Directors under the Equity Incentive Plan is summarized below:

<TABLE>

<CAPTION>

<S>	2004		
	<C>	<C>	<C>
	Shares	Option Price	Weighted Average Exercise Price
Granted	633,080	\$1.90-3.44	\$2.56
Canceled	-	-	-
Exercised	-	-	-
Outstanding end of year	633,080 =====	\$1.90-3.44	\$2.56
Exercisable	538,432 =====	\$2.60-3.44	\$2.68
Weighted average remaining contractual life (years)	-10 years =====		
Exercised in current year	- =		
Available for future grants	7,366,920 =====		

</TABLE>

(ii) Stock warrants

Number of warrants exercisable into shares of common stock

<TABLE>

<CAPTION>

<S>	2002			2003			2004		
	<C>	<C>	<C>	<C>	<C>	<C>	<C>	<C>	
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	
Outstanding beginning of			0			0			0

year	6,927,110	\$1.75-16.0	\$4.77	7,967,810	\$1.75-16.0	\$3.18	11,502,796	\$1.74-16.0	\$3.57
Granted	1,802,000	\$2.00-6.00	\$2.07	4,623,024	\$1.68-2.57	\$2.32	4,791,187	\$2.58-4.20	\$3.25
Canceled	(750,000)	\$3.50-6.00	\$3.72	(276,000)	\$4.00-10.00	\$6.54	(858,360)	\$4.00-8.00	\$5.34
Exercised	(11,300)	\$1.75-7.50	\$3.30	(812,038)	\$1.68-1.75	\$1.69	(2,268,586)	\$1.74-3.50	\$2.32
Outstanding end of year	7,967,810	\$1.75-16.0	\$3.18	11,502,796	\$1.74-16.0	\$3.57	13,167,037	\$1.75-16.0	\$3.46
Exercisable	6,345,810	\$1.75-16.00	\$3.48	8,635,560	\$1.74-16.00	\$4.11	12,667,037	\$1.75-16.00	\$3.46
Weighted average remaining contractual life (years)	4.03 years			4.04 years			4.3 years		
Years exercisable	2003-2008			2004-2008			2005-2009		

</TABLE>

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The following table summarizes information about stock warrants outstanding at December 31, 2004:

<TABLE>

<CAPTION>

<S>	Exercise price range			Total
	<C> \$1.75-\$5.00	<C> \$6.00-\$9.00	<C> \$10.00-\$16.00	<C> \$1.75-\$16.00
Outstanding warrants				
Number outstanding	11,703,387	863,650	600,000	13,167,037
Weighted average remaining contractual life(years)	4.00	2.22	1.46	4.30
Weighted average exercise price	\$2.85	\$6.89	\$12.33	\$3.46
Exercisable warrants				
Number outstanding	11,203,387	836,650	600,000	12,667,037
Weighted average exercise price	\$2.88	\$6.89	\$12.33	\$3.46

</TABLE>

Certain of the stock warrants outstanding are subject to adjustments for stock splits and dividends.

#### Warrants issued to stockholders

At December 31, 2001 there were 232,160 warrants remaining. In 2002, 10,000 were converted to common stock. At December 31, 2002 and 2003 there were 222,160 warrants remaining. These warrants had an exercise price of \$3.50 per share and expired in October 2004.

#### Other stock warrants

The Company has issued other stock warrants outstanding - totaling 13,167,037 which consists of the following:

In November 1994, the Company granted Rule 701 Warrants to purchase an aggregate of 2,080,000 shares of Common Stock to certain officers and directors. These Warrants are exercisable at \$3.50 per share and, if not exercised, were to expire in September, 1999. On February 19, 1999 the Board of Directors extended the expiration date for three more years. In 1999 235,000 warrants were exercised and 5,000 warrants were exercised in 2000. At December 31, 2000, there were 1,840,000 Rule 701 warrants remaining. In 2001 20,000 of these warrants expired, leaving a balance of 1,820,000 in warrants outstanding at December 31, 2001. During 2002, 420,000 warrants expired and the Company extended the expiration date of the remaining balance of 1,400,000 for a period of five years to now expire on September 30, 2007. These stock warrants have an exercise price of \$3.50. 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.

In May 1995, the Company and certain officers, directors and shareholders entered into a standby finance agreement pursuant to which the parties agreed to provide an aggregate of \$5,500,000 in financing to the Company during 1995 in the event that existing and additional financing was insufficient to cover the cash needs of the Company through December 31, 1996. In exchange, the Company issued warrants to purchase an aggregate of 2,750,000 shares of Common Stock at \$1.75 per share to the parties. In 1999, 290,000, in 2000, 216,500, in 2001, 200,000, 2002, 1,300, 2003 35,000 and in 2004 205,000 of these warrants were exercised, leaving a balance of these warrants of 1,210,200. These warrants expire June 30, 2005.

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In the years 2001, 2002 and 2003, the Company issued 450,000, 25,000 and no warrants, respectively, exclusive of warrants issued in connection with the

Company's 2003 Debenture issuances (see below), to investment banking firms for services performed on behalf of the Company. Accordingly, the Company recorded stock compensation of 637,000, 133,000 and none for the years 2001, 2002 and 2003, respectively. These warrants have various vesting dates and exercisable prices ranging from \$4.00 to \$16.00 per share. 1,193,800 warrants were outstanding at December 31, 2002. In 2003, 225,000 of these warrants expired leaving a balance of 968,800 warrants at December 31, 2003. In 2004, 193,800 of these warrants expired leaving a balance of 775,000 warrants at December 31, 2004. These warrants are exercisable in five years from the date of issuance.

In 2002, 2003 and 2004 the Company had non-public warrants outstanding of 3,701,650, 5,100,650, and 4,645,650 respectively. These warrants are exercisable at rates of \$2.20 to \$10.00 per share of common stock. The exercise price was equal to the fair market value of the stock on the date of grant. During 2003 the Company granted 1,450,000 warrants to employees with an exercise price of \$2.20 for services performed and 51,000 warrants expired. During 2002, the Company granted 1,777,000 warrants to employees for services performed. These warrants have a weighted average exercise price of \$2.07 per share, and have been included in the pro-forma loss calculation in note 2(n). 2,254,650 of the non-public warrants were outstanding at December 31, 2002. During 2002, none of these warrants were exercised and 750,000 expired. 3,701,650 of the non-public warrants were outstanding at December 31, 2002. At December 31, 2003, 5,100,650 warrants were outstanding. During 2004, 15,000 warrants were issued and 470,000 expired leaving a balance of 4,645,650 at December 31, 2004. During 2002 the Company also extended the expiration date of 322,000 of these warrants for a period of five years to now expire in the years ending 2007 and 2008. These stock warrants have exercise prices ranging from \$3.50 to \$4.00. 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.

In 2003 the company issued warrants to acquire 3,173,024 shares in connection with the financing of the purchase of the assets of Interferon Sciences, Inc. During 2003, 777,038 of these warrants were exercised leaving a balance of 2,395,986 at December 31, 2003. During 2004, 4,776,187 shares were issued related to debt financing and 2,035,986 shares were exercised leaving a balance of 5,136,189 shares at December 31, 2004.

(e) Stock Repurchase

The Company's repurchases of shares of common stock are recorded as "Treasury Stock" and result in a reduction of "Stockholders' equity." When treasury shares are reissued, the Company uses a first-in, first-out method and the excess of repurchase cost over reissuance price is treated as a reduction of "Additional paid-in capital." At December 31, 2003 there were 443 shares in the treasury. During 2003 most of the then existing treasury shares were either re-issued or retired. There was no Treasury Stock repurchased, re-issued or retired in 2004.

(f) Rights offering

On November 19, 2002, the Board of Directors of Hemispherx Biopharma, Inc. (the "Company") declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on <PAGE> F-30 November 29, 2002 (the "Record Date"). Each Right entitles the registered holder to purchase from the Company a unit consisting of one one-hundredth of a share (a "Unit") of Series A Junior Participating Preferred Stock, par value \$.01 per share (the "Series A Preferred Stock") at a Purchase Price of \$30.00 per Unit, subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement (the "Rights Agreement") between the Company and Continental Stock Transfer & Trust Company, as Rights Agent.

Initially, the Rights are attached to all Common Stock certificates representing shares then outstanding, and no separate Rights Certificates will be distributed. Subject to certain exceptions specified in the Rights Agreement, the Rights will separate from the Common Stock and a Distribution Date will occur upon the earlier of (i) 10 days following a public announcement that a person or group of affiliated or associated persons (an "Acquiring Person") has acquired beneficial ownership of 15% or more (or 20% or more for William A. Carter, M.D.) of the outstanding shares of Common Stock (the "Stock Acquisition Date"), other than as a result of repurchases of stock by the Company or certain inadvertent actions by institutional or certain other stockholders or (ii) 10 business days (or such later date as the Board shall determine) following the commencement of a tender offer or exchange offer that would result in a person or group becoming an Acquiring Person. Until the Distribution Date, (i) the Rights will be evidenced by the Common Stock certificates and will be transferred with and only with such Common Stock certificates, (ii) new Common Stock certificates issued after the Record Date will contain a notation incorporating the Rights Agreement by reference and (iii) the surrender for transfer of any certificates for Common Stock outstanding will also constitute the transfer of the Rights associated with the Common Stock represented by such certificate. Pursuant to the Rights Agreement, the Company reserves the right to require prior to the occurrence of a Triggering Event (as defined below) that, upon any exercise of Rights, a number of Rights be exercised so that only whole shares of Preferred Stock will be issued.

(9) Segment and Related Information

The Company operates in one segment, which performs research and development activities related to Ampligen(R) and other drugs under development, and sales and marketing of Alferon(R).

The following table presents revenues by country based on the location of the use of the product services.

	(000's omitted)		
	2002	2003	2004
	-----	-----	-----
United States	\$237	\$655	\$1,225
Belgium	74	2	4
Other	30	-	-
	--	----	-----
	\$ 341	\$ 657	\$1,229
	=====	=====	=====

In addition, in 2002, the Company recorded License Fee Income in the amount of \$563,000 from a Company located in Europe. The Company employs an insignificant amount of net property and equipment in its foreign operations.

<PAGE> F-31  
(10) Research, Consulting and Supply Agreements

In December, 1999, the Company 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 the Company's 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 the Company' products. Biovail agrees to work with the Company in preparing and filing of a New Drug Submission with Canadian Regulatory Authorities. Biovail invested \$2.25 million in Hemispherx equity at prices above the then current market price and agreed to make further payments based on reaching certain regulatory milestones. The Agreement requires Biovail to penetrate certain market segments at specific rates in order to maintain market exclusivity.

The Company has entered into agreements for consulting services, which are performed at medical research institutions and by medical and clinical research individuals. The Company's 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, 2002, 2003 and 2004 the Company incurred approximately \$389,000, \$395,000 and \$220,000 respectively, of consulting service fees under these agreements. These costs are charged to research and development expense as incurred.

(11) 401(K) Plan

The Company has a defined contribution plan, entitled the Hemispherx Biopharma Employees 401(K) Plan and Trust Agreement (the 401(K) Plan). Full time employees of the Company 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 the Company at a rate determined annually by the Board of Directors.

Each participant immediately vests in his or her deferred salary contributions, while Company contributions will vest over one year. In 2002, 2003 and 2004 the Company provided matching contributions to each employee for up to 6% of annual pay aggregating \$38,000, \$34,000 and \$77,000 respectively.

(12) Royalties, License, and Employment Agreements

The Company also has entered into a licensing agreement with a group of individuals and Hahnemann University relating to their contributions to the development of certain compounds, including Ampligen(R), and to obtain exclusive information and regulatory rights relating to these compounds. Under this agreement, the Company will pay 2% of net sales proceeds of Ampligen(R) not to exceed an aggregate amount of \$6 million per year through 2005.

In August 1988, the Company entered into a pharmaceutical use license agreement with Temple University (the Temple Agreement). In July, 1994, Temple terminated the Temple Agreement. In November 1994, the Company filed suit against Temple in the Superior Court of the State of Delaware seeking a declaratory judgment that the agreement was unlawfully terminated by Temple and therefore remained in full force and effect. Temple filed a separate suit against the Company seeking a declaratory judgment that its agreement with the Company was properly  
<PAGE> F-32

terminated. These legal actions have now been settled. Under the settlement, the parties have entered into a new pharmaceutical use license agreement (New Temple Agreement) that is equivalent in duration and scope to the previous license. Under the terms of the New Temple Agreement, Temple granted the Company an exclusive world-wide license for the term of the agreement for the commercial sale of Oragen products using patents and related technology held by Temple, which license is exclusive except to the extent Temple is required to grant a license to any governmental agency or non-profit organization as a condition of funding for research and development of the patents and technology licensed to the Company.

In October 1994, the Company entered into a licensing agreement with Bioclones (Propriety) Limited (SAB/Bioclones) with respect to co-development of various RNA drugs, including Ampligen(R), for a period ending three years from the expiration of the last licensed patents. The licensing agreement provides SAB/Bioclones with an exclusive manufacturing and marketing license for certain southern hemisphere countries (including certain countries in South America, Africa and Australia as well as the United Kingdom and Ireland (the licensed territory). In exchange for these marketing and manufacturing rights, the licensing agreement provides for: (a) a \$3 million cash payment to the Company, all of which was received during the year ended December 31, 1995; (b) the formation and issuance to the Company of 24.9% of the capital stock of Ribotech, Ltd., a company which developed and operates a new manufacturing facility that produces raw material components of Ampligen(R) and (c) royalties of 6% to 8% of net sales of the licensed products in the licensed territories as defined, after the first \$50 million of sales. SAB/Bioclones will be granted a right of first refusal to manufacture and supply to the Company licensed products for not less than one third of its world-wide sales of Ampligen(R), excluding SAB/Bioclones related sales. In addition, SAB/Bioclones will have the right of first refusal for oral vaccines in the licensed territory. In 2000, the Company paid to Ribotech a total of \$500,000 for the current and future purchases and delivery of polymers. Of the \$500,000 advanced in 2000, a balance of \$390,000 was included in other assets in 2000 and was used for purchases of polymers in 2001. In 2002, \$262,000 was paid to Ribotech for delivery of Polymers.

On December 27, 2004, we initiated a lawsuit in Federal Court identifying a conspiratorial group seeking to illegally manipulate our stock for purposes of bringing about a hostile takeover of Hemispherx. This conspiratorial group includes Bioclones. This legal action may adversely affect our relationship and collaborative agreement with Bioclones.

In October 1994, the Board of Directors granted a director of the Company the right to receive 3% of gross proceeds of any licensing fees received by the Company pursuant to the SAB/Bioclones licensing agreement, a fee of .75% of gross proceeds in the event that SAB Bioclones makes a tender offer for all or substantially all of the Company's assets, including a merger, acquisition or related transaction, and a fee of 1% on all products manufactured by SAB Bioclones. The Company may prepay in full its obligation to provide commissions within a ten year period.

On March 20, 2002, our European subsidiary Hemispherx Biopharma Europe, S.A. ("Hemispherx S.A.") entered into a sales and Distribution agreement with Laboratories Del Dr. Esteve S.A. ("Esteve"). Pursuant to the terms of the agreement, Esteve was granted the exclusive right to market Ampligen(R) in Spain, Portugal and Andorra for the treatment of Myalgic/Chronic Fatigue Syndrome ("ME/CFS"). In addition to other terms and other projected payments, Esteve paid an initial and non-refundable fee of 625,000 Euros (approximately \$563,000) to Hemispherx S.A. on April 24, 2002. Esteve is to pay a fee of 1,000,000 Euros after U.S. Food and Drug Administration approval of Ampligen(R) <PAGE> F-33 for the treatment of ME/CFS and a fee of 1,000,000 Euros upon Spain's approval of the final marketing authorization for using Ampligen(R) for the treatment of ME/CFS.

In connection with the two agreements entered into with ISI, the Company is obligated to pay ISI a 6% royalty on the net sales of the Alferon N Injection product.

The Company has contractual agreements with two of its officers. The aggregate annual base compensation under these contractual agreements for 2002, 2003 and 2004 was \$620,000, \$637,000 and \$761,000 respectively. In addition, certain of these officers are entitled to receive performance bonuses of up to 25% of the annual base salary (in addition to the bonuses described below). In 2002 no performance bonuses were granted. In 2003 and 2004, bonuses of \$266,100 and \$165,300 respectively were granted. In 2002, certain officers were granted warrants and option to purchase 1,220,000 shares of common stock at \$2.00 - \$4.03 per share. In 2003, the Chief Executive Officer of the Company was granted warrants to purchase 1,450,000 shares of common stock at \$2.20 per share. The Chief Executive Officer's employment agreement provides for bonuses based on gross proceeds received by the Company from any joint venture or corporate partnering agreement. In 2004, the Chief Executive Officer of the Company was granted options to purchase 320,000 shares of common stock at \$2.60 per share and \$3.44 per share and the Chief Financial Officer of the Company was granted options to purchase 63,824 shares of common stock at \$2.60 and \$3.44 per share.

In order to facilitate the Company's 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, the Company's 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 based on Black Scholes calculations with an exercise price of \$2.20 per share. This additional compensation was reviewed by an independent valuation firm and found to be fair and reasonable within the context of total compensation paid to chief executive officers of comparable biotechnology companies. These warrants vest

upon the earlier of the second ISI Asset closing or the filing by the Company with the U.S. Food and Drug Administration of a new drug application. Upon the occurrence of either of these events, the Company will expense the intrinsic value, if any, of the warrants.

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(13) Leases

The Company has several noncancelable operating leases for the space in which its principal offices are located and certain office equipment.

Future minimum lease payments under noncancelable operating leases are as follows:  
(000's omitted)

Year ending December 31, -----	Operating leases -----
2005 . . . . .	187
2006 . . . . .	193
2007 . . . . .	65
	-----
Total minimum lease payments . . . . .	\$ 445
	=====

Rent expense charged to operations for the years ended December 31, 2002, 2003 and 2004 amounted to approximately \$307,000, \$266,000 and \$269,000 respectively. The term of the lease for the Rockville, Maryland facility is through June, 2005 with an average rent of \$8,000 per month, plus applicable taxes and charges. The term of the lease for the Philadelphia, Pennsylvania offices is through April, 2007 with an average rent of \$15,000 per month, plus applicable taxes and charges.

(14) Income Taxes

As of December 31, 2004, the Company has approximately \$88,000,000 of federal net operating loss carryforwards (expiring in the years 2005 through 2025) available to offset future federal taxable income. The Company also has approximately \$24,000,000 of state net operating loss carryforwards (expiring in the years 2005 through 2009) available to offset future state taxable income. The utilization of certain state net operating loss carryforwards may be subject to annual limitations.

Under the Tax Reform Act of 1986, the utilization of a corporation's net operating loss carryforward is limited following a greater than 50% change in ownership. Due to the Company's prior and current equity transactions, the Company's net operating loss carryforwards may be subject to an annual limitation generally determined by multiplying the value of the Company on the date of the ownership change by the federal long-term tax exempt rate. Any unused annual limitation may be carried forward to future years for the balance of the net operating loss carryforward period.

Deferred income taxes reflect the net tax effects of temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the carrying amounts used for income tax purposes. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences representing net future deductible amounts become deductible. Due to the uncertainty of the Company's ability to realize the benefit of the deferred tax asset, the deferred tax assets are fully offset by a valuation allowance at December 31, 2003 and 2004.

<PAGE> F-35

The components of the net deferred tax asset of December 31, 2003 and 2004 consists of the following:

	(000,s omitted)	
Deferred tax assets:	2003	2004
	----	----
Net operating losses	\$24,700	\$29,863
Accrued Expenses and Other	12	41
Capitalized Research and development costs	2,825	2,664
	-----	-----
	27,537	32,568
Less: Valuation Allowance	(27,537)	(32,568)
	-----	-----
Balance	\$ -0-	\$ -0-
	=====	=====

(15) Contingencies

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 has now petitioned the Supreme Court of Pennsylvania for allowance of an appeal. We have opposed Asensio's petition for allowance of appeal and the matter is now pending before the Supreme Court of Pennsylvania.

In June 2002, a former ME/CFS clinical trial patient and her husband filed a claim in the Superior Court of New Jersey, Middlesex County, against us, one of our clinical trial investigators and others alleging that she was harmed in the ME/CFS clinical trial as a result of negligence and breach of warranties. On June 25, 2004 all claims against us were dismissed with prejudice. The former ME/CFS clinical trial patient and her husband have now appealed the dismissal of their claims to the New Jersey Superior Court, Appellate Division, where the matter is now pending.

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 our 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 June 2004, One Penn Associates, L.P. filed a claim in the Philadelphia Municipal Court for the Commonwealth of Pennsylvania seeking <PAGE> F-36 \$44,242.68 for alleged unpaid rent and charges related to our offices in One Penn Center in Philadelphia. We believe this claim is without merit and are defending same pursuant to the terms of our lease as we were damaged and deprived of the use of a portion of the offices due to water from the landlord's faulty sprinkler system.

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 Donninger, R. B. Kebble, H. C. Buitendag, Bart Goemaere, and John Doe(s).

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 Hemispherx's public shareholders. 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.

#### (16) Related Party Transactions

We have employment agreements with certain of our executive officers and have granted such officers and directors of the Company options and warrants to purchase common stock of the Company, as discussed in Notes 2(n) and 9.

A director of the Company, is an attorney in private practice, who has rendered corporate legal services to us from time to time, for which he has received fees and options to purchase Company stock valued at \$237,000 in 2002 using the Black Scholes pricing model and recorded as stock compensation expense. A Director of the Company, lives in Paris, France and assisted our European subsidiaries in their dealings with medical institutions and the European Medical Evaluation Authority. A Director of the Company assisted us in establishing clinical trial protocols as well as performs other scientific work for us from time to time. The services provided by these latter two Directors were terminated in September 2003. For these services, these Directors were paid an aggregate of \$170,150 and \$100,100 for the years ending December 31, 2002 and 2003 respectively.

Through November 2002, William A. Carter, Chief Executive Officer of the Company, received an aggregate of \$12,106 in short term advances which were repaid as of December 31, 2002. All advances bore interest at 6% per annum. The Company loaned \$60,000 to, a Director of the Company in November, 2001 for the purpose of exercising 15,000 class A redeemable warrants. This loan bears

interest at 6% per annum.

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We paid \$33,450, \$18,800 and \$7,600 for the years ending December 31, 2002, 2003 and 2004, respectively to Carter Realty for the rent of property used at various times in years 2002, 2003 and 2004 by us. The property is owned by others and managed by Carter Realty. Carter Realty is owned by Robert Carter, the brother of William A. Carter.

(17) Concentrations of credit risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash, cash equivalents and investments. The Company places its cash with high-quality financial institutions. At times, such amount may be in excess of Federal Deposit Insurance Corporation insurance limits of \$100,000.

(18) Quarterly Results of Operation (unaudited)  
(in thousand except per share data)

	2003				Total
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	
Revenue	\$ 66	\$ 94	\$ 194	\$ 303	\$ 657
Costs and expenses	1,658	1,730	1,960	2,561	7,909
Net loss	(1,617)	(3,689)	(5,422)	(4,042)	(14,770)
Basic and diluted loss per share	\$ (.05)	\$ (.11)	\$ (.15)	\$ (.11)	\$ (.42)

(1) During the fourth quarter 2003, the Company recorded stock compensation of \$237,000.

	2004 (2)				Total
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	
Revenues and license fee income	\$ 308	\$ 331	\$ 258	\$ 332	\$ 1,229
Costs and expenses	4,409	2,526	2,972	2,211	12,118
Net loss	(8,042)	(5,956)	(7,007)	(3,135)	(24,140)
Basic and diluted loss per share	\$ (.20)	\$ (.14)	\$ (.15)	\$ (.06)	\$ (.53)

(2) During the first quarter 2004, the Company recorded stock compensation of \$1,769,000 and during the third quarter 2004, the Company recorded stock compensation of \$231,000.

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Exhibit 31.1

CERTIFICATIONS PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, William A. Carter, Chief Executive Officer of Hemispherx Biopharma, Inc. (the "Registrant"), certify that:

1. I have reviewed this annual report on Form 10-K of the Registrant;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and

internal control over financial reporting (as defined in Exchange Act Rules 13a-15 (f) and 15d-15(f)) for the Registrant and have:

- a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
- c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
- b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 16, 2005

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

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Exhibit 31.2

CERTIFICATIONS PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Robert Peterson, Chief Financial Officer of Hemispherx Biopharma, Inc. (the "Registrant"), certify that:

- 1. I have reviewed this annual report on Form 10-K of the Registrant;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report,

fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

- a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
- c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
- b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 16, 2005

/s/ Robert E. Peterson  
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Robert Peterson  
Chief Financial Officer

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Exhibit 32.1

In connection with the Annual Report of Hemispherx Biopharma, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William A. Carter, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ William A. Carter  
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William A. Carter, M.D.  
Chief Executive Officer  
March 11, 2005

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Exhibit 32.2

CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Hemispherx Biopharma, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert Peterson, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Robert E. Peterson  
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Robert Peterson  
Chief Financial Officer  
March 11, 2005

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CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Hemispherx Biopharma, Inc.  
Philadelphia, Pennsylvania

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-119017) and Form S-8 (No. 333-57134 and 333-118903) of Hemispherx Biopharma, Inc. and subsidiaries of our reports dated February 4, 2005, relating to the consolidated financial statements, and the effectiveness of Hemispherx Biopharma, Inc. and subsidiaries internal control over financial reporting which appear in the Company's Annual Report on form 10-K.

/s/ BDO Seidman, LLP  
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BDO Seidman, LLP

Philadelphia, Pennsylvania  
March 14, 2005

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