

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

HEMISPHERX BIOPHARMA INC
Form 10-K/A
September 09, 2003

FORM 10-K/A-2
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, 2002
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. 0-27072

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

Delaware	52-0845822
----- (State or other jurisdiction of incorporation or organization)	----- (I.R.S. Employer Identification Number)
1617 JFK Boulevard Phila., Pennsylvania	19103
----- (Address of principal executive offices)	----- (Zip Code)

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

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

Common Stock, \$.001 par value

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

NONE

Indicate by check mark whether the registrant (1) has filed all reports to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes (X) No ()

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K/A or any amendment to this Form 10-K/A.

Yes () No (X)

The aggregate market value of Common Stock held by non-affiliates at June 30, 2002 was \$80,226,755. For purposes of this calculation, it was assumed that all Common Stock is valued at the closing price of the stock as of June 30, 2002.

The number of shares of the registrant's Common Stock outstanding as of March 31, 2003 was 32,941,445.

DOCUMENTS INCORPORATED BY REFERENCE

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

None.

TABLE OF CONTENTS

	Page
PART I	
Item 1. Business	1
Item 2. Properties	32
Item 3. Legal Proceedings	33
Item 4. Submission of Matters to a Vote of Security Holders	34
PART II	
Item 5. Market for the Registrant's Common Equity and Related Stockholder Matters	34
Item 6. Selected Financial Data	36
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	37
Item 7A. Quantitative and Qualitative Disclosure About Market Risk	48
Item 8. Financial Statements and Supplementary Data	48
Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosures	48
PART III	
Item 10. Directors and Executive Officers of the Registrant	48
Item 11. Executive Compensation	51
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	59
Item 13. Certain Relationships and Related Transactions	61
Item 14. Controls and Procedures	62
PART IV	
Item 15. Principal Accountant Fees and Services	62
Item 16. Exhibits, Financial Statement Schedules and Reports on Form 8-K	62

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K/A (this "Form 10-K/A"), including statements under "Item 1. Business," "Item 3 Legal Proceedings" and "Item 7. Management's Discussion and Analysis of Financial Condition and Result of Operations," constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995 (collectively, the "Reform Act"). Certain, but not necessarily all, of such forward-looking statements can be identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should," or "anticipates" or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. All statements other than statements of historical fact included in this Form 10-K/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 "Company", "we or "us") to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements and other factors referenced in this Form 10-K/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 were founded in the early 1970s as a contract researcher for the National Institutes of Health (NIH). Dr. William A. Carter, M.D., joined the Company in 1976 and ultimately became its CEO in 1988. He has focused the Company on exploring, understanding and mastering the mechanism of nucleic acid technology to produce a promising new class of drugs for treating chronic viral diseases and disorders of the immune system. 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 use our proprietary drug, Ampligen(R), to treat diseases for which adequate treatment is not available. We seek the required regulatory approvals which will allow the

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

progressive introduction of Ampligen(R) for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome ("ME/CFS"), HIV, Hepatitis C ("HCV") and Hepatitis B ("HBV") in the U.S., Canada, Europe and Japan. Ampligen(R) is currently in phase III clinical trials in the U.S. for use in treatment of ME/CFS and is in Phase IIb clinical trials in the U.S. for the treatment of newly emerged multi-drug resistant HIV, and for the induction of cell mediated immunity in HIV patients that are under control using potentially toxic drug cocktails.

In March, 2003, the Company acquired from Interferon Sciences Inc. ("ISI"), all of ISI's raw materials, work-in-progress and finished product of ALFERON N Injection(R), together with a limited license for the production, manufacture, use, marketing and sale of the product. ALFERON N Injection(R) [interferon alfa-n3 (human derived)] is a natural alpha interferon that has been approved by the U.S. Food and Drug Administration ("FDA") for commercial sale for the treatment of certain types of genital warts. We intend to market this product in the United States through sales facilitated via third party marketing agreements. In the future, we expect to implement studies, beyond those conducted by ISI, for testing the potential treatment of HIV, Hepatitis C and other indications, including multiple sclerosis. This acquisition notwithstanding, our primary focus remains the development of Ampligen(R) for treating ME/CFS and HIV diseases.

In March, 2003, we entered into an agreement with ISI subject to certain events that would grant us global rights to sell ALFERON N Injection(R) as well as acquire certain other assets of ISI which include but are not limited to real estate and property, plant and equipment.

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.

AMPLIGEN (R)

Our proprietary drug technology Ampligen(R) utilizes specially configured ribonucleic acid ("RNA") and is protected by more than 350 patents worldwide with over 80 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. The main U.S. ME/CFS treatment patent (#6130206) expires January 23, 2015. Our main patents covering HIV treatment (#4795744, #4820696, #5063209, and #5091374) expire on August 26, 2006, September 30, 2008, August 10, 2010, respectively; Hepatitis treatment coverage is conveyed by U.S. patent #5593973 which expires on October 15, 2014. The U.S. Ampligen(R) Trademark (#1,515,099) expires on December 6, 2008 and can be renewed thereafter for an additional ten years. The U.S. FDA has granted us "orphan drug status" for our nucleic acid-derived therapeutics for ME/CFS, HIV, and renal cell carcinoma and malignant melanoma. Orphan drug status grants the Company protection against competition for a period of seven years following FDA approval, as well as certain federal tax incentives, and other regulatory benefits.

Nucleic acid compounds represent a potential new class of pharmaceutical products that are designed to act at the molecular level for treatment of human diseases. There are two forms of nucleic acids, DNA and RNA. DNA is a group of naturally occurring molecules found in chromosomes, the cell's genetic machinery. RNA is a group of naturally occurring informational molecules which orchestrate a cell's behavior and which regulate the action of groups of cells, including the cells, which comprise the body's immune system. RNA directs the production of proteins and regulates certain cell activities including the activation of an otherwise dormant cellular defense against virus and tumors.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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

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

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)

ME/CFS is a debilitating disease that is difficult to diagnose and for which, at present, there is no cure. People suffering from this illness experience, among other symptoms, a constant tiredness, recurring dull headaches, joint and muscle aches, a feeling of feverishness and chills low grade fever, depression, difficulty in concentrating on tasks, and tender lymph glands. With progression of the disease they can become bed-ridden, lose their jobs and become dependent upon the state for support and medical care.

ME/CFS has been given official recognition by the U.S. Social Security Administration, and some European nations, rendering ME/CFS patients eligible for disability benefits and heightening awareness of this debilitating disease in the medical community. A further scientific publications by independent academicians on the accurate laboratory diagnosis of ME/CFS appeared in a peer-reviewed journal (American Journal of Medicine) in February 2000. The U.S. Centers for Disease Control ("CDC") reconfirmed its research commitment to ME/CFS following an audit by the U.S. Government Accounting Office ("GAO") which was announced July 28, 1999.

Estimates of ME/CFS patient numbers in the range from a low of 500,000 (1995-Centers for Disease Control, Atlanta, GA) to a high of 1,000,000 (1999-DePaul University study). Estimates of patient numbers in Europe range from 600,000 to 2,200,000 as reported in the British Medical Journal in January 2000. It is believed worldwide patient totals may be as high as ten million.

