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HEMISPHERX BIOPHARMA INC
Form 10-K/A
June 05, 2006

FORM 10-K/A
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, 2005

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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes () No (X)

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

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

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

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

Large accelerated filer() Accelerated filer(X) Non-accelerated filer ()

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

The aggregate market value of Common Stock held by non-affiliates at June 30, 2005, the last business day of the registrant's most recently completed second fiscal quarter, was \$91,919,360.

The number of shares of the registrant's Common Stock outstanding as of May 26, 2006 was 62,261,349.

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

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

PART I

ITEM 1. Business.

GENERAL

We are a biopharmaceutical company engaged in the clinical development, manufacture, marketing and distribution of new drug entities based on natural immune system enhancing technologies 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. Since that time, we have established a strong foundation of laboratory, pre-clinical, and clinical data with respect to the development of nucleic acids to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of chronic diseases. We own a U.S. Food and Drug Administration ("FDA") approved GMP (good manufacturing practice) manufacturing facility in New Jersey.

Our flagship products include Ampligen(R) and Alferon N Injection(R). Ampligen(R) is an experimental drug currently undergoing clinical development for the treatment of: Myalgic Encephalomyelitis/Chronic Fatigue Syndrome ("ME/CFS" or "CFS"), and HIV. In August 2004, we completed a Phase III clinical trial ("AMP 516") treating over 230 ME/CFS patients with Ampligen(R) and are presently in the process of preparing a new drug application ("NDA") to be filed with the FDA. Over its developmental history, Ampligen(R) has received various designations, including Orphan Drug Product Designation (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports (AHRQ, Agency Health Research Quality). In response to our application for Fast Track Designation, the FDA has requested additional information to support the potential of Ampligen(R) to treat a serious or life threatening aspect of ME/CFS. The definition of the "seriousness of a condition", according to Guidance for Industry documents published in July, 2004 is "a matter of judgment, but generally based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one". The FDA requested a "complete and audited report of the Amp 516 study to determine whether Ampligen(R) has a clinically meaningful benefit on a serious or life threatening aspect of ME/CFS in order to evaluate whether the Amp 516 study results do or do not support a "fast track designation". The FDA has also invited us to include a schedule for completion of all ME/CFS studies as well as a proposed schedule for our NDA submission. Because we believe our ME/CFS studies are complete, we intend to request a pre-NDA meeting to obtain advice on preparing and submitting our NDA, which may eliminate the need for Fast Track Designation. Meanwhile, we continue with our existing ongoing efforts to prepare a complete and audited report of our various studies, including the well-controlled Amp 516 study. We are using our best efforts to complete the requisite reports including the hiring of additional staff and various expert medical/regulatory consultants, but can provide no assurance as to whether the outcome of this large data collection and filing process (approximately 750 patients, treated more than 45,000 times) will be favorable or unfavorable, specifically with respect to the FDA's perspective. We plan to use an independent contractor to file the NDA electronically to facilitate the review by the FDA. Also, we can provide no guidance as to the tentative date at which the compilation and filing of such data will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the ability of Hollister-Stier facilities to interface with our own New Brunswick staff/facilities to meet the manufacturing regulatory standards. In addition, Ampligen(R) is undergoing pre-clinical testing for possible treatment of avian influenza ("bird flu").

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

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

In antimicrobial (antibacterial) therapy, which is the best-studied

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

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We recently announced that true therapeutic synergy had been observed in the interaction between Ampligen(R) and Tamiflu in the inhibition of the avian influenza virus. The same synergy was observed in the interaction between Ampligen(R) and Relenza in lab tests in December 2005. Cell destruction was measured in vitro using different drug combinations. True therapeutic synergy is defined by mathematical equations which indicate that the therapeutic effect observed is in fact greater than the expected arithmetic sum of the two drugs working independently, and is referred to by pharmacologists as the "Chou/Talalay" equations developed at Johns Hopkins University.

In a recently reported study from a vaccine group in Japan, the incorporation of poly I: poly C (dsRNA) into a nasal administration of a killed influenza A preparation converted a poorly immunogenic response into a highly efficacious vaccine in protection of mice from lethal infection from human influenza A. Ampligen(R) is a dsRNA which currently is undergoing testing in this animal model.

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

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

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afforded for 21 days with two doses of dsRNA. It is believed that in humans with active flu infection, Tamiflu, given twice daily, may ameliorate symptoms.

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We have over 100 patents worldwide with 9 additional patents pending comprising our intellectual property. We continually review our patents rights to determine whether they have continuing value. Such review includes an analysis of the patent's ultimate revenue and profitability potential. In addition, management's review addresses whether each patent continues to fit into our strategic business plans. We have a fully commercialized product (Alferon N Injection(R)), and a GMP certified manufacturing facility.

In March 2004, we completed the step-by-step acquisition from Interferon Sciences, Inc. ("ISI") of ISI's commercial assets, Alferon N Injection(R) inventory, a worldwide license for the production, manufacture, use, marketing and sale of Alferon N Injection(R), as well as, a 43,000 square foot manufacturing facility in New Jersey and the acquisition of all intellectual property related to Alferon Injection(R). Alferon N Injection(R) 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.

We completed the transfer and consolidation of our Rockville Quality Assurance Lab and equipment into our New Brunswick facility in 2005. We believe this newly consolidated lab will provide more efficiency with regard to the quality assurance needs for both Ampligen(R) and Alferon N Injection(R).

On December 9, 2005, we executed a Supply Agreement with Hollister-Stier Laboratories LLC of Spokane, Washington ("Hollister-Stier"), for the contract manufacturing of Ampligen(R) for a five year term. Pursuant to the agreement we will supply the key raw materials and Hollister-Stier will formulate and bottle the Ampligen(R). In November 2005, we paid \$100,000 as a deposit in order to initiate the manufacturing project. This deposit was expensed as research and development during the 4th Quarter 2005. The achievement of the initial objectives described in the agreement, in combination with our polymer production facility under construction in New Brunswick, N.J., may enable us to manufacture the raw materials for approximately 10,000 doses of Ampligen(R) per week. We executed a confidentiality agreement with Hollister-Stier; therefore, we commenced the transfer of our manufacturing technology to Hollister-Stier. Currently, Hollister-Stier has completed two pilot manufacturing runs of Ampligen(R) for stability testing.

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

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.

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The installation of a raw material production line within our New

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Brunswick facility has been completed and is now in production. The production of Ampligen(R) raw materials in our own facilities has obvious advantages with respect to overall control of the manufacturing procedure of Ampligen(R)'s raw materials, keeping costs down and controlling regulatory compliance issues (other parts of our 43,000 sq. ft. wholly owned FDA approved facility are already in compliance for Alferon N Injection(R) manufacture). This will also allow us to obtain Ampligen(R) raw materials on a more consistent manufacturing basis. As of April 30, 2006, we have capitalized approximately \$1,400,000 towards the construction and installation of this production line at our New Jersey facility. We expect the first lot of Ampligen(R) raw material to be produced in the second quarter 2006. We estimate the total cost of establishing this production line to be \$1,900,000, including modifications to our New Brunswick facility. We have also identified three manufacturers to expand polymer manufacture, if necessary, and obtained preliminary proposals from two and have initiated discussions with the third.

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 proposals or agreements have resulted from the dialogue, nor can we be assured that any proposals or agreements will result from these inquiries.

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

AVAILABLE INFORMATION

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

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

OUR PRODUCTS

Our primary products consist of our experimental compound, Ampligen(R), our FDA approved natural interferon product, Alferon N Injection(R) 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

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activation of an otherwise dormant cellular defense against virus and tumors. Our double-stranded, specifically configured, 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.

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Our proprietary development drug technology including Ampligen(R), which utilizes specially configured ribonucleic acid ("RNA") is currently protected by more than 100 patents worldwide with 9 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 2005, we reviewed our portfolio of patents and patent applications. As a result of this review, various patents and patent applications were not 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 (#4820696, #5063209, and #5091374) expired or expire on April 11, 2006, November 5, 2008, and February 25, 2009, respectively; Hepatitis treatment coverage is conveyed by U.S. patent #5593973 which expires on January 14, 2014. The U.S. Ampligen(R) Trademark (#1,515,099) expires on December 6, 2008 and can be renewed thereafter for an additional 10 years. The FDA has granted us "orphan drug status" for our nucleic acid-derived therapeutics for ME/CFS, HIV, and renal cell carcinoma and malignant melanoma. Orphan drug status grants us protection against competition for a period of seven years following FDA approval, as well as certain federal tax incentives, and other regulatory benefits. Patent coverage for the HIV indication following the expiration of patent #4820696, #5063209 and #5091374 is planned to be obtained from patent pending application #PCT/US 0239890. In the event that this patent application is not approved, we still have the marketing protection provided by the orphan drug designation for using Ampligen(R) to treat HIV.

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. Approximately 750 patients have participated in Ampligen(R) 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.

We are in the process of preparing an NDA to file with the FDA for the use of Ampligen(R) in the treatment of patients with ME/CFS. We plan to complete and file the NDA before year end 2006.

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

The FDA approved Alferon N Injection(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(R) 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(R) 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(R) LDO

Alferon(R) LDO is an experimental low-dose, oral liquid formulation of Natural Alpha Interferon and like Alferon N Injection(R) should not cause antibody formation, which is a problem with recombinant interferon. It is an experimental immunotherapeutic believed to work by stimulating an immune cascade response in the cells of the mouth and throat, enabling it to bolster an immune response through the entire body orally. Oral interferon would be much more economically feasible for patients and logistically manageable in development

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programs in third-world countries primarily affected by HIV and other emerging viruses (SARS, Ebola, bird flu, etc.). Oral administration of Alferon(R) N, with its affordability, low toxicity, no production of antibodies, and broad range of potential bio activity, could be a breakthrough treatment for viral diseases.

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A clinical study to evaluate the use of Alferon(R) LDO in HIV infected volunteers was initiated during the second quarter 2005 in Philadelphia, PA. The study is currently being conducted at Drexel University and Philadelphia FIGHT, a comprehensive AIDS service organization providing primary care, consumer education, advocacy and research on potential treatments and vaccines. The study is designed to determine whether Alferon(R) LDO can resuscitate the broad-spectrum antiviral and immunostimulatory genes. As of May 30, 2006, fourteen patients have enrolled and twelve completed dosing. We are currently receiving data from this study and we are in the process of analyzing the results. The trial methodology may have implications for treating other emerging viruses such as avian influenza (bird flu).

Oragens

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

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

The bioactive 2-5A molecules can be degraded by various hydrolytic enzymes, resulting in a short half life. Analogues of these bioactive 2-5As, termed Oragen RNA compounds, have been produced to increase stability and maintain or increase biological activity without demonstrable toxicity.

Pursuant to the terms of our agreement with Temple, we are obligated to pay royalties of 2% to 4% of sales depending on the amount of technical assistance required. We currently pay a royalty of \$30,000 per year to Temple.

RESEARCH AND DEVELOPMENT ("R&D")

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

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

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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

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misunderstood, under-recognized, and under-diagnosed, ME/CFS is now recognized by both the government and private sector as a major health problem, including the National Institutes of Health, U.S. Centers for Disease Control and Prevention ("CDC"), FDA and Social Security Administration, recognizes 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 CDC. Furthermore, 90% of the patients with the illness are struggling without the benefit of medical diagnosis or treatment. While ME/CFS strikes people of all age, racial, ethnic, and socioeconomic groups, it is most prevalent amongst women. Research has shown that ME/CFS is about three times as common in women as men, a rate similar to that of many autoimmune diseases, such as multiple sclerosis and lupus. To put this into perspective, ME/CFS is over four times more common than HIV infection in women, and the rate of ME/CFS in women is considerably higher than a woman's lifetime risk of getting lung cancer as published by the CFIDS Association of America.

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

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

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

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

In 1998, we were authorized by the FDA to initiate a Phase III multicenter, placebo-controlled, randomized, double blind clinical trial to treat 230 patients with ME/CFS in the U.S. The objective of this Phase III, clinical study, denoted as Amp 516, was to evaluate the safety and efficacy of Ampligen(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(R) improved exercise treadmill performance by 19.0% versus 4.2% in the placebo group, or more than twice the minimum considered medically significant (6.5%), a statistically significant increase ($p=0.025$). The major significance is the ability to safely obtain medical benefits (increased physical performance) which have largely eluded others. Also, Ampligen(R) 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(R) Treatment Protocol Status and Orphan Drug Status based on earlier studies, we believe these medically and statistically significant results, when finalized, will facilitate FDA review and approval of Ampligen(R) as a therapy to treat ME/CFS.

Human Immunodeficiency Virus ("HIV")

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

We believe that the concept of Strategic Therapeutic Interruption ("STI") of HAART provides a unique opportunity to minimize the current deficiencies of HAART while retaining the HIV suppression capacities of HAART. STI is the cessation of HAART until HIV again becomes detectable (i.e., rebounds) followed by resumption of HAART with subsequent suppression of HIV. By re-institution of HAART, HIV may be suppressed before it can inflict damage to the immune system of the patient. We believe that Ampligen(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

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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.

Our 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. 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.

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

Human Papilloma Virus (HPV)

Human papilloma virus ("HPV") is one of the most common causes of sexually transmitted infection in the world. Experts estimate that there are more cases of genital HPV infection than of any other sexually transmitted disease ("STD") in the United States. Overall, in the United States, an estimated 20 million people (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 a least 50% of sexually active men and women acquire genital HPV infection at some point in their lives.

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

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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.

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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. Condysil 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(R) N, which is the only natural source, multi-species alpha interferon currently sold in the US for HPV treatment, is injected twice weekly.

Hepatitis C Virus ("HCV")

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

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

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

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

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We are evaluating the possibility of conducting a pivotal trial for HCV. This trial would be designed to evaluate the efficacy and safety of Alferon N Injection(R) in comparison with an untreated control group in previously untreated patients with chronic HCV. The primary endpoint would be the proportion of patients in whom ALT is normal at the end of 40 weeks of treatment and at the end of the 24 week follow-up period. We would plan on enrolling approximately 208 patients. We will be making a decision on this clinical trial by June 2006.

Other Diseases

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"). This study completed the dosing of ten patients during the fourth quarter 2005 and we expect to complete analyzing the results of this study in the coming months.

SARS 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 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 was designed to respond to any reemergence of SARS with a prophylaxis trial at epidemic sites to be conducted to evaluate the activity of Alferon(R) LDO (low dose oral) to prevent symptomatic infection by SARS-CoV. Gene microarray analysis of infection by SARS-CoV and the effect of Alferon(R) LDO are used in the design and conduct of this clinical trial. Differential cellular gene responses to infection and the response to Alferon(R) may predict clinical outcomes.

This trial methodology may have implications for treating other emerging viruses such as avian influenza. 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 convened World Health Organization expert panel in November 2004. Health officials are also concerned that bird flu could mutate to cause the next pandemic and render present vaccines under development ineffective. We have prepared more than 300,000 doses of Alferon(R) LDO for appropriate clinical programs.

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

In antimicrobial (antibacterial) therapy, which is the best-studied

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

In a recently reported study from a vaccine group in Japan, the incorporation of poly I: poly C (dsRNA) into a nasal administration of a killed influenza A preparation converted a poorly immunogenic response into a highly efficacious vaccine in protection of mice from lethal infection from human influenza A. Ampligen(R) is a dsRNA which currently is undergoing testing in the animal model.

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

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

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

In November 2005, we entered into an agreement with Defence R&D Canada, Suffield ("DRDC Suffield"), an agency of the Canadian Department of National Defence, to evaluate the antiviral efficacy of our experimental therapeutic Ampligen(R) and Alferon(R) for protection against human respiratory influenza virus infection in well validated animal models. DRDC Suffield is conducting research and development of new drugs that could potentially become part of the arsenal of existing antiviral weapons to combat the bird flu. The initial study will focus on the testing of potential drugs against the respiratory influenza virus infection on a mouse-adapted strain of human influenza. DRDC Suffield has already conducted extensive research in the use of liposome delivery technology to enhance the antiviral activity of a closely-allied Ampligen(R) analogue, Poly ICLC (an immunomodulating dsRNA) which is very similar to Ampligen(R). Results

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suggest that ribo nucleic acid-based drugs have the ability to elicit protective broad-spectrum antiviral immunity against various pathogenic viruses. Hence, there is the potential for efficacy to be maintained against mutating strains of an influenza virus. Liposomes, a carrier system for nucleic acid-based drugs, have shown an ability to protect these drugs against in vivo degradation, delivering them to intracellular sites of infection, thereby reducing any toxicity and prolonging their therapeutic effectiveness. Protection can be afforded for 21 days with two doses of dsRNA. It is believed that in humans with active flu infection, Tamiflu, given twice daily, may ameliorate symptoms.

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A clinical study to evaluate the use of Alferon(R) LDO in HIV infected volunteers was initiated during the second quarter 2005 in Philadelphia, PA. The study is currently being conducted at two sites, Drexel University and Philadelphia FIGHT, a comprehensive AIDS service organization providing primary care, consumer education, advocacy and research on potential treatments and vaccines. The study is designed to determine whether Alferon(R) LDO can resuscitate the broad-spectrum antiviral and immunostimulatory genes. The initial patient enrolled in this study in July 2005 and, as of December 2005, seven patients have enrolled and completed dosing. We are currently receiving data from this study and we are in the process of analyzing the results. 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 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.

In September 2004, we commenced a clinical trial using Alferon N Injection(R) to treat patients infected with the West Nile Virus. The infectious Disease section of New York Queens Hospital and the Weill Medical College of Cornell University are conducting this double-blinded, placebo controlled trial. This study plans to enroll 60 patients as they become available. As of May 30, 2006, nine patients have entered this study. The CDC reports that 2,819 cases of West Nile Virus have been reported in the US as of January 10, 2006, including 105 deaths.

In 2005 we completed the transfer and consolidation of our Rockville Quality Assurance Lab and equipment into our New Brunswick facility. We believe this newly consolidated lab will provide more efficiencies with regard to the quality assurance needs for both Ampligen(R) and Alferon N Injection(R).

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.

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MANUFACTURING

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Historically, we have 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 previously acquired our raw materials from Ribotech, Ltd. ("Ribotech") located in South Africa. Ribotech, is jointly owned by us (24.9%) and Bioclones (Proprietary), Ltd. (75.1%). Bioclones manages and operates Ribotech. There are a limited number of manufacturers in the United States available to provide the polymers. At present, we do not have any agreements with third parties for the supply of any of such materials. In order to obtain Ampligen(R) raw materials of higher quality (GMP certified) and on a more regular production basis, we are setting up polymer manufacturing operations in our New Brunswick facility. 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). We have also identified and contacted two manufacturers for the possible manufacture of polymers. Engagement of either of these facilities would provide back up to our NJ facility and additional production capacity. This transfer of polymer manufacturing to our own facilities, and/or to another contract manufacturer may delay certain steps in commercialization process, specifically, our 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 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.

On December 9, 2005, we executed a Supply Agreement with Hollister-Stier Laboratories LLC of Spokane, Washington ("Hollister-Stier"), for the contract manufacturing of Ampligen(R) for a five year term. Pursuant to the agreement we will supply the key raw materials and Hollister-Stier will formulate and bottle the Ampligen(R). In November 2005, we paid \$100,000 as a deposit in order to initiate the manufacturing project. This deposit was expensed as research and development during the 4th Quarter 2005. The achievement of the initial objectives described in the agreement, in combination with our polymer production facility under construction in New Brunswick, N.J., may enable us to manufacture the raw materials for approximately 10,000 doses of Ampligen(R) per week. We executed a confidentiality agreement with Hollister-Stier; therefore, we commenced the transfer of our manufacturing technology to Hollister-Stier. Currently, Hollister-Stier has completed two pilot manufacturing runs of Ampligen(R) for stability testing.

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

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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) was formulated and packaged at a production facility formerly owned and operated by Abbott Laboratories located in Kansas. Abbott Laboratories has sold the facility to Hospira. Hospira recently completed the production of 11,590 vials. Hospira is ceasing the labeling and packaging of Alferon N Injection(R) as they are seeking larger production runs for cost efficiency purposes. We have identified two manufacturers and, on February 8, 2006, we executed a Manufacturing and Safety Agreement with Hyaluron, Inc. ("Hyaluron") of Burlington, Massachusetts, for the formulation, packaging and labeling of Alferon N Injection(R). Pursuant to the Agreement, we will supply raw materials in sufficient quantity and provide any pertinent information to the project.

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

The transfer of Ampligen(R) raw materials production to our own facilities has obvious advantages with respect to overall control of the manufacturing procedure of Ampligen(R)'s raw materials, keeping costs down and controlling regulatory compliance issues (other parts of the of our 43,000 sq. ft. wholly owned FDA approved facility are already in compliance for Alferon N Injection(R) manufacture). This will also allow us to obtain Ampligen(R) raw materials on a more consistent manufacturing basis. As of April 30, 2006, we have capitalized approximately \$1,400,000 towards the construction and installation of this production line at our New Jersey facility. The installation of a raw material production line has been completed and is now in production with the first lot of Ampligen(R) raw material being produced in the second quarter 2006. We estimate the total cost of establishing this production line to be some \$1,900,000, including modifications to our New Brunswick facility. This polymer production line will have the capacity to produce up to four kilograms per week, or 100 kilograms per year which should allow us to manufacture up to one-half million 400 mg doses per year. We have also identified three contract manufacturers to expand polymer manufacture, if necessary, and obtained preliminary proposals from two and initiated discussions with the third.

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. In October 1994, we entered into a licensing agreement with Bioclones (Propriety) Limited ("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 provided 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 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. In Spain, Portugal and Andorra we have entered into a Sales Distribution Agreement with Laboratorios del Dr. Esteve, S. A., a major pharmaceutical firm headquartered in Spain.

We continue our efforts to establish an internal marketing and sales infrastructure to support the sales of Alferon N Injection(R) in the United States. We continually search for qualified sales managers to increase sales coverage in all major US markets. Our current sales force includes three regional sales managers in Texas, Florida and New York. Our sales force will introduce Alferon N Injection(R) and promote Alferon N Injection(R) to OB GYN's, dermatologists, and infectious disease physicians and particularly STD Clinics, who are involved in the treatment of patients with refractory or recurring external genital warts, as well as physicians about the growing problem and the risks of HPV. We also intend to expand our marketing/sales programs on an international basis with our primary focus on Europe. This program is being designed to engage European pharmaceutical distributors to market and distribute Alferon N Injection(R).

COMPETITION

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

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

The major competitors with drugs to treat HIV diseases include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs, Glaxo Smithkline, Merck and Schering-Plough Corp. Alferon N Injection(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, Aldera, for the treatment of genital and perianal warts. We believe the approval and marketing of this product is the main reason that sales of Alferon N Injection(R) have not met our expectations in the current year.

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 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 intra-lesional 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 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.

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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). 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.

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, we may mitigate the necessity of incurring certain up-front costs. Accredo has also worked with us in connection with the Amp 511 ME/CFS cost recovery treatment program, Amp 516 ME/CFS Phase III clinical trial and the Amp 719 (combining Ampligen(R) 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.

We acquired a series of patents on Oragens, potentially a set of oral broad spectrum antivirals and immunological enhancers, through a licensing agreement with Temple University in Philadelphia, PA. We were granted an exclusive worldwide license from Temple for the Oragens products. These compounds have been evaluated in various academic laboratories for application to chronic viral and immunological disorders. The 2', 5' oligoadenylate synthetase/RNase L system is an important and widely distributed pathway for the inhibition of viral replication and tumor growth. The 2', 5' oligoadenylate synthetase, up activation by double-stranded RNA, synthesizes 2', 5' oligoadenylates (2-5A) from ATP. These bioactive 2-5As directly activate RNase L, which degrades viral and cellular RNAs resulting in the inhibition of protein synthesis. The bioactive 2-5A molecules can be degraded by various hydrolytic enzymes, resulting in a short half life. Analogues of these bioactive 2-5As, termed Oragen RNA compounds, have been produced to increase stability and maintain or increase biological activity without demonstrable toxicity. Pursuant to the terms of our agreement with Temple, we are obligated to pay royalties of 2% to 4% of sales depending on the amount of technical assistance required. We currently pay a royalty of \$30,000 per year to Temple. This agreement is to

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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. We record the payment of the royalty as research and development cost for the period incurred.

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In December 1999, we entered into an agreement with Biovail Corporation International ("Biovail"). Biovail is an international full service pharmaceutical company engaged in the formulation, clinical testing, registration and manufacture of drug products utilizing advanced drug delivery systems. Biovail is headquartered in Toronto, Canada. The agreement grants Biovail the exclusive distributorship of our product in the Canadian territories subject to certain terms and conditions. In return, Biovail agrees to conduct certain pre-marketing clinical studies and market development programs, including without limitation, expansion of the Emergency Drug Release Program in Canada with respect to our products. In addition, Biovail agrees to work with us in preparing and filing a New Drug Submission with Canadian Regulatory Authorities at the appropriate time. Biovail invested \$2,250,000 in Hemispherx equity at prices above the then current market price and agreed to make an additional investment of \$1,750,000 based on receiving approval to market Ampligen(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 for research and development in an effort to develop intellectual property on potential new products for diagnosing and treating various chronic illnesses such as ME/CFS. These costs were expensed as incurred. The strategic alliance agreement provides us certain royalty rights with respect to certain diagnostic technology developed from this research and a right of first refusal to license certain therapeutic technology developed from this research. The strategic alliance agreement provides us with a royalty payment of 10% of all net sales of diagnostic technology developed by Chronix for diagnosing Chronic Fatigue Syndrome, Gulf War Syndrome and Human Herpes Virus-6 associated diseases. The royalty continues for the longer of 12 years from September 15, 2000 or the life of any patent(s) issued with regard to the diagnostic technology. The strategic alliance agreement also provides us with the right of first refusal to acquire an exclusive worldwide license for any and all therapeutic technology developed by Chronix on or before September 14, 2012 for treating Chronic Fatigue Syndrome, Gulf War Syndrome and Human Herpes Virus-6 associated diseases. 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.

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In March 2002, our European subsidiary Hemispherx S.A. entered into a

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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, but did not proceed with the trials due to an inability to enroll a sufficient number of patients. We are discussing with Esteve their initiation of another clinical trial utilizing Ampligen(R) in another indication. 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.

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

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

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

We have entered into agreements for consulting services, which are

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performed at medical research institutions and by medical and clinical research individuals. Our obligation to fund these agreements can be terminated after the initial funding period, which generally ranges from one to three years or on an as-needed monthly basis. During the year ending December 31, 2003, 2004 and 2005 we incurred approximately \$389,000, \$220,000 and \$236,000 respectively, of consulting service fees under these agreements. These costs are charged to research and development expense as incurred.

On December 9, 2005, we executed a Supply Agreement with Hollister-Stier Laboratories LLC of Spokane, Washington ("Hollister-Stier"), for the contract manufacturing of Ampligen(R) for a five year term. Pursuant to the agreement we will supply the key raw materials and Hollister-Stier will formulate and bottle the Ampligen(R). In November 2005, we paid \$100,000 as a deposit in order to initiate the manufacturing project. This deposit was expensed as research and development during the 4th Quarter 2005. The achievement of the initial objectives described in the agreement, in combination with our polymer production facility under construction in New Brunswick, N.J., may enable us to manufacture the raw materials for approximately 10,000 doses of Ampligen(R) per week. We executed a confidentiality agreement with Hollister-Stier; therefore, we commenced the transfer of our manufacturing technology to Hollister-Stier. Currently, Hollister-Stier has completed two pilot manufacturing runs of Ampligen(R) for stability testing.

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

The development of our nucleic acid based products requires the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market and to establish commercial-scale production and marketing capabilities. During our last three fiscal years, we have directly spent approximately \$12,210,000 in research and development, of which approximately \$5,218,000 was expended in the year ended December 31, 2005. These direct costs do not include the overhead and administrative costs necessary to support the research and development effort.

HUMAN RESOURCES

As of May 26, 2006, we had 62 personnel consisting of 43 full time employees, 19 regulatory/research medical personnel on a part-time basis. Part time personnel are paid on a per diem or monthly basis. 43 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.

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

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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.

ITEM 1A. Risk Factors.

The following cautionary statements identify important factors that could cause our actual result to differ materially from those projected in the forward-looking statements made in this Form 10-K/A. 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 FDA for commercial sale.

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

Over its developmental history, Ampligen(R) has received various designations, including Orphan Drug Product Certification (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports (AHRQ, Agency Health Research Quality). However to date, the FDA has determined it has yet to receive sufficient information to support the potential of Ampligen(R) to treat a serious or life threatening aspect of ME/CFS. The definition of the "seriousness of a condition", according to Guidance for Industry documents published in July 2004 is "a matter of judgment, but generally based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one". The FDA has recently requested a "complete and audited report of the Amp 516 study to determine whether Ampligen(R) has a clinically meaningful benefit on a serious or life threatening aspect of ME/CFS in order to evaluate whether the Amp 516 study results do or do not support a "fast track designation". The FDA has also invited us to include a schedule for completion of all ME/CFS studies as well as a proposed schedule for our NDA submission. Because we believe our ME/CFS studies are complete, we intend to request a pre-NDA meeting to obtain advice on preparing and submitting our NDA, which may eliminate the need for Fast Track Designation. Meanwhile, we will continue with our existing ongoing efforts to prepare a complete and audited report of our various studies, including the well-controlled Amp 516 study. We are using our best efforts to complete the requisite reports including the hiring of new staff and various recognized expert medical/regulatory consultants, but can provide no assurance as to

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whether the outcome of this large data collection and filing process (approximately 750 patients, treated more than 45,000 times) will be favorable or unfavorable, specifically with respect to the FDA's perspective. Also, we can provide no guidance as to the tentative date at which the compilation and filing of such data will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the ability of Hollister-Stier facilities to interface with our own New Brunswick staff/facilities to meet the manufacturing regulatory standards.

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

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

All of our drugs and associated technologies, other than Alferon N Injection(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 intra-lesional 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. In this regard, 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 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 Agency for the Evaluation of Medicinal Products ("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, 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.

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

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

In addition, Ampligen(R) is being tested on one strain of avian flu. There are a number of strains and strains mutate. No assurance can be given that a Ampligen(R) will be effective on any strains that might infect humans.

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

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses, as we pursued our clinical trial effort and expanded our efforts in Europe. As of December 31, 2005 our accumulated deficit was approximately \$147,652,000. 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 April 30, 2006, we had approximately \$23,900,000 in cash and cash equivalents and short-term investments. These funds should be sufficient to meet our operating cash requirements, including debt service, for the near term.

On April 12, 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC, pursuant to which Fusion Capital has agreed, under certain conditions and with certain limitations, to purchase on each trading day \$100,000 of our common stock up to an aggregate of \$50.0 million over a 25 month period (see "Financing; Equity Financing" in Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity And Capital Resources; Capital Resources" in Part II below). The extent to which we rely on Fusion Capital as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources.

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If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive and if we are unable to commercialize and sell Ampligen(R) and/or increase sales of Alferon N Injection(R) or our other products, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full \$50.0 million under the common stock purchase agreement with Fusion Capital, we may need to raise additional funds through additional equity or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes including the commercializing of Ampligen(R) products. There can be no assurances that we will raise adequate funds which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

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

We need to preserve and acquire enforceable patents covering the use of Ampligen(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

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patents do not exist or could not be filed which would have a materially adverse effect on our ability to develop or market our products or to obtain or maintain any competitive position that we may achieve with respect to our products. Our patents also may not prevent others from developing competitive products using related technology.

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

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

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

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

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

We have limited marketing and sales capability. We are dependent upon existing and, possibly future, marketing agreements and third party distribution agreements for our products in order to generate significant revenues and become profitable. As a result, any revenues received by us will be dependent on the efforts of third parties, and there is no assurance that these efforts will be successful. Our agreement with Accredo offers the potential to provide some marketing and distribution capacity in the United States while agreements with Biovail Corporation and Laboratorios Del Dr. Esteve S.A. may provide a sales force in Canada, Spain and Portugal. We also had an agreement with Bioclones (Proprietary), Ltd ("Bioclones") that covered South America, Africa, United Kingdom, Australia and New Zealand. However, we deem this marketing arrangement with Bioclones void due to the numerous and long standing failures of performance by Bioclones. In addition, in December 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.

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

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

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

If we are unable to obtain or manufacture the required raw materials, we may be required to scale back our operations or stop manufacturing. The costs and availability of products and materials we need for the production of Ampligen(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, including commercial scale-up, may affect the chemical structure of Ampligen(R) and other RNA drugs, as well as their safety and efficacy, and can, among other things, require new clinical studies and affect orphan drug status, particularly, market exclusivity rights, if any, under the Orphan Drug Act. The transition from limited production of pre-clinical and clinical research quantities to production of commercial quantities of our products will involve distinct management and technical challenges and will require additional management and technical personnel and capital to the extent such manufacturing is not handled by third parties. There can be no assurance that our manufacturing will be successful or that any given product will be determined to be safe and effective, capable of being manufactured economically in commercial quantities or successfully marketed.

We have limited manufacturing experience and capacity.

Ampligen(R) has been only produced in limited quantities for use in our clinical trials and we are dependent upon third party suppliers for

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

We may not be profitable unless we can produce Ampligen(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 lot 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.

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.

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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

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obtaining FDA, HPB or other regulatory product approvals more rapidly than us. There are no drugs approved for commercial sale with respect to treating ME/CFS in the United States. The dominant competitors with drugs to treat HIV diseases include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs, Glaxo Smith Kline, Merck and Schering-Plough Corp. These potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Although we believe our principal advantage is the unique mechanism of action of Ampligen(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 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.

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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,

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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 intra-lesional (within the lesion) treatment of refractory or recurring external genital warts in adults. In clinical trials conducted for the treatment of genital warts with Alferon N Injection(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), Alferon N Injection(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 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(R) and/or Alferon N Injection(R) product liability claims. A successful product liability claim against us in excess of Ampligen(R)'s \$1,000,000 in insurance coverage; \$3,000,000 in aggregate, or in excess of Alferon N Injection(R)'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.

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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 December 31, 2010. However, Dr. Carter has the right to terminate his employment upon not less than 30 days prior written notice. The loss of Dr. Carter or other personnel, or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

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Uncertainty of health care reimbursement for our products.

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

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

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

Risks Associated With an Investment in Our Common Stock

We reported material weaknesses in our internal control over financial reporting that, if not remedied, could adversely affect our internal controls.

We have assessed the effectiveness of our internal control over financial reporting as of December 31, 2005. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control--Integrated Framework (COSO). Based on this assessment, management has identified the following material weaknesses as of December 31, 2005. A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

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1. Financial Statement Close and Reporting Process - We did not maintain effective controls over the financial statement close and reporting process because we lacked a complement of personnel able to devote sufficient time and adequate financial reporting expertise commensurate with quarterly and year-end financial statement close requirements, which include the financial statement preparation and disclosures. Additionally, we had inadequate policies and procedures providing for a detailed comprehensive review of the underlying information supporting the amounts including in our annual and interim consolidation financial statements and disclosures. The lack of personnel resources with specific technical accounting and financial accounting expertise contributed to the material weakness discussed in number two below.

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2. We did not maintain effective controls over the initial recording of our convertible debentures that contained beneficial conversion features (including incorrect recording of investment banking fees incurred and subsequent conversion price resets) and the accounting for warrants and options issued to non-employees. Our interpretation and application of EITF No. 00-27, FASB Statement 133, EITF 98-5 and EITF 00-19 was not correct at the time the convertible debentures were initially recorded (2003 through July 2004), and our interpretation and application of FASB statement No. 123 was not correct in recording certain warrant and option issuances to non-employees. These control deficiencies resulted in the restatement of the 2004 and 2003 annual consolidated financial statements as well as to the unaudited consolidated interim financial statements for each of the three years in the period ended December 31, 2005.

The result of applying the proper accounting treatment increased our net loss applicable to common stockholders by \$0.01 per share, from \$0.42 per share to \$0.43 per share, for the year ended December 31, 2003 and decreased our net loss applicable to common stockholders by \$0.07 per share, from \$0.53 per share to \$0.46 per share, for the year ended December 31, 2004.

Although the recording of the convertible debentures occurred during the periods from March 2003 through July 2004, and we have not issued any debentures since July 2004, we have taken and plan to take, during 2006, additional steps to remediate these internal control weaknesses. In March 2006, we increased the time allocated by our financial consultant with regards to remediating these disclosed internal control weaknesses and will spend additional time monitoring our internal controls on an on-going basis. In addition, we have subscribed to CCH's "Accounting Research Manager," a recognized on-line service in order to maintain up-to-date accounting guidance to enhance internal control over both financial reporting and disclosure requirements. Notwithstanding the foregoing, and the measures we have taken and any future measures we may take to remediate the reported internal control weaknesses, we may not be able to maintain effective internal controls over financial reporting in the future. In addition, deficiencies in our internal controls may be discovered in the future. Any failure to remediate the reported material weaknesses, or to implement new or improved controls, or difficulties encountered in their implementation, could harm our operating results, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Any such failure also could affect the ability of our management to certify in our 2006 Forms 10-K and 10-Q that our internal controls are effective when it provides an assessment of our internal control over financial reporting, and could affect the results of our independent registered public accounting firm's related attestation report regarding our management's assessment. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our securities.

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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;

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- 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; 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 May 31, 2006, the price of our common stock has ranged from \$1.45 to \$3.99 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 May 26, 2006, approximately 1,095,882 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act. Also, we are committed to register 27,609,364 shares issuable (i) to Fusion Capital pursuant to the April 12, 2006 common stock purchase agreement with Fusion Capital; (ii) upon conversion of approximately 135% of Debentures that we issued in 2003 and 2004; (iii) as payment of 135% of the interest on all of the Debentures; (iv) upon exercise of 135% of certain Warrants; and (v) upon exercise of certain other warrants. Registration of the shares permits the sale

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of the shares in the open market or in privately negotiated transactions without compliance with the requirements of Rule 144. To the extent the exercise price of the warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the conversion price and exercise price of these securities are adjusted pursuant to anti-dilution protection, the securities could be exercisable or convertible for even more shares of common stock. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock. Sales of substantial amounts of our common stock in the public market could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

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

The sale by Fusion Capital and other selling stockholders of our common stock will increase the number of our publicly traded shares, which could depress the market price of our common stock. Moreover, the mere prospect of resales by Fusion Capital and other selling stockholders could depress the market price for our common stock. The issuance of shares to Fusion Capital under the common stock purchase agreement dated April 12, 2006, will dilute the equity interest of existing stockholders and could have an adverse effect on the market price of our common stock.

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

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November 2002, we adopted a stockholder rights plan and, under the Plan, our Board of Directors declared a dividend distribution of

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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 9.3% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at \$.01 per Right under certain circumstances.

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We have a limited number of authorized shares that are not issued or reserved for issuance. If we do not increase our authorized shares, our ability to raise capital may be hindered.

Our Certificate of Incorporation currently authorizes the issuance of 100,000,000 common shares and 5,000,000 Preferred Shares. As of May 26, 2006, we had 62,261,349 common shares outstanding and 35,380,005 common shares reserved for future issuance under our existing stock option plan and outstanding options, warrants, convertible debentures, and the 2006 Purchase Agreement with Fusion, leaving only 2,358,646 common shares available for future use. In April 2006, our Board of Directors adopted a resolution proposing that our Certificate of Incorporation be amended to increase the authorized number of common shares to 200,000,000 subject to stockholder approval of such amendment. If stockholders do not approve the amendment to our Certificate of Incorporation at our next Annual Stockholders Meeting, it could harm our business by preventing us from utilizing the daily purchase amounts available under the 2006 Purchase Agreement in full, raising capital from the issuance of our common stock or delaying the payment of services via issuances of our common stock.

Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Our research in clinical efforts may continue for the next several years and we may continue to incur losses due to clinical costs incurred in the development of Ampligen(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 1B. Unresolved Staff Comments.

None.

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ITEM 2. Properties.

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

In 2005, we initiated the transfer of Ampligen(R) raw materials production to our own facilities, which is now completed and in production. This transition of Ampligen(R) raw material production has obvious advantages with respect to overall control of the manufacturing procedure of Ampligen(R)'s raw materials, keeping costs down and controlling regulatory compliance issues (other parts of the of our 43,000 sq. ft. wholly owned FDA approved facility are already in compliance for Alferon N Injection(R) manufacture). This will also allow us to obtain Ampligen(R) raw materials on a more consistent manufacturing basis. As of April 30, 2006, we have capitalized approximately \$1,400,000 towards the construction and installation of this production line at our New Jersey facility. The installation of a raw material production line within our New Brunswick facility has been completed and is now in production with the first lot of Ampligen(R) raw material being produced in the second quarter 2006. We estimate the total cost of establishing this production line to be some \$1,900,000, including modifications to our New Brunswick facility. This polymer production line will have the capacity to produce up to four kilograms per week, or 100 kilograms per year which should allow us to manufacture up to one-half million 400 mg doses per year.

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

ITEM 3. Legal Proceedings.

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

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the Philadelphia Common Pleas Court.

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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, upheld the dismissal of all claims against us and the matter is now concluded.

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 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). Bioclones, Johannesburg Consolidated Investments, Cyril Donninger, R. B. Kebble and H.C. Buitendag filed a motion to dismiss the complaint, which was granted by the court. We are in the process of appealing this decision to the 11th federal circuit court of appeals.

On January 10, 2005, we initiated a multicount lawsuit in the United States District Court for the Eastern District of Pennsylvania seeking injunctive relief and damages against a conspiratorial group, many of whom are foreign nationals or companies located outside the United States alleging that the conspiratorial group has engaged in secret meetings, market manipulations, fraudulent misrepresentations, utilization of foreign accounts and foreign secrecy laws all in furtherance of an illegal scheme to take over Hemispherx and enrich themselves at the expense of 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. Pursuant to an agreement in which R.E.D. Laboratories, N.V./S.A. and Dr. Kenny DeMeirleir agreed not to participate in a hostile takeover of Hemispherx for a period of five years, R.E.D. Laboratories, N.V./S.A. and Dr. Kenny DeMeirleir have been dismissed as defendants in the litigation. The litigation is proceeding against the remaining defendants.

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

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No matters were submitted to a vote of the security holders during the last quarter of the year ended December 31, 2005.

PART II

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

In 2005 we issued 6,632,389 shares of common stock consisting of 1) 1,614,628 shares for debt repayment, debt conversion and interest payments related to the October 2003, January 2004 and July 2004 Convertible Debentures; 2) 338,995 shares in payment of services rendered 3) 4,673,766 shares issued pursuant to the 2005 Purchase Agreement with Fusion Capital and 4) 5,000 shares issued upon conversion of warrants.

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

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

On April 3, 2006, we received a notice from the staff of The American Stock Exchange ("AMEX") indicating that we were not in compliance with Sections 134 and 1101 of the AMEX Company Guide and our listing agreement due to our failure to file our annual report on Form 10-K for the fiscal year ended December 31, 2005 with audited financial statements on a timely basis. The AMEX has granted an extension of the listing of our common stock until June 30, 2006, provided that we file our Form 10-K for 2005 by June 2, 2006 and provided that we file our Form 10-Q for the first quarter of 2006 by June 30, 2006. During the extension period, we will be subject to periodic review by AMEX staff. If we fail to meet any of the foregoing deadlines, the AMEX has indicated that it will begin delisting proceedings.

| COMMON STOCK | High | Low |
|---|------|------|
| | ---- | --- |
| 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 |
| January 1, 2005 through March 31, 2005 | 2.24 | 1.25 |
| April 1, 2005 through June 30, 2005 | 1.96 | 1.30 |
| July 1, 2005 through September 30, 2005 | 1.90 | 1.36 |
| October 1, 2005 through December 31, 2005 | 3.70 | 1.70 |

As of May 26, 2006, there were approximately 278 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.

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On May 26, 2006, the last sale price for our common stock on the AMEX was \$2.74 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.

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, 2005.

| Plan Category ----- | Number of Securities to be issued upon exercise of outstanding options, warrants and rights ----- | Weighted-average Exerco price of Outstanding options, warrants and rights ----- |
|--|---|---|
| | (a) | (b) |
| Equity compensation plans approved by security holders: | 2,400,382 | \$ 2.31 |
| Equity compensation plans not approved by security holders: | 11,529,837 | 3.32 |
| Total | 13,930,219 ===== | \$ 3.19 ===== |

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

The selected consolidated financial data set forth below should be read in conjunction with our consolidated financial statements, and the related notes thereto, and "Management's Discussion and Analysis of Financial Condition and Results of Operations", included in this Annual Report. The statement of operations and balance sheet data presented below for, and as of the end of, each of the years in the five year period ended December 31, 2005 are derived from our audited consolidated financial statements. Historical results are not necessarily indicative of the results to be expected in the future.

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| Year Ended December 31 ----- | 2001 ---- | 2002 ---- | 2003 (2) ----- (restated) | 2004 ----- (restated) |
|------------------------------------|--------------|--------------|---------------------------------|-----------------------------|
| Statement of Operations Data: | | | | |
| Revenues and License fee Income | \$ 390 | \$ 904 | \$ 657 | \$ 1,229 |

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| | | | | |
|---|------------|------------|------------|------------|
| Total Costs and Expenses(1) | 9,192 | 6,961 | 7,909 | 12,118 |
| Interest Expense and Financing Costs(3) | -- | -- | 6,723 | 5,674 |
| Net loss | (9,083) | (7,424) | (13,895) | (16,887) |
| Deemed Dividend | -- | -- | (1,320) | (4,031) |
| Net loss applicable to common stockholder | (9,083) | (7,424) | (15,215) | (20,918) |
| Basic and diluted net loss per share | (0.29) | (0.23) | (0.43) | (0.46) |
| Shares used in computing basic and diluted net loss per share | 31,433,208 | 32,085,776 | 35,234,526 | 45,177,862 |
| Balance Sheet Data: | | | | |
| Working Capital | \$ 7,534 | \$ 2,925 | \$ 7,000 | \$ 13,934 |
| Total Assets | 12,035 | 6,040 | 13,638 | 25,293 |
| Debt, net of discount(3) | -- | -- | 3,123 | 4,312 |
| Stockholders Equity | 10,763 | 3,630 | 8,417 | 19,443 |
| Other Cash Flow Data: | | | | |
| Cash used in operating activities | \$ (7,281) | \$ (6,409) | \$ (7,022) | \$ (7,240) |
| Capital expenditures | -- | -- | (19) | (150) |

(1) General and Administrative expenses include stock compensation expense totaling \$673,000, \$132,000, \$237,000, \$2,000,000 and \$391,000 for the years ended December 31, 2001, 2002, 2003, 2004 and 2005, respectively.

(2) For information concerning the acquisition of certain assets of ISI and related financing see Note 5 and Note 8 to our consolidated financial statements for the year ended December 31, 2005 contained herein.

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(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, \$4,000,000 and \$2,000,000, respectively, and related embedded conversion features and warrant issuances, we recorded debt discounts which, in effect, reduced the carrying value of the debt. For additional information refer to Note 8 to our consolidated financial statements for the year ended December 31, 2005.

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

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The following discussion and analysis is related to our financial condition and results of operations for the three years ended December 31, 2005. 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/A.

Statement of Forward-Looking Information

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

Background

We 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. In 2004, we completed a phase III clinical trial in the U.S. for use of Ampligen(R) 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 with the FDA. We are also testing Ampligen(R) 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 100 patents worldwide, with over 9 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 intra-lesional 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(R) LDO in early stage HIV positive patients.

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

Restatements

In 2003 and 2004 we, entered into convertible debenture arrangements which are inherently complicated, which have been and continue to be the subject of numerous intricate accounting pronouncements and interpretations and which are not classified as normal recurring transactions. Our convertible debenture transactions were reported within our previously filed financial statements for the years ended December 31, 2003 and 2004. After an extensive review and consultation with our independent registered public accountants and our audit committee, we determined that we must restate our historical financial statements for the years ended December 31, 2003 and 2004 as well as the interim financial statements for 2003, 2004, and 2005. Specifically, we have determined that, with respect to the accounting for the convertible debentures, the interpretation and application of EITF No. 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" was not correct at the time the convertible debentures were initially recorded and upon conversion price resets related to the convertible debentures. As a result of this determination, we restated our financial statements and quarterly results of operations (unaudited) included in this annual report and are in the process of restating the consolidated condensed interim financial statements for the 2005 and 2004 periods contained in our 2005 quarterly reports on Form 10-Q. The modifications in the restated financial statements relate to non-cash charges that do not affect our revenues, cash flows from operations or liquidity. These restated financials reflect an increase in per share loss to common stockholders of \$0.01 for the year ended December 31, 2003 and a decrease in per share loss to common stockholders of \$0.07 for the year ended December 31, 2004.

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(a)Based on SEC guidance presented at the 2005 annual AICPA National Conference on current SEC and PCAOB developments, we re-evaluated the accounting for our March 2003, July 2003, October 2003, January 2004 and July 2004 Debentures (collectively, "the Debentures") to determine whether the embedded conversion options required bifurcation and fair value accounting in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities", and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock". We concluded that bifurcation was not required and that EITF 00-27 should have been applied. We did initially apply EITF 00-27, however as part of performing an analysis on the guidelines set forth in EITF 00-27 it was determined that the initial accounting treatment and subsequent price resets for the Debentures that were originally applied and reflected in the financial statements included in our Annual Report on Form 10-K for the years ended December 31, 2003 and 2004, and in our Quarterly Reports on Form 10-Q during the quarterly periods in fiscal 2003, 2004 and 2005 were not correctly applied and that, therefore, a restatement of the our financial statements for the periods referenced above was required. To properly account for the initial calculation of the discount and the conversion

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price resets triggered upon the issuance of the issuance of the October 2003 Debenture and the August 2004 Private Placement (See Notes 8 & 9 to the consolidated financial statements contained herein for more details on these resets), it was determined, under guidance from EITF 00-27 that the debt discount should be restated for the Debentures. The total impact of this restatement on our statement of operations was to decrease the net loss applicable to common stockholders for the year ended December 31, 2004 by \$2,959,000 or \$0.07 per share, and to increase the net loss applicable to common stockholders by \$287,000 or \$0.01 per share for the year ended December 31, 2003.

(b) The estimation of fair value ascribed to and the accounting treatment of the investment banking fees paid to Cardinal Capital, LLC ("Cardinal") in connection with the Debenture issuances, at inception, was inaccurately reflected in the financial statements included in our Annual Report on Form 10-K for the years ended December 31, 2003 and 2004, and our Quarterly reports on Form 10-Q for the periods ended March 31, 2005, June 30, 2005 and September 30, 2005 and that, therefore, a restatement of our financial statements for the periods referenced above was required. In connection with the initial recording of the Debentures mentioned above, it was determined that the fair value of the warrants issued as investment banking fees paid to Cardinal, be accounted for as a discount to the Debentures. These investment banking fees should have been capitalized as deferred financing costs and amortized over the life of the Debentures or charged to earnings on the earlier conversion thereof. In addition, the initial calculation of the fair value of the warrants issued to Cardinal as part of the Debenture issuances was determined to have been applied incorrectly at the time of issuance. The total impact of this restatement on our statement of operations was to decrease the net loss applicable to common stockholders for the year ended December 31, 2004 by \$263,000 or \$0.01 per share, and to increase the net loss applicable to common stockholders for the year ended December 31, 2003 by \$158,000 or \$0.00 per share.

(c) The accounting treatment set forth in FASB Statement No. 123, "Accounting for Stock-Based Compensation", for the issuance of the June 2008, May 2009 and June 2009 Warrants (collectively "the Warrants") (See Note 8 in the consolidated financial statements contained herein for more detail on these transactions) that was originally interpreted and reflected in the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2003 and 2004, was not correctly applied and that, therefore, a restatement of our financial statements for the period referenced above was required. The warrants issued as incentive to exercise prior warrant issuances are reflected as a deemed dividend at the date of issuance, where previously these warrants were either recorded as additional debt discount or as a financing charge at date of issuance. The total impact of this restatement on our statement of operations was to decrease non-cash finance charges for the years ended December 31, 2003 and 2004 by \$1,320,000 and \$4,031,000, or \$0.04 and \$0.08 per share, respectively, and increase the net loss to common stockholders for the years ended December 31, 2003 and 2004 due to the deemed dividend by \$1,320,000 and \$4,031,000, or \$0.04 and \$0.08 per share, respectively.

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As a result of the corrections of the errors as of December 31, 2004 and for the years ended December 31, 2003 and 2004 described above, we have restated our consolidated financial statements in this amended Annual Report on Form 10-K/A.

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HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Audited Consolidated Balance Sheet
(in Thousands)

| | December 31, 2004 As previously Reported | Adjustments |
|---|---|---------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 8,813 | |
| Short term investments | 7,924 | |
| Inventory | 2,148 | |
| Accounts and other receivables | 139 | |
| Prepaid expenses and other current assets | 266 | |
| | ----- | |
| Total current assets | 19,290 | |
| | ----- | |
| Property and equipment, net | 3,303 | |
| Patent and trademark rights, net | 908 | |
| Investment | 35 | |
| Deferred financing costs | 319 | 121 (b) |
| Advance receivable | 1,300 | |
| Other assets | 17 | |
| | ----- | |
| Total assets | \$ 25,172 | 121 |
| | ===== | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 526 | |
| Accrued expenses | 1,012 | |
| Current portion of long-term debt | 3,248 | 570 (a) (b) (c) |
| | ----- | |
| Total current liabilities | 4,786 | 570 |
| | ----- | |
| Long-term debt-net of current portion | 305 | 189 (a) (b) (c) |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock | - | - |
| Common stock | 50 | |
| Additional paid-in capital | 158,024 | (3,415) (a) (b) (c) |
| Accumulated other comprehensive income | (10) | |
| Accumulated deficit | (137,983) | 2,777 (a) (b) (c) |

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| | | |
|--|--------------------------|-------|
| Total stockholders' equity | ----- 20,081 ----- | (638) |
| Total liabilities and stockholders' equity | \$ 25,172 ===== | 121 |

- (a) Includes restatement adjustments for the Debentures relating to the initial recording of and the effect of certain Conversion Price Resets on the Debentures, as described above.
- (b) Includes restatement adjustment for investment banking fees related to Cardinal, as described above.
- (c) Includes restatement adjustment for the issuance of the June 2008, May 2009 and June 2009 warrants as incentives to exercise prior warrant issuance, as described above.

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HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Audited Consolidated Statements of Operations
(in thousands, except share and per share data)
Year Ended December 31, 2003

| | December 31, 2003 ----- As previously Reported | Adjustments | |
|-------------------------------|--|-------------|-------------|
| Revenues: | | | |
| Sales of product net | \$ 509 | | |
| Clinical treatment programs | 148 | | |
| | ----- | | |
| Total Revenues: | 657 | | |
| Costs and expenses: | | | |
| Production/cost of goods sold | 502 | | |
| Research and development | 3,150 | | |
| General and administrative | 4,257 | | |
| | ----- | | |
| Total costs and expenses | 7,909 | | |
| Interest and other income | 80 | | |
| Interest expense | (253) | | |
| Financing costs | (7,345) | 875 | (a) (b) (c) |
| | ----- | | |
| Net loss | \$ (14,770) | 875 | (a) (b) (c) |
| Deemed dividend | - | (1,320) | (c) |
| | ----- | | |

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| | | | |
|--|-------------|-----------|-------------|
| Net loss applicable to common stockholders | \$ (14,770) | (445) | (a) (b) (c) |
| | ===== | | |
| Basic and diluted loss per share | \$ (.42) | \$ (0.01) | |
| | ===== | ===== | |
| Weighted average shares outstanding | 35,234,526 | | |
| | ===== | | |

- (a) Includes restatement adjustments for the Debentures relating to the initial recording of and the effect of certain Conversion Price Resets on the Debentures, as described above.
- (b) Includes restatement adjustment for investment banking fees related to Cardinal, as described above.
- (c) Includes restatement adjustment for the issuance of the June 2008, May 2009 and June 2009 warrants as incentives to exercise prior warrant issuance, as described above.

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HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
 Audited Consolidated Statements of Operations
 (in thousands, except share and per share data)
 Year Ended December 31, 2004

| | December 31, 2004 ---- | Adjustments |
|---|------------------------------|-------------------|
| | As previously Reported | |
| Revenues: | | |
| Sales of product net | \$ 1,050 | |
| Clinical treatment programs | 179 | |
| Total Revenues: | 1,229 | |
| Costs and expenses: | | |
| Production/cost of goods sold | 2,112 | |
| Research and development | 3,842 | |
| General and administrative | 6,164 | |
| | ----- | |
| Total costs and expenses | 12,118 | |
| Equity loss and write off of investments in unconsolidated affiliates | (373) | |
| Interest and other income | 49 | |
| Interest expense | (384) | |
| Financing costs | (12,543) | 7,253 (a) (b) (c) |
| | ----- | |

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| | | |
|--|-------------|-------------|
| Net loss | \$ (24,140) | 7,253 |
| Deemed dividend | - | (4,031) (c) |
| | ----- | ----- |
| Net loss applicable to common stockholders | \$ (24,140) | 3,222 |
| | ===== | |
| Basic and diluted loss per share | \$ (.53) | \$ 0.07 |
| | ===== | ===== |
| Weighted average shares outstanding | 45,177,862 | |
| | ===== | |

- (a) Includes restatement adjustments for the Debentures relating to the initial recording of and the effect of certain Conversion Price Resets on the Debentures, as described above.
- (b) Includes restatement adjustment for investment banking fees related to Cardinal, as described above.
- (c) Includes restatement adjustment for the issuance of the June 2008, May 2009 and June 2009 warrants as incentives to exercise prior warrant issuance, as described above.

Result of Operations

Years Ended December 31, 2005 vs. 2004 (restated)

Net loss applicable to common stockholders

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

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

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Revenues

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

Production costs/cost of goods sold

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

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

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

The installation of a Ampligen(R) raw material production line within our

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

Research and Development costs

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

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

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

We had originally targeted a late 2004 filing date for this NDA for Ampligen(R). In order to respond to changes in the regulatory environment that

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place a greater emphasis on the safety and efficacy of all new experimental drug candidates, we are now incorporating a larger sample of data from our previous trials. The NDA filing will now include data accumulated from 45,000 administrations of the studied drug to approximately 750 ME/CFS patients. We plan to complete and file the NDA before year end 2006.

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

Over its developmental history, Ampligen(R) has received various designations, including Orphan Drug Product Certification (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports (AHRQ, Agency Health Research Quality). However to date, the FDA has determined it has yet to receive sufficient information to support the potential of Ampligen(R) to treat a serious or life threatening aspect of ME/CFS. The definition of the "seriousness of a condition", according to Guidance for Industry documents published in July, 2004 is "a matter of judgment, but generally based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one". The FDA has recently requested a "complete and audited report of the Amp 516 study to determine whether Ampligen(R) has a clinically meaningful benefit on a serious or life threatening aspect of ME/CFS in order to evaluate whether the Amp 516 study results do or do not support a "fast track designation". The FDA has also invited us to include a schedule for completion of all ME/CFS studies as well as a proposed schedule for our NDA submission. Because we believe our ME/CFS studies are complete, we intend to request a pre-NDA meeting to obtain advice on preparing and submitting our NDA. At the same time we will continue with our existing ongoing efforts to prepare a complete and audited report of our various studies, including the well-controlled Amp 516 study. We are using our best efforts to complete the requisite reports including the hiring of new staff and various recognized expert medical/regulatory consultants, but can provide no assurance as to whether the outcome of this large data collection and filing process (approximately 750 patients, treated more than 45,000 times) will be favorable or unfavorable, specifically with respect to the FDA's perspective. We plan to use an independent contractor to file the NDA electronically to facilitate the review by the FDA. Also, we can provide no guidance as to the tentative date at which the compilation and filing of such data will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the ability of Hollister-Stier facilities (or the facilities of such other manufacturer as we may retain in the event that we do not come to definitive terms with Hollister-Stier) to interface with our own New Brunswick staff/facilities to meet the manufacturing regulatory standards.

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

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Our 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. 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.

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

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

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

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In a recently reported study from a vaccine group in Japan, the incorporation of poly I: poly C (dsRNA) into a nasal administration of a killed influenza A preparation converted a poorly immunogenic response into a highly efficacious vaccine in protection of mice from lethal infection from human influenza A. Ampligen(R) is a dsRNA which currently is undergoing testing in the animal model.

Recently, at the fourth annual Biodefense Research Meeting of the American Society of Microbiology held in Washington, D.C., we presented results of laboratory testing that showed our two investigational immunotherapeutics, Ampligen(R) and Alferon(R), are potentially useful against H5N1, or avian flu, virus. The pre-clinical research indicates that Ampligen(R), a specifically configured double-stranded RNA, can provide cross-protection against avian flu viral mutations as well as boost the effectiveness of Tamiflu and Relenza, the only two drugs formally recognized for combating bird flu, up to 100 times. Other lab tests, in healthy human volunteers, indicate that Alferon(R) LDO (Low Dose Oral), a new delivery form of an anti-viral with prior regulatory approval

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for a category of sexually transmitted diseases, can stimulate genes that induce the production of interferon and other immune compounds, key building blocks in the body's defense system. The studies were conducted in conjunction with the National Institute of Infectious Diseases of Japan.

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

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

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

In October 2005, we also engaged the Sage Group, Inc., a health care, technology oriented, strategy and transaction advisory firm, to assist us in obtaining a strategic alliance in Japan for the use of Ampligen(R) in treating

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Chronic Fatigue Syndrome or CFS. In the past year leaders in the Japanese medical community have established the Japanese Society of the Fatigue Science and the Osaka City University Hospital opened the Fatigue Clinical Center as the initial step in their Fatigue Research Project.

A clinical study has been approved by the Clinical Research Ethics Committee of the Kowloon West Cluster at the Princess Margaret Hospital in Hong Kong to evaluate the use of Alferon(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 SARS. This study completed the dosing of ten patients during the fourth quarter 2005 and we expect to complete analyzing the results of this study in the coming months.

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

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

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

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 beyond 2004 and would assist us in an orderly transfer of said activities to other non Schering facilities.

On December 9, 2005, we executed a Supply Agreement with Hollister-Stier Laboratories LLC of Spokane, Washington, for the contract manufacturing of

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

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

General and Administrative Expenses

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

Interest and Other Income

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

Interest Expense and Financing Costs

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

Deemed Dividend

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

Years Ended December 31, 2004 (as restated) vs. 2003 (as restated)

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(R) N, 3) completed drug dosing in our Phase III AMP 516 ME/CFS clinical trial and 4) continued our efforts to develop Ampligen(R)/Alferon(R) 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 allowed us to start the next step towards completing data collection and analysis.

Net loss applicable to common stockholders

Non-cash charges materially affected our net losses applicable to common stockholders for the years ended December 31, 2004 and 2003. Our losses, as restated, of \$20,918,000 for the year ended December 31, 2004, include non-cash financing charges of \$5,290,000, non-cash charges of \$2,000,000 for stock compensation expenses and a \$4,031,000 non-cash charge due to the fair value ascribed to warrant issuances to our debenture holders as incentive to exercise prior warrant issuances. The losses for the same period, as restated, in 2003 of \$15,215,000 included non-cash financing charges of \$6,470,000. This \$5,703,000 increase in net loss primarily represents an increase of \$692,000 in research and development expenses, an increase of \$1,610,000 in production/cost of goods sold and an increase of \$2,711,000 attributed to the warrants issued as incentive to or debenture holders to exercise prior warrant issuances. The non-cash charge due to the fair value ascribed to the warrant issuance to our debenture holders as incentive to exercise prior warrant issuances was \$1,320,000 in 2003. The increase in our research and development costs were the result of 1) costs incurred in the development of a more efficient bottling manufacturing process for Alferon N Injection(R), 2) vials abstracted from the third lot of Alferon N Injection(R) inventory for research and development purposes, and 3) costs associated with using Alferon N Injection(R) 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(R) 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.

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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(R) N totaled \$1,050,000 versus \$509,000 for the period of March 11, 2003, the date we acquired the rights to the Alferon(R) N business from ISI, through December 31, 2003. Sales of Alferon(R) 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

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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 treatment 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.

We executed a Memorandum of Understanding (MOU) in January 2004 with Astellas Pharma ("Astellas"), formally Fujisawa Deutschland GmbH, 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 Astellas by May 31, 2004. If the full report was not provided to Astellas by May 31, 2004 and Astellas 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 Astellas on May 28, 2004 and responded to subsequent inquiries for additional information. The option period ends 12 weeks after the later of Astellas's review of the full report on the results of our Amp 516 clinical trial and Astellas'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 Astellas did not wish to exercise its option, we would be required to refund the entire fee. On November 9, 2004, Astellas exercised their right to terminate the MOU. 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 the agreement of the parties we refunded 200,000 Euros (\$248,000 USD) to Astellas in the fourth quarter 2004. We recorded the remaining 200,000 Euros (\$271,000 and \$241,000 USD) as an accrued liability as of December 31, 2004 and 2005, respectively.

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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 represented expenditures associated with preparing the New Brunswick facility for the installation of the lab previously 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(R) 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(R). 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

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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 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(R), 2) vials abstracted from the third lot of Alferon N Injection(R) inventory for research and development purposes, and 3) costs associated with using Alferon N Injection(R) in a clinical trial to treat patients infected with the West Nile Virus.

In 2004 we 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(R) 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(R) 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.

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Ampligen(R) is 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(R) 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(R) 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 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,

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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).

HIV

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 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 will complete this trial and/or obtain revenues from our HIV treatment indications.

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In September, 2004 we commenced a clinical trial using Alferon N Injection(R) 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 were reported in 40 states.

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

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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(R) N manufacture), may delay certain steps in the commercialization process, specifically a targeted NDA filing.

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

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

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) was formulated and packaged at a production facility formerly owned and operated by Abbott Laboratories located in Kansas. Abbott Laboratories has sold the facility to Hospira. Hospira recently completed the production of 11,590 vials. Hospira is ceasing the labeling and packaging of Alferon N Injection(R) as they are seeking larger production runs for cost efficiency purposes. We have identified two manufacturers and, on February 8, 2006, we executed a Manufacturing and Safety Agreement with Hyaluron, Inc. ("Hyaluron") of Burlington, Massachusetts, for the formulation, packaging and labeling of Alferon N Injection(R). Pursuant to the Agreement, we will supply raw materials in sufficient quantity and provide any pertinent information to the project.

General and Administrative Expenses

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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. In addition, investment banking fees relating to assistance in financing matters increased in 2004 by approximately \$124,000. These increases were offset by a decrease in professional fees in 2004 of approximately \$191,000 as compared to a year earlier. These services fees related to the acquisition of ISI.

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

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Interest expense and financing costs, as restated, were \$5,674,000 for the year ended December 31, 2004 versus \$6,723,000 for the same period in 2003. Non-cash financing costs consist of the amortization of Original Issue Discounts and the amortization 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."

Deemed Dividend

Deemed dividend for the years ended December 31, 2003 and 2004, was \$1,320,000 and \$4,031,000, respectively. This represents the fair value of the warrants issued to our debenture holders as incentive to exercise prior warrant issuances.

Liquidity and Capital Resources

Cash used in operating activities for the year ended December 31, 2005 was \$7,231,000. Cash provided by financing activities for the year ended December 31, 2005 amounted to \$8,029,000, primarily from the sale of common stock. As of April 30, 2006, we had approximately \$23,900,000 in cash and cash equivalents and short-term investments, or an increase of \$7,630,000 from December 31, 2005. These funds should be sufficient to meet our operating cash requirements including debt service for the next 18 months.

On April 12, 2006 we entered into a common stock purchase agreement with Fusion Capital. Fusion Capital has agreed to purchase up to \$50,000,000 of our common stock over a period of approximately 25 months. Refer to the "Financing; Equity Financing" section below for more details on this agreement. Over the long term, we may need to raise additional funds through additional equity or

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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. 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.

FINANCING

Debentures

As of May 24, 2006, the investors have received installment payments of \$2,388,888 and have converted an aggregate \$14,503,023 principal amount of debt from the debentures as noted below:

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| Debenture | Original Principal Amount | Debt Conversion to Common Shares | Installment payments in Common Shares | Remaining Principal Amount |
|-----------|------------------------------|-------------------------------------|---|----------------------------------|
| Mar 2003 | \$ 5,426,000 | \$ 5,426,000 | \$ -- | \$ -- |
| Jul 2003 | 5,426,000 | 5,426,000 | -- | -- |
| Oct 2003 | 4,142,357 | 2,071,178 | -- | 2,071,179 |
| Jan 2004 | 4,000,000 | 1,079,845 | 1,888,888 | 1,031,268 |
| Jul 2004 | 2,000,000 | 500,000 | 500,000 | 1,000,000 |
| Totals | \$20,994,357 | \$14,503,023 | \$ 2,388,888 | \$ 4,102,447 |

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

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

We failed to timely file our 2005 Annual Report on Form 10-K with the Securities and Exchange Commission pursuant to the 1934 Act, and therefore, were in violation of our covenant within our debenture agreements to timely file. We obtained waiver letters from the debenture holders regarding the failure to meet this covenant.

See Note 8 of the consolidated financial statements for a full description of

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all Debentures.

Equity Financing

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

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

The purchase price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction. Fusion Capital may not purchase shares of our common stock under the common stock purchase agreement if it, together with its affiliates, would beneficially own more than 9.9% of our common stock outstanding at the time of the purchase by Fusion Capital. Fusion Capital has the right at any time to sell any shares purchased under the 2006 Purchase Agreement which would allow it to avoid the 9.9% limitation. Without prior stockholder approval, we do not have the right or the obligation under the Agreement to sell shares to Fusion Capital in excess of 12,386,723 shares (i.e. 19.99% of the 61,964,598 outstanding shares of our common stock on April 12, 2006, the date the 2006 Purchase Agreement) inclusive of the commitment shares (discussed below). We would have to average a purchase price of approximately \$4.28 per share to receive the full \$50.0 million under the common stock purchase agreement if we do not receive stockholder approval.

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

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

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

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- o \$2,000,000 if our common stock trades at \$8.00 or better for five trading days.

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

We have agreed to file a registration statement with the Securities and Exchange Commission on or before June 30, 2006 covering the shares of our common stock to be issued under the 2006 Purchase Agreement and to keep it effective until the earlier of the date that all shares are sold or can be sold pursuant to the provisions of Rule 144(k) under the Securities Act. While there are no liquidated damages provisions, as noted below, if we do not timely file the registration statement or keep it effective, Fusion Capital may terminate the agreement.

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

- o our failure to timely file the registration statement or, once the registration statement is declared effective, the effectiveness of the registration statement lapses for any reason or is unavailable to Fusion Capital for sale of our common stock and such lapse or unavailability continues for a period of 10 consecutive trading days or for more than an aggregate of 30 trading days in any 365-day period;
- o suspension by our principal market of our common stock from trading for a period of three consecutive trading days;
- o the de-listing of our common stock from the American Stock Exchange, our principal market, provided our common stock is not immediately thereafter trading on the Nasdaq National Market, the Nasdaq SmallCap Market or the New York Stock Exchange or the OTC Bulletin Board;

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- o the transfer agent's failure for five trading days to issue to Fusion Capital shares of our common stock which Fusion Capital is entitled to under the 2006 Purchase Agreement;
- o any material breach of the representations or warranties or covenants contained in the 2006 Purchase Agreement or any related agreements which has or which could have a material adverse effect on us subject to a cure period of 10 trading days;
- o any participation or threatened participation in insolvency or bankruptcy proceedings by or against us;
- o a material adverse change in our business, properties, operations, financial condition or results of operations; or
- o the issuance of an aggregate of 12,386,723 shares to Fusion Capital under our agreement and we fail to obtain the requisite stockholder approval.

We have the unconditional right at any time for any reason to give notice to Fusion Capital terminating the 2006 Purchase Agreement. Such notice shall be

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effective one trading day after Fusion Capital receives such notice.

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

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

On July 8, 2005, we entered into a common stock purchase agreement (the "2005 Agreement") with Fusion Capital, pursuant to which Fusion Capital agreed, under certain conditions, to purchase on each trading day \$40,000 of our common stock, unless our stock price equals or exceeds \$2.00 in which case the daily amount may be increased under certain conditions as the price of the common stock increases, up to an aggregate of \$20.0 million over approximately a 25 month period, subject to earlier termination at our discretion. As of April 3, 2006, Fusion Capital purchased 8,791,838 shares for gross proceeds of the full \$20.0 million. Pursuant to the Agreement, in our discretion, we could elect to sell less common stock to Fusion Capital than the daily amount or increase the daily amount as the market price of our stock increases. The purchase price of the shares of common stock was equal to a price based upon the market price of the common stock without any fixed discount to the market price. Fusion Capital did not have the right or the obligation to purchase shares of our common stock in the event that the price of the common stock is less than \$1.00. Pursuant to our agreement with Fusion Capital, on July 31, 2005, we registered for public sale by Fusion Capital up to 10,795,597 shares of our common stock.

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

Please see Note 8 - "Debenture Financing" and Note 9 "Stockholder's Equity" in the consolidated financial statements contained herein for more details on debenture and stock financings.

| | (dollars in thousands) | | |
|------------------------------|--------------------------------|-------|-----------|
| | Obligations Expiring by Period | | |
| Contractual Cash Obligations | Total | 2006 | 2007-2008 |
| | ===== | ===== | ===== |
| | | | |

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| | | | |
|----------------------------------|---------|--------|---------|
| Operating Leases | \$ 258 | \$ 193 | \$ 65 |
| Convertible Debentures | | | |
| October 2003 | 2,071 | - | 2,071 |
| January 2004 | 1,365 | - | 1,365 |
| July 2004 | 1,500 | - | 1,500 |
| Interest on 7% Convertible Notes | 524 | 175 | 349 |
| | ----- | ----- | ----- |
| Total | \$5,718 | \$ 368 | \$5,350 |
| | ===== | ===== | ===== |

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

New Accounting Pronouncements

On December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (Revised 2004), "Share-Based Payment" ("SFAS 123R"). On April 14, 2005, the Securities and Exchange Commission issued an amendment to Rule 4-01 of Regulation S-X that allows companies to implement SFAS 123R at the beginning of their next fiscal year, instead of the next reporting period that begins after June 15, 2005 as originally required. Accordingly, we will adopt SFAS 123R effective January 1, 2006 using the "modified prospective" method in which compensation cost is recognized beginning with the effective date base on (a) the requirements of SFAS 123R for all share-based payments granted after the effective date and (b) the requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date. In addition, we expect to continue to utilize the Black-Scholes option-pricing model, which is an acceptable option valuation model in accordance with SFAS 123R, to estimate the value of stock options granted to employees.

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Beyond those restricted stock and stock option awards previously granted, we cannot predict with certainty the impact of SFAS 123R on its future consolidated financial statements as the type and amount of such awards are determined on an annual basis and encompass a potentially wide range depending upon the compensation decisions made by the Human Resources Committee of our Board of Directors. SFAS 123R also requires the benefits of tax deductions in excess of compensation cost recognized in the financial statements to be reported as a financing cash flow, rather than an operating cash flow as currently required under Statement of Financial Accounting Standards No. 95, "Statement of Cash Flows" ("SFAS 95"). This requirement, to the extent it exists, will decrease net operating cash flows and increase net financing cash flows in periods subsequent to adoption. We believe this pronouncement will have a material impact on our consolidated financial statements.

On March 29, 2005, the SEC issued Staff Accounting Bulletin No. 107 ("SAB 107") which expresses the view of the SEC Staff regarding the interaction of SFAS 123R and certain SEC rules and regulations and provides the staff's views regarding the valuation of share-based payment arrangements. We believe that the views provided in SAB 107 are consistent with the approach taken in the valuation and accounting associated with share-based compensation issued in prior periods as well as those issued during 2005.

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In June 2005, the FASB's Emerging Issues Task Force ("EITF") issued EITF Issue No. 05-02 "The Meaning of "Conventional Convertible Debt Instrument" in EITF Issue 00-19 "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, A Company's Own Stock", which retains the exception in paragraph 4 of EITF Issue No. 00-19 for conventional debt instruments. Those instruments in which the holder has an option to convert the instrument into a fixed number of shares (or a corresponding amount of cash at the issuer's discretion) and its ability to exercise the option is based on either (a) the passage of time or (b) a contingent event, should be considered "conventional" for purposes of applying that exception. The consensus should be applied on a prospective basis for new or modified instruments starting from the third quarter of 2005. The adoption of EITF No. 05-02 did not have a material effect on our consolidated financial statements or results of operations.

In November 2005, FASB issued FSP FAS 115-1 and FAS 124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments" ("FSP FAS 115-1"), which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether an impairment is other-than-temporary, and on measuring such impairment loss. FSP FAS 115-1 also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. FSP FAS 115-1 is required to be applied to reporting periods beginning after December 15, 2005. We are required to adopt FSP FAS 115-1 in the first quarter of 2006. We do not expect the adoption of this statement to have a material impact on our consolidated results of operations or financial condition.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs - An amendment of ARB No. 43, Chapter 4" ("SFAS No. 151"). SFAS No. 151 amends the guidance in Accounting Research Bulletin No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Additionally, SFAS No. 151 requires that the allocation of fixed production overheads to the cost of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is required to be adopted in the first quarter of 2006. We have determined that the adoption of SFAS No. 151 will not have a material impact on the consolidated financial statements.

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In December 2004, the FASB issued Statement of Financial Accounting Standards No. 153 ("SFAS 153"), "Exchanges of Non-monetary Assets—an amendment of APB Opinion No. 29." SFAS 152 addresses the measurement of exchanges of non-monetary assets. It eliminates the exception from fair value measurement for non-monetary exchanges of similar productive assets in paragraph 21(b) of APB Opinion No. 29 "Accounting for Non-monetary Transactions" and replaces it with an exception for exchanges that do not have commercial substance. A non-monetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. As required by SFAS 153, we adopted this new accounting standard effective July 1, 2005. The adoption of SFAS 153 did not have a material impact on our financial statements.

In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections. SFAS No. 154 establishes retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. SFAS No. 154 also provides guidance for determining whether retrospective application is impractical. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not

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expect that the adoption of SFAS No. 154 will have a material impact on its results of operations or financial position.

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 and issued Dr. Carter 1,450,000 warrants to purchase common stock at \$2.20 per share in 2003 that vested in the first quarter 2004 upon the second ISI asset closing.

Critical Accounting Policies

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

Revenue

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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.

Short-term Investments

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

Inventories

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

Patents and Trademarks

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

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into our strategic business plans.

Convertible Securities with Beneficial Conversion Features

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

Stock Based Compensation

We follow 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.

We provide 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."

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For stock warrants or options granted to non-employees, we measure the 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. We amortize such cost over the related period of service.

Concentration of Credit Risk

Our policy is to limit the amount of credit exposure to any one financial institution and place investments with financial institutions evaluated as being credit worthy, or in short-term money markets, which are exposed to minimal interest rate and credit risks. At and since December 31, 2005, we have had bank deposits and overnight repurchase agreements that exceed federally insured limits.

Concentration of credit risk, with respect to receivables, is limited through our credit evaluation process. We do not require collateral on our receivables. Our receivables consist principally of amounts due from wholesale drug companies as of December 31, 2005.

Item 7A. Quantitative And Qualitative Disclosures About Market Risk

We had approximately \$16,204,000 in cash and cash equivalents and short-term investments at December 31, 2005. To the extent that our cash and cash equivalents exceed our near term funding needs, we invest the excess cash in three to twelve month high quality interest bearing financial instruments. We employ established conservative policies and procedures to manage any risks with respect to investment exposure.

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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, 2004 and 2005, 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, 2005, 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

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As of December 31, 2005, the end of the period covered by this report, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Act of 1934, as amended, as of December 31, 2005. Our disclosure controls and procedures are intended to ensure that the information we are required to disclose in the reports that we file or submit under the Securities Exchange Act of 1934 is (i) recorded, processed, summarized and reported within the time periods specified in the Securities Exchange Commission's rules and forms and (ii) accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as the principal executive and financial officers, respectively, to allow final decisions regarding required disclosures. Because of the material weaknesses described in Management's Report on Internal Control Over Financial Reporting, our management has concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were not effective. Notwithstanding the material weaknesses discussed below, our management has concluded that the financial statements included in this Form 10-K present fairly, in all material respects our financial position, results of operations and cash flows for the periods presented in conformity with generally accepted accounting principles.

Changes in Internal Control over Financial Reporting

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

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Management's Report on Internal Control Over Financial Reporting

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

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

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Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2005. In making this assessment, management used the criteria set forth in the framework established by the Committee of Sponsoring Organizations of the Treadway Commission Internal Control--Integrated Framework, (COSO). Based on this assessment, management has identified the following material weaknesses as of December 31, 2005. A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

1. Financial Statement Close and Reporting Process - We did not maintain effective controls over the financial statement close and reporting process because we lacked a complement of personnel able to devote sufficient time and adequate financial reporting expertise commensurate with quarterly and year-end financial statement close requirements, which include the financial statement preparation and disclosures. Additionally, we had inadequate policies and procedures providing for a detailed comprehensive review of the underlying information supporting the amounts including in our annual and interim consolidation financial statements and disclosures. The lack of personnel resources with specific technical accounting and financial accounting expertise contributed to the material weakness discussed in number two below.
2. We did not maintain effective controls over the initial recording of our convertible debentures that contained beneficial conversion features (including incorrect recording of investment banking fees incurred and subsequent conversion price resets) and the accounting for warrants and options issued to non-employees. Our interpretation and application of EITF No. 00-27, FASB Statement 133, EITF 98-5 and EITF 00-19 was not correct at the time the convertible debentures were initially recorded (2003 through July 2004), and our

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interpretation and application of FASB statement No. 123 was not correct in recording certain warrant and option issuances to non-employees. These control deficiencies resulted in the restatement of the 2004 and 2003 annual consolidated financial statements as well as to the unaudited consolidated interim financial statements for each of the three years in the period ended December 31, 2005.

Because of these material weaknesses, management has concluded that we did not maintain effective internal control over financial reporting as of December 31, 2005, based on the criteria set forth in "Internal Control--Integrated Framework" issued by the COSO.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by BDO Seidman LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Plans for Remediation of Material Weaknesses

Convertible debenture arrangements are inherently complicated and are not classified as normal recurring transactions. The root of the referenced non-cash restatements above stems from our entering into complex convertible debenture arrangements during the periods from March 2003 through July 2004. We have not entered into any debenture arrangements thereafter. We have taken, and plan to take, additional steps to remediate the material weaknesses concerning convertible debentures that contained beneficial conversion features (including incorrect recording of investment banking fees incurred and subsequent conversion price resets) and the accounting for warrants and options issued to non-employees. Our interpretation and application of EITF No. 00-27, FASB Statement 133, EITF 98-5 and EITF 00-19 was not correct at the time the convertible debentures were initially recorded (2003 through July 2004), and our interpretation and application of FASB statement No. 123 was not correct in recording certain warrant and option issuances to non-employees. In March 2006, we increased the time allocated by our financial consultant with regards to remediating these disclosed internal control weaknesses and the financial consultant will spend additional time monitoring our internal controls on an on-going basis. In addition, we have subscribed to CCH's "Accounting Research Manager," a recognized on-line service in order to maintain up-to-date accounting guidance to enhance internal control over both financial reporting and disclosure requirements.

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

Board of Directors and Stockholders
Hemispherx Biopharma, Inc.
Philadelphia, Pennsylvania

We have audited management's assessment, included in Management's Report on Internal Control Over Financial Reporting, that Hemispherx Biopharma, Inc. did not maintain effective internal control over financial reporting as of December 31, 2005, because of the effect of material weaknesses identified in management's assessment based on criteria established in Internal Control--Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Hemispherx Biopharma, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal

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control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

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

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

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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.

A material weakness is a control deficiency, or combination of control deficiencies, that result in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. The following material weaknesses have been identified and included in management's assessment.

As of December 31, 2005, the Company did not maintain effective controls over the financial statement close and reporting process because the Company lacked a complement of personnel able to devote sufficient time and adequate financial reporting expertise commensurate with the quarterly and year-end financial statement close requirements, which include financial statement preparation and disclosures.

As of December 31, 2005 the Company did not maintain effective control over the initial recording of the convertible debentures that contained beneficial conversion features, including incorrect recording of investment banking fees incurred and subsequent debenture conversion price resets dating back to 2003 and the accounting for warrants and options.

The material weaknesses were considered in determining the nature, timing and extent of the audit tests applied in our audit of the Company's consolidated financial statements as of and for the year ended December 31, 2005, and this

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report does not affect our report dated June 1, 2006 on those consolidated financial statements.

In our opinion, management's assessment that Hemispherx Biopharma, Inc. did not maintain effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the criteria established in Internal Control-Integrated Framework issued by COSO. Also, in our opinion, Hemispherx Biopharma, Inc. because of the effect of the material weaknesses described above on the achievement objectives and control criteria, the Company has not maintained effective control over financial reporting as of December 31, 2005, based on the criteria established in Internal Control-Integrated Framework issued by COSO.

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, 2005 and 2004, 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, 2005, and our report dated June 1, 2006 expressed an unqualified opinion thereon.

/s/ BDO SEIDMAN LLP

Philadelphia, PA
June 1, 2006

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ITEM 9B. Other Information.

None.

PART III

Item 10. Directors and Executive Officers of the Registrant.

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

| Name | Age | Position |
|---------------------------|-----|--|
| William A. Carter, M.D. | 68 | Chairman, Chief Executive Officer |
| R. Douglas Hulse | 62 | President |
| Robert E. Peterson | 69 | Chief Financial Officer |
| David R. Strayer, M.D. | 60 | Medical Director, Regulatory Affairs |
| Mei-June Liao, Ph.D. | 55 | Vice President of Regulatory Affairs, Quality Control and Research and Development |
| Robert Hansen | 62 | Vice President of Manufacturing |
| Carol A. Smith, Ph.D. | 56 | Director of Process Development |
| Richard C. Piani | 79 | Director |
| William M. Mitchell, M.D. | 71 | Director |

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| | | |
|--------------------------|----|---|
| Ransom W. Etheridge | 66 | Director, Secretary and General Counsel |
| Steven D. Spence | 46 | Director |
| Iraj Eqhbal Kiani, Ph.D. | 60 | Director |

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.

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WILLIAM A. CARTER, M.D., the co-inventor of Ampligen(R), 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

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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.

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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(R) N. Mr. Hansen had been Vice President of Manufacturing for ISI since 1997, and served in various capacities in manufacturing since joining ISI in 1987. He has a B.S. degree in Chemical Engineering from Columbia University in 1966.

CAROL A. SMITH, Ph.D. is Director of Process Development and has served as our Director of Manufacturing and Process Development since April 1995, as Director of Operations since 1993 and as the Manager of Quality Control from 1991 to 1993, with responsibility for the manufacture, control and chemistry of Ampligen(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.

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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.

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

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

Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Exchange Act requires our officers and directors, and persons who own more than ten percent of a registered class of equity securities, to file reports with the Securities and Exchange Commission reflecting their initial position of ownership on Form 3 and changes in ownership on Form 4 or Form 5. Based solely on a review of the copies of such Forms received by us, we believe that, during the fiscal year ended December 31, 2005, all of our officers, directors and ten percent stockholders complied with all applicable Section 16(a) filing requirements on a timely basis.

Audit Committee and Audit Committee Expert

Our Audit Committee of the Board of Directors consists of Richard Piani, Committee Chairman, William Mitchell, M.D. and Steven Spence. Mr. Piani, Dr. Mitchell and Mr. Spence 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-Eqhbali 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

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and discussing the statements and reports with management, including any significant adjustments, management judgments and estimates, new accounting policies and disagreements with management; (iii) disclosures by independent accountants concerning relationships with our company and the performance of our independent accountants; and (iv) reviewing and updating our Audit Committee Charter.

Code of Ethics

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

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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, 2005, 2004 and 2003 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").

EXECUTIVE COMPENSATION SUMMARY COMPENSATION TABLE

| Name and Principal Position | Year | Salary (\$) | Restricted Stock Awards | Warran |
|---|------|---------------|----------------------------|--------|
| William A. Carter Chairman of the Board and CEO | 2005 | (2) 623,330 | - | |
| | 2004 | (2) 605,175 | - | |
| | 2003 | (2) 582,461 | - | |
| R. Douglas Hulse President and COO | 2005 | (6) \$110,000 | - | |
| | 2004 | - | - | |
| | 2003 | - | - | |
| Robert E. Peterson Chief Financial Officer | 2005 | (7) 253,350 | - | |
| | 2004 | (7) 221,242 | - | |
| | 2003 | (7) 193,816 | - | |
| David R. Strayer, M.D. Medical Director | 2005 | (10) 207,304 | - | |
| | 2004 | 180,394 | - | |
| | 2003 | 190,096 | - | |
| Carol A. Smith, Ph.D. Director of Process Development | 2005 | 138,697 | - | |
| | 2004 | 134,658 | - | |
| | 2003 | 140,576 | - | |
| Mei-June Liao, Ph.D., V.P. of Quality Control | 2005 | 153,470 | - | |
| | 2004 | 149,000 | - | |
| | 2003 | (13) 100,575 | - | |

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| | | | |
|-----------------------|------|-------------|---|
| Robert Hansen | 2005 | 135,968 | - |
| V.P. of Manufacturing | 2004 | 132,000 | - |
| | 2003 | (13)104,500 | - |

- (1) Consists of insurance premiums paid by us with respect to term life and disability insurance for the benefit of the named executive officer.

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- (2) Includes bonuses of \$99,481, \$121,035 and \$124,666 in 2003, 2004 and 2005, respectively.
- (3) Consists of stock option grants to a) acquire 100,000 shares at \$1.75 per share, b) acquire 10,000 shares at \$2.61 per share, c) acquire 70,000 shares at \$2.87 and d) to acquire 465,000 shares at \$1.86. In 2005, Dr. Carter had 535,000 previously issued options expire.
- (4) Consist of a stock option grant of 320,000 shares exercisable at \$2.60 per share.
- (5) Represents warrants to purchase 1,450,000 shares of common stock exercisable at \$2.20 per share.
- (6) Reflects compensation beginning February 2005. Stock options issued to Sage Healthcare Advisors, LLC, pursuant to Mr. Hulse's employment agreement. Mr. Hulse has direct interest in 41,667 of these options.
- (7) 2003 includes a bonus of \$37,830, 2004 includes a bonus of \$44,248 and 2005 includes a bonus of \$50,670.
- (8) Reflects options to purchase 100,000 shares of Common Stock at \$1.75 and 10,000 shares at \$2.61 per share.
- (9) 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.
- (10) Includes a bonus of \$30,000.
- (11) Consists of stock options exercisable at \$2.61 per share.
- (12) Consists of stock option grant exercisable at \$1.90 per share.
- (13) Compensation from March 2005. Employed by ISI prior to that.

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The following table sets forth certain information regarding stock options and warrants granted during 2005 to the executive officers named in the Summary Compensation Table.

Individual Grants

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| Name | Number Of Securities Underlying Options/Warrants Granted | Percentage Of Total Options/Warrants Granted To Employees In Fiscal Year 2005(1) | Exercise Price Per Share (2) | Expiration Date | Potential Assumptions Appre |
|----------------|--|--|------------------------------|-----------------|-----------------------------|
| Carter, W.A. | 100,000 | 47.6 | \$1.75 | 4/26/15 | |
| | 70,000 | | 2.87 | 12/9/15 | |
| | 10,000 | | 2.61 | 12/8/15 | |
| | 465,000 | | 1.86 | 7/1/11 | |
| Hulse, R.D.(4) | 250,000 | 18.5 | \$1.55 | 2/14/15 | |
| Peterson, R. | 100,000 | 8.1 | \$1.75 | 4/26/15 | |
| | 10,000 | | \$2.61 | 12/8/15 | |
| Strayer, D. | 10,000 | * | \$2.61 | 12/8/15 | |
| Smith, C. | 10,000 | * | \$2.61 | 12/8/15 | |
| Liao, M. | 10,000 | * | \$2.61 | 12/8/15 | |
| Hansen, R. | 10,000 | * | \$2.61 | 12/8/15 | |

- (1) Total stock options and warrants issued to employees in 2005 were 1,352,600.
- (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.
- (4) Reflects compensation beginning February 2005. Stock options issued to Sage Healthcare Advisors, LLC, pursuant to Mr. Hulse's employment agreement. Mr. Hulse has direct interest in 41,567 of these options.

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The following table sets forth certain information regarding the stock options and warrants held as of December 31, 2005 by the individuals named in the above Summary Compensation Table.

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

Securities Underlying Unexercised
Warrants/
Options at Fiscal Year End Numbers

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| Name | Shares Acquired on Exercise (#) | Value Realized (\$) | Exercisable | Unexercisable |
|-----------------|---------------------------------------|------------------------|---------------|---------------|
| William Carter | - | - | 5,515,378 (2) | 257,500 (3) |
| Robert Peterson | - | - | 567,574 (4) | 10,000 (5) |
| David Strayer | - | - | 137,500 (6) | 12,500 (7) |
| Carol Smith | - | - | 49,291 (8) | 12,500 (7) |
| Mei-June Liao | - | - | 7,500 (9) | 12,500 (7) |
| Robert Hansen | - | - | 7,500 (9) | 12,500 (7) |

(1) Computation based on \$2.17, the December 31, 2005 closing bid price for the common stock on the American Stock Exchange.

(2) Includes shares issuable upon the exercise of (i) warrants issued in 2001 to purchase 376,650 shares of common stock consisting of 188,325 exercisable at \$6.00 per share and 188,325 exercisable at \$9.00 per share, all of which expired on February 22, 2006; (ii) stock options issued in 2001 to purchase 10,000 shares of common stock at \$4.03 per share expiring January 3, 2011; (iii) warrants issued in 2002 to purchase 750,000 shares of common stock exercisable at \$2.00 per share expiring on August 7, 2007; (iv) warrants issued in 2003 to purchase 1,450,000 shares of common stock exercisable at \$2.20 per share expiring on September 8, 2008; (v) stock options issued in 2004 to purchase 320,000 shares of common stock at \$2.60 per share expiring on September 7, 2014; (vi) Stock Options issued in 2005 to purchase 100,000 shares of common stock at \$1.75 per share expiring on April 26, 2015; (vii) stock options issued in 2005 to purchase 465,000 shares of common stock at \$1.86 per share expiring July 1, 2011; (viii) stock options issued in 2005 to purchase 70,000 shares of common stock at \$2.87 per share expiring December 9, 2015; and (ix) stock options issued in 2005 to purchase 10,000 shares of common stock at \$2.61 per share expiring Decemner 8, 2015. Also includes 1,963,728 warrants and options originally issued to William A. Carter and subsequently transferred to Carter Investments of which Dr. Carter is the beneficial owner. These securities consist of warrants issued in 1998(a) to purchase 490,000 shares of common stock consisting of 190,000 exercisable at \$4.00 per share expiring on January 1, 2008 and 300,000 exercisable at \$6.00 per share that expired on January 1, 2006; (b) stock options granted in 1991 and extended in 1998 to purchase 73,728 shares of common stock exercisable at \$2.71 per share expiring on August 8, 2008 and (c) Warrants issued in 2002 to purchase 1,400,000 shares of common stock at \$3.50 per share expiring on September 30, 2007. The 376,650 warrants expired on February 22, 2006 and the 300,000 warrants that expired on January 1, 2006 were replaced by the Board of Directors (refer to Item 12. Security Ownership of Certain Beneficial Owners and Management).

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- (3) Consists of (i) 250,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007 and 7,500 stock options exercisable at \$2.61 per share expiring on December 8, 2015.
- (4) Includes shares issuable upon exercise of (i) options issued in 1997 to purchase 13,750 shares of common stock at \$3.50 per share and expiring on January 22, 2007, (ii) options issued in 2001 to purchase 10,000 shares of common stock at \$4.03 per share and expiring on January 3, 2011, (iii) warrants issued in 2002 to purchase 200,000 shares of common stock at \$2.00 per share expiring on August 13, 2007; (iv) options issued in 2005 to purchase 100,000 shares of common stock at \$1.75 per share expiring April 26, 2015. Also includes 243,824 warrants/options originally issued to Robert E. Peterson and subsequently transferred to the Robert E. Peterson Trust of which Robert E. Peterson is owner and Trustee. These securities include options issued in 1996 to purchase 50,000 shares of common stock exercisable at \$3.50 per share and expired on February 28, 2006; warrants issued in 1998 to purchase 100,000 shares of common stock at \$5.00 per share expiring on April 14, 2006; warrants issued in 2002 to purchase 30,000 shares of common stock exercisable at \$5.00 per share expiring on April 30, 2006 and 63,824 stock options issued in 2004 consisting of 50,000 options to acquire common stock at \$3.44 per share expiring on June 22, 2014 and 13,824 options to acquire common stock at \$2.60 per share expiring on September 7, 2014. The 50,000 options that expired on February 28, 2006 were replaced by the Board of Directors (refer to Item 12. Security Ownership of Certain Beneficial Owners and Management).
- (5) Consists 10,000 options issued in 2005 exercisable at \$2.61 per share.
- (6) 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; (iv) 20,000 stock options exercisable at \$3.50 per share expiring on January 22, 2007; and (v) 5,000 stock options exercisable at \$1.90 per share expiring on December 7, 2014 and 2,500 stock options exercisable at \$2.61 per share expiring on December 8, 2015.
- (7) Consists of 5,000 stock options exercisable at \$1.90 per share expiring on December 7, 2014 and 7,500 stock options exercisable at \$2.61 per share expiring on December 8, 2015.
- (8) 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; (iv) 6,791 stock options exercisable at \$3.50 per share expiring on January 22, 2007; and (v) 5,000 stock options exercisable at \$1.90 per share expiring on December 7, 2014 and 2,500 stock options exercisable at \$2.61 per share expiring on December 8, 2015.
- (9) Consists of 5,000 options to purchase common stock at \$1.90 per share expiring on December 7, 2014 and 2,500 stock options exercisable at \$2.61 per share expiring on December 8, 2015.

Employment and Change in Control Agreements

On March 11, 2005, our board of directors, at the recommendation of the

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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 was 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

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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 were 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. We valued these warrants at \$256,000 utilizing the Black-Scholes Method. As of December 31, 2005, the \$150,000 was expensed to stock compensation expense. 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 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(R). 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. 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 non-employee members of the Board of Directors was changed on September 9, 2003. Board member compensation consists

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of an annual retainer of \$100,000 to be paid 50% in cash and 50% in our common stock. On September 9, 2003 the Directors approved a 10 year plan which authorizes up to 1,000,000 shares for use in supporting this compensation plan. The number of shares paid shall have a value of \$12,500 with the value of the shares being determined by the closing price of our common stock on the American Stock Exchange on the last day of the calendar quarter. 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 31, 2005, 6,014,320 shares were available for grants under the 2004 Plan, 633,080 and 1,352,600 options were issued in 2004 and 2005, respectively. 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 and 2005, 18,881 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

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In December 1995, we established a defined contribution plan, effective January 1, 1995, entitled the Hemispherx Biopharma employees 401(K) Plan and Trust Agreement. All of our full time employees are eligible to participate in the 401(K) plan following one year of employment. Subject to certain limitations imposed by federal tax laws, participants are eligible to contribute up to 15% of their salary (including bonuses and/or commissions) per annum. Participants' contributions to the 401(K) plan may be matched by Hemispherx at a rate determined annually by the board of directors. Each participant immediately vests in his or her deferred salary contributions, while our contributions will vest over one year. See Note 12 to the consolidated financial statements

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contained herein.

Compensation Committee Interlocks and Insider Participation

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

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 2005.

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.

Base Salary

The Summary Compensation Table shows amounts earned during 2005 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 \$290,888. 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 \$207,777. 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 allows for annual cost of living increases and a performance bonus.

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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

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cash bonus awarded to our Chief Executive Officer in 2004 and 2005 and the cash bonus awarded to the Chief Financial Officer in 2004 and 2005 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 645,000 stock options in 2005 of which 535,000 were issued to replace options previously awarded that expired. These options are exercisable at rates varying from \$1.75 to \$2.87 per share. The options vested on the date of grant.

On April 26, 2005, our Chief Financial Officer, Robert E. Peterson, was granted 100,000 stock options exercisable at \$1.75 per share expiring on April 26, 2015 unless previously exercised. On December 8, 2005 Mr. Peterson was granted 10,000 stock options exercisable at \$2.61 per share expiring on December 8, 2015.

Ransom Etheridge, our Corporate Secretary and General Counsel, was awarded 100,000 stock options on April 26, 2005 exercisable at \$1.75 per share expiring April 26, 2015, unless previously exercised.

Performance Graph

Total Return to Shareholders
(Includes reinvestment of dividends)

| Company Name / Index | ANNUAL RETURN PERCENTAGE | | | | |
|--------------------------|--------------------------|--------|--------|--------|--------|
| | Years Ending | | | | |
| | Dec 01 | Dec 02 | Dec 03 | Dec 04 | Dec 05 |
| HEMISPHERX BIOPHARMA INC | -5.26 | -52.67 | 6.10 | -15.93 | 14.21 |
| S&P 600 INDEX | 6.54 | -14.63 | 38.79 | 22.65 | 7.68 |
| PEER GROUP | 48.39 | -45.76 | 5.33 | -52.63 | -41.59 |

| Company Name / Index | Base Period Dec 00 | INDEXED RETURNS | | | | |
|--------------------------|--------------------------|-----------------|--------|--------|--------|--------|
| | | Years Ending | | | | |
| | Dec 01 | Dec 02 | Dec 03 | Dec 04 | Dec 05 | |
| HEMISPHERX BIOPHARMA INC | 100 | 94.74 | 44.84 | 47.58 | 40.00 | 45.68 |
| S&P 600 INDEX | 100 | 106.54 | 90.95 | 126.23 | 154.82 | 166.71 |
| PEER GROUP | 100 | 148.39 | 80.49 | 84.78 | 40.16 | 23.46 |

Peer Group Companies

 AVI BIOPHARMA INC
 IMMUNE RESPONSE CORP/DE

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LA JOLLA PHARMACEUTICAL CO
MAXIM PHARMACEUTICALS INC

[BAR CHART]

TOTAL SHAREHOLDER RETURNS

| Company Name / Index | Base Period Dec 00 | Years Ending | | | | |
|--------------------------|--------------------------|--------------|--------|--------|--------|--------|
| | | Dec 01 | Dec 02 | Dec 03 | Dec 04 | Dec 05 |
| HEMISPHERX BIOPHARMA INC | 100 | 94.74 | 44.84 | 47.58 | 40.00 | 45.68 |
| S&P 600 INDEX | 100 | 106.54 | 90.95 | 126.23 | 154.82 | 166.71 |
| PEER GROUP | 100 | 148.39 | 80.49 | 84.78 | 40.16 | 23.46 |

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

The following table sets forth as of May 26, 2006, 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 24, 2006, 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.

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| Name and Address of Beneficial Owner | Shares Beneficially Owned |
|--|---------------------------|
| William A. Carter, M.D. | 6,272,868 (1) |
| Robert E. Peterson | 585,574 (2) |
| Ransom W. Etheridge 2610 Potters Rd. Virginia Beach, VA 23452 | 642,560 (3) |
| Richard C. Piani 97 Rue Jeans-Jaures Levaillois-Perret France 92300 | 450,602 (4) |
| Doug Hulse | 131,067 (5) |

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Sage Group, Inc.
3322 Route 22 West
Building 2, Suite 201
Branchburg, NJ 08876

| | |
|--|--------------|
| William M. Mitchell, M.D. Vanderbilt University Department of Pathology Medical Center North 21st and Garland Nashville, TN 37232 | 397,884 (6) |
| David R. Strayer, M.D. | 160,746 (7) |
| Carol A. Smith, Ph.D. | 61,791 (8) |
| Iraj-Eqhbali Kiani, Ph.D. Orange County Immune Institute 18800 Delaware Street Huntingdon Beach, CA 92648 | 97,797 (9) |
| Steven Spence | 197,883 (10) |
| Mei-June Liao, Ph.D. | 20,000 (11) |
| Robert Hansen | 20,000 (11) |
| All directors and executive officers as a group (11 persons) | 9,038,772 |

* Less than 1%

- (1) Includes shares issuable upon the exercise of (i) replacement options issued in 2006 to purchase 376,650 shares of common stock exercisable at \$3.78 per share expiring on February 22, 2016; (ii) stock options issued in 2001 to purchase 10,000 shares of common stock at \$4.03 per share expiring January 3, 2011; (iii) warrants issued in 2002 to purchase 1,000,000 shares of common stock exercisable at \$2.00 per share expiring on August 7, 2007; (iv) warrants issued in 2003 to purchase 1,450,000 shares of common stock exercisable at \$2.20 per share expiring on September 8, 2008; (v) stock options issued in 2004 to purchase 320,000 shares of common stock at \$2.60 per share expiring on September 7, 2014; (vi) Stock Options issued in 2005 to purchase 100,000 shares of common stock at \$1.75 per share expiring on April 26, 2015; (vii) Stock options issued in 2005 to purchase 465,000 shares of common stock at \$1.86 per share expiring July 1, 2011; and (viii) stock options issued in 2005 to purchase 70,000 shares of Common Stock at \$2.87 per share expiring December 9, 2015; (ix) stock options issued in 2005 to purchase 10,000 shares of Common Stock at \$2.61 per share expiring December 8, 2015; and (x) 507,490 shares of Common Stock. Also includes 1,963,728 warrants and options originally issued to William A. Carter and subsequently transferred to Carter Investments of which Dr. Carter is the beneficial owner. These securities consist of warrants issued in 1998(a) to purchase 490,000 shares of common stock consisting of 190,000 exercisable at \$4.00 per share expiring on January 1, 2008 and 300,000 exercisable at \$2.38 per share expiring January 1, 2016; (b) stock options granted in 1991 and extended in 1998 to purchase 73,728 shares of common stock exercisable at \$2.71 per share expiring on August 8, 2008 and (c) Warrants issued in 2002 to purchase 1,400,000 shares of common stock at \$3.50 per share expiring on September 30, 2007.

- (2) Includes shares issuable upon exercise of (i) options issued in 1997 to purchase 13,750 shares of common stock at \$3.50 per share and expiring on January 22, 2007; (ii) options issued in 2001 to purchase 10,000 shares of common stock at \$4.03 per share and expiring on January 3, 2011; (iii) warrants issued in 2002 to purchase 200,000 shares of common stock at \$2.00 per share expiring on August 13, 2007; (iv) options issued in 2005 to purchase 100,000 shares of common stock at \$1.75 per share expiring April 26, 2015; (v) options issued in 2005 to purchase 10,000 shares of Common Stock at \$2.61 per share expiring December 8, 2015; and (vi) 8,000 shares of Common Stock. Also includes 243,824 warrants/options originally issued to Robert E. Peterson and subsequently transferred to the Robert E. Peterson Trust of which Robert E. Peterson is owner and Trustee. These securities include options issued in 2006 to purchase 50,000 shares of common stock exercisable at \$3.66 per share expiring on February 28, 2016; replacement options issued in 2006 to purchase 100,000 shares of common stock at \$3.48 per share expiring on April 14, 2016; replacement options issued in 2006 to purchase 30,000 shares of common stock exercisable at \$3.55 per share expiring on April 30, 2016 and 63,824 stock options issued in 2004 consisting of 50,000 options to acquire common stock at \$3.44 per share expiring on June 22, 2014 and 13,824 options to acquire common stock at \$2.60 per share expiring on September 7, 2014.
- (3) Includes shares issuable upon exercise of (i) 20,000 warrants issued in 1998 to purchase common stock at \$4.00 per share, originally expiring on January 1, 2003 and extended to January 1, 2008; (ii) 100,000 warrants issued in 2002 exercisable \$2.00 per share expiring on August 13, 2007; (iii) stock options issued in 2005 to purchase 100,000 shares of common stock exercisable at \$1.75 per share expiring on April 26, 2015; and (iv) stock options issued in 2004 to purchase 50,000 shares of common stock exercisable at \$2.60 per share expiring on September 7, 2014; (v) stock options issued in 2006 to purchase 50,000 shares of common stock exercisable at \$3.86 per share expiring February 24, 2006 and (vi) 122,560 shares of common stock. Also includes 200,000 stock options originally granted to Ransom Etheridge in 2003 and subsequently transferred to relatives and family trusts. These stock options are exercisable at \$2.75 per share and expires on December 4, 2013. The transfers consist of 25,000 options to Julianne Inqlima; 25,000 options to Thomas Inqlima; 25,000 options to R. Etheridge-BMI Trust; and 25,000 options to R. Etheridge-TCI Trust. Julianne and Thomas are Mr. Etheridge's daughter and son-in-law.

- (4) Includes shares issuable upon exercise of (i) 20,000 warrants issued in 1998 to purchase common stock at \$4.00 per share originally expiring on January 1, 2005 and extended to January 1, 2008; (ii) 100,000 warrants issued in 2003 exercisable at \$2.00 per share expiring on August 13, 2007; (iii) options granted in 2004 to purchase 54,608 shares of common stock exercisable at \$2.60 per share expiring on September 17, 2014; (iv) options granted in 2005 to purchase 100,000 shares of common stock exercisable at \$1.75 per share expiring on April 26, 2015; (v) stock options issued in 2006 to purchase 50,000 shares of common stock exercisable at \$3.86 per share expiring February 24, 2006; (vi) 108,094 shares of common stock owned by Mr. Piani; (vii) 12,900 shares of common stock owned jointly by Mr. and Mrs. Piani; and (viii) and 5,000 shares of common stock owned by Mrs. Piani.

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- (5) Consists of 41,667 options exercisable at \$1.55 per share expiring February 14, 2015. Shares owned includes 89,400 shares of common stock in which Mr. Hulse has an undivided interest. These shares are held by Sage Healthcare Advisors, LLC of which Mr. Hulse is a principal.
- (6) Includes shares issuable upon exercise of (i) warrants issued in 1998 to purchase 12,000 shares of common stock at \$6.00 per share, expiring on August 25, 2008; (ii) 100,000 warrants issued in 2002 exercisable at \$2.00 per share expiring on August 13, 2007; (iii) 50,000 stock options issued in 2004 exercisable at \$2.60 per share expiring on September 7, 2014; (iv) 100,000 stock options issued in 2005 exercisable at \$1.75 per share expiring on April 26, 2015; (v) stock options issued in 2006 to purchase 50,000 shares of common stock exercisable at \$3.86 per share expiring February 24, 2006; and (vi) 85,884 shares of common stock.
- (7) (i) stock options issued in 1997 to purchase 20,000 shares of common stock at \$3.50 per share expiring on February 22, 2007; (ii) warrants issued in 1998 to purchase 50,000 shares of common stock exercisable at \$4.00 per share expiring on February 28, 2008; (iii) stock options granted in 2001 to purchase 10,000 shares of common stock exercisable at \$4.03 per share expiring on January 3, 2011; (iv) warrants issued in 2002 to purchase 50,000 shares of common stock exercisable at \$2.00 per share expiring on August 13, 2007; (v) stock options issued in 2004 to purchase 10,000 shares of common stock exercisable at \$1.90 per share expiring on December 7, 2014; (vi) stock options issued in 2005 to purchase 10,000 shares of Common Stock at \$2.61 per share expiring December 8, 2015 and (vii) 10,746 shares of common stock.
- (8) Consists of shares issuable upon exercise of (i) 5,000 warrants issued in 1998 to purchase common stock at \$4.00 per share expiring June 7, 2008; (ii) 20,000 warrants issued in 2002 exercisable at \$2.00 per share expiring in August 13, 2007; (iii) 6,791 stock options issued in 1997 exercisable at \$3.50 expiring January 22, 2007; (iv) 10,000 stock options issued in 2001 exercisable at \$4.03 per share expiring January 3, 2011; (v) 10,000 stock options issued in 2004 exercisable at \$1.90 expiring on December 7, 2014; and 10,000 stock options issued in 2005 to purchase Common Stock at \$2.61 per share expiring December 8, 2015.

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- (9) Consists of shares issuable upon exercise of (i) 12,000 options issued in 2005 exercisable at \$1.63 per share expiring on June 2, 2015; (ii) 15,000 options issued in 2005 exercisable at \$1.75 per share expiring on April 26, 2015; (iii) stock options issued in 2006 to purchase 50,000 shares of common stock exercisable at \$3.86 per share expiring February 24, 2006; and (iv) 20,797 shares of common stock.
- (10) Consists of 15,000 stock options granted in 2005 exercisable at \$1.75 per share expiring on April 26, 2015; stock options issued in 2006 to purchase 50,000 shares of common stock exercisable at \$3.86 per share expiring February 24, 2006; and 132,883 shares of common stock.
- (11) Consists of 10,000 stock options granted in 2004 exercisable at \$1.90 per share of common stock expiring on December 7, 2014; and 10,000 stock options issued in 2005 to purchase Common Stock at \$2.61 per share expiring December 8, 2015.

Item 13. Certain Relationships and Related Transactions.

We have employment agreements with certain of our executive officers and

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have granted such officers and directors options and warrants to purchase our common stock, as discussed under the headings, "Item 11. Executive Compensation," and "Item 12. Security Ownership of Certain Beneficial Owners and Management," above.

Ransom W. Etheridge, our Secretary, General Counsel and one of our directors, is an attorney in private practice, who renders corporate legal services to us from time to time, for which he has received fees totaling \$88,000 in 2005. In addition, Mr. Etheridge serves on the Board of Directors for which he received Director's Fees of cash and stock valued at \$100,000 in 2005. We loaned \$60,000 to Ransom W. Etheridge in November, 2001 for the purpose of exercising 15,000 class A redeemable warrants. This loan bore interest at 6% per annum. This loan was granted prior to the enactment of the Sarbanes Oxley Act of 2002 prohibiting such transactions. In lieu of granting Mr. Etheridge a bonus for outstanding legal work performed on behalf of the Company, the Board of Directors forgave the loan and accrued interest on February 24, 2006.

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

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

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. 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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We have engaged the Sage Group, Inc., a health care, technology oriented, strategy and transaction advisory firm, to assist us in obtaining a strategic alliance in Japan for the use of Ampligen(R) in treating Chronic Fatigue Syndrome (CFS) and Avian Flu. R. Douglas Hulse, our President and Chief Operating Officer, is a member and an executive director of The Sage Group, Inc. Please see "Employment and Change in Control Agreements" in Item 11. Executive Compensation above for more information.

ITEM 14. Principal Accounting Fees and Services.

All audit and professional services provided by BDO Seidman, LLP are approved in advance by the Audit Committee to assure such services do not impair the auditor's independence from us. The total fees billed by BDO Seidman, LLP were \$226,484 in 2004 and \$176,202 in 2005. The following table shows the aggregate fees billed to us by BDO Seidman, LLP for professional services rendered during the year ended December 31, 2005.

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| Description of Fees | Amount (\$) | |
|---------------------|--------------------|--------------------|
| | 2004 | 2005* |
| Audit Fees | \$189,475 | \$194,800 |
| Audit-Related Fees | 37,009 | -- |
| Tax Fees | -- | -- |
| All Other Fees | -- | -- |
| Total | \$226,484 ===== | \$194,800 ===== |

* Fees for 2005 have not yet been finalized.

Audit Fees

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

Audit-Related Fees

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

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 pre-approved the charges for services performed in 2005.

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

PART IV

ITEM 15. Exhibits and Financial Statement Schedules

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

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

(b) Exhibits - See exhibit index below.

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

Exhibit

| No. | Description |
|-------|--|
| --- | ----- |
| 2.1 | First Asset Purchase Agreement dated March 11, 2003, by and between the Company and ISI.(1) |
| 2.2 | Second Asset Purchase Agreement dated March 11, 2003, by and between the Company and ISI.(1) |
| 3.1 | Amended and Restated Certificate of Incorporation of the Company, as amended, along with Certificates of Designations. |
| 3.1.1 | Series E Preferred Stock. |
| 3.2 | By-laws of Registrant, as amended. |
| 4.1 | Specimen certificate representing our Common Stock. |
| 4.2 | Rights Agreement, dated as of November 19, 2002, between the Company and Continental Stock Transfer & Trust Company. The Right Agreement includes the Form of Certificate of Designation, Preferences and Rights of the Series A Junior Participating Preferred Stock, the Form of Rights Certificate and the Summary of the Right to Purchase Preferred Stock.(2) |
| 4.3 | Form of 6% Convertible Debenture of the Company issued in March 2003.(1) |
| 4.4 | Form of Warrant for Common Stock of the Company issued in March 2003.(1) |
| 4.5 | Form of Warrant for Common Stock of the Company issued in June 2003.(3) |
| 4.6 | Form of 6% Convertible Debenture of the Company issued in July 2003.(4) |
| 4.7 | Form of Warrant for Common Stock of the Company issued in July 2003.(4) |
| 4.8 | Form of 6% Convertible Debenture of the Company issued in October 2003.(5) |
| 4.9 | Form of Warrant for Common Stock of the Company issued in October 2003.(5) |
| 4.10 | Form of 6% Convertible Debenture of the Company issued in January 2004.(6) |
| 4.11 | Form of Warrant for Common Stock of the Company issued in January 2004.(6) |
| 4.12 | Form of Warrant for Common Stock of the Company. (9) |
| 4.13 | Amendment Agreement, effective October 6, 2005, by and among the Company and debenture holders.(11) |
| 4.14 | Form of Series A amended 7% Convertible Debenture of the Company (amending Debenture due October 31, 2005).(11) |
| 4.15 | Form of Series B amended 7% Convertible Debenture of the Company (amending Debenture issued on January 26, 2004 and due January 31, 2006).(11) |
| 4.16 | Form of Series C amended 7% Convertible Debenture of the Company (amending Debenture issued on July 13, 2004 and due January 31, 2006).(11) |
| 4.17 | Form of Warrant issued effective October 6, 2005 for Common Stock of the Company.(11) |
| 10.1 | 1990 Stock Option Plan. |
| 10.2 | 1992 Stock Option Plan. |
| 10.3 | 1993 Employee Stock Purchase Plan. |
| 10.4 | Form of Confidentiality, Invention and Non-Compete Agreement. |
| 10.5 | Form of Clinical Research Agreement. |
| 10.6 | Form of Collaboration Agreement. |
| 10.7 | Amended and Restated Employment Agreement by and between the Company and Dr. William A. Carter, dated as of July 1, 1993. (7) |

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- 10.8 Employment Agreement by and between the Registrant and Robert E. Peterson, dated April 1, 2001.
- 10.9 License Agreement by and between the Company and The Johns Hopkins University, dated December 31, 1980.
- 10.10 Technology Transfer, Patent License and Supply Agreement by and between the Company, Pharmacia LKB Biotechnology Inc., Pharmacia P-L Biochemicals Inc. and E.I. du Pont de Nemours and Company, dated November 24, 1987.
- 10.11 Pharmaceutical Use Agreement, by and between the Company and Temple University, dated August 3, 1988.
- 10.12 Assignment and Research Support Agreement by and between the Company, Hahnemann University and Dr. David Strayer, Dr. Isadore Brodsky and Dr. David Gillespie, dated June 30, 1989.
- 10.13 Lease Agreement between the Company and Red Gate Limited Partnership, dated November 1, 1989, relating to the Company's Rockville, Maryland facility.
- 10.14 Agreement between the Company and Bioclones (Proprietary) Limited.
- 10.15 Amendment, dated August 3, 1995, to Agreement between the Company and Bioclones (Proprietary) Limited (contained in Exhibit 10.14).
- 10.16 Licensing Agreement with Core BioTech Corp.
- 10.17 Licensing Agreement with BioPro Corp.
- 10.18 Licensing Agreement with BioAegean Corp.
- 10.19 Agreement with Esteve.
- 10.20 Agreement with Accredo (formerly Gentiva) Health Services.
- 10.21 Agreement with Biovail Corporation International.
- 10.22 Forbearance Agreement dated March 11, 2003, by and between ISI, the American National Red Cross and the Company.(1)
- 10.23 Forbearance Agreement dated March 11, 2003, by and between ISI, GP Strategies Corporation and the Company.(1)
- 10.24 Securities Purchase Agreement, dated March 12, 2003, by and among the Company and the Buyers named therein.(1)
- 10.25 Registration Rights Agreement, dated March 12, 2003, by and among the Company and the Buyers named therein.(1)
- 10.26 Securities Purchase Agreement, dated July 10, 2003, by and among the Company and the Buyers named therein.(4)
- 10.27 Registration Rights Agreement, dated July 10, 2003, by and among the Company and the Buyers named therein.(4)
- 10.28 Securities Purchase Agreement, dated October 29, 2003, by and among the Company and the Buyers named therein.(5)
- 10.29 Registration Rights Agreement, dated October 29, 2003, by and among the Company and the Buyers named therein.(5)
- 10.30 Securities Purchase Agreement, dated January 26, 2004, by and among the Company and the Buyers named therein.(6)
- 10.31 Registration Rights Agreement, dated January 26, 2004, by and among the Company and the Buyers named therein.(6)

- 10.32 Memorandum of Understanding with Fujisawa. (8)
- 10.33 Securities Purchase Agreement, dated July 30, 2004, by and among the Company and the Purchasers named therein.(9)
- 10.34 Registration Rights Agreement, dated July 30, 2004, by and among the Company and the Purchasers named therein. (9)
- 10.35 Agreement for services of R. Douglas Hulse, (12)
- 10.36 Amended and Restated Employment Agreement of Dr. William A. Carter. (10)
- 10.37 Engagement Agreement with Dr. William A. Carter. (10)
- 10.38 Amended and restated employment agreement of Dr. William A. Carter (12)
- 10.39 Amended and restated engagement agreement with Dr. William A. Carter (12)
- 10.40 Amended and restated engagement agreement with Robert E. Peterson (12)
- 10.41 Engagement Agreement with Ransom W. Etheridge (12)
- 10.42 Change in control agreement with Dr. William A. Carter (12)

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- 10.43 Change in control agreement with Dr. William A. Carter (12)
- 10.44 Change in control agreement with Robert E. Peterson (12)
- 10.45 Change in control agreement with Ransom Etheridge (12)
- 10.46 Supply Agreement with Hollister-Stier Laboratories LLC
- 10.47 Manufacturing and Safety Agreement with Hyaluron, Inc.
- 10.48 Common Stock Purchase Agreement, dated July 8, 2005, by and among the Company and Fusion Capital.(13)
- 10.49 Registration Rights Agreement, dated July 8, 2005, by and among the Company and Fusion Capital.(13)
- 10.48 Common Stock Purchase Agreement, dated April 12, 2006, by and among the Company and Fusion Capital.(14)
- 10.49 Registration Rights Agreement, dated April 12, 2006, by and among the Company and Fusion Capital.(14)
- 21 Subsidiaries of the Registrant.
- 23.1 BDO Seidman, LLP consent.(15)
- 31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer.(15)
- 31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer.(15)
- 32.1 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer.(15)
- 32.2 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer.(15)

(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.

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(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

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Company's Current Report on Form 8-K (No. 1-13441) dated August 6, 2004 and is hereby incorporated by reference.

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

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

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

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

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

(15) Filed 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 amended 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

June 1, 2006

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

| | | |
|---|---|--------------|
| /s/ William A. Carter ----- William A. Carter, M.D. | Chairman of the Board, Chief Executive Officer and Director | June 1, 2006 |
|---|---|--------------|

| | | |
|---|----------|--------------|
| /s/ Richard Piani ----- Richard Piani | Director | June 1, 2006 |
|---|----------|--------------|

| | | |
|---|-------------------------|--------------|
| /s/ Robert E. Peterson ----- Robert E. Peterson | Chief Financial Officer | June 1, 2006 |
|---|-------------------------|--------------|

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| | | |
|--|------------------------|--------------|
| /s/ Ransom Etheridge ----- Ransom Etheridge | Secretary And Director | June 1, 2006 |
| /s/ William Mitchell ----- William Mitchell, M.D., Ph.D. | Director | June 1, 2006 |
| /s/ Steven Spence ----- Steven Spence | Director | June 1, 2006 |
| /s/ Iraj E. Kiani ----- Iraj E. Kiani, Ph.D. | Director | June 1, 2006 |

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HEMISPHERx BIOPHARMA, INC AND SUBSIDIARIES
Index to Consolidated Financial Statements

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| Report of Independent Registered Public Accounting Firm | F-2 |
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| Consolidated Statements of Operations for each of the years in the three-year period ended December 31, 2005 (as restated for the years ended December 31, 2003 and 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, 2005 (as restated for the years ended December 31, 2003 and 2004) | F-5 |
| Consolidated Statements of Cash Flows for each of the years in the three-year period ended December 31, 2005 (as restated for the years ended December 31, 2003 and 2004) | F-6 |
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| Schedule II - Valuation and qualifying Accounts for each of the years in the three year period ended December 31, 2005 | F-63 |

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Hemispherx Biopharma, Inc.

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We have audited the accompanying consolidated balance sheets of Hemispherx Biopharma, Inc. and subsidiaries as of December 31, 2004 and 2005 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, 2005. We have also audited the financial statement schedule listed under Item 15(a). These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Hemispherx Biopharma, Inc. and subsidiaries as of December 31, 2004 and 2005 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the financial statement schedule presents fairly, in all material respects, the information set forth therein for each of the three years in the period ended December 31, 2005.

As discussed in Note 2, the Company has restated its balance sheet as of December 31, 2004 and the statements of operations, changes in stockholders equity and comprehensive loss and cash flows for the years ended December 31, 2003 and 2004.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Hemispherx Biopharma, Inc.'s internal control over financial reporting as of December 31, 2005, 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 June 1, 2006 expressed an unqualified opinion on management's assessment of the effectiveness of internal control over financial reporting and adverse opinion on the effectiveness of internal control over financial reporting because of the existence of material weaknesses.

/s/ BDO SEIDMAN, LLP

Philadelphia, Pennsylvania
June 1, 2006

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HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2004 and 2005
(in thousands)

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| | 2004 ---- (restated) | 2005 ---- |
|--|----------------------------|--------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents (Note 3 & 18) | \$ 8,813 | \$ 3,827 |
| Short term investments (Note 3 & 6) | 7,924 | 12,377 |
| Inventories (Note 4) | 2,148 | 1,767 |
| Accounts and other receivables (Note 3) | 139 | 96 |
| Prepaid expenses and other current assets | 266 | 142 |
| | ----- | ----- |
| Total current assets | 19,290 | 18,209 |
| | ----- | ----- |
| Property and equipment, net (Note 3) | 3,303 | 3,364 |
| Patent and trademark rights, net (Note 3) | 908 | 795 |
| Investment (Note 3) | 35 | 35 |
| Construction in progress (Note 3) | -- | 821 |
| Deferred financing costs (Note 3) | 440 | 113 |
| Advance receivable (Note 8) | 1,300 | 1,300 |
| Other assets | 17 | 17 |
| | ----- | ----- |
| Total assets | \$ 25,293 | \$ 24,654 |
| | ===== | ===== |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 526 | \$ 991 |
| Accrued expenses (Note 7) | 1,012 | 865 |
| Current portion of long-term debt (Notes 3, 8 & 20) | 3,818 | -- |
| | ----- | ----- |
| Total current liabilities | 5,356 | 1,856 |
| | ----- | ----- |
| Long-term debt-net of current portion (Notes 3, 8 & 20) | 494 | 4,171 |
| Commitments and contingencies (Notes 11, 13, 14, 16 and 20) | | |
| Stockholders' equity (Notes 9 and 20): | | |
| Preferred stock, par value \$0.01 per share, authorized 5,000,000; issued and outstanding; none | -- | -- |
| Common stock, par value \$0.001 per share, authorized 100,000,000 shares; issued and outstanding 49,631,766 and 56,264,155, respectively | 50 | 56 |
| Additional paid-in capital | 154,609 | 166,394 |
| Accumulated other comprehensive loss | (10) | (171) |
| Accumulated deficit | (135,206) | (147,652) |
| | ----- | ----- |
| Total stockholders' equity | 19,443 | 18,627 |
| | ----- | ----- |
| Total liabilities and stockholders' equity | \$ 25,293 | \$ 24,654 |
| | ===== | ===== |

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See accompanying notes to consolidated financial statements.

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HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations
(in thousands, except share and per share data)

| | Years ended December 31, | |
|--|----------------------------|----------------------------|
| | 2003 ---- (restated) | 2004 ---- (restated) |
| Revenues: | | |
| Sales of product net | \$ 509 | \$ 1,050 |
| Clinical treatment programs | 148 | 179 |
| | ----- | ----- |
| Total Revenues: | 657 | 1,229 |
| Costs and expenses: | | |
| Production/cost of goods sold | 502 | 2,112 |
| Research and development | 3,150 | 3,842 |
| General and administrative | 4,257 | 6,164 |
| | ----- | ----- |
| Total costs and expenses | 7,909 | 12,118 |
| Write off of investments in unconsolidated affiliates (Note 3c) | -- | (373) |
| Interest and other income | 80 | 49 |
| Interest expense | (253) | (384) |
| Financing costs (Note 8) | (6,470) | (5,290) |
| | ----- | ----- |
| Net loss | (13,895) | (16,887) |
| Deemed Dividend (Note 8) | (1,320) | (4,031) |
| | ----- | ----- |
| Net loss applicable to common stockholders | \$ (15,215) | \$ (20,918) |
| | ===== | ===== |
| Basic and diluted loss per share | \$ (.43) | \$ (.46) |
| | ===== | ===== |
| Weighted average shares outstanding | 35,234,526 | 45,177,862 |
| | ===== | ===== |

See accompanying notes to consolidated financial statements.

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HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
 Consolidated Statements of Changes in Stockholders' Equity
 and Comprehensive loss
 (in thousands except share data)

| | Common Stock Shares ----- | Common Stock .001 Par Value ----- |
|--|------------------------------------|--|
| Balance at December 31, 2002 | 32,650,178 | 33 |
| Debt conversion and interest payments | 4,334,916 | 4 |
| Fair value ascribed to debenture beneficial conversion features and related warrants issued | -- | -- |
| Loan settlement costs | -- | -- |
| Deemed dividend upon issuance of inducement warrants | -- | -- |
| Warrants exercised | 790,745 | 1 |
| Common stock issued in connection with ISI acquisition | 1,068,789 | 1 |
| Reclassification of redeemable Common Stock in connection with ISI acquisition | -- | -- |
| Treasury stock purchased | -- | -- |
| Treasury Stock retired | (339,543) | -- |
| Conversion of minority interest of subsidiary into common stock | 347,445 | -- |
| Stock issued in settlement of debt | 215,047 | -- |
| Stock warrant compensation expense | -- | -- |
| Net comprehensive loss | -- | -- |
| | ----- | ----- |
| Balance December 31, 2003 (restated) | 39,067,577 | 39 |
| Treasury shares sold | -- | -- |
| Shares issued for: | | |
| Payment of accounts payable | 127,243 | -- |
| Original Issue Discount on convertible debt | 158,104 | -- |
| Purchase of building | 487,028 | 1 |
| Conversion of debt | 3,691,695 | 5 |
| Interest on convertible debt | 170,524 | -- |
| Private placement, net of issuance costs | 3,617,306 | 3 |
| Warrants exercised | 2,268,586 | 2 |
| Stock Issued with convertible debt | 43,703 | -- |
| Fair value ascribed to debenture beneficial conversion features and related warrant issued | -- | -- |
| Deemed dividend upon issuance of inducement warrants | -- | -- |
| Loan settlement costs | -- | -- |
| Reclassification of redeemable Common Stock in connection with ISI acquisition | -- | -- |
| Options and warrants issued for services | -- | -- |
| Revaluation of redemption obligation | -- | -- |
| Net comprehensive loss | -- | -- |
| | ----- | ----- |
| Balance December 31, 2004 (restated) | 49,631,766 | 50 |
| | ===== | ===== |
| Shares issued for: | | |
| Payment of accounts payable | 338,995 | -- |
| Conversion of debt | 1,358,887 | 1 |
| Warrants converted | 5,000 | -- |
| Interest on convertible debt | 255,741 | -- |
| Private placement, net of issuance costs | 4,673,766 | 5 |
| Options and warrants issued for services | -- | -- |
| Conversion price adjustment | -- | -- |
| Discount resulting from debt refinance | -- | -- |

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| | | |
|---|-------------|-----------|
| Net comprehensive loss | -- | -- |
| | ----- | ----- |
| Balance December 31, 2005 | 56,264,155 | \$ 56 |
| | ===== | ===== |
| | Accumulated | Treasury |
| | deficit | stock |
| | ----- | shares |
| | ----- | ----- |
| Balance at December 31, 2002 | (99,073) | 543,206 |
| Debt conversion and interest payments | -- | -- |
| Fair value ascribed to debenture beneficial conversion features and related warrants issued | -- | -- |
| Loan settlement costs | -- | -- |
| Deemed dividend upon issuance of inducement warrants | (1,320) | -- |
| Warrants exercised | -- | -- |
| Common stock issued in connection with ISI acquisition | -- | -- |
| Reclassification of redeemable Common Stock in connection with ISI acquisition | -- | -- |
| Treasury stock purchased | -- | 43,000 |
| Treasury Stock retired | -- | (339,543) |
| Conversion of minority interest of subsidiary into common stock | -- | -- |
| Stock issued in settlement of debt | -- | (246,220) |
| Stock warrant compensation expense | -- | -- |
| Net comprehensive loss | (13,895) | -- |
| | ----- | ----- |
| Balance December 31, 2003 (restated) | (114,288) | 443 |
| Treasury shares sold | -- | (443) |
| Shares issued for: | | |
| Payment of accounts payable | -- | -- |
| Original Issue Discount on convertible debt | -- | -- |
| Purchase of building | -- | -- |
| Conversion of debt | -- | -- |
| Interest on convertible debt | -- | -- |
| Private placement, net of issuance costs | -- | -- |
| Warrants exercised | -- | -- |
| Stock Issued with convertible debt | -- | -- |
| Fair value ascribed to debenture beneficial conversion features and related warrant issued | -- | -- |
| Deemed dividend upon issuance of inducement warrants | (4,031) | -- |
| Loan settlement costs | -- | -- |
| Reclassification of redeemable Common Stock in connection with ISI acquisition | -- | -- |
| Options and warrants issued for services | -- | -- |
| Revaluation of redemption obligation | -- | -- |
| Net comprehensive loss | (16,887) | -- |
| | ----- | ----- |
| Balance December 31, 2004 (restated) | (135,206) | -- |
| | ===== | ===== |
| Shares issued for: | | |
| Payment of accounts payable | -- | -- |
| Conversion of debt | -- | -- |
| Warrants converted | -- | -- |
| Interest on convertible debt | -- | -- |
| Private placement, net of issuance costs | -- | -- |
| Options and warrants issued for services | -- | -- |
| Conversion price adjustment | -- | -- |
| Discount resulting from debt refinance | -- | -- |
| Net comprehensive loss | (12,446) | -- |

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Balance December 31, 2005

\$ (147,652)

See accompanying notes to consolidated financial statements

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

| | Years ended December 31, | | |
|---|----------------------------|----------------------------|--------------|
| | 2003 ---- (restated) | 2004 ---- (restated) | 2005 ---- |
| Cash flows from operating activities: | | | |
| Net loss | \$ (13,895) | \$ (16,887) | \$ (12,446) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation of property and equipment | 80 | 113 | 114 |
| Amortization and write off of patent and trademark rights | 127 | 327 | 281 |
| Amortization of deferred financing costs | 6,470 | 5,290 | 2,733 |
| Write off of Investments in unconsolidated affiliates | -- | 373 | -- |
| Stock option and warrant compensation and service expense | 237 | 2,000 | 391 |
| Inventory reserve | -- | 225 | (125) |
| Interest on Convertible Debt | 253 | 430 | 409 |
| Changes in assets and liabilities: | | | |
| Inventory | (1,429) | 523 | 505 |
| Accounts and other receivables | 1,225 | 143 | 43 |
| Prepaid expenses and other current assets | (98) | (96) | 124 |
| Accounts payable | (551) | 36 | 687 |
| Accrued expenses | 553 | 277 | 53 |
| Other assets | 6 | 6 | -- |
| | ----- | ----- | ----- |
| Net cash used in operating activities | (7,022) | (7,240) | (7,231) |
| | ----- | ----- | ----- |
| Cash flows from investing activities: | | | |
| Purchase of property and equipment, net | (19) | (150) | (175) |
| Additions to patent and trademark rights | (154) | (208) | (168) |
| Construction in progress | -- | -- | (827) |

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| | | | |
|---------------------------------------|---------|---------|----------|
| Maturity of short term investments | 520 | 1,496 | 7,934 |
| Purchase of short term investments | (1,496) | (7,934) | (12,548) |
| Deferred acquisition costs | (638) | -- | -- |
| | ----- | ----- | ----- |
| Net cash used in Investing Activities | (1,787) | (6,796) | (5,784) |
| | ----- | ----- | ----- |

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

| | Years ended December 31, | | |
|--|--------------------------|------------|----------|
| | 2003 | 2004 | 2005 |
| | ---- | ---- | ---- |
| | (restated) | (restated) | |
| Cash flows from financing activities: | | | |
| Proceeds from issuance of common stock, net | \$ -- | \$ 6,984 | \$ 8,020 |
| Deferred financing costs | (835) | (542) | -- |
| Proceeds from long-term borrowing | 11,300 | 7,550 | -- |
| Advance receivable | (1,300) | -- | -- |
| Proceeds from exercise of stock warrants | 1,235 | 5,093 | 9 |
| Purchase of treasury stock | (83) | -- | -- |
| | ----- | ----- | ----- |
| Net cash provided by financing Activities | 10,317 | 19,085 | 8,029 |
| | ----- | ----- | ----- |
| Net increase (decrease) in cash and cash equivalents | 1,508 | 5,049 | (4,986) |
| Cash and cash equivalents at beginning of year | 2,256 | 3,764 | 8,813 |
| | ----- | ----- | ----- |
| Cash and cash equivalents at end of year | \$ 3,764 | \$ 8,813 | \$ 3,827 |
| | ===== | ===== | ===== |
| Supplemental disclosures of cash flow information: | | | |
| Issuance of common stock for accounts payable and accrued expenses | \$ 931 | \$ 382 | \$ 413 |
| | ===== | ===== | ===== |
| Issuance of Common Stock for Acquisition of ISI assets | \$ 1,667 | \$ 1,626 | \$ -- |

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| | | | |
|---|----------|----------|----------|
| Stock Options and Warrants Issued for Services | ===== | ===== | ===== |
| | \$ 237 | \$ 2,000 | \$ 391 |
| | ===== | ===== | ===== |
| Issuance of Common Stock for Debt Conversion, Interest Payments and debt payments | ===== | ===== | ===== |
| | \$ 6,741 | \$ 7,669 | \$ 2,628 |
| | ===== | ===== | ===== |
| Common Stock Issued for Conversion of Minority Interest in Subsidiary | ===== | ===== | ===== |
| | \$ 946 | -- | -- |
| | ===== | ===== | ===== |

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 biopharmaceutical company engaged in the clinical development, manufacture, marketing and distribution of new drug entities based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. The Company was founded in the early 1970s, as a contract researcher for the National Institutes of Health. The Company has 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. The Company owns a U.S. Food and Drug Administration ("FDA") approved GMP (good manufacturing practice) manufacturing facility in New Jersey.

The Company's flagship products include Ampligen(R) and Alferon N Injection(R). Ampligen(R) is an experimental drug undergoing clinical development for the treatment of: Myalgic Encephalomyelitis/Chronic Fatigue Syndrome ("ME/CFS" or "CFS"), and HIV. In August 2004, we completed a Phase III clinical trial ("AMP 516") treating over 230 ME/CFS patients with Ampligen(R) and are in the process of preparing a new drug application ("NDA") to be filed with the FDA.

In March 2004, the Company completed the step-by-step acquisition from Interferon Sciences, Inc. ("ISI") of ISI's commercial assets, Alferon N Injection(R) inventory, a worldwide license for the production, manufacture, use, marketing and sale of Alferon N Injection(R), as well as, a 43,000 square foot manufacturing facility in New Jersey and the acquisition of all intellectual property related to Alferon N Injection(R). Alferon N Injection(R) 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 consolidated financial statements include the financial statements of Hemispherx Biopharma, Inc. and its wholly-owned subsidiaries. The Company has

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three domestic subsidiaries BioPro Corp., BioAegean Corp. and Core BioTech Corp., all of which are incorporated in Delaware and are dormant. The Company's foreign subsidiaries include Hemispherx Biopharma Europe N.V./S.A. established in Belgium in 1998 and Hemispherx Biopharma Europe S. A. incorporated in Luxemburg in 2002, which have limited or no activity. All significant intercompany balances and transactions have been eliminated in consolidation.

(2) Restatements

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- (a) Based on SEC guidance presented at the 2005 annual AICPA National Conference on current SEC and PCAOB developments, the Company re-evaluated its accounting for its March 2003, July 2003, October 2003, January 2004 and July 2004 Debentures (collectively, "the Debentures") to determine whether the embedded conversion options required bifurcation and fair value accounting in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities", and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock". The Company concluded that bifurcation was not required and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") should have been applied. The Company did initially apply EITF 00-27, however as part of performing an analysis on the guidelines set forth in EITF 00-27 it was determined that the initial accounting treatment for the Debentures and conversion price resets that was originally applied and reflected in the financial statements included in the Company's Annual Reports on Form 10-K for the years ended December 31, 2004 and 2003, and in the Company's Quarterly Reports on Form 10-Q during the quarterly periods in fiscal 2003, 2004 and 2005 were not correctly applied and that, therefore, a restatement of the Company's financial statements for the periods referenced above was required. To properly account for the initial calculation of the discount and the conversion price resets triggered upon the issuance of the issuance of the October 2003 Debenture and the August 2004 Private Placement (See Notes 8 & 9 below for more details on these resets), it was determined, under guidance from EITF 00-27 that the debt discount should be restated for the Debentures. The total impact of this restatement on the Company's statement of operations was to decrease the net loss applicable to common stockholders for the year ended December 31, 2004 by \$2,959,000 or \$0.07 per share, and to increase the net loss applicable to common stockholders by \$287,000 or \$0.01 per share for the year ended December 31, 2003.
- (b) The estimation of fair value ascribed to and the accounting treatment of the investment banking fees paid to Cardinal Capital, LLC ("Cardinal") in connection with the Debenture issuances, at inception, was inaccurately reflected in the financial statements included in the Company's Annual Report on Form 10-K for the years ended December 31, 2004 and 2003, and the Company's Quarterly reports on Form 10-Q during the quarterly periods in fiscal 2003, 2004 and 2005 and as a result a restatement of the Company's financial statements for the periods referenced above was required. In connection with the initial recording of the Debentures mentioned above, it was determined that the fair value of the warrants issued as investment banking fees paid to Cardinal, be accounted for as a discount to the Debentures. These investment banking fees should have been capitalized as deferred financing costs and amortized over the life of the Debentures or charged to earnings on the earlier

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conversion thereof. In addition, the initial calculation of the fair value of the warrants issued to Cardinal as part of the Debenture issuances was determined to be computed incorrectly at the time of issuance. The total impact of this restatement on the Company's statement of operations was to decrease the net loss applicable to common stockholders for the year ended December 31, 2004 by \$263,000 or \$0.01 per share and to increase the net loss applicable to common stockholders for the year ended December 31, 2003 by \$158,000 or \$0.00 per share.

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- (c) The accounting treatment set forth in FASB Statement No. 123, "Accounting for Stock-Based Compensation", for the issuance of the June 2008, May 2009 and June 2009 Warrants (collectively "the Warrants") (See Note 8 below for more details on these transactions) that was originally interpreted and reflected in the financial statements included in our Annual Report on Form 10-K for the years ended December 31, 2003 and 2004, was not correctly applied and as a result a restatement of our financial statements for the period referenced above was required. The Warrants issued as incentive to exercise prior warrant issuances should be reflected as a deemed dividend at the date of issuance where previously these warrants were either recorded as additional debt discount or as a financing charge at date of issuance. The total impact of this restatement on our statement of operations was to decrease finance charges for the years ended December 31, 2003 and 2004 by \$1,320,000 and \$4,031,000 or \$0.04 and \$0.08 per share, respectively and increase the net loss applicable to common stockholders due to the deemed dividend for the years ended December 31, 2003 and 2004 by \$1,320,000 and \$4,031,000 or \$0.04 and \$0.08 per share, respectively.

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As a result of the corrections of the errors described above, the Company restated its financial statements included in this Annual Report on Form 10-K/A as follows:

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Audited Consolidated Balance Sheet
(in Thousands)

| | December 31, 2004 | Adjustments |
|---|---------------------------|-------------|
| | As previously Reported | |
| | | |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 8,813 | |
| Short term investments | 7,924 | |
| Inventory | 2,148 | |
| Accounts and other receivables | 139 | |
| Prepaid expenses and other current assets | | |
| | 266 | |

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| | | | |
|--|-----------------------------|---------|-------------|
| Total current assets | ----- 19,290 ----- | | |
| Property and equipment, net | 3,303 | | |
| Patent and trademark rights, net | 908 | | |
| Investment | 35 | | |
| Deferred financing costs | 319 | 121 | (b) |
| Advance receivable | 1,300 | | |
| Other assets | 17 | | |
| Total assets | ----- \$ 25,172 ===== | 121 | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | | |
| Current liabilities: | | | |
| Accounts payable | \$ 526 | | |
| Accrued expenses | 1,012 | | |
| Current portion of long-term debt | 3,248 | 570 | (a) (b) (c) |
| Total current liabilities | ----- 4,786 ----- | 570 | |
| Long-term debt-net of current portion | 305 | 189 | (a) (b) (c) |
| Commitments and contingencies | | | |
| Stockholders' equity: | | | |
| Preferred stock | - | - | |
| Common stock | 50 | | |
| Additional paid-in capital | 158,024 | (3,415) | (a) (b) (c) |
| Accumulated other comprehensive income | (10) | | |
| Accumulated deficit | (137,983) | 2,777 | (a) (b) (c) |
| Total stockholders' equity | ----- 20,081 ----- | (638) | |
| Total liabilities and stockholders' equity | \$ 25,172 ===== | 121 | |

(a) Includes restatement adjustments for the Debentures relating to the initial recording of and the effect of certain Conversion Price Resets on the Debentures, as described above.

(b) Includes restatement adjustment for investment banking fees related to Cardinal, as described above.

(c) Includes restatement adjustments for the issuance of the June 2008, May 2009 and June 2009 warrants as incentive to exercise prior warrant issuance, as described above.

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HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
 Audited Consolidated Statements of Operations
 (in thousands, except share and per share data)
 Year Ended December 31, 2003

| | December 31, 2003 ---- | Adjustments | |
|---|------------------------------|-------------|-------------|
| | As previously Reported | | |
| ----- | | | |
| Revenues: | | | |
| Sales of product net | \$ 509 | | |
| Clinical treatment programs | 148 | | |
| | ----- | | |
| Total Revenues: | 657 | | |
| Costs and expenses: | | | |
| Production/cost of goods sold | 502 | | |
| Research and development | 3,150 | | |
| General and administrative | 4,257 | | |
| | ----- | | |
| Total costs and expenses | 7,909 | | |
| Interest and other income | 80 | | |
| Interest expense | (253) | | |
| Financing costs | (7,345) | 875 | (a) (b) (c) |
| | ----- | | |
| Net loss | \$ (14,770) | 875 | (a) (b) (c) |
| Deemed dividend | - | (1,320) | (c) |
| | ----- | | |
| Net loss applicable to common stockholders | \$ (14,770) | (445) | (a) (b) (c) |
| | ===== | | |
| Basic and diluted loss per share | \$ (.42) | \$ (0.01) | |
| | ===== | ===== | |
| Weighted average shares outstanding | 35,234,526 | | |
| | ===== | | |

(a) Includes restatement adjustments for the Debentures relating to the initial recording of and the effect of certain Conversion Price Resets on the Debentures, as described above.

(b) Includes restatement adjustment for investment banking fees related to Cardinal, as described above.

(c) Includes restatement adjustments for the issuance of the June 2008, May 2009 and June 2009 warrants as incentives to exercise prior warrant issuance, as described above.

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HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
 Audited Consolidated Statements of Operations
 (in thousands, except share and per share data)
 Year Ended December 31, 2004

| | December 31, 2004 ---- | Adjustments | |
|--|------------------------------|-------------|-------------|
| | As previously Reported | | |
| | | | |
| Revenues: | | | |
| Sales of product net | \$ 1,050 | | |
| Clinical treatment programs | 179 | | |
| | | | |
| Total Revenues: | 1,229 | | |
| Costs and expenses: | | | |
| Production/cost of goods sold | 2,112 | | |
| Research and development | 3,842 | | |
| General and administrative | 6,164 | | |
| | | | |
| Total costs and expenses | 12,118 | | |
| Equity loss and write off of investments in unconsolidated affiliates | (373) | | |
| Interest and other income | 49 | | |
| Interest expense | (384) | | |
| Financing costs | (12,543) | 7,253 | (a) (b) (c) |
| | | | |
| Net loss | \$ (24,140) | 7,253 | |
| Deemed dividend | - | (4,031) | (c) |
| | | | |
| Net loss applicable to common stockholders | \$ (24,140) | 3,222 | |
| | | | |
| Basic and diluted loss per share | \$ (.53) | \$ 0.07 | |
| | | | |
| Weighted average shares outstanding | 45,177,862 | | |
| | | | |

(a) Includes restatement adjustments for the Debentures relating to the initial recording of and the effect of certain Conversion Price Resets on the Debentures, as described above.

(b) Includes restatement adjustment for investment banking fees related to Cardinal, as described above.

(c) Includes restatement adjustments for the issuance of the June 2008, May 2009 and June 2009 warrants as incentive to exercise prior warrant

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issuance, as described above.

The Company and the Company's audit committee have discussed the above errors and adjustments with the Company's current independent registered public accounting firm and have determined that a restatement is necessary for the periods described above. This Annual Report on Form 10-K/A for the fiscal year ended December 31, 2005 reflects the changes for the annual results for the years ended December 31, 2003 and December 31, 2004. The Company will file the Company's Quarterly Reports on Form 10-Q/A for the quarterly periods ended March 31, 2005, June 30, 2005 and September 30, 2005, which will include the quarters ended in 2004, as soon as practicable in connection with the restatements described above.

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(3) 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 \$8,813,000 and \$3,827,000 at December 31, 2004 and 2005, respectively.

(b) Short-term Investments

Investments with original maturities of more than three months and less than 12 months and marketable equity securities are considered available for sale. The investments classified as available for sale include debt securities and equity securities carried at estimated fair value of \$7,924,000 and \$12,377,000 at December 31, 2004 and 2005 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% and does not exercise a significant influence are accounted for using the cost method of accounting.

In May 2000, the Company acquired an interest in Chronix Biomedical Corp. ("CHRONIX"). Chronix focuses upon the development of diagnostics for chronic diseases. The Company issued 100,000 shares of common stock to Chronix toward a total equity investment of \$700,000. Pursuant to a strategic alliance agreement, the Company provided Chronix with \$250,000 for research and development in an effort to develop intellectual property on potential new products for diagnosing and treating various chronic illnesses such as ME/CFS. These costs were expensed as incurred. The strategic alliance agreement provides the Company 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 the Company 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 the Company with the right of first refusal to acquire an exclusive worldwide license for any and all therapeutic technology developed by Chronix on

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or before September 14, 2012 for treating Chronic Fatigue Syndrome, Gulf War Syndrome and Human Herpes Virus-6 associated diseases. During the quarters ended December 31, 2002 and September 30, 2004, the Company recorded a non-cash charge of \$292,000 and \$373,000, respectively, with respect to the Company's investment in Chronix. This impairment reduces the Company's carrying value to reflect a permanent decline in Chronix's market value based on its then proposed equity offerings.

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(d) Property and Equipment

| | (in thousands) | |
|--|----------------|---------|
| | ----- | |
| | December 31, | |
| | 2004 | 2005 |
| | ----- | ----- |
| Land and buildings | \$3,316 | \$3,371 |
| Furniture, fixtures, and equipment | 786 | 907 |
| Leasehold improvements | 85 | 85 |
| | ----- | ----- |
| Total property and equipment | 4,187 | 4,363 |
| Less accumulated depreciation and amortization | 884 | 999 |
| | ----- | ----- |
| Property and equipment, net | \$3,303 | \$3,364 |
| | ===== | ===== |

Property and equipment consist 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 \$80,000, \$113,000 and \$114,000 for 2003, 2004 and 2005, respectively.

Construction in progress consists of funds used for the construction and installation of the Company's Ampligen(R) raw material production line within the Company's New Jersey facility. As of December 31, 2005, construction in progress was \$821,000. The Company estimates the total cost of establishing the production line to be \$1,900,000.

(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. Management's review addresses whether each patent continues to fit into the Company's strategic business plans. During the years ended December 31, 2003, 2004 and 2005, the Company decided not to pursue the technology in certain countries for strategic reasons and recorded impairment charges of \$5,000, \$223,000 and \$194,000 respectively. Amortization expense was \$122,000, \$104,000 and \$87,000 in 2003, 2004 and 2005, respectively. The accumulated amortization as of December 31, 2003, 2004 and 2005 is \$2,150,000, \$1,807,000 and \$1,572,000, respectively.

As of December 31, 2005, the weighted average remaining life of the patents and trademarks was 9 years. Amortization of patents and trademarks for each of the next five years is as follows: 2006 - \$86,000, 2007 - \$86,000, 2008 - \$86,000, 2009 - \$86,000 and 2010 - \$86,000.

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(f) Revenue and License Fee Income

The Company executed a Memorandum of Understanding (MOU) in January 2004 with Astellas Pharma ("Astellas"), formally Fujisawa Deutschland GmbH, 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 Company received an initial fee of 400,000 Euros (approximately \$497,000 US) in 2004. On November 9, 2004, Astellas exercised their right to terminate the MOU. The Company 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, the Company has determined to follow a decentralized filing procedure which was not anticipated in the MOU. The Company believed that it was in the best interest of the Company's stockholders to potentially accelerate entry into selected European markets whereas the original MOU specified a centralized registration procedure. Pursuant to the agreement of the parties the Company refunded 200,000 Euros (\$248,000 USD) to Astellas during the fourth quarter 2004. The Company recorded the remaining 200,000 Euros (\$271,000 USD and \$241,000 USD) as an accrued liability as of December 31, 2004 and 2005, respectively.

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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 including the Company's convertible debentures, amounted to 19,566,217, 20,413,024 and 25,635,142 shares, are excluded from the calculation of diluted net loss per share for the years ended December 31, 2003, 2004 and 2005, respectively, since their effect is antidilutive.

(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.

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(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 and are included in interest and other income on the consolidated statement of operations.

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(l) Recent Accounting Standard and Pronouncements:

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (Revised 2004), "Share-Based Payment" ("SFAS 123R"). On April 14, 2005, the Securities and Exchange Commission issued an amendment to Rule 4-01 of Regulation S-X that allows companies to implement SFAS 123R at the beginning of their next fiscal year, instead of the next reporting period that begins after June 15, 2005 as originally required. Accordingly, the Company will adopt SFAS 123R effective January 1, 2006 using the "modified prospective" method in which compensation cost is recognized beginning with the effective date based on (a) the requirements of SFAS 123R for all share-based payments granted after the effective date and (b) the requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date. In addition, the Company expects to continue to utilize the Black-Scholes option-pricing model, which is an acceptable option valuation model in accordance with SFAS 123R, to estimate the value of stock options granted to employees.

Beyond those restricted stock and stock option awards previously granted, the Company cannot predict with certainty the impact of SFAS 123R on its future consolidated financial statements as the type and amount of such awards are determined on an annual basis and encompass a potentially wide range depending upon the compensation decisions made by the Compensation Committee of the Company's Board of Directors. SFAS 123R also requires the benefits of tax deductions in excess of compensation cost recognized in the financial statements to be reported as a financing cash flow, rather than an operating cash flow as currently required under Statement of Financial Accounting Standards No. 95, "Statement of Cash Flows" ("SFAS 95"). This requirement, to the extent it exists, will decrease net operating cash flows and increase net financing cash flows in periods subsequent to adoption. The Company believes this pronouncement will have a material impact on its consolidated financial statements.

On March 29, 2005, the SEC issued Staff Accounting Bulletin No. 107 ("SAB 107") which expresses the view of the SEC Staff regarding the interaction of SFAS 123R and certain SEC rules and regulations and provides the staff's views regarding the valuation of share-based payment arrangements. The Company believes that the views provided in SAB 107 are consistent with the approach taken in the valuation and accounting associated with share-based compensation

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issued in prior periods as well as those issued during 2005.

In June 2005, the FASB's Emerging Issues Task Force ("EITF") issued EITF Issue No. 05-02 "The Meaning of "Conventional Convertible Debt Instrument" in EITF Issue 00-19 "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, A Company's Own Stock", which retains the exception in paragraph 4 of EITF Issue No. 00-19 for conventional debt instruments. Those instruments in which the holder has an option to convert the instrument into a fixed number of shares (or a corresponding amount of cash at the issuer's discretion) and its ability to exercise the option is based on either (a) the passage of time or (b) a contingent event, should be considered "conventional" for purposes of applying that exception. The consensus should be applied on a prospective basis for new or modified instruments starting from the third quarter of 2005. The adoption of EITF No. 05-02 did not have a material effect on the Company's consolidated financial statements or results of operations.

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In November 2005, FASB issued FSP FAS 115-1 and FAS 124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments" ("FSP FAS 115-1"), which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether an impairment is other-than-temporary, and on measuring such impairment loss. FSP FAS 115-1 also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. FSP FAS 115-1 is required to be applied to reporting periods beginning after December 15, 2005. The Company is required to adopt FSP FAS 115-1 in the first quarter of 2006. The Company does not expect the adoption of this statement to have a material impact on the Company's consolidated results of operations or financial condition.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs - An amendment of ARB No. 43, Chapter 4" ("SFAS No. 151"). SFAS No. 151 amends the guidance in Accounting Research Bulletin No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Additionally, SFAS No. 151 requires that the allocation of fixed production overheads to the cost of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is required to be adopted in the first quarter of 2006. The Company has determined that the adoption of SFAS No. 151 will not have a material impact on the consolidated financial statements.

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 153 (SFAS 153), "Exchanges of Non-monetary Assets-an amendment of APB Opinion No. 29." SFAS 152 addresses the measurement of exchanges of non-monetary assets. It eliminates the exception from fair value measurement for non-monetary exchanges of similar productive assets in paragraph 21(b) of APB Opinion No. 29 "Accounting for Non-monetary Transactions" and replaces it with an exception for exchanges that do not have commercial substance. A non-monetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. As required by SFAS 153, the Company adopted this new accounting standard effective July 1, 2005. The adoption of SFAS 153 did not have a material impact on the Company's financial statements.

In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections. SFAS No. 154 establishes retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. SFAS

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No. 154 also provides guidance for determining whether retrospective application is impractical. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Company does not expect that the adoption of SFAS No. 154 will have a material impact on its results of operations or financial position.

(m) Research and Development Costs

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Research and development related to both future and present products are charged to operations 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 the Company's employees.

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:

| | 2003 | December 31, 2004 | 2005 |
|-------------------------|---------|----------------------|-----------|
| | ---- | ---- | ---- |
| Risk-free interest rate | 5.23% | 2.25 - 3.4% | 4.81% |
| Expected dividend yield | - | - | - |
| Expected lives | 2.5 yrs | 5-10 yrs | 2.5-5 yrs |
| Expected volatility | 98.07% | 68.92-71.16% | 78.12% |

Weighted average fair value of options and warrants issued in the years 2003, 2004 and 2005 respectively

| | | |
|-------------|-----------|-------------|
| \$1,825,000 | \$638,000 | \$1,371,000 |
|-------------|-----------|-------------|

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, 2003, 2004, and 2005 would have been as follows:

| | 2003 | 2004 |
|---|--|-------------|
| | ---- | ---- |
| For the years ended December 31, | | |
| | (restated) | (restated) |
| | (In Thousands except for per share data) | |
| Net loss applicable to common stockholders, as reported | \$ (15,215) | \$ (20,918) |
| Add: Stock based compensation included in net loss as reported, net of related tax effects | -- | 1,769 |

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| | | | |
|--|-------------|-------------|-------|
| Deduct: Stock based compensation determined under fair value based method for all awards, net of related tax effects | (1,825) | (638) | |
| | ----- | ----- | ----- |
| Pro forma - net loss | \$ (17,040) | \$ (19,787) | \$ (|
| | ===== | ===== | ===== |
| Basic and diluted loss per share - as reported | \$ (.43) | \$ (.46) | \$ |
| Basic and diluted loss per share - pro forma | \$ (.48) | \$ (.44) | \$ |

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For stock warrants or options 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.

Stock compensation expense in 2004 resulted from having 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 Company's annual meeting of stockholders in September 2003. Prior to the meeting, to permit consummation of the sale of the July 2003 Debentures and the related warrants, the Chief Executive Officer, Dr. Carter, agreed that he would not exercise his warrants or options unless and until the Company's stockholders approve an increase in the Company's 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 the Company's authorized shares, the Company agreed to compensate Dr. Carter and issued Dr. Carter 1,450,000 warrants to purchase common stock at \$2.20 per share in 2003 that vested in the first quarter 2004 upon the second ISI asset closing. The Company recorded a charge to stock compensation expense of \$1,769,000 for the intrinsic value of these warrants in the first quarter of 2004.

(o) 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 wholesale drug companies as of December 31, 2004 and 2005 and all amounts are deemed collectible. The Company has agreements requiring its wholesaler drug companies to assess credit worthiness. The Company assesses collectability monthly by review of the accounts receivable aging report.

(p) Deferred Financing Issuance Costs

Deferred financing issuance costs represent costs incurred by the Company to issue convertible debt instruments. The costs are being amortized in accordance with the interest method of accounting over the terms of the debt.

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(q) Convertible Securities with Beneficial Conversion Features

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

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(4) 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:

| | (in thousands) | |
|--|----------------|---------|
| | December 31, | |
| | 2004 | 2005 |
| Raw materials and work in process | \$1,711 | \$ 444 |
| Finished goods, net of reserves of \$225,000 and \$100,000 at December 31, 2004 and 2005 | 437 | 1,323 |
| | \$2,148 | \$1,767 |
| | ===== | ===== |

(5) Acquisition of Assets of Interferon Sciences, Inc.

On March 11, 2003, the Company 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, the Company issued 487,028 shares of its common stock to ISI. Pursuant to their agreements with ISI, the Company registered these shares for public sale and ISI reported that it sold all of these shares. The Company also agreed to pay ISI 6% of the net sales of Alferon N Injection(R).

On March 11, 2003, the Company 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, the Company issued to ISI an additional 487,028 shares and issued 314,465 shares and 267,296 shares, respectively to the American National Red Cross and GP Strategies Corporation, two creditors of ISI. The Company guaranteed the market value of all but 62,500 of these shares to be \$1.59 per share on the termination date. ISI, GP Strategies and the American National Red Cross reported that they sold all of their shares.

Pursuant to the acquisition agreement, the Company satisfied other liabilities of ISI which were past due and secured by a lien on ISI's real estate and pays ISI a 6% royalty on the net sales of products containing natural alpha interferon.

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On May 30, 2003, the Company issued the shares to GP Strategies and the American National Red Cross. Pursuant to the Company's agreements with ISI and these two creditors, the Company registered the foregoing shares for public sale. 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, the Company 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.

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

The Company accounted for these transactions as a Business Combination under SFAS No. 141 Accounting for Business Combinations.

The following table represents the audited 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, as restated | (15,340) |
| Net Loss, as restated | (14,441) |
| Deemed dividend | (1,320) |
| Net loss applicable to common stockholders | (15,761) |
| Basic and diluted loss per share | \$ (.45) |
| Weighted average shares outstanding | 35,326,594 |
| | ===== |

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(6) Short-term investments:

Securities classified as available for sale consisted of:

| Name of security | December 31, 2004 | | |
|---------------------------|--------------------|--------------------|------------------------|
| | Cost | Market value | Unrealized gain (loss) |
| General Motors | \$988,000 | \$991,000 | \$3,000 |
| Ford Motor Credit | 3,194,000 | 3,142,000 | (52,000) |
| General Motors | 3,655,000 | 3,591,000 | (64,000) |
| Accrued interest acquired | 97,000 | 200,000 | 103,000 |
| | <u>\$7,934,000</u> | <u>\$7,924,000</u> | <u>\$(10,000)</u> |

No investment securities were pledged to secure public funds at December 31, 2004.

The table below indicates the length of time individual securities have been in a continuous unrealized loss position at December 31, 2004.

| Name of security | Number of Securities | Less than 12 months | | 12 months or longer | |
|---------------------------------------|----------------------|---------------------|-----------------|---------------------|-----------------|
| | | Fair value | Unrealized loss | Fair value | Unrealized loss |
| Ford Motor Credit | 1 | \$3,142,000 | \$ - | \$ - | \$ - |
| General Motors | 1 | 3,591,000 | - | - | - |
| Total temporary impairment securities | 2 | \$6,733,000 | (116,000) | - | - |

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In management's opinion, the unrealized losses reflect changes in interest rates subsequent to the acquisition of specific securities. There are two securities in the less than 12 month category.

The Company has the ability to hold these securities until maturity or market

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price recovery; therefore, management believes that the unrealized losses represent temporary impairment of the securities.

| December 31, 2005 | | | |
|-------------------------------|--------------|--------------|------------------------|
| Name of security | Cost | Market value | Unrealized gain (loss) |
| Ford Motor Credit | \$3,194,000 | \$3,043,000 | \$(151,000) |
| General Motors | 3,655,000 | 3,497,000 | (158,000) |
| General Electric | 791,000 | 790,000 | (1,000) |
| American General Finance | 788,000 | 787,000 | (1,000) |
| LaSalle Bank Corp. | 784,000 | 782,000 | (2,000) |
| Prudential Corp. | 783,000 | 781,000 | (2,000) |
| Federal Home Loan | 781,000 | 780,000 | (1,000) |
| General Electric | 775,000 | 774,000 | (1,000) |
| AIG Discount Commercial Paper | 946,000 | 943,000 | (3,000) |
| Accrued interest acquired | 51,000 | 200,000 | 149,000 |
| | \$12,548,000 | \$12,377,000 | \$(171,000) |

No investment securities were pledged to secure public funds at December 31, 2005.

The table below indicates the length of time individual securities have been in a continuous unrealized loss position at December 31, 2005.

| Name of security | Number of Securities | Less than 12 months | 12 months or longer | | |
|---------------------------|----------------------|---------------------|---------------------|-------------|-----------------|
| | | Fair value | Unrealized loss | Fair value | Unrealized loss |
| Ford Motor Credit | 1 | \$ - | \$ - | \$3,043,000 | \$(151,000) |
| General Motors | 1 | - | - | 3,497,000 | (158,000) |
| Accrued interest acquired | | - | - | 200,000 | 149,000 |
| General Electric | 2 | 1,564,000 | (2,000) | - | - |
| American General Finance | 1 | 787,000 | (1,000) | - | - |
| LaSalle Bank Corp | 1 | 782,000 | (2,000) | - | - |
| Prudential Corp. | 1 | 781,000 | (2,000) | - | - |

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| | | | | | |
|---------------------------------------|---|-------------|------------|-------------|-------------|
| Federal Home Loan | 1 | 780,000 | (1,000) | - | - |
| AIG Discount Commercial Paper | 1 | 943,000 | (3,000) | - | - |
| Total temporary impairment securities | 9 | \$5,637,000 | \$(11,000) | \$6,740,000 | \$(160,000) |

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In management's opinion, the unrealized losses reflect changes in interest rates subsequent to the acquisition of specific securities. There are seven securities in the less than 12 months category and two in the more than a twelve month category.

The Company has the ability to hold these securities until maturity or market price recovery; therefore, management believes that the unrealized losses represent temporary impairment of the securities.

(7) Accrued Expenses

Accrued expenses at December 31, 2004 and 2005 consists of the following:

| | (in thousands) December 31, | |
|---------------------------|--------------------------------|--------|
| | 2004 | 2005 |
| Compensation | 385 | 337 |
| Interest | 112 | 91 |
| Commissions and royalties | 47 | 14 |
| Professional fees | 50 | 42 |
| Other expenses | 147 | 140 |
| Other liability | 271 | 241 |
| | \$1,012 | \$ 865 |

(8) Debenture Financing

Long term debt consists of the following:

| | (in thousands) | |
|--------------|-------------------|-------------------|
| | December 31, 2004 | December 31, 2005 |
| | (restated) | |
| October 2003 | \$ 2,071 | \$ 2,071 |
| January 2004 | 3,083 | 1,365 |
| July 2004 | 2,000 | 1,500 |
| Total | 7,154 | 4,936 |

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| | | |
|--|---------|----------|
| Less Discounts | (2,842) | (765) |
| | ----- | ----- |
| Balance | 4,312 | 4,171 |
| Less Current Portion of long-term debt (net of discounts of \$2,337) | 3,818 | -- |
| | ----- | ----- |
| Total long-term debt | \$ 494 | \$ 4,171 |
| | ===== | ===== |

As of December 31, 2004, the Company made installment payments of \$777,777 and the investors converted an aggregate \$13,062,328 principal amount of debt from the debentures as noted below:

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| Debenture | Original Principal Amount | Debt Conversion to Common Shares | Installment payments in Common Shares | Remaining Principal Amount | Com is Co |
|--------------|---------------------------|----------------------------------|---------------------------------------|----------------------------|-----------------|
| March 2003 | \$5,426,000 | \$5,426,000 | \$ - | \$ - | |
| July 2003 | 5,426,000 | 5,426,000 | - | - | |
| October 2003 | 4,142,357 | 2,071,178 | - | 2,071,179 | |
| January 2004 | 4,000,000 | 139,150 | 777,777 | 3,083,073 | |
| July 2004 | 2,000,000 | - | - | 2,000,000 | |
| Totals | \$20,994,357 | \$13,062,328 | \$777,777 | \$7,154,252 | |

As of December 31, 2005, the Company made installment payments of \$2,388,888 and investors converted an aggregate \$13,669,688 principal amount of debt from the debentures as noted below:

| Debenture | Original Principal Amount | Debt Conversion to Common Shares | Installment payments in Common Shares | Remaining Principal Amount | Co i C |
|-----------|---------------------------|----------------------------------|---------------------------------------|----------------------------|--------------|
| Mar 2003 | \$5,426,000 | \$5,426,000 | \$ - | \$ - | |
| Jul 2003 | 5,426,000 | 5,426,000 | - | - | |
| Oct 2003 | 4,142,357 | 2,071,178 | - | 2,071,179 | |
| Jan 2004 | 4,000,000 | 746,510 | 1,888,888 | 1,364,602 | |

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| | | | | |
|----------|--------------|--------------|-------------|-------------|
| Jul 2004 | 2,000,000 | - | 500,000 | 1,500,000 |
| Totals | \$20,994,357 | \$13,669,688 | \$2,388,888 | \$4,935,781 |

March 2003 Debentures

On March 12, 2003, the Company issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due January 2005 (the "March 2003 Debentures") and an aggregate of 743,288 warrants to two investors in a private placement for aggregate gross proceeds of \$4,650,000. Pursuant to the terms of the March 2003 Debentures, \$1,550,000 of the proceeds from the sale of the March 2003 Debentures was held back and to be released to the Company if, and only if, the Company acquired ISI's facility within a set timeframe (see Note 5 above). These funds were released to the Company in July 2003 although the Company had not acquired ISI's facility at that time. The Company recorded an additional debt discount of \$259,000 upon receiving the held back proceeds of \$1,550,000 in July 2003. The March 2003 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 2003 Debentures, the Company pledged all of the Company's assets, other than the Company's intellectual property, as collateral and was subject to comply with certain financial and negative covenants, which included but were not limited to the repayment of principal balances upon achieving certain revenue milestones (see "Collateral and Financial Covenants" below).

The March 2003 Debentures were convertible at the option of the investors at any time through January 31, 2005 into shares of the Company's common stock. The conversion price under the March 2003 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. In addition, in the event that the Company did pay the redemption price at maturity, the Debenture holders, at their option, could have converted the balance due at the lower of (a) the conversion price then in effect and (b) 95% of the lowest closing sale price of the Company's common stock during the three trading days ending on and including the conversion date.

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The investors also received detachable 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 (the "March 2008 Warrants"). As of December 31, 2005 all of these warrants have been exercised.

Pursuant to the Company's agreement with these investors, as discussed below in "Registration Rights Agreements", the Company registered the shares issuable upon conversion of the March 2003 Debentures and upon exercise of the June 2008 Warrants for public sale.

The March 2003 Debentures, were recorded at a discount on issuance and with an original issue discount of approximately \$2,098,000 and \$776,000, respectively, due to ascribing value to the beneficial conversion feature and fair value of warrants based on the relative fair value of the proceeds.

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The conversion option and detachable warrant carry registration rights and a feature that in certain circumstances, deemed in the control of the Company, could require partial settlement of the conversion options to be in cash. In addition the March 2003 Debentures include other features including mandatory conversion option and optional redemption rights if contingent transactions occur. To determine whether the March 2003 Debentures had embedded derivatives, including the conversion option, that required bifurcation and fair value accounting, the Company analyzed the terms of the debentures in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"), and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock" ("EITF 00-19"). The Company concluded that bifurcation was not required for the conversion option and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") was the appropriate accounting to be applied. The warrants were deemed to be permanent equity. The mandatory conversion option and optional redemption rights were deemed to be derivatives requiring bifurcation and thus the Company obtained a third party valuation for the aggregate fair value of these derivatives that showed the fair value to be immaterial at inception and for each subsequent reporting period.

On June 25, 2003, the Company issued to each of the March 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 and were fair valued utilizing the Black-Scholes Method at \$1,320,000. This issuance, as restated (See Note 2), was reflected as a deemed dividend and a related increase to additional paid in capital.

The investors exercised all 743,288 of the March 2008 Warrants in July 2003 which produced gross proceeds in the amount of approximately \$1,249,000. Pursuant to the Company's agreement with the Debenture holders, as discussed below in "Registration Rights Agreements", the Company registered the shares issuable upon exercise of these June 2008 Warrants for public sale.

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On May 14, 2004, in consideration for the March 2003 Debenture holders' exercise of all of the June 2008 Warrants, the Company issued to the holders warrants (the "May 2009 Warrants") to purchase an aggregate of 1,300,000 shares of the Company's common stock. The Company issued 1,000,000 shares of common stock and received gross proceeds of \$2,400,000 from the exercise of the June 2008 Warrants.

Pursuant to the Company's agreement with the holders, as discussed below in "Registration Rights Agreements", the Company registered the shares issuable upon exercise of the May 2009 Warrants for public sale.

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. This warrant issuance, as restated, was fair valued using the Black-Scholes Method, and was reflected as a deemed dividend of approximately \$2,355,000 during the second quarter of 2004. 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. Upon completion of the August 2004 Private Placement (see Note 9), the exercise price was lowered to \$4.008 per share. On May 14, 2005, the exercise price of these May

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2009 Warrants was set 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 May 15, 2004 and May 13, 2005; however, since the exercise price was previously set to the floor price of \$4.008 per share this provision did not impact these warrants.

As of December 31, 2003, the investors had converted the total \$5,426,000 principal of the March 2003 Debentures into 3,716,438 shares of the Company's common stock. Financing costs and interest expense incurred for the year ended December 31, 2003, on the March 2003 Debenture amounted to \$2,874,000 and \$111,000, respectively. The interest due on this debenture was paid in cash of \$17,000 with \$94,000 being paid by the issuance of shares of the Company's common stock.

July 2003 Debentures

On July 10, 2003, the Company 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") in a private placement for aggregate proceeds of \$4,650,000. At this time, the \$1,550,000 of proceeds from the March 2003 Debentures previously held back from the Company was released to the Company. However, pursuant to the terms of the July 2003 Debentures, \$1,550,000 of the proceeds from the sale of the July 2003 Debentures was held back and to be released to the Company if, and only if, the Company acquired ISI's facility within a set timeframe (see Note 5 above). These funds were released to the Company in October 2003 although the Company had not acquired ISI's facility at that time. The Company recorded an additional debt discount of \$259,000 upon receiving the held back proceeds of \$1,550,000 in October 2003. The July 2003 Debentures were to mature on July 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 July 2003 Debentures, the Company pledged all of the Company's assets, other than the Company's intellectual property, as collateral and was subject to comply with certain financial and negative covenants, which included but were not limited to the repayment of principal balances upon achieving certain revenue milestones (see "Collateral and Financial Covenants" below).

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The July 2003 Debentures were convertible at the option of the investors at any time through July 31, 2005 into shares of the Company's 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 was 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 the Company did pay the redemption price at maturity, the Debenture holders, at their option, could have converted the balance due at the lower of (a) the conversion price then in effect and (b) 95% of the lowest closing sale price of the Company's common stock during the three trading days ending on and including the conversion date. In 2003, the Company recorded a debt discount of approximately \$741,000 upon the conversion price reset to \$1.89 per share. The additional debt discount is amortized over the remaining life of these Debenture or, in the event of a conversion, written off to financing costs on a pro-rata basis.

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The July 2008 Warrants received by the investors, as amended, were exercisable for an aggregate of 507,102 shares of common stock at a price of \$2.46 per share. These Warrants, as amended, did not result in any additional debt. These Warrants were exercised in July 2004 which produced gross proceeds in the amount of \$1,247,000.

Pursuant to the Company's agreement with the holders, as discussed below in "Registration Rights Agreements", the Company registered the shares issuable upon conversion of the July 2003 Debentures and upon exercise of the July 2008 Warrants for public sale.

The July 2003 Debentures were recorded at a discount on issuance and with an original issue discount of approximately \$2,280,000 and \$517,000, respectively, due to ascribing value to the beneficial conversion feature and fair value of warrants based on the relative fair value of the proceeds.

The conversion option and detachable warrant carry registration rights and a feature that in certain circumstances, deemed in the control of the Company, could require partial settlement of the conversion options to be in cash. In addition, the July 2003 Debentures include other features including mandatory conversion option and optional redemption rights if contingent transactions occur. To determine whether the July 2003 Debentures had embedded derivatives, including the conversion option, that required bifurcation and fair value accounting, the Company analyzed the terms of the debentures in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"), and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock" ("EITF 00-19"). The Company concluded that bifurcation was not required for the conversion option and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") was the appropriate accounting to be applied. The warrants were deemed to be permanent equity. The mandatory conversion option and optional redemption rights were deemed to be derivatives requiring bifurcation and thus the Company obtained a third party valuation for the aggregate fair value of these derivatives that showed the fair value to be immaterial at inception and for each subsequent reporting period.

F-28

During 2003, the investors had converted approximately \$1,169,000 principal of the July 2003 debentures into 618,478 shares of the Company's common stock. During 2004, the investors had converted \$4,257,071 principal of the July 2003 debentures into 2,252,417 shares of the Company's common stock. As of December 31, 2004, the investors had converted the total \$5,426,000 principal of the July 2003 Debentures into 2,870,900 shares of common stock.

The Company recorded financing costs for the years ended December 31, 2004 and 2003, with regard to the July 2003 Debentures of \$2,301,000 and \$1,496,000, respectively. Interest incurred for the years ended December 31, 2003 and 2004 was \$117,000 and \$3,000, respectively.

October 2003 Debentures

On October 29, 2003, the Company 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 the Company if, and only if, the Company acquired ISI's

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facility within 90 days of January 26, 2004 and provided a mortgage on the facility as further security for the October 2003 Debentures (see Note 5 above). In April 2004, the Company acquired the facility and the Company subsequently provided the mortgage of the facility to the Debenture holders and the above funds were released. The Company recorded an additional debt discount of \$259,000 upon receiving these held back proceeds. The October 2003 Debentures were to mature on October 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 are to 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. Pursuant to the terms and conditions of the October 2003 Debentures, the Company pledged all of the Company's assets, other than the Company's intellectual property, as collateral and was subject to comply with certain financial and negative covenants, which included but were not limited to the repayment of principal balances upon achieving certain revenue milestones (see "Collateral and Financial Covenants" below).

The October 2003 Debentures are convertible at the option of the investors at any time through October 31, 2005 into shares of the Company's 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 the Company does 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 the Company's 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 approximately \$952,000.

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Pursuant to the Company's agreement with the holders, as discussed below in "Registration Rights Agreements", the Company registered the shares issuable upon conversion of the October 2003 Debentures and upon exercise of the October 2008 Warrants for public sale.

The October 2003 Debentures were recorded at a discount on issuance and with an original issue discount of \$2,000,000 and \$333,000, respectively, due to ascribing value to the beneficial conversion feature and fair value of warrants based on the relative fair value of the proceeds.

The conversion option and detachable warrant carry registration rights and a feature that in certain circumstances, deemed in the control of the Company, could require partial settlement of the conversion options to be in cash. In addition, the October 2003 Debentures include other features including mandatory conversion option and optional redemption rights if contingent transactions occur. To determine whether the October 2003 Debentures had embedded derivatives, including the conversion option, that required bifurcation and fair value accounting, the Company analyzed the terms of the debentures in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"), and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock" ("EITF 00-19"). The Company concluded that bifurcation was not required for the

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conversion option and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") was the appropriate accounting to be applied. The warrants were deemed to be permanent equity. The mandatory conversion option and optional redemption rights were deemed to be derivatives requiring bifurcation and thus the Company obtained a third party valuation for the aggregate fair value of these derivatives that showed the fair value to be immaterial at inception and for each subsequent reporting period.

In October 2005, the Company entered into an amendment agreement with the October 2003 Debenture holders to amend the maturity date from October 31, 2005 to June 30, 2007, and increase the interest rate from 6% to 7% (see "Debenture Agreement Amendment" below for more details).

On July 13, 2004, in consideration for the Debenture holders' exercise of all of the July 2003 ("July 2008 Warrants") and October 2003 ("October 2008 Warrants") Warrants amounting to approximately \$2,199,000 in gross proceeds, the Company issued to these holders warrants (the "June 2009 Warrants") to purchase an aggregate of 1,300,000 shares of common stock. The Company recorded charges associated with the issuance of these warrants, as restated, fair valued using the Black-Scholes Method, at \$1,676,000, which has been reflected as a deemed dividend.

Pursuant to the Company's agreement with the holders, as discussed below in "Registration Rights Agreements", the Company registered the shares issuable upon exercise of these Warrants for public sale.

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 was reset to \$3.33, 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. 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.

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The Company has 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, 2005 have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of December 31, 2005. The cash collateral account provides partial security for repayment of the outstanding principal and accrued interest on the Debentures in the event of default.

As of December 31, 2005, the investors had converted \$2,071,178 principal amount of the October 2003 Debenture into 1,025,336 shares of Common Stock. The remaining balance of \$2,071,178 is convertible into 1,025,336 shares of common stock.

The Company recorded financing costs for the years ended December 31, 2003, 2004 and 2005, with regard to the October 2003 Debentures of \$361,000, \$1,366,000 and \$865,000, respectively. Interest expense for the years ended

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December 31, 2005, 2004 and 2003, with regard to the October 2003 Debentures was \$129,000, \$118,000 and \$24,000, respectively.

January 2004 Debentures

On January 26, 2004, the Company 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 158,104 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 were to 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. As discussed below, the maturity date and interest rate were amended. 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. Pursuant to the terms of the January 2004 Debentures, commencing July 26, 2004, the Company began to repay the then outstanding principal amount under the Debentures in monthly installments amortized over 18 months in cash or, at the Company's option, in shares of common stock. 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. Pursuant to the terms and conditions of the January 2004 Debentures, the Company pledged all of the Company's assets, other than the Company's intellectual property, as collateral and was subject to comply with certain financial and negative covenants, which included but were not limited to the repayment of principal balances upon achieving certain revenue milestones (see "Collateral and Financial Covenants" below).

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The January 2004 Debentures are convertible at the option of the investors at any time through January 31, 2006 into shares of the Company's 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 the Company does 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 the Company's common stock during the three trading days ending on and including the conversion date. Upon completion of the August 2004 Private Placement (see Note 9), the conversion price was lowered to \$2.08 per share. The Company recorded an additional debt discount as restated (see Note 2), of approximately \$915,000 due to this conversion price reset.

In October 2005, the Company entered into an amendment agreement with the January 2004 Debenture holders to amend the maturity date from October 31, 2005 to June 30, 2007, and increase the interest rate from 6% to 7% (see "Debenture Agreement Amendment" below for more details).

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 were 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 9), the exercise price was lowered to \$2.58 per share.

Pursuant to the Company's agreement with these investors, as discussed below in "Registration Rights Agreements"), the Company registered the shares issuable upon conversion of the January 2004 Debentures and upon exercise of the July 2009 Warrants for public sale.

The January 2004 Debentures were recorded at a discount on issuance and with an original issue discount of \$306,000 and \$465,000, respectively, due to ascribing value to the beneficial conversion feature and fair value of warrants based on the relative fair value of the proceeds.

The conversion option and detachable warrant carry registration rights and a feature that in certain circumstances, deemed in the control of the Company, could require partial settlement of the conversion options to be in cash. In addition, the January 2004 Debentures include other features including mandatory conversion option and optional redemption rights if contingent transactions occur. To determine whether the January 2004 Debentures had embedded derivatives, including the conversion option, that required bifurcation and fair value accounting, the Company analyzed the terms of the debentures in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"), and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock" (EITF "00-19"). The Company concluded that bifurcation was not required for the conversion option and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") was the appropriate accounting to be applied. The warrants were deemed to be permanent equity. The mandatory conversion option and optional redemption rights were deemed to be derivatives requiring bifurcation and thus the Company obtained a third party valuation for the aggregate fair value of these derivatives that showed the fair value to be immaterial at inception and for each subsequent reporting period.

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Section 713 of the American Stock Exchange Company Guide

Section 713 of the American Stock Exchange ("AMEX") Company Guide provides that the Company 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 the Company's outstanding common stock (the "Exchange Cap"). The Debentures and Warrants have provisions that require the Company to pay cash in lieu of issuing shares upon conversion of the Debentures or exercise of the Warrants if the Company is 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.

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Taken separately, the March, July, October and January 2004 debenture transactions do not trigger Section 713. However, the AMEX took the position that these 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 the Company 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, the Company recorded on January 26, 2004, a redemption obligation of approximately \$2,160,000, as restated, with a corresponding increase to debt discount to be amortized over the life of the debt or until the Company obtains shareholder approval. Any remaining discount would be reclassified to additional paid in capital.

In addition, in accordance with EITF 00-19, the Company revalued this redemption obligation as of March 31, 2004. The Company increased the redemption obligation and recorded additional finance charge of \$1,024,000 as a result of this revaluation. The Company also incurred \$104,000 in financing charges related to the amortization of the related discount during the first quarter of 2004.

Stockholder approval was obtained at the Company's Annual Meeting of Stockholders on June 23, 2004. In accordance with EITF 00-19, the Company revalued this redemption obligation associated with the 1,299,000 shares as of June 23, 2004 (date of shareholder approval). The Company recorded a reduction in the value of the redemption obligation and financing charge of \$839,000 as a result of this revaluation and additional financing charge of \$242,000 related to the amortization of the debt discount in the second quarter 2004. In addition, upon receiving the requisite stockholder approval on June 23, 2004, the redemption obligation of \$2,345,000 and the remaining unamortized debt discount of \$1,815,000 were reclassified as additional paid in capital.

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During 2004, the investors made installment payments of \$777,000 and converted \$139,150 of principal amount of the January 2004 debenture into 358,932 and 55,000 shares of common stock, respectively. During 2005, the investors had made installment payments of \$1,111,111 and converted approximately \$608,000 principal amount of the January 2004 Debentures into 735,217 and 292,000 shares of common stock, respectively. The remaining principal on these Debentures was \$1,364,602 as of December 31, 2005.

The Company recorded financing costs for the years ended December 31, 2004 and 2005 with regard to the January 2004 Debentures of \$720,000 and \$917,000, respectively. Interest expense for the years ended December 31, 2005 and 2004, with regard to the January 2004 Debentures was \$145,000 and \$207,000, respectively.

July 2004 Debentures

Pursuant to the Additional Investment Rights issued in connection with the January 2004 Debentures, the Company issued to the investors an additional \$2,000,000 principal amount of January 2004 Debentures (the "July 2004 Debentures"). 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 the Company received net proceeds of \$1,860,000. Upon completion of the August 2004 Private Placement (see Note 9), the conversion price of the July 2004 Debentures was lowered to \$2.08 per share. The Company recorded an additional debt discount of approximately \$632,000 upon the conversion price reset to \$2.08 per share, which

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is being amortized over the remaining life of the debenture in accordance with the effective interest method of accounting.

The July 2004 Debentures were recorded at a discount on issuance of \$628,000 due to ascribing value to the beneficial conversion feature and fair value of warrants based on the relative fair value of the proceeds.

The conversion option and detachable warrant carry registration rights and a feature that in certain circumstances, deemed in the control of the Company, could require partial settlement of the conversion options to be in cash. In addition, the July 2004 Debentures include other features including mandatory conversion option and optional redemption rights if contingent transactions occur. To determine whether the July 2004 Debentures had embedded derivatives, including the conversion option, that required bifurcation and fair value accounting, the Company analyzed the terms of the debentures in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"), and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock" (EITF 00-19"). The Company concluded that bifurcation was not required for the conversion option and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") was the appropriate accounting to be applied. The warrants were deemed to be permanent equity. The mandatory conversion option and optional redemption rights were deemed to be derivatives requiring bifurcation and thus the Company obtained a third party valuation for the aggregate fair value of these derivatives that showed the fair value to be immaterial at inception and for each subsequent reporting period.

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In October 2005, the Company entered into an amendment agreement with the July 2004 Debenture holders to amend the maturity date from October 31, 2005 to June 30, 2007, and increase the interest rate from 6% to 7% (see "Debenture Agreement Amendment" below for more details).

As of December 31, 2005, the Company made installment payments of \$500,000 resulting in the issuance of 331,669 shares of the Company's common stock. The Debenture holders had not converted any portion of this debenture as of December 31, 2005.

The Company recorded financing costs for the years ended December 31, 2005 and 2004 with regard to the July 2004 Debentures of \$481,000 and \$248,000, respectively. Interest expense for the years ended December 31, 2005 and 2004, with regard to the January 2004 Debentures was \$113,000 and \$61,000, respectively.

Debenture Agreement Amendment

On October 6, 2005, the Company entered into a material definitive agreement with the October 2003, January 2004 and July 2004 debenture holders to 1) amend the remaining outstanding Debentures that were to mature on October 31, 2005 (as amended, the "October 2003 Debenture") and the two tranches of outstanding debentures due to mature on January 31, 2006 (as amended, respectively, the "January 2004 and July 2004 Debentures"), to a maturity date of June 30, 2007, 2) to increase the interest rate from 6% per annum to 7% per annum. In consideration for extending the maturity date of the outstanding debentures, the Company issued an aggregate of 225,000 Warrants (the "October 2009 Warrants") to the debenture holders to acquire common stock at a price of \$2.50 per share at any time from October 31, 2005 through October 31, 2009. The October 2009 Warrants contain provisions for adjustment of the exercised price in the event of certain anti-dilution events. The Company agreed to register

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135% of the shares issuable as interest shares that might result due to the amendments to the Debentures and issuable upon exercise of the October 2009 Warrants.

In accordance with EITF 96-19, "Debtor's Accounting for a Modification or Exchange of Debt Instruments", the Company has treated the change in terms to the original debentures as non-substantial in nature and have not accounted for such modification as an extinguishment of debt, but rather a debt modification. In addition, the 225,000 warrants issued to the debenture holders as consideration for extending the maturity date were valued using the Black-Scholes method and \$189,000 of additional debt discount on the July 2004 Debenture was recorded. The discount will be amortized as interest expense over the new term of the debt instrument in accordance with the effective interest of accounting. Any costs incurred by third parties were expensed as incurred.

Registration Rights Agreements

The Company entered into Registration Rights Agreements with the investors in connection with the issuance of (i) the above 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 the Company has 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 the Company 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 liquidated damages. As a result of the Company's inability to timely file its annual report on Form 10-K for the year ended December 31, 2005, the Company currently is subject to liquidated damages until such time as the Shares are again registered for public resale or eligible for resale pursuant to Rule 144(k) under the Securities Act. (See Note 20- subsequent events for more information on liquidated damages).

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Investment Banking Fees

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 and July 2004, the Company paid Cardinal Securities, LLC an investment banking fee equal to 7% of the investments made by the Debenture holders and issued to Cardinal the following warrants to purchase common stock: (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, the Company has registered all of the foregoing shares and shares issuable upon exercise of the above mentioned warrants for public resale. As a result of the transactions discussed above, the Company recorded \$538,000 and \$149,000, as restated, as deferred financing costs on the balance sheet as of December 31, 2003 and 2004, respectively, with a related increase to additional paid in capital. These costs are amortized over

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the life of the debenture. Amortization expense was \$360,000, \$263,000 and \$161,000 as of December 31, 2003, 2004 and 2005.

Conversion of Convertible Debt

The maximum number of shares issuable upon debt conversion, including interest as well as 135% of the shares issuable upon conversion and interest payments were 5,011,525 and 3,667,662 shares at December 31, 2004 and 2005, respectively.

Collateral and Financial Covenants

The Company paid \$1,300,000 in 2003 into the debenture cash collateral account held by the debenture holders as required by the terms of the October 2003 Debentures. The amounts paid have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of December 31, 2005. The cash collateral account provides partial security for repayment of the outstanding Debentures in the event of default.

Pursuant to the terms and conditions of all of the outstanding Debentures, the Company has pledged all of the Company's assets, other than the Company's intellectual property, as collateral, and the Company is subject to comply with certain financial covenants. The Company failed to timely file its Annual Report on Form 10-K with the Securities and Exchange Commission pursuant to the 1934 Act, and therefore, was in violation of its covenant to timely file. See Note 20 - Subsequent Events for more details on this and the Company's receipt of a waiver of this covenant.

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Debenture Acceleration Provisions

Upon an Event of Default as described in the Debentures, and for so long as such Event of Default shall be continuing, unless waived by a Debenture holder, a Debenture holder, on written notice to the Company may consider the Debenture immediately due and payable. Events of Default include: (a) any Event of Default under any other Debenture; (b) suspension from trading or failure of the Common Stock to be listed on the AMEX for more than an aggregate of ten trading days in any 365-day period; (c) Any money judgment, writ or warrant of attachment, or similar process in excess of \$250,000 in the aggregate is entered or filed against the Company, its Subsidiaries or any of their properties or other assets and which remains unpaid, unvacated, unbonded and unstayed for a period of 75 days; (d) the Company defaults in the payment when due of (i) interest on the Debenture, and such default continues for 30 days, or (ii) the outstanding principal amount of the Debenture; (e) any Company representations or warranties in the Debentures and the related documents (the "Transaction Documents") or any mortgage are untrue in any material respect when made and are not cured, provided they are curable, within a specified period and such breach of representations and warranties would have a material adverse effect on the Company or materially impair the ability of the Company to satisfy its obligations to the Holders; (f) the Company fails to perform or observe in any material respect any material covenant in the Debenture or any relevant Transaction Document (such as the failure to honor any conversion notice); (g) the Company becomes insolvent or certain other events that trigger creditors' rights, bankruptcy, liquidation or similar proceedings occur; (h) the Company fails to pay any indebtedness (other than the Debentures), or any interest or premium thereon, when due in an outstanding principal amount equal to or greater than \$1,000,000 and such failure continues after the applicable grace period, if any, or such indebtedness is declared be due and payable prior to the stated maturity thereof; (i) unless the Company has made cash collateral payments in an amount equal to the entire outstanding principal amount of all Debentures,

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together with accrued and unpaid interest thereon, the Registration Statement required to register the shares issuable upon conversion of the Debentures and exercise of the related warrants is not declared effective by the SEC and available for the sale on or before certain specified dates; (j) the Security Agreement, any Mortgage or any other security document, after delivery thereof pursuant to the relevant securities purchase agreement, fails or ceases to create a valid and perfected and, except to the extent permitted by the relevant Transaction Documents, first priority lien in favor of the agent for the benefit of the holders of Debentures on any collateral covered thereby; (k) the Cash Collateral Account Bank shall fail to comply with any of the terms of the Account Control Agreement; (l) at any time required to be in full force and effect, the Letters of Credit ceases to be in full force and effect and such breach is not cured within a specified time; (m) the report of the Company's auditors on the Company's consolidated audited financial statements for the year ended prior to the issuance of the relevant Debenture contained any going concern qualification; or (n) any material damage to, or loss, theft or destruction of, any Collateral, or any adverse event such as a labor dispute or act of God, which causes, for more than 15 consecutive days, the cessation or substantial curtailment of revenue producing activities at any material facility of the Company or any of its Subsidiaries. Upon the occurrence of an Event of Default described in subsection (g) above, the Debentures become automatically due and payable. In such event the Debentures are to be redeemed at a redemption price equal to 100% of the outstanding principal amount, plus accrued and unpaid interest thereon. In addition, upon an Event of Default, the interest rate on the Debentures permanently increases by two percent and, solely in the case of an Event of Default triggered by a conversion failure ((f) above), higher, but in no event can the interest rate increase above the lower of 20% or the highest rate permitted by applicable law (See Note 20).

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

(9) Stockholders' Equity

(a) Preferred Stock

The Company is authorized to issue 5,000,000 shares of \$.01 par 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, 2004 and 2005.

(b) Common Stock

On July 31, 2003, we had approximately 104,000 shares of the Company's \$.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 2003 Debenture, Dr. Carter, the Company's Chief Executive Officer and Cardinal Capital, LLC, the placement agent, agreed that they would not exercise their warrants or options unless and until the Company's stockholders approved an increase in the Company's authorized shares of common stock. This action freed up 3,206,650 shares. For Dr. Carter's waiver of his right to exercise certain options and warrants prior to approval of the increase in the Company's authorized shares, the Company agreed to compensate Dr. Carter and issued Dr. Carter 1,450,000 warrants to purchase common stock at \$2.20 per share in 2003 that vested in the first quarter 2004 upon the second ISI asset closing. The Company recorded a charge to stock compensation expense during the first quarter of 2004 of \$1,769,000 upon the full vesting of these warrants at their intrinsic value.

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

As of December 31, 2004 and 2005, 49,631,766 and 56,264,155 shares, net of shares held in the treasury, were outstanding, respectively.

(c) Minority Shareholder Interest

On March 20, 2002 the Company's 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") (Note 17). 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.

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During March 2002, Hemispherx, S.A. was authorized to issue up to 22,000,000 Euros of seven percent (7%) convertible preferred securities. Such securities are guaranteed by the parent company and are convertible 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. in the event that a European IPO was not completed by September 30, 2003. The conversion rate was 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 the Company's proposal and we registered these shares for public sale.

On March 13, 2003, we issued 347,445 shares of the Company's common stock to Provesan S.A., an affiliate of Esteve S.A., in exchange for 1,000,000 Euros of convertible 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.

(d) Equity Financings

On August 5, 2004, the Company closed a private placement with select institutional investors ("August 2004 Private Placement") for 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 warrants to purchase Common Stock. The Company raised approximately \$6,984,000 net proceeds from this

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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 registered the resales of the shares issued to the Purchasers and shares issuable upon the exercise of the Warrants.

By agreement with Cardinal Securities, LLC, for general financial advisory services and in conjunction with the August 2004 Private Placement with select institutional investors, the Company paid Cardinal Securities, LLC an investment banking fee of \$140,000. The Company paid Cardinal one-half of the fee in cash with the remainder being paid with the issuance of 50,000 warrants to purchase common stock exercisable at \$2.50 per share expiring on March 31, 2010 and 46,667 shares of common stock. By agreement with Cardinal Securities, LLC, the Company registered all of the foregoing shares and shares issuable upon exercise of the above mentioned warrants for public resale.

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On July 8, 2005, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"), pursuant to which Fusion Capital has agreed, under certain conditions, to purchase on each trading day \$40,000 of the Company's common stock up to an aggregate of \$20.0 million over approximately a 25 month period, subject to earlier termination at the Company's discretion. In the Company's discretion, it may elect to sell less common stock to Fusion Capital than the daily amount and we may increase the daily amount as the market price of the Company's stock increases. The purchase price of the shares of common stock will be equal to a price based upon the future market price of the common stock without any fixed discount to the market price. Fusion Capital does not have the right or the obligation to purchase shares of the Company's common stock in the event that the price of the common stock is less than \$1.00.

Pursuant to the Company's agreement with Fusion Capital, the Company has registered for public sale by Fusion Capital up to 10,795,597 shares of our common stock. However, in the event that the Company decides to issue more than 10,113,278, i.e. greater than 19.99% of the outstanding shares of common stock as of the date of the agreement, the Company would first seek stockholder approval in order to be in compliance with American Stock Exchange rules. As of December 31, 2005, Fusion Capital has purchased 4,007,255 shares amounting to approximately \$8,020,000 in gross proceeds to the Company.

In connection with entering into the above agreement with Fusion Capital, the Company, in July 2005, issued to Fusion Capital 402,798 shares of its common stock. 392,798 of these shares represented 50% of the commitment fee due Fusion Capital with the remaining 10,000 shares issued as reimbursement for expenses. An additional 392,799 shares, representing the remaining balance of the commitment, are issuable in conjunction with daily purchases of common stock by Fusion Capital. These additional commitment shares will be issued in an amount equal to the product of (x) 392,799 and (y) the Purchase Amount Fraction. The "Purchase Amount Fraction" means a fraction, the numerator of which is the purchase price at which the shares are being purchased by Fusion Capital and the denominator of which is \$20,000,000. As of December 31, 2005, Fusion Capital was issued 263,713 shares towards this commitment fee. In total, Fusion Capital has purchased 4,673,766 shares in connection with this private placement as of December 31, 2005 (See Note 20).

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(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:

| | 2003 | | | 2004 | | | | |
|---|----------|--------------|---------------------------------|----------|--------------|---------------------------------|---------|-----|
| | Shares | Option Price | Weighted Average Exercise Price | Shares | Option Price | Weighted Average Exercise Price | | |
| Outstanding, beginning of year | 294,665 | \$1.06-4.34 | \$3.50 | 433,134 | \$1.06-4.34 | \$3.10 | 414,702 | \$2 |
| Granted | 200,000 | \$2.75 | \$2.75 | - | - | - | - | |
| Canceled | (61,531) | \$3.80-4.03 | \$3.97 | (18,432) | \$4.34 | \$4.34 | - | |
| Exercised | - | - | - | - | - | - | - | |
| Outstanding, end of year | 433,134 | \$1.06-4.34 | \$3.10 | 414,702 | \$2.71-4.03 | \$3.11 | 414,702 | \$2 |
| Exercisable | 433,134 | \$1.06-4.34 | \$3.10 | 414,702 | \$2.71-4.03 | \$3.11 | 414,702 | \$2 |
| Weighted average remaining contractual life (years) | 3.37 | | | 8.24 | | | 5.10 | |
| | years | - | - | years | - | - | years | |

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| | | | | | | | |
|--------------------------------------|----------|---|---|----------|---|---|----------|
| Exercised in current and prior years | (27,215) | - | - | (27,215) | - | - | (27,215) |
| | ===== | = | = | ===== | = | = | ===== |
| Available for future grants | 27,664 | - | - | 46,096 | - | - | 46,096 |
| | ===== | = | = | ===== | = | = | ===== |

The following table summarizes information about these options outstanding at December 31, 2005:

| | | Exercise Price Range | |
|---------------------------------|---------|----------------------|-----------------|
| | | ----- | ----- |
| | | \$2.71 - \$2.75 | \$3.50 - \$4.03 |
| | | ----- | ----- |
| Outstanding Options: | | | |
| Number Outstanding | 273,728 | 54,974 | 86,000 |
| Remaining contracted life years | 8.0 | 2.0 | 5.1 |
| Weighted average exercise price | \$2.68 | \$3.21 | \$4.03 |
| Exercisable Options: | | | |
| Number outstanding | 273,728 | 54,974 | 86,000 |
| Weighted average exercise price | \$2.68 | \$3.21 | \$4.03 |

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.

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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. There was no stock

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compensation expense in 2004 and 2005 recorded as there were no options granted under this plan.

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 the 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:

| | 2004 | | | 2005 | |
|-------------------------------|-----------------|-----------------------|---|-----------------|-----------------------|
| | Shares ----- | Option Price ----- | Weighted Average Exercise Price ----- | Shares ----- | Option Price ----- |
| Outstanding beginning at year | - | - | - | 633,080 | \$1.90-3.44 |
| Granted | 633,080 | \$1.90-3.44 | \$2.56 | 1,352,600 | \$1.63-2.56 |
| Canceled | - | - | - | - | - |
| Exercised | - | - | - | - | - |

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| | | | | | |
|---|--------------------|-------------|--------|--------------------|-------------|
| Outstanding end of year | 633,080 ===== | \$1.90-3.44 | \$2.56 | 1,985,680 ===== | \$1.63-2.00 |
| Exercisable | 538,432 ===== | \$2.60-3.44 | \$2.68 | 1,373,250 ===== | \$1.63-2.00 |
| Weighted average remaining contractual life (years) | 10 years ===== | | | 8-9 years ===== | |
| Available for future grants | 7,366,920 ===== | | | 6,014,320 ===== | |

The following table summarizes information about these options outstanding at December 31, 2005:

| | \$1.63-\$1.90 | Exercise Price Range \$2.00-2.87 | \$3.44 |
|---------------------------------|---------------|-------------------------------------|--------|
| Outstanding options: | | | |
| Number outstanding | 1,101,648 | 834,032 | 50,000 |
| Remaining contracted life years | 8.3 | 8.7 | 8.5 |
| Weighted average exercise price | \$1.81 | \$2.51 | \$3.44 |
| Exercisable options: | | | |
| Number outstanding | 575,918 | 747,332 | 50,000 |
| Weighted average exercise price | \$1.76 | \$2.52 | \$3.44 |

(ii) Stock warrants

Number of warrants exercisable into shares of common stock

| | 2003 | | | 2004 | | | |
|-------------------------------|---------------------|--------------|---------------------------------|---------------------|--------------|---------------------------------|---------------------|
| | Shares | Option Price | Weighted Average Exercise Price | Shares | Option Price | Weighted Average Exercise Price | Shares |
| Outstanding beginning of year | 7,967,810 | \$1.75-16.00 | \$3.18 | 11,502,796 | \$1.74-16.00 | \$3.57 | 13,167,037 |
| Granted | 4,623,024 | \$1.68-2.57 | \$2.32 | 4,791,187 | \$2.58-4.20 | \$3.25 | 56,000,000 |
| Canceled | (276,000) | \$4.00-10.00 | \$6.54 | (858,360) | \$4.00-8.00 | \$5.34 | (2,197,000) |
| Exercised | (812,038) | \$1.68-1.75 | \$1.69 | (2,268,586) | \$1.74-3.50 | \$2.32 | (5,000,000) |
| Outstanding end of year | 11,502,796 ===== | \$1.74-16.00 | \$3.57 | 13,167,037 ===== | \$1.75-16.00 | \$3.46 | 11,520,000 ===== |

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| | | | | | | | |
|---|---------------------|--------------|--------|---------------------|--------------|--------|---------------------|
| Exercisable | 8,635,560 ===== | \$1.74-16.00 | \$4.11 | 12,667,037 ===== | \$1.75-16.00 | \$3.46 | 11,529,837 ===== |
| Weighted average remaining contractual life (years) | 4.04 years ===== | | | 4.3 years ===== | | | 4.43 years ===== |
| Years exercisable | 2004-2008 ===== | | | 2005-2009 ===== | | | 2006-2008 ===== |

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The following table summarizes information about stock warrants outstanding at December 31, 2005:

| | Exercise price range | | |
|--|----------------------|---------------|-----------------|
| | \$1.75-\$5.00 | \$6.00-\$9.00 | \$10.00-\$16.00 |
| Outstanding warrants | | | |
| Number outstanding | 10,416,187 | 713,650 | 400,000 |
| Weighted average remaining contractual life (years) | 4.2 | 2.2 | 1.46 |
| Weighted average exercise price | \$2.89 | \$6.80 | \$13.00 |
| Exercisable warrants | | | |
| Number outstanding | 10,416,187 | 713,650 | 400,000 |
| Weighted average exercise price | \$2.89 | \$6.80 | \$13.00 |

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 issued to stockholders 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.

Other stock warrants

The Company has issued other stock warrants outstanding - totaling 11,529,837, 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

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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.

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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 1996, 597,000, in 1999, 290,000, in 2000, 216,500, in 2001, 200,000, in 2002, 1,300, in 2003, 35,000 and in 2004, 205,000 of these warrants were exercised leaving a balance of these warrants of 1,205,200. 5,000 of these remaining warrants were exercised in 2005 and the remaining expired on June 30, 2005.

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 Note 8), 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. In total, 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. In 2005, 350,000 of these warrants expired leaving a balance of 425,000. These warrants are exercisable in five years from the date of issuance.

In 2003, 2004 and 2005 the Company had warrants outstanding, issued to employees, directors and consultants, of 5,100,650, 4,645,650 and 4,268,650 respectively. These warrants were not issued pursuant to an equity plan and are exercisable at rates of \$1.55 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. At December 31, 2002, 3,701,650 of the non-public warrants were outstanding. 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. At December 31, 2003, 5,100,650 warrants were outstanding. During 2004, 15,000 warrants were issued to consultants and 470,000 expired leaving a balance of 4,645,650 at December 31, 2004. During 2005, 265,000 warrants were issued to consultants and 642,000 expired leaving a balance of 4,268,650 at December 31, 2005. These stock warrants have exercise prices ranging from \$3.50 to \$4.00.

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 warrants were issued related to debt financing and 2,035,986 warrants were exercised leaving a balance of 5,136,189 warrants at December 31, 2004. During 2005, 300,000 warrants were issued leaving a balance of 5,436,189 at December 31, 2005.

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(f) 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 and the balance of 443 shares were sold in 2004.

(g) 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 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.

(10) 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).

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

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| | (in thousands) | | |
|---------------|----------------|---------|---------|
| | 2003 | 2004 | 2005 |
| | ----- | ----- | ----- |
| United States | \$ 655 | \$1,225 | \$1,083 |
| Belgium | 2 | 4 | -- |
| Other | -- | -- | -- |
| | ----- | ----- | ----- |
| | \$ 657 | \$1,229 | \$1,083 |
| | ===== | ===== | ===== |

The Company employs an insignificant amount of net property and equipment in its foreign operations.

(11) Research, Consulting and Supply Agreements

In 1994, the Company 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). On December 27, 2004 the Company initiated a lawsuit in Federal Court identifying a conspiratorial group seeking to illegally manipulate the Company's stock for purposes of bringing about a hostile takeover of Hemispherx. This conspiratorial group includes Bioclones.

In 1998, the Company 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, the Company may mitigate the necessity of incurring certain up-front costs. Accredo has also worked with the Company 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(R) 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 the Company's 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.

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's 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 agreement terminates on December 15, 2009, subject to

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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 the Company's product from Canada for a period of more than ninety days for serious adverse health or safety reasons.

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In May 2000, the Company acquired an interest in Chronix Biomedical Corp. ("CHRONIX"). Chronix focuses upon the development of diagnostics for chronic diseases. The Company issued 100,000 shares of common stock to Chronix toward a total equity investment of \$700,000. Pursuant to a strategic alliance agreement, the Company 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 the Company 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 the Company 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 the Company 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 the Company recorded a noncash charge of \$292,000 and \$373,000, respectively, with respect to the Company's investment in Chronix. This impairment reduces the Company's carrying value to reflect a permanent decline in Chronix's market value based on its then proposed equity offerings.

In March 2002, the Company's 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, but did not proceed with the trials due to an inability to enroll a sufficient number of patients. The Company is discussing with Esteve their initiation of another clinical trial utilizing Ampligen(R) in another indication. 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.

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In October 2005, the Company signed a research agreement with the National Institute of Infectious Diseases, in Tokyo, Japan. The collaboration, by Hideki Hasegawa, M.D., Ph.D., Chief of the Laboratory of Infectious Disease Pathology, will assess the Company's experimental therapeutic Ampligen(R) as a co-administered immunotherapeutic to the Institution's nasal flu vaccine.

In October 2005, the Company also engaged the Sage Group, Inc., a health care, technology oriented, strategy and transaction advisory firm, to assist the Company in obtaining a strategic alliance in Japan for the use of Ampligen(R) in treating Chronic Fatigue Syndrome or CFS (see Note 17). The Company is in discussions with the Sage Group, Inc. to expand its engagement to assist the Company in obtaining strategic alliance in Japan for the use of Ampligen(R) in treating Avian Flu.

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

On December 9, 2005, the Company executed a Supply Agreement with Hollister-Stier Laboratories LLC of Spokane, Washington ("Hollister-Stier"), for the contract manufacturing of Ampligen(R) for a five year term. Pursuant to the agreement the Company will supply the key raw materials and Hollister-Stier will formulate and bottle the Ampligen(R). In November 2005, the Company paid \$100,000 as a deposit in order to initiate the manufacturing project. This deposit was expensed as research and development during the 4th Quarter 2005. The achievement of the initial objectives described in the agreement, in combination with the Company's polymer production facility under construction in New Brunswick, N.J., may enable the Company to manufacture the raw materials for approximately 10,000 doses of Ampligen(R) per week. The Company executed a confidentiality agreement with Hollister-Stier; therefore, the Company commenced the transfer of the Company's manufacturing technology to Hollister-Stier. Currently, Hollister-Stier has completed two pilot manufacturing runs of Ampligen(R) for stability testing.

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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, 2003, 2004 and 2005 the Company incurred approximately \$389,000, \$220,000 and \$236,000 respectively, of consulting service fees under these agreements. These costs are charged to research and development expense as incurred.

(12) 401(K) Plan

The Company has a defined contribution plan, entitled the Hemispherx

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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 2003, 2004 and 2005 the Company provided matching contributions to each employee for up to 6% of annual pay aggregating \$38,000, \$77,000 and \$89,000 respectively.

(13) 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.

The Company acquired a series of patents on Oragens, potentially a set of oral broad spectrum antivirals and immunological enhancers, through a licensing agreement with Temple University in Philadelphia, PA. The Company was granted an exclusive worldwide license from Temple for the Oragens products. These compounds have been evaluated in various academic laboratories for application to chronic viral and immunological disorders. The 2', 5' oligoadenylate synthetase/RNase L system is an important and widely distributed pathway for the inhibition of viral replication and tumor growth. The 2', 5' oligoadenylate synthetase, up activation by double-stranded RNA, synthesizes 2', 5' oligoadenylates (2-5A) from ATP. These bioactive 2-5As directly activate RNase L, which degrades viral and cellular RNAs resulting in the inhibition of protein synthesis. The bioactive 2-5A molecules can be degraded by various hydrolytic enzymes, resulting in a short half life. Analogues of these bioactive 2-5As, termed Orogen(TM) RNA compounds, have been produced to increase stability and maintain or increase biological activity without demonstrable toxicity. Pursuant to the terms of the Company's agreement with Temple, the Company is obligated to pay royalties of 2% to 4% of sales depending on the amount of technical assistance required. The Company currently pays a royalty of \$30,000 per year to Temple. This agreement is to remain in effect until the date that the last licensed patent expires unless terminated sooner by mutual consent or default due to royalties not being paid. The last Orogen(TM) patent expires on June 1, 2018. The Company records the payment of the royalty as research and development cost for the period incurred.

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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 provided 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)). We deem this marketing arrangement with Bioclones void due to the numerous and long standing failures of performance by Bioclones.

In December 2004, the Company filed a multicount complaint in federal court (Southern District of Florida) against a conspiratorial group, which

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includes Bioclones, seeking to illegally manipulate the Company's stock for purposes of bringing about a hostile takeover of Hemispherx (see Note 16).

In October 1994, the Board of Directors granted an at the time 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.

On March 20, 2002, the Company's 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) 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 asset purchase agreement entered into with ISI, the Company is obligated to pay ISI a 6% royalty on the net sales of the Alferon N Injection(R) product.

The Company has contractual agreements with two of its officers. The aggregate annual base compensation under these contractual agreements for 2003, 2004 and 2005 was \$637,000, \$761,000 and \$701,000 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 2003, 2004 and 2005, bonuses of \$266,100, 165,300 and \$175,300 respectively were granted. In 2003, the Chief Executive Officer, Dr. William A. Carter, 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 (see below) 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 2005, the Chief Executive Officer of the Company was granted options to purchase 645,000 shares of common stock at \$1.75 to \$2.87 per share and the Chief Financial Officer of the Company was granted options to purchase 110,000 shares of common stock at \$1.75 to \$2.61 per share.

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On March 11, 2005, the Company's 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 the Company's Chief Executive Officer and Chief Scientific Officer until December 31, 2010 unless sooner terminated for cause or disability. The agreement automatically renews for successive one year periods after the initial termination date unless the Company or Dr. Carter give written notice otherwise at least ninety days prior to the termination date or any renewal period. Dr.

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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 the Company's operating results. Dr. Carter will not participate in any discussions concerning the determination of his annual bonus. Dr. Carter is also entitled to an incentive bonus of 0.5% of the gross proceeds received by us from any joint venture or corporate partnering arrangement. Dr. Carter's agreement also provides that he be paid a base salary and benefits through the last day of the then term of the agreement if he is terminated without "cause", as that term is defined in agreement. In addition, should Dr. Carter terminate the agreement or the agreement be terminated due to his death or disability, the agreement provides that Dr. Carter be paid a base salary and benefits through the last day of the month in which the termination occurred and for an additional twelve month period. Pursuant to his original agreement, Dr. Carter was granted options to purchase 73,728 (post split) shares in 1991. The exercise period of these options is extended through December 31, 2010 and, should Dr. Carter's employment agreement be extended beyond that date, the option exercise period is further extended to the last day of the extended employment period. In accordance with FASB Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation, no compensation expense was recognized as the exercise price at the extension date exceeded the fair value of the underlying common stock.

The amended and restated engagement agreement, retroactive to January 1, 2005, provides for the Company's engagement of Dr. Carter as a consultant related to patent development, as one of the Company's directors and as chairman of the Executive Committee of the Company's 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 the Company's 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.

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On February 14, 2005 the Company entered into an agreement with The Sage Group of Branchburg, New Jersey for R. Douglas Hulse, an Executive Director of The Sage Group, to serve as President and Chief Operating Officer of the Company. In addition, other Sage Group principals and Senior Directors will be made available to assist as needed. The engagement is expected to continue for a period of 18 months; however, it is terminable on 30 days written notice by either party after 12 months. Compensation for the services includes a ten year warrant to purchase 250,000 shares of the Company's common stock at an exercise

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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 the Company's 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 the Company's business. The Company used the Black-Scholes valuation model to value the shares received by the Sage Group pursuant to the agreement. The Company recorded a charge to earnings of approximately \$124,000 in 2005 with a related increase to additional paid in capital.

The Company entered into an engagement agreement, retroactive to January 1, 2005, with Ransom W. Etheridge which provides for Mr. Etheridge's engagement as the Company's General Counsel until December 31, 2009 unless sooner terminated for cause or disability. The agreement automatically renews for successive one year periods after the initial termination date unless the Company 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 the Company's business.

The Company 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 the Company's 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 the Company's 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(R). 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 the Company's business.

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On March 11, 2005 the Board of Directors, deeming it essential to the best interests of the Company's 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 the Company and the Company's shareholders, determined to reinforce and encourage the continued attention and dedication of members of the Company's management to their engagement without distraction in the face of potentially disturbing circumstances arising from the possibility of a change in control of the Company and entered into identical agreements regarding change in control with William A. Carter, the Company's Chief Executive Officer and Chief Scientific Officer, Robert E. Peterson, the Company's Chief Financial Officer and Ransom W. Etheridge, the Company's 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 the Company gave notice to the other party prior to the date of such extension that the agreement term will not be extended. Notwithstanding the foregoing, if a change in control occurs during the term of the agreements, the term of the agreements will continue through the second anniversary of the date on which the change in control occurred. Each of the agreements entitles William A. Carter, Robert E. Peterson and Ransom W. Etheridge, respectively, to change of control benefits, as defined in the agreements and summarized below, upon their respective termination of employment/engagement with the 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.

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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.

In order to facilitate the Company's need to obtain financing and prior to the Company's shareholders approving an amendment to the Company's 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 the Company's shareholder approved an increase in

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the Company's authorized shares of Common Stock.

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

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

(14) Leases

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

Future minimum lease payments under noncancellable operating leases are as follows:

| Year ending December 31, ----- | (000's omitted) Operating leases ----- |
|---------------------------------------|---|
| 2006. | \$ 193 |
| 2007. | 65 |
| | ----- |
| Total minimum lease payments. | \$ 258 ===== |

Rent expense charged to operations for the years ended December 31, 2003, 2004 and 2005 amounted to approximately \$266,000, \$269,000 and \$284,000 respectively. The term of the lease for the Rockville, Maryland facility expired June 2005. The Company transferred this operational site to the Company's New Jersey facility. 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.

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(15) Income Taxes

As of December 31, 2005, the Company has approximately \$81,500,000 of federal net operating loss carryforwards (expiring in the years 2006 through 2026) available to offset future federal taxable income. The Company also has approximately \$28,000,000 of state net operating loss carryforwards (expiring in the years 2006 through 2010) 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

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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, 2004 and 2005.

The components of the net deferred tax asset of December 31, 2004 and 2005 consists of the following:

| | (000's omitted) | |
|--|-----------------|-----------|
| Deferred tax assets: | 2004 | 2005 |
| | ----- | ----- |
| | (restated) | |
| Net operating losses | \$ 26,864 | \$ 27,715 |
| Accrued Expenses and Other | 77 | (43) |
| Capitalized Research and development costs | 1,059 | 1,348 |
| | ----- | ----- |
| Total | 28,000 | 29,020 |
| Less: Valuation Allowance | (28,000) | (29,020) |
| | ----- | ----- |
| Balance | \$ -0- | \$ -0- |
| | ===== | ===== |

(16) Contingencies

On September 30, 1998, the Company filed a multi-count complaint against Manuel P. Asensio, Asensio & Company, Inc. ("Asensio"). The action included claims of defamation, disparagement, tortuous 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 the Company 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, the Company made defamatory statements about Asensio. The Company denied the material allegations of the counterclaim. In July 2000, following dismissal in federal court for lack of subject matter jurisdiction, the Company 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 the Company a directed verdict on the counterclaim. On July 2, 2002 the Court entered an order granting the Company a new trial against Asensio for defamation and disparagement. Thereafter, Asensio appealed the granting of a new trial to the Superior Court of Pennsylvania. The Superior Court of Pennsylvania has denied Asensio's appeal. Asensio petitioned the Supreme Court of Pennsylvania for allowance of an appeal, which was denied. The Company now anticipates the scheduling of a new trial against Asensio for defamation and disparagement in the Philadelphia Common Pleas Court.

In June 2002, a former ME/CFS clinical trial patient and her husband filed a claim in the Superior Court of New Jersey, Middlesex County, against the Company, one of its 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 the Company 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, who upheld the dismissal of all claims against the Company and the matter is now concluded.

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

In December 2004, the Company filed a multicount complaint in federal court (Southern District of Florida) against a conspiratorial group, which includes Bioclones, seeking to illegally manipulate its 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 its cash and proprietary assets by an illegal campaign to drive down its stock price and publish disparaging reports on the Company's 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 the Company (see Note 13), and Johannesburg Consolidated Investments, a South African corporation, Cyril Donninger, R. B. Kebble, H. C. Buitendag, Bart Goemaere, and John Doe(s). Bioclones, Johannesburg Consolidated Investments, Cyril Donninger, R. B. Kebble and H.C. Buitendag filed a motion to dismiss the complaint, which was granted by the court. The Company is in the process of appealing this decision to the 11th federal circuit court of appeals.

On January 10, 2005, the Company 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 the Company filed an amended complaint in the same lawsuit joining Redlabs, USA, Inc. as a defendant with the existing defendants R.E.D. Laboratories, N.V./S.A., Bart Goemaere, Jan Goemaere, Dr. Kenny De Meirleir, Kenneth Schepmans, Johan Goossens, Lieven Vansacker and John Does. Pursuant to an agreement in which R.E.D. Laboratories, N.V./S.A. and Dr. Kenny DeMeirleir agreed not to participate in a hostile takeover of Hemispherx for a period of five years, R.E.D. Laboratories, N.V./S.A. and Dr. Kenny DeMeirleir have been dismissed as defendants in the litigation. The litigation is proceeding against the remaining defendants.

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The Company has employment agreements with certain of its executive officers and have granted such officers and directors options and warrants to purchase its common stock, as discussed in Note 9.

Ransom W. Etheridge, the Company's Secretary, General Counsel and one of its 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 \$88,000 in 2005. In addition, Mr. Etheridge serves on the Board of Directors for which he received Director's Fees of cash and stock valued at \$100,000 in 2005. 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. This loan was granted prior to the enactment of the Sarbanes Oxley Act of 2002 prohibiting such transactions. In lieu of granting Mr. Etheridge a bonus for outstanding legal work performance on behalf of the Company, the Board of Directors forgave the loan and accrued interest on February 24, 2006.

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

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

Antoni Esteve, one of the Company's former directors, was a Member of the Executive Committee and Director of Scientific and Commercial Operations of Laboratorios Del Dr. Esteve S.A (see Note 9(c)).

On February 14, 2005 the Company entered into an agreement with The Sage Group of Branchburg, New Jersey for R. Douglas Hulse, an Executive Director of The Sage Group, to serve as President and Chief Operating Officer of the Company (See Notes 3 and 11 for additional information concerning this agreement).

(18) Concentrations of credit risk

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Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash, cash equivalents, investments and accounts receivable. 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.

Sales to three large wholesalers represented approximately 74% and 80% of the Company's total sales for the years ended December 31, 2004 and 2005, respectively.

(19) Quarterly Results of Operation (unaudited)

The following is a summary of the unaudited quarterly results of operations:

2004

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(in thousand except per share data)

| | March 31, 2004 As previously reported(1) | March 31, 2004 Restated(2) | June 30, 2004 As previously reported | June 30, 2004 Restated(2) | September 30, 2004 As previously reported | September 30, 2004 Restated(2) |
|--|--|----------------------------------|--|---------------------------------|---|--------------------------------------|
| Revenues | \$308 | \$308 | \$331 | \$331 | \$258 | \$258 |
| Costs and expenses | 4,409 | 4,409 | 2,526 | 2,526 | 2,972 | 2,972 |
| Net loss | (8,042) | (7,064) | (5,956) | (2,784) | (7,007) | (4,152) |
| Deemed dividend(4) | - | - | - | (4,031) | - | - |
| Net loss applicable to common stockholders | \$(8,042) | \$(7,064) | \$(5,956) | \$(6,815) | \$(7,007) | \$(4,152) |
| Basic and diluted loss per share | \$ (.20) | \$ (.17) | \$ (.14) | \$ (.15) | \$ (.15) | \$ (.09) |

See Note 2 for restated year end results for the year ended December 31, 2004. As discussed in Note 2, the Company will file its quarterly reports on Form 10-Q/A for the quarterly periods ended March 31, 2005, June 30, 2005 and September 30, 2005, which will include the quarters ended in 2004 as soon as practicable.

- (1) During the first quarter 2004, the Company recorded stock compensation of \$1,769,000 (See Note 9(b)) and during the third quarter 2004, the Company recorded stock compensation of \$231,000.
- (2) The Company re-evaluated the accounting for the March 2003, July 2003, October 2003, January 2004 and July 2004 Debentures (collectively, "the Debentures") to determine whether the embedded conversion options required bifurcation and fair value accounting in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities", and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock". The Company concluded that bifurcation was not required and that EITF 00-27 should have been applied. The Company did initially apply EITF 00-27, however as part of performing an analysis on the guidelines set forth in EITF 00-27 it was determined that the initial accounting treatment and subsequent price resets for the Debentures that were originally applied and reflected in the financial statements. To properly account for the initial calculation of the discount and the conversion price resets triggered upon the issuance of the issuance of the October 2003 Debenture and the August 2004 Private Placement (See Notes 8 & 9 for more details on these resets), it was determined, under guidance from EITF 00-27 that the debt discount should be restated for the Debentures.

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- (3) The estimation of fair value ascribed to and the accounting treatment of the investment banking fees paid to Cardinal Capital, LLC ("Cardinal") in connection with the Debenture issuances, at inception, was inaccurately reflected in the financial statements included in our Quarterly reports on Form 10-Q and that, therefore, a restatement of our financial statements for the periods referenced above was required. In connection with the initial recording of the Debentures mentioned above, it was determined that the fair value of the warrants issued as investment banking fees paid to Cardinal, be accounted for as a discount to Debentures. These investment banking fees should have been capitalized as deferred financing costs and amortized over the life of the Debentures or charged to earnings on the earlier conversion thereof. In addition, the initial calculation of the fair value of the warrants issued to Cardinal as a part of the Debenture issuances was determined to have been applied incorrectly at the time of issuance.
- (4) The accounting treatment set forth is FASB Statement No. 123, "Accounting for Stock-Based Compensation", for the issuance of the June 2008, May 2009 and June 2009 Warrants (collectively "the Warrants") (See Note 8) that was originally interpreted and reflected in the financial statements, was not correctly applied. The warrants issued as incentive to exercise prior warrant issuances are reflected as a deemed dividend at the date of issuance, where previously these warrants were either recorded as additional debt discount or as a financing charge at date of issuance.

2005

(in thousand except per share data)

| | March 31, 2005 As previously reported | March 31, 2005 Restated (1) (2) (4) | June 30, 2005 As previously reported | June 30, 2005 Restated (1) (2) (4) | September 30, 2005 As previously reported | Sept 30, Rest (1) (2) |
|--|---|--|--|---|---|--------------------------------|
| Revenues | \$258 | \$258 | \$300 | \$300 | \$271 | |
| Costs and expenses | 2,348 | 2,393 | 2,670 | 2,784 | 2,386 | |
| Net loss applicable to common stockholders | (3,055) | (2,980) | (3,816) | (3,345) | (2,887) | (|
| Basic and diluted loss per share | \$ (.07) | \$ (.07) | \$ (.08) | \$ (.07) | \$ (.06) | |

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- (1) The Company re-evaluated the accounting for the March 2003, July 2003, October 2003, January 2004 and July 2004 Debentures (collectively, "the Debentures") to determine whether the embedded conversion options required bifurcation and fair value accounting in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities", and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed

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to, and Potentially Settled in a Company's Own Stock". The Company concluded that bifurcation was not required and that EITF 00-27 should have been applied. The Company did initially apply EITF 00-27, however as a part of performing an analysis on the guidelines set forth in EITF 00-27 it was determined that the initial accounting treatment and subsequent price resets for the Debentures that were originally applied and reflected in the financial statements. To properly account for the initial calculation of the discount and the conversion price resets triggered upon the issuance of the issuance of the October 2003 Debenture and the August 2004 Private Placement (See Notes 8 & 9 for more details on these resets), it was determined, under guidance from EITF 00-27 that the debt discount should be restated for the Debentures.

- (2) The estimation of fair value ascribed to and the accounting treatment of the investment banking fees paid to Cardinal Capital, LLC ("Cardinal") in connection with the Debenture issuances, at inception, was inaccurately reflected in the financial statements included in our Quarterly Reports on Form 10-Q and that, therefore, a restatement of our financial statements for the periods referenced above was required. In connection with the initial recording of the Debentures mentioned above, it was determined that the fair value of the warrants issued as investment banking fees paid to Cardinal, be accounted for as a discount to Debentures. These investment banking fees should have been capitalized as deferred financing costs and amortized over the life of the Debentures or charged to earnings on the earlier conversion thereof. In addition, the initial calculation of the fair value of the warrants issued to Cardinal as a part of the Debenture issuances was determined to have been applied incorrectly at the time of issuance.
- (3) The Company incorrectly recorded \$241,000 in other income in the third quarter 2005 related to the termination of the MOU notice received by Astellas. This amount was subsequently adjusted back to an accrued liability as of December 31, 2005, as the agreement has not yet been formally terminated.
- (4) The accounting for certain warrants and options issued to non-employees and our interpretation and application of FASB No. 123 was not correct in 2005.

(20) Subsequent Events

On February 8, 2006, the Company executed a Manufacturing and Safety Agreement with Hyaluron, Inc. ("Hyaluron") of Burlington, Massachusetts, for the formulation, packaging and labeling of Alferon N Injection(R). Pursuant to the Agreement, the Company will supply raw materials in sufficient quantity and provide any pertinent information to the project.

On March 21, 2006, the debenture holders converted \$500,000 of the July 2004 debenture into 240,385 shares of common stock.

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The Company failed to timely file its Annual Report on Form 10-K with the Securities and Exchange Commission pursuant to the 1934 Act, and therefore, was in violation of its covenant to timely file within its debenture agreements. The Company obtained a waiver letter from its debenture holders regarding the failure to meet this covenant. In addition, as a result of the Company's inability to timely file its annual report on Form 10-K for the year ended December 31, 2005, the Company currently is subject to liquidated damages until such time as the shares issuable upon conversion of and interest under the

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debentures, and shares issuable upon exercise of the warrants are again registered for public resale or eligible for resale pursuant to Rule 144(k) under the Securities Act. The Company anticipates the liquidated damages not to exceed \$250,000.

During 2006, the Company has issued an additional 4,913,669 shares for proceeds of \$11,979,994 which completes the terms of the July 8, 2005, Fusion Capital agreement (see Note 9(d)).

On April 3, 2006, the Company received a notice from the staff of The American Stock Exchange ("AMEX") indicating that it is not in compliance with Sections 134 and 1101 of the AMEX Company Guide and its listing agreement due to the Company's failure to file its annual report on Form 10-K for the fiscal year ended December 31, 2005 with audited financial statements on a timely basis. The AMEX has granted an extension of the listing of the Company's common stock until June 30, 2006, provided that the Company files its Form 10-K for 2005 by June 2, 2006 and provided that it files its Form 10-Q for the first quarter of 2006 by June 30, 2006. During the extension period, the Company will be subject to periodic review by AMEX staff. If the Company fails to meet any of the foregoing deadlines, the AMEX has indicated that it will begin delisting proceedings.

On April 12, 2006, the Company entered into a Common Stock Purchase Agreement ("Purchase Agreement") with Fusion Capital. Pursuant to the terms of the Purchase Agreement, Fusion Capital has agreed to purchase from the Company up to \$50,000,000 of common stock over a period of approximately twenty-five (25) months. Pursuant to the terms of the Registration Rights Agreement, dated as of April 12, 2006, we agreed to file a registration statement (the "Registration Statement") with the Securities and Exchange Commission on or before June 30, 2006 covering the shares which are issued to or may be issued to Fusion Capital under the Purchase Agreement. Once the Registration Statement has been declared effective, each trading day during the term of the Purchase Agreement we have the right to sell to Fusion Capital up to \$100,000 of our common stock on such date or the arithmetic average of the three lowest closing trade prices of the common stock during the immediately preceding 12 trading day period. At our option under certain conditions, Fusion Capital can be required to purchase greater amounts of common stock during a given period. In connection with entering into the Purchase Agreement, the Company issued to Fusion Capital 321,751 shares of our common stock. This offering was made pursuant to an exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended.

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Hemispherx Biopharma, Inc.
Schedule II -Valuation and Qualifying Accounts
(dollars in thousands)

| Column A | Column B | Column C | Column D | Column E |
|------------------------------|--------------------------------------|----------------------|----------------|--------------------------------|
| Description | Balance at beginning of period | Charge to expense | Write- offs | Balance at end of period |
| ----- | ----- | ----- | ---- | ----- |
| Year Ended December 31, 2005 | | | | |
| Reserve for inventory | \$ 225 | - | (125) | \$ 100 |
| Year Ended December 31, 2004 | | | | |
| Reserve for inventory | \$ - | 225 | - | \$ 225 |

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Year Ended December 31, 2003

| | | | | | | |
|-----------------------|----|---|---|---|----|---|
| Reserve for inventory | \$ | - | - | - | \$ | - |
|-----------------------|----|---|---|---|----|---|

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