In 1989, we received FDA authorization to conduct a Phase II study of Ampligen(R) for ME/CFS. In 1991, we completed a 24-week, 92 patient, randomized, placebo-controlled, double-blinded, multi-center trial of Ampligen(R) for treating patients with ME/CFS. The results, published in a peer review journal in 1994, suggested enhanced physical performance, greater cognitive functions and improved ability to perform daily living activities. Patients required reduced hospitalization and medical care, while suffering little or no significant adverse side effects. The FDA raised certain issues with respect to this clinical trial, which required further study. These issues were reviewed and satisfactorily resolved.

In February 1993, Hemispherx presented results of its Phase II study of Ampligen(R) for ME/CFS to a FDA Advisory Committee and these results were published in early 1994 in Clinical Infectious Diseases, a peer reviewed medical journal, which emphasizes the understanding and potential treatment of infectious diseases. The results suggested that patients on Ampligen(R), in contrast to those receiving a placebo, showed significant improvement in physical capacity as determined by performance on treadmill testing. The Ampligen(R) treated patient group also required less pain medication than did the placebo group.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

In late 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, deemed as Amp 516, is to evaluate the safety and efficacy of Ampligen(R) as a treatment for ME/CFS. As of April 1, 2003 we have engaged the services of eleven (11) clinical investigators at Medical Centers in California, New Jersey, Florida, North Carolina, Wisconsin, Nevada, Illinois and Connecticut. These clinical investigators are 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 now has over 230 ME/CFS patients participating. The patients complete a stage I, forty week, double-blind, randomized, placebo-controlled portion of the clinical trial and then move into the stage II or the open label treatment portion of the clinical trial. To date there have been no serious adverse events reported related to the study medication. Additional ME/CFS patients have been recruited by the clinical investigators to, in effect, over-enroll the program. We expect to have in excess of the full enrollment in order to compensate for potential patient "drop outs", i.e.; patients that discontinue the program prematurely for various reasons. The next stage in our program is final data collection, quality assurance of data to insure its accuracy and analysis of the data according to regulatory guidelines to facilitate filing for commercial approval to sell.

Human Immunodeficiency Virus (HIV)

About fifteen antiviral drugs are currently approved by the FDA for the treatment of HIV infection. All 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. Treatments include different classes of drugs, but they all work by stopping parts of the virus so the virus cannot reproduce. Experience has shown that using combinations of drugs from different classes is a more effective strategy than using only one or two drugs. HAART has provided dramatic decreases in morbidity and mortality of HIV infection. Reduction of the viral load to undetectable levels in patients with wild type virus (i.e., non-drug-resistant virus) is routinely possible with the appropriate application of HAART. HIV mainly infects important immune system cells called CD4 cells. After HIV has infected a CD4 cell, the CD4 cell becomes damaged and is eventually destroyed. Fewer CD4 cells means more damage to the immune system and, ultimately, results in AIDS. Originally, reduction of HIV loads was seen as possibly allowing the reconstitution of the immune system and led to early speculation that HIV might be eliminated by HAART.

Subsequent experience has provided a more realistic view of HAART and the realization that chronic HIV suppression using HAART, as currently practiced, would require treatment for life with resulting significant cumulative toxicities. The various deferred as "RT" on page 6 and protease inhibitor drugs that go into HAART have significantly reduced the morbidity and mortality connected with HIV; however there has been a significant cost due to drug toxicity. It is estimated that 50% of HIV deaths are from the toxicity of the drugs in HAART. Current 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 makes this goal impractical.

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

Failure of antiretroviral therapies over time and the demonstration of

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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

We believe that the concept of Strategic Therapeutic Interruption ("STI") of HAART provides a unique opportunity to minimize the current deficiencies of HAART while retaining the HIV suppression capacities of HAART. STI is the cessation of HAART until HIV again becomes detectable (i.e., rebounds) followed by resumption of HAART with subsequent suppression of HIV. By re-institution of HAART, HIV is suppressed before it can inflict damage to the immune system of the patient. Based on recent publications (AIDS 2001,15: E19-27 and AIDS 2001, 15:1359-1368) in peer reviewed medical literature, it is expected that in just 30 days after stopping HAART, approximately 80% to 90% of the patients will suffer a relapse evidencing detectable levels of HIV. The Company believes that Ampligen(R) combined with the STI (strategic treatment interruption) approach may offer a unique opportunity to retain HAART's superb ability to suppress HIV while potentially minimizing its deficiencies. All present approved drugs block certain steps in the life cycles of HIV. None of these drugs address the immune system, as Ampligen(R) potentially does, although HIV is an immune-based disease.

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. The Company's minimum expectation is that Ampligen(R) has the 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. We plan to present the follow on clinical results of using our technology at several International AIDS Scientific Forums in 2003, including the XVI International Conference on Antiviral Research in Savannah, Georgia in April 2003.

Our AMP 720 HIV Clinical Trial is being conducted with individuals infected with HIV who are responding well to HAART at the moment. Patients in this study are required to meet minimum immune system requirements of CD4 cell levels greater than 400, maximum HIV infection levels of less than 50 copies/ml, and a HAART regimen containing at least one antiviral drug showing therapeutic synergy with Ampligen(R) based on recently reported ex vivo studies in peer-reviewed scientific journals. All patients are chronically HIV infected and will have been receiving the indicated HAART regimen prior to starting the STI. The trial applies STI of HAART based on the hypothesis that careful management of HIV rebound following STI may have potential to result in the development of protective immune responses to HIV in order to achieve control of HIV replication. The Company believes that the addition of Ampligen(R), with its potential immunomodulatory properties, may reasonably achieve this outcome. Half of the participants in the trial are given 400 mg of Ampligen(R) twice a week and once they start the STI will remain off of HAART until such time as their HIV rebounds. The other half of the participants (the control group) are on STI, but they are given no Ampligen(R) during the "control" portion of the clinical test.

The targeted enrollment in the AMP 720 clinical trial is 120 HIV-infected persons who meet the criteria. We expect to have 60 people on STI with Ampligen(R) and 60 people on STI without Ampligen(R). Presently, this study is approximately 35% enrolled at ten medical centers around the U.S. The Company expects enrollment in this clinical trial to accelerate as we recruit more investigators and based on the analysis and presentation of results in Prague, Czech Republic, Barcelona, Spain and Naples, FL (December, 2002). The length of this stage of the trial will be determined by an analysis of the interim results.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Hepatitis C Virus (HCV)

We currently have an informal arrangement with the California Institute of Molecular Medicine ("CIMM") to collaborate and assist their efforts to replicate human Kupffer's cells obtained from HCV infected patients. This proprietary CIMM approach involves the in vitro growth of hepatic macrophages (called Kupffer's cells) from the failing liver of a patient and reinfusion of the in vitro grown Kupffer's liver cells into the same patient. The ability to grow HCV in long term culture that would allow the testing of potential anti-HCV drugs in vitro would permit us to conduct and obtain valuable research data in using Ampligen(R) to treat HCV prior to engaging and clinical trial. This would not raise the question of immunological incompatibility. Testing by CIMM indicates that their process of Kupffer's cells application in vitro is reproducible (>95% efficacy) from individual patients. CIMM is also developing a process for maintaining and propagating Kupffer's cells reproducibly in defined cell cultures from fine needle liver aspirates from living human volunteers with potential as patients with failing liver due to a variety of etiologies.

In January 2001 CIMM filed a Notice of Invention with the U.S. Patent Office. As a result, a patent titled "Replication of Human Kupffer's cell obtained from HCV infected patients by Fine Needle Biopsy Technique", was issued. This method can potentially salvage critically needed liver function without major surgery or aggressive medical intervention.

The immediate and potential market for the Kupffer's maintenance and propagation techniques will be more than 14,000 people in the U.S. actively seeking a liver transplant. Additional thousands are progressing towards a failing liver and will soon need transplantation or a successful alternative method to restore function. Several hundred thousand who have alcoholic cirrhosis may also benefit from the proprietary process. Medical costs of a liver transplant are approximately \$300,000 and are far beyond the financial reserves of most families. Reimbursement of these costs by health insurance carriers is problematic at best. We have a 30% equity position in CIMM, recently opened a new state-of-the-art research laboratory in Ventura, California.

We are also evaluating potential novel clinical programs which would involve using Ampligen(R) to treat both HCV and HIV when they coexist on the same patient. We expect to commence these studies in collaboration with one or more prospective corporate partners. A collaborative Clinical study in Europe, in conjunction with Laboratorios Del Dr. Esteve S.A., is expected to commence during the first half of 2003.

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

Other Diseases

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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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.

Other Antiviral/ Immunologic Treatments

After the terrorist acts of September 11, 2001 and the resultant International concern for bio-terrorism (including smallpox), we filed a regulatory application with the FDA for permission to conduct a clinical trial, in the event of smallpox dissemination, using Ampligen(R) therapy as a treatment. This proposed study was based on an earlier peer reviewed laboratory study from Yale University in Partnership with the U.S. Military Command at Fort Detrick, the U.S. Biological Defense Specialty Research Center. The result of this study indicated Ampligen(R) to be promising in a laboratory model of smallpox.

Based on these and other recent positive results (see below), we have retained FDA regulatory counsel in Washington D.C., to advise us on a commercialization path and to arrange relevant meetings with the FDA.

During the 30 day review period of our clinical application by the FDA, we became aware of a new ongoing laboratory study of Ampligen(R) in smallpox at the Riga Medical Institute in Belgium. Our Medical Director had authorized the Institute to use samples of Ampligen(R) for research purposes only. The result of this study became available in early 2003. In the interim, we withdrew our FDA application to review the results of the Belgium study and incorporate such data into our clinical study design and protocol before resubmission. Positive new results on Ampligen(R) were thereafter reported by branches of the U.S. government using animal models of smallpox and new guidelines on bio-terrorism approvals were established which mandated only animal studies for full commercialization.

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(R) Injection product contains a multi-species form of alpha interferon. The worldwide market for injectable alpha interferon-based products has experienced rapid growth and various alpha interferon injectable products are approved for many major medical uses worldwide.

Alpha interferons are manufactured commercially in three ways: by genetic engineering, by cell culture, and from human white blood cells. In the United States, all three of these types of alpha interferon are approved for commercial sale. Our Natural Alpha Interferon is produced from human white blood cells.

The potential advantages of natural alpha interferon over recombinant interferon may be based upon their respective molecular compositions. Natural Interferon is composed of a family of proteins containing many molecular species of interferon. In contrast, recombinant alpha interferons each contain only a single species. Researchers have reported that the various species of interferon may have differing antiviral activity depending upon the type of virus. Natural alpha interferon presents a broad complement of species, which the Company believes may account for its higher efficacy in laboratory studies. Natural alpha interferon is also glycosylated (partially covered with sugar molecules). Such glycosylation is not present on the currently marketed recombinant alpha interferons. The Company believes 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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

culture-derived interferon is also composed of multiple glycosylated alpha interferon species, the types and relative quantity of these species are different from the Company's natural alpha interferon.

On October 10, 1989, the FDA approved ALFERON N Injection 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 cases of genital warts occur annually in the alone.

Basically, our interest in acquiring ALFERON N was driven by two factors;

- 1) Our belief that its use 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 immune response
- 2) New knowledge about the competitive products in the Interferon arena that we believe imply a large untapped market and potential new therapeutic indication for ALFERON N which could accelerate its revenues in the near term. Specifically, the recombinant DNA derived alpha interferons are now reported to have dramatically decreased effectiveness after one year, probably due to antibody formation and other severe toxicities. These detrimental effects have not been reported with ALFERON N which could allow this product to assume a much larger market share. These revenues would provide operational capital to complete the Phase III clinical trials of our experimental drug, Ampligen(R) in a more cost effective, non-dilutive manner on a shareholder's equity.

ALFERON N Injection(R) [Interferon alfa-n3 (human leukocyte derived)] is a highly purified, natural-source, glycosylated, multispecies alpha interferon product. There are essentially no antibodies observed against natural interferon to date and the product has a relatively low side-effect profile. Alferon is the only natural-source, multispecies alpha interferon currently sold in the U.S. and is also approved for sale in Mexico, Germany, Singapore and Hong Kong.

The ALFERON targeted market consists of urologists, proctologists, dermatologists, and obstetricians/gynecologists. These physicians normally see patients with papilloma condylomas (genital warts) in their practice. This will be done in existing partnership with our strategic partners including Gentiva Health Services, Biovail Corporation and Esteve Laboratories. All have proven marketing expertise.

According to the NIH, there are one million new cases of venereal warts every year.

Pipeline Products (Alpha Interferon)

The following products, together with other assets are to be acquired upon the closing of the second ISI agreement, which is anticipated to occur in May 2003.

ALFERON N Injection(R) -Other Applications

ALFERON N Injection(R) has been approved by the U.S. FDA for the treatment of certain types of genital warts and has been studied for the potential treatment of HIV, Hepatitis C and other indications. ISI, the company from which we obtained our rights to ALFERON N Injection had conducted clinical trials with

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

regard to the use of ALFERON N Injection in the treatment of HIV and Hepatitis C. While ISI found the results to be encouraging, in both instances, the FDA determined that additional trials were necessary.

ALFERON N Gel(R)

ALFERON N GEL(R) is the Company's registered trademark for its topical (dermatological) natural alpha interferon preparation in a hydrophilic gel base. This product is still in research and development.

ALFERON LDO(R)

ALFERON LDO(R) is the registered trademark for the low-dose, oral liquid formulation of natural alpha interferon. Two Phase 2 clinical trials using ALFERON LDO for the treatment of HIV-infected patients have been completed.

There can be no assurance that any of these proposed products will be cost-effective, safe, and effective or that the Company will be able to obtain FDA approval for such use. Furthermore, even if such approval is obtained, there can be no assurance that such products will be commercially successful or will produce significant revenues or profits for the Company.

EUROPEAN OPERATIONS

Our European operations were set up to prepare for the introduction of Hemispherx products and to accelerate market penetration into the European market once full approval is obtained from the European Medicine Evaluation Agency ("EMEA"). The EMEA is the equivalent of the United States FDA. From a regulatory point of view the member countries of the European Economic Union ("EEU") represent a common market under the jurisdiction of the EMEA. However, from a practical point of view, every country is different regarding developing relations with the medical community, patient associations and obtaining reimbursement for treatment from the equivalent of Social Security Agencies and insurance carriers. This program will be integrated into our new commercial asset, ALFERON N Injection, as well.

Our European operations have assisted the growth of a number of patient/physician educational associations. The French Chronic Fatigue Syndrome Association has grown from ten members in the year 2000 to 800 currently. Every major country now has an active educational association with substantial numbers of members who regularly meet and "network". These programs have been modeled on the successful experience in the U.S. of conducting twice a year meetings on ME/CFS with Health and Human Services, FDA, NIH and Centers for Disease Control.

We maintain contact with the EMEA, keeping the agency aware of our activities, as well as the health ministries in numerous countries in the European Union. In early 2001, our application for "orphan" drug status for the use of Ampligen(R) in ME/CFS was rejected because the Board found that the prevalence of ME/CFS was significantly above the five person per 10,000 limit required to grant orphan drug status in the European Union. In addition, we are exploring various ways to accelerate the commercial availability of our products in the various nations of the EEU, including potential appreciation of the "foreign import" rule for accepting products already approved in the U.S.

Limited number ME/CFS patients were treated during 2002 with Ampligen(R) in the United Kingdom, Austria and Belgium under existing regulatory procedures in these countries, which allow the therapeutic use of an experimental drug under certain conditions. These procedures allowed us to recover the cost of Ampligen(R) used as well as to collect additional clinical data. Corresponding

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

procedures are being considered in several other countries at the request of locally based physicians.

Our European operations are considering implementing clinical trials in Europe for the use of Ampligen(R) in the treatment of HIV/AIDS on the basis of the new U.S. Protocols involving the use of the drug either in combination with "cocktail" therapies or as part of a strategic interruption of the "cocktail" therapies. We plan to present these programs at European scientific conferences in 2003.

The efforts of our European operation has started to produce results. In March 2002, our European subsidiary Hemispherx Biopharma Europe, S.A. ("Hemispherx, S.A.") entered into a Sales and Distribution Agreement with Laboratorios Del Dr. Esteve S.A. ("Esteve"). Pursuant to the terms of the Agreement, Esteve was granted the exclusive right to market Ampligen(R) in Spain, Portugal and Andorra ("Territory") for the treatment of 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. FDA 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.

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). 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.

MANUFACTURING

We outsource 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 acquire 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. Two manufacturers in the United States are available to provide the polymers if Ribotech is unable to supply our needs. Sourcing our needs from other suppliers could result in a cost increase for our raw materials.

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). At the present time, we have engaged the services of Schering-Plough Products to mass produce ready-to-use Ampligen(R) doses. There are other pharmaceutical processing companies that can supply our production needs.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Bioclones (PTY) Ltd. is headquartered in South Africa and is the majority owner in Ribotech, Ltd. (the Company owns 24.9%) which produces most of the polymers used in manufacturing Ampligen(R). The licensing agreement with Bioclones presently includes South Africa, South America, Ireland, New Zealand and the United Kingdom.

We currently occupy and use the New Brunswick, New Jersey laboratory and production facility owned by ISI. We are in the process of acquiring title to these facilities pursuant to our second asset acquisition agreement with ISI (see RECENT FINANCING AND ASSET ACQUISITIONS below for more details). This facility is approved by the FDA for the manufacture of ALFERON N.

All Production Facilities Employ Good Manufacturing Practices.(GMP)

Good Manufacturing Practices (GMP) require that a product be consistently manufactured to an identical potency (strength) and purity with each lot, and that the manufacturing facility itself and all the equipment therein, be certified to operate within a strict set of performance standards.

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, 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 provide 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, the Company and Gentiva Health Services (formerly Olstein 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 area. 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 South America, the United Kingdom, Ireland, Africa, Australia, Tasmania, New Zealand, and certain other countries and territories, we contemplate marketing our product through our relationship with Bioclones pursuant to the Bioclones Agreement.

Our marketing and distribution plan for ALFERON N is focused on increasing the sales of ALFERON N INJECTION for the intralesional treatment of refractory and recurring external genital warts in adults. We will reach out to a targeted audience of physicians consisting of OB/GYNS, Urologists, Proctologists and Dermatologists and simultaneously create product awareness in the patient

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

population through several media and health organizations. Different regional meetings and seminars are scheduled during which guest speakers will explain the therapeutic benefits and safety profile of ALFERON. Additional exposure will be created by exhibiting at several STD-related conferences, expanded web presence, and mailings and publications. We also plan to engage a contract sales organization in order to build up a nationwide network of dedicated representatives in the U.S. and Europe. This will be done while working with our strategic partners including Gentiva Health Services, Biovail Corporation and Esteve Laboratories.

For more information about our arrangements with Gentiva Health Services, Bioclones, Esteve and Biovail see below, "RESEARCH AND DEVELOPMENT/COLLABORATIVE AGREEMENTS".

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 and Schering-Plough Corp. ("Schering"). ALFERON N Injection currently competes with a product produced by Schering for treating genital warts. 3M Pharmaceutical also has received FDA approval for its immune response modifier product for the treatment of genital and perianal warts.

GOVERNMENT REGULATION

Regulation by governmental authorities in the U.S. and foreign countries is and will be a significant factor in the manufacture and marketing of ALFERON N products and our ongoing research and product development activities. Ampligen(R) and the products developed from the ongoing research and product development activities will require regulatory clearances prior to commercialization. In particular, new 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 the

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Company and its 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 is only approved for use in treating genital warts. Use of ALFERON N 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 March 31, 2003, we have not received a Fast-Track designation for any of our potential therapeutic indications although we have received "Orphan Drug Designation" for both ME/CFS and HIV/AIDS in the U.S. We will continue to present data from time to time in support of obtaining accelerated review. We have not yet submitted any New Drug Application (NDA) for Ampligen(R) or any other drug to a North American regulatory authority. There are no assurances that such designation will be granted, or if granted, there are no assurances that Fast Track designation will materially increase the prospect of a successful commercial application. 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 the Company's drug is combined with certain presently available antiretroviral agents. Interim results were presented in 2002 at various international scientific meetings.

We are subject to various federal, state and local laws, regulations and recommendations relating to such matters as safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use of and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. We believe that our Rockville, Maryland manufacturing and quality assurance/control facility is in substantial compliance with all material regulations applicable to these activities as advanced by the European Union Inspections team which conducted detailed audits in year 2000. 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. These third party facilities include manufacturing operations in San Juan, Puerto Rico; Capetown, South Africa; Columbia, Maryland; Melbourne, Australia; and potential expansion within the United States to new and larger facilities in 2003.

RESEARCH AND DEVELOPMENT/COLLABORATIVE AGREEMENTS

In 1994, we entered into a licensing agreement with Bioclones (Proprietary) see page 13 limited ("Bioclones") for manufacturing and international market development in Africa, Australia, New Zealand, Tasmania, the United Kingdom, Ireland and certain countries in South Africa, of Ampligen(R) and Oragen(TM). Bioclones is to pursue regulatory approval in the areas of its franchise and is required to conduct Hepatitis clinical trials, based on international GMP and GLP defense standards. Thus far, these Hepatitis studies have not yet commenced to a meaningful level. Bioclones has been given the first right of refusal, subject to pricing, to manufacture that amount of polymers utilized in the production of Ampligen(R) sufficient to satisfy at least one-third of the worldwide sales requirement of Ampligen(R) and other nucleic acid-derived drugs. Pursuant to this arrangement, we received: 1) access to worldwide markets, 2)

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

commercial-scale manufacturing resources, 3) a \$3 million cash payment in 1995 from Bioclones, 4) a 24.9% ownership in Ribotech, Ltd., a company set up by Bioclones to develop and manufacture RNA drug compounds, and 5) royalties of 8% on Bioclones nucleic acid-derived drug sales in the licensed territories. The agreement with Bioclones terminates three years after the expiration of the last of the patents supporting the license granted to Bioclones, subject to earlier termination by the parties for uncured defaults under the agreement, or bankruptcy or insolvency of either party. The last patent expires on December 22, 2012.

In August 1998, we entered into a strategic alliance with Gentiva already deferred to develop certain marketing and distribution capacities for Ampligen(R) in the United States. Gentiva is one of the nation's largest home health care companies with over 400 offices and 60,000 caregivers nationwide. Pursuant to the agreement, Gentiva assumed certain responsibilities for distribution of Ampligen(R) for which they receive a fee. Through this arrangement, Hemispherx may mitigate the necessity of incurring certain up-front costs. Gentiva also works with us in connection with the Amp 511 ME/CFS cost recovery treatment program, Amp 516 ME/CFS PIII clinical trial and the Amp 719 (combining Ampligen with other antiviral drugs in HIV-salvage therapy and Amp 720 HIV Phase IIb clinical trials now under way. There can be no assurances that this alliance will develop a significant commercial position in any of its targeted chronic disease markets. The agreement had an initial one year term from February 9, 1998 with successive additional one year terms unless either party notifies the other not less than 180 days prior to the anniversary date of its intent to terminate the agreement. Also, the agreement may be terminated for the 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 Gentiva or another major drug distributor. There were no initial fees and subsequent fees paid under this agreement total \$59,000 for services performed.

We have acquired a series of patents on Oragen(TM), potentially an oral broad spectrum antiviral, immunological enhancer through a licensing agreement with Temple University. We were granted an exclusive worldwide license from Temple for the Oragen(TM) products. Pursuant to the arrangement, we are obligated to pay royalties of 2% to 4% on sales of Oragen(TM), depending on how much technological assistance is required of Temple. There were no initial fees and we currently pay minimum royalties of \$30,000 per year to Temple. These compounds have been evaluated in various academic and government laboratories for application to chronic viral and immunological disorders. This agreement is to remain in effect until the date that the last licensed patent expires unless terminated sooner by mutual consent or default due to royalties not being paid. The last Oragen(TM) patent expires on August 22, 2015.

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. 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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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

In May 2000, we acquired an interest in Chronix Biomedical Corp. ("CHRONIX"). Chronix focuses upon the development of diagnostics for chronic diseases. We issued 100,000 shares of common stock to Chronix toward a total equity investment of \$700,000. Pursuant to a strategic alliance agreement, we provided Chronix with \$250,000 to conduct research in an effort to develop intellectual property on potential new products for diagnosing and treating various chronic illnesses such as ME/CFS. The strategic alliance agreement provides us certain royalty rights with respect to certain diagnostic technology developed from this research and a right of first refusal to license certain therapeutic technology developed from this research. The strategic alliance agreement provides us with a royalty payment of 10% of all net sales of diagnostic technology developed by Chronix for diagnosing Chronic Fatigue Syndrome, Gulf War Syndrome and Human Herpes Virus-6 associated diseases. The royalty continues for the longer of 12 years from September 15, 2000 or the life of any patent(s) issued with regard to the diagnostic technology. The strategic alliance agreement also provides us with the right of first refusal to acquire an exclusive worldwide license for any and all therapeutic technology developed by Chronix on or before September 14, 2012 for treating Chronic Fatigue Syndrome, Gulf War Syndrome and Human Herpes Virus-6 associated. During the quarter ended December 31, 2002, we recorded a noncash charge of \$292,000 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 their current proposed equity offerings.

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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

the Consolidated Statements of Operations under the caption "Equity loss in unconsolidated affiliate". We still believe CIMM will succeed in their efforts to advance therapeutic treatment of HCV. We believe that CIMM's Hepatitis C diagnostic technology has great promise and will fill a long-standing global void in the collective abilities to diagnose and treat Hepatitis C infection at an early stage of the disorder.

In March 2002, our European subsidiary Hemispherx, S.A. entered into a Sales and Distribution Agreement with Esteve. Pursuant to the terms of the agreement, Esteve was granted the exclusive right to market Ampligen(R) in Spain, Portugal and Andorra for the treatment of ME/CFS. In addition to other terms and other projected payments, Esteve agreed to conduct certain clinical trials using Ampligen(R) in the patient population coinfecting with Hepatitis C 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). The agreement is terminable by either party if Ampligen(R) is withdrawn from the territory for a specified period due to serious adverse health or safety reasons; bankruptcy, insolvency or related issues of one of the parties; or material breach of the agreement. Hemispherx may transform the agreement into a non-exclusive agreement or terminate the agreement in the event that Esteve does not meet specified percentages of its annual minimum purchase requirements under the agreement. Esteve may terminate the agreement in the event that Hemispherx fails to supply Ampligen(R) to the territory for a specified period of time or certain clinical trials being conducted by Hemispherx are not successful. The last patent with respect to this agreement expires on June 5, 2012.

The development of our nucleic acid based products requires the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market and to establish commercial-scale production and marketing capabilities. During our last three fiscal years, we have directly spent approximately \$16,862,000 in research and development, of which approximately \$4,946,000 was expended in the year ended December 31, 2002. These direct costs do not include the overhead and administrative costs necessary to support the research and development effort. Our European subsidiary has an exclusive license on all the technology and support from us concerning Ampligen(R) for the use of ME/CFS and other applications for all countries of the European Union (excluding the UK where Bioclones has a marketing license) and Norway, Switzerland, Hungary, Poland, the Balkans, Russia, Ukraine, Romania, Bulgaria, Slovakia, Turkey, Iceland and Liechtenstein. As mentioned above, Hemispherx S.A. entered into a Sales and Distribution Agreement with Esteve. Pursuant to the terms of this agreement, Esteve has been granted the exclusive right in Spain, Portugal and Andorra to market Ampligen(R) for the treatment of ME/CFS. See "EUROPEAN OPERATIONS" above for more detailed information.

HUMAN RESOURCES

As of March 31, 2003 we had 40 personnel working on the development of Ampligen(R) consisting of 19 full time employees, 3 part-time employees and 18 regulatory/research medical personnel on a part time basis. Part time parties are paid on a per diem or monthly basis. Thirty personnel are engaged in our research, development, clinical, & manufacturing effort. Ten of our personnel perform regulatory, general administration, data processing, including bio-statistics, financial and investor relations functions.

In addition to the foregoing personnel, on March 11, 2003, pursuant to our agreement with ISI, we added personnel from ISI to our payroll, consisting of 12 part-time and 17 full-time employees.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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

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

RECENT FINANCING AND ASSET ACQUISITIONS

On March 12, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due January 31, 2005 and an aggregate of 743,288 Warrants to two investors in a private placement for aggregate anticipated gross proceeds of \$4,650,000 realizing net proceeds of \$4,423,000 after legal and related costs. Pursuant to the terms of the Debentures, \$1,550,000 of the proceeds from the sale of the Debentures have been held back and will be released to us if, and only if, we acquire ISI's facility within 90 days from March 12, 2003. Consummation of the acquisition of ISI's facility requires, among other things, approval by ISI's shareholders and certain environmental approvals. As of the date hereof, there is the possibility that either or both approvals may not be obtained within the required 90 day period. Our failure to complete the acquisition within the 90 day period would be a technical default of the terms of the Debentures and, absent consent from the Debenture holders for additional time, would result in our having to redeem the securities. If we do not receive the additional Debenture funds as planned and, especially if we are required to redeem the Debentures, our financial condition would be materially and adversely affected and we would probably have to reduce or possibly curtail operational spending including some critical clinical effort. The Debentures mature on January 31, 2005 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Pursuant to the terms and conditions of the Senior Convertible Debentures, we have pledged all of our assets other than intellectual property, as collateral and are subject to comply with certain financial and negative covenants, which include but are not limited to the repayment of principal balances upon achieving certain revenue milestones.

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

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

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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

conversion of the Debentures, as interest shares under the Debenture and upon exercise of the Warrants. In accordance with this agreement, we filed a Registration Statement on Form S-3 with the Securities and Exchange Commission. If the Registration Statement is not declared effective within the time period required by the agreement or, after it is declared effective and subject to certain exceptions, sales of all shares required to be registered thereon cannot be made pursuant thereto, then we will be required to pay to the investors their pro rata share of \$3,635 for each day any of the above conditions exist with respect to this Registration Statement.

On March 11, 2003, we executed two agreements with ISI to purchase certain assets of ISI.

In the first agreement with ISI, the Company acquired ISI's inventory of ALFERON N Injection(R), and a limited license for the production, manufacture, use, marketing and sale of this product. For these assets, the Company:

- (i) issued 487,028 shares of its common stock; and
- (ii) agreed to pay ISI 6 % of the net sales of the product.

The Company also is required to pay ISI a service fee and pay certain of ISI's obligations related to the product and their employees. These costs approximate \$1,170,996.

In the second agreement with ISI, ISI has agreed to sell to the Company all of ISI's 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 will:

- (i) issue an additional 487,028 shares of its common stock; and
- (ii) continue to pay ISI 6 % of the net sales of the product.

In addition, the Company will be required to satisfy three obligations of ISI. The Company will satisfy two of these obligations, pursuant to Forbearance Agreements with The American National Red Cross and GP Strategies Corporation, two of ISI's creditors, by issuing an aggregate of 581,761 shares of common stock to these creditors. The third obligation is approximately \$521,000 and is secured by a lien on the property.

Pursuant to the agreements with ISI and its creditors, the Company is in the process of registering the foregoing shares issued and to be issued to ISI and its creditors for public sale in the Registration Statement on Form S-3 mentioned above. Except for 125,000 of the shares issued and to be issued to ISI, the Company has guaranteed the market value of the shares retained by ISI and the two creditors through March 11, 2005 to be \$1.59 per share for a total of \$2,275,000. ISI and the creditors are permitted to periodically sell certain amounts of their shares.

Our overall consideration for the assets acquired in the first and second agreement consisting of stock, assumption of debt, commitments and obligations relating to the real estate and equipment is expected to be \$4,149,996 of which \$1,691,996 will be cash.

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

During March 2002, Hemispherx Biopharma Europe, S.A., our Luxembourg subsidiary, was authorized to issue up to 22,000,000 Euros of (7%) convertible preferred securities. Such securities will be guaranteed by the Company and will be converted into a specified number of shares pursuant to the Securities

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Agreement. Conversion is to occur on the earlier of an initial public offering of Hemispherx S.A. on a European stock exchange on September 30, 2003.

On March 13, 2003, we issued 347,445 shares of our common stock to Provesan SA, an affiliate of Esteve, in exchange for 1,000,000 Euros of convertible preferred equity certificates of Hemispherx S.A., owned by Esteve, and all dividends earned and to be earned through September 30, 2003. We agreed to register the shares issued to Provesan SA, and we are in the process of registering these shares for public sale in the Registration Statement on Form S-3 mentioned above.

On March 31, 2003 we settled our outstanding claim with an insurance company relating to reimbursement of expenses in connection with our Asensio law suits. See Legal Proceedings for more detailed information. The terms of the settlement are confidential. We have applied the net proceeds of approximately \$1,050,000 as a reduction in general and administrative expenses in our Statement of Operations for the year ended December 31, 2002.

As of December 31, 2002, we had approximately \$2,811,000 in cash and short term investments. We believe that these funds plus 1) the anticipated infusion of approximately \$4.4 million in net proceeds from the Debenture placement, 2) projected net cash flow from the acquisition of ALFERON N and 3) the funds received from the insurance settlement should be sufficient to meet our operating requirements for the next 12 months.

In addition, we may raise additional funds through additional equity or debt financing, collaborative arrangements with corporate partners, lease financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes and begin commercializing our products. If adequate funds are not available from operations and if we are not able to secure additional sources of financing on acceptable terms, we would be materially adversely affected in our commercialization process.

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, or if ever, Ampligen(R) or our other products will be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the U.S. Food and Drug Administration ("FDA") for commercial sale.

ALFERON N Injection(R). Although ALFERON N Injection is approved for marketing for the treatment of genital warts, to date it has not been approved for other applications. 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.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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

All of our drugs and associated technologies other than ALFERON N Injection are investigational and must receive prior regulatory approval by appropriate regulatory authorities for general use and are currently legally available only through clinical trials with specified disorders. At present, ALFERON N Injection is only approved for the treatment of genital warts. Use of ALFERON N Injection for other applications will require regulatory approval. In this regard, Interferon Sciences, Inc., ("ISI") the company from which we obtained our rights to ALFERON N Injection, conducted clinical trials related to use of ALFERON N Injection for treatment of HIV and Hepatitis C. In both instances, the FDA determined that additional studies were necessary in order to fully evaluate the efficacy of ALFERON N Injection(R) in the treatment of HIV and Hepatitis C diseases. We have no obligation or plans to conduct these additional studies at this time. Our principal development efforts are currently focused on Ampligen(R), which has not been approved for commercial use. Our products, including Ampligen(R), are subject to extensive regulation by numerous governmental authorities in the U.S. and other countries, including, but not limited to, the FDA in the U.S., the Health Protection Branch("HPB") of Canada, and the European Medical Evaluation Agency ("EMEA") in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen(R) or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen(R) will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligen(R) is authorized for use in clinical trials in the US and other countries, we cannot assure you that additional clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials. If Ampligen(R), or one of our other products does not receive regulatory approval in the U.S. or elsewhere, our operations will be materially adversely effected.

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, 2002 our accumulated deficit was approximately \$99,000,000. 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 profitably.

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. Based upon our current operating plan, we anticipate that we will need approximately \$5,400,000 over the next 12 months, inclusive of

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

revenues and financing, to sustain our operations. In March 2003, we received \$2,873,000 in initial net proceeds from the sale of the Debentures and Warrants and, pursuant to the terms of the Debentures, if and when we close on the second ISI asset acquisition, we will receive additional net proceeds of \$1,550,000. We anticipate receipt of revenues and proceeds from the sales of Ampligen(R) under the Cost Recovery Clinical Programs and, possibly, funds from the exercise of outstanding non-public warrants. We also anticipate significant revenues from our recently acquired commercial product, ALFERON N. As of May 1, 2003, we had approximately \$3.6 Million in cash and short term investments. We believe that these funds plus 1) the anticipated infusion of approximately \$1.55 million in remaining net proceeds from the Debenture placement and 2) the projected net cash flow from the sale of ALFERON N should be sufficient to meet our operating requirement for the next 12 months. We may need to raise additional funds through additional equity or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes and begin commercializing Ampligen(R) products. There can be no assurances that we will raise adequate funds from these or other sources, which may have a material effect on our ability to develop our products. In addition, if we do not timely complete the second ISI asset acquisition, our financial condition could be materially and adversely affected (see the next risk factor).

If we do not complete the second Interferon Sciences, Inc. ("ISI") asset acquisition, our ability to generate revenues from the sale of ALFERON N Injection and our financial condition will be adversely affected.

In March, 2003 we executed two agreements with Interferon Sciences, Inc. ("ISI") to purchase certain assets of ISI. In the first agreement we acquired ISI's inventory of ALFERON N Injection(R) and a limited license for the production, manufacture, use, marketing and sale of this product. Our ability to generate sustained revenues from sales of this product is dependent, among other things, on our completing the terms of the second agreement to acquire the balance of ISI's rights to its product as well as ISI's production facility used to formulate and purify the drug concentrate of ALFERON N Injection(R). In addition, pursuant to the terms of the Debentures, we are required to acquire ISI's facility within 90 days from March 12, 2003 and, unless and until we acquire the facility, \$1,550,000 of the proceeds from the sale of the Debentures has been held back. Consummation of the second agreement requires, among other things, approval by ISI's shareholders and certain environmental approvals with regard to the sale of the facility. As of the date hereof, there is the possibility that either or both approvals may not be obtained within the required 90 day period. Our failure to complete the acquisition within the 90 day period would be a technical default of the terms of the Debentures and, absent consent from the Debenture holders for additional time, most likely would result in our having to redeem the securities. If we do not receive the additional Debenture funds as planned and, especially if we are required to redeem the Debentures, our financial condition would be materially and adversely affected and we would probably have to reduce or possibly curtail operational spending including some critical clinical effort.

The limited number of unissued and unreserved authorized shares of common stock severely restricts our ability to raise funds through the sale of our securities.

We have 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. As of May 1, 2003, only approximately 809,000 shares of our authorized shares of common stock will not be issued or reserved for issuance. Unless and until we are able to increase the number of authorized shares of common stock, our ability to raise funds through the sale of common stock or instruments that are convertible into or exercisable for common stock will be severely restricted. Although we intend to ask our stockholders at our next annual meeting to approve

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

an amendment to our Certificate of Incorporation to increase the shares of common stock we are authorized to issue, we cannot assure you that we will be able to obtain this approval.

We have guaranteed the value of a number of shares issued and to be issued as a result of our acquisition of assets from Interferon Sciences. If our share price is not above \$1.59 per share 12 or 18 months after the dates of issuance of the guaranteed shares, our financial condition could be adversely affected.

In March 2003 we issued 487,028 shares to Interferon Sciences and, upon the completion of the second Interferon Sciences asset acquisition, we will issue an additional 487,028 shares to Interferon Sciences and an aggregate of 581,761 shares to two of Interferon Sciences' creditors. We anticipate, but cannot assure, that we will close the second Interferon Sciences asset acquisition by mid June, 2003. We have guaranteed the value of up to 1,430,817 of these shares to be \$1.59 per share or \$2,275,000 in the aggregate on the relevant termination dates. The termination dates are 18 months after the dates of issuance of the guaranteed shares to ISI and GP Strategies, and 12 months after the date of issuance of the guaranteed shares to the American National Red Cross. The guarantee relates only to those shares still held by Interferon Sciences and the two creditors on the applicable termination date. If, within 30 days after the relevant termination date, holders of the guaranteed shares request that we honor the guarantees, we will reacquire the holders' remaining guaranteed shares and pay the holders \$1.59 per share. By way of example, assuming that all 1,430,817 shares are still held on the relevant termination dates, we would be obligated to pay to Interferon Sciences and these two creditors an aggregate of \$2,275,000. The reported last sale price for our common stock on the American Stock Exchange on May 16, 2003 was \$2.84 per share. If, during the 31 days commencing on the relevant termination dates, the market price of our stock is not above \$1.59 per share, we most likely would be requested and obligated to pay the guaranteed amount on the guaranteed shares outstanding on the relevant termination dates. We believe that the number of guaranteed shares still outstanding on the relevant termination dates will be a factor of the market price and sales volume of our common stock during the 18 month period prior to the relevant termination date.

If the holders of the guaranteed shares do not sell a significant amount of their guaranteed shares prior to the relevant termination dates and the price of our common stock during the 31 day period commencing on the relevant termination dates is not above \$1.59 per share, we most likely will be required to repurchase a significant number of guaranteed shares and our financial condition could be materially and adversely affected.

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. If and when we obtain all rights to ALFERON N Injection, we will need to preserve and acquire enforceable patents covering its use for a particular disease too. 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 US for the use of Ampligen(R) as

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

a sole treatment for any of the cancers which we have sought to target. With regard to ALFERON N Injection, ISI has a patent for natural alpha interferon produced from human peripheral blood leukocytes and its production process and has additional patent applications pending. We will acquire this patent and related patent applications if and when we close on the second ISI asset acquisition. We cannot assure you that any of these applications will be approved or that our competitors will not seek and obtain patents regarding the use of our products in combination with various other agents, for a particular target indication prior to us. If we cannot protect our patents covering the use of our products for a particular disease, or obtain additional pending 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 patents and intellectual property rights. Such litigation could require substantial resources from us and we may not have the financial resources necessary to enforce the patent rights that we hold. No assurance can be made that our patents will provide competitive advantages for our products or will not be successfully challenged by competitors. No assurance can be given that patents do not exist or could not be filed which would have a materially adverse effect on our ability to develop or market our products or to obtain or maintain any competitive position the 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 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 product successfully, we may not generate significant revenues or become profitable.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

We have limited marketing and sales capability. We need to enter into marketing agreements and third party distribution agreements for our products in order to generate significant revenues and become profitable. To the extent that we enter into co-marketing or other licensing arrangements, 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 Gentiva Health Services offers the potential to provide significant marketing and distribution capacity in the United States while licensing and marketing agreements with certain foreign firms should provide an adequate sales force in South America, Africa, United Kingdom, Australia and New Zealand, Canada, Austria, Spain and Portugal.

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

No guaranteed source of required materials.

A number of essential materials are used in the production of ALFERON N Injection, including human white blood cells, and we have a limited number of sources from which to obtain such materials. 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. 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. The costs and availability of products and materials we need for the commercial production of ALFERON N Injection and other products which we may commercially produce are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, and FDA and other governmental regulations and there can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all.

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

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

We have limited manufacturing experience and capacity.

Ampligen(R) is currently produced only in limited quantities for use in our clinical trials and we are dependent upon certain third party suppliers for key components of our products and for substantially all of the production process. The failure to continue these arrangements or to achieve other such

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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 and HPB pertaining to current Good Manufacturing Practices ("cGMP") regulations. There can be no assurance that such facilities can be used, built, or acquired on commercially acceptable terms, or that such facilities, if used, built, or acquired, will be adequate for our long-term needs.

The purified drug concentrate utilized in the formulation of ALFERON N Injection is manufactured in ISI's facility and ALFERON N Injection is formulated and packaged at a production facility operated by Abbott laboratorie in Kansas. If and when we close on the second ISI asset acquisition, we will acquire the manufacture in NB, NJ facility. We still will be dependent upon Abbott Laboratories and/or another third party for product formulation and packaging.

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

We have never produced Ampligen(R) or any other products in large commercial quantities. Ampligen(R) is currently produced for use in clinical trials. 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.

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

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

Our products may be subject to substantial competition.

Ampligen(R). Competitors may be developing technologies that are, or in the future may be, the basis for competitive products. Some of these potential products may have an entirely different approach or means of accomplishing similar therapeutic effects to products being developed by us. These competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments may offer competition to our products. Furthermore, many of our competitors have significantly greater experience than us in pre-clinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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 and we have no knowledge of any ME/CFS drugs being developed by others. The dominant competitors with drugs to treat HIV diseases include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs 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 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 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 also competes with surgical, chemical, and other methods of treating genital warts. We cannot assess the impact products developed by our competitors, or advances in other methods of the treatment of genital warts, will have on the commercial viability of ALFERON N Injection. If and when we obtain additional approvals of uses of this product, we expect to compete primarily on the basis of product performance. Our 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, two recombinant forms of beta interferon have been approved for the treatment of relapsing-remitting multiple sclerosis. There can be no assurance that, if we are able to obtain regulatory approval of ALFERON N Injection for the treatment of new indications, we will be able to achieve any significant penetration into those markets. In addition, because certain competitive products are not dependent on a source of human blood cells, such products may be able to be produced in greater volume and at a lower cost than ALFERON N Injection. Currently, ISI's wholesale price on a per unit basis of ALFERON N Injection is substantially higher than that of the competitive recombinant alpha and beta interferon products.

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

Possible side effects from the use of Ampligen(R) or ALFERON N Injection could adversely effect 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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

rapid heart beat, a tightness of the chest, urticaria (swelling of the skin), anxiety, shortness of breath, subjective reports of "feeling hot," sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by slowing the infusion rate. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, transient visual disturbances, irregular heart rate, decreased visual activity 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 effect potential revenues and physician/patient acceptability of our product.

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

We may be subject to product liability claims from the use of Ampligen(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 product liability claims. A successful product liability claim against us in excess of our \$1,000,000 in insurance coverage or for which coverage is not provided could have a negative effect on our business and financial condition.

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

Our success is dependent on the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen(R), and his knowledge of our overall activities, including patents, & clinical trials. The loss of Dr. Carter's services could have a material adverse effect on our operations and chances for success. While we have an employment agreement with Dr. Carter, and have secured key man life insurance in the amount of \$2 million on the life of Dr. Carter, the loss of Dr. Carter or other personnel, or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

Uncertainty of health care reimbursement for our products.

Our ability to successfully commercialize our products will depend, in part, on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Significant uncertainty exists as to the reimbursement status of newly approved health care products, and from time to time legislation is proposed, which, if adopted, could further restrict the prices charged by and/or amounts reimbursable to manufacturers of pharmaceutical products. We cannot predict what, if any, legislation will ultimately be adopted or the impact of such legislation on us. There can be no assurance that third party insurance companies will allow us to charge and receive payments for products sufficient to realize an appropriate return on our investment in product development.

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

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

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

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

- o announcements of the results of clinical trials by us or our competitors;
- o adverse reactions to products;
- o governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- o changes in U.S. or foreign regulatory policy during the period of product development;
- o developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- o announcements of technological innovations by us or our competitors;
- o announcements of new products or new contracts by us or our competitors;
- o actual or anticipated variations in our operating results due to the level of development expenses and other factors; o changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates; o conditions and trends in the pharmaceutical and other industries; o new accounting standards; and o the occurrence of any of the risks described in these "Risk Factors."

Our common stock is listed for quotation on the American Stock Exchange. For the 12-month period ended December 31, 2002, the price of our common stock has ranged from \$0.74 to \$4.95. 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.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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 1, 2003, approximately 834,445 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act of 1933. In addition, we are registering 5,967,820 shares issuable upon the conversion of 135% of the Debentures and as payment of interest thereon. All of these shares are being registered in the Form S-3 Registration Statement discussed above pursuant to agreements between us and the purchasers in our recent private placements, requiring us to register their shares for resale under the Securities Act. This permits the sale of registered shares of common stock in the open market or in privately negotiated transactions without compliance with the requirements of Rule 144. In addition, as of May 1, 2003, we had options and warrants outstanding for the purchase of an aggregate of approximately 9,710,035 shares of our common stock, which includes 135% of the shares issuable upon exercise of the Warrants. To the extent the exercise price of the options and warrants is less than the market price of the common stock, the holders of the options and 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. Moreover, we anticipate that we will be issuing and registering for public resale 1,068,789 shares if and when we acquire additional assets from ISI and, possibly, additional shares to raise funding or compensate employees, consultants and/or directors. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock. Sales of substantial amounts of our common stock in the public market could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November, 2002 we adopted a Shareholder Rights Plan and, under the Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of common stock to stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one unit of preferred stock for \$30.00. The

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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, M.D., our Chief Executive Officer, who already beneficially owns 11.4% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at \$.01 per Right under certain circumstances.

Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Our research in clinical efforts may continue for the next several years and we may continue to incur losses due to clinical costs incurred in the development of Ampligen(R) for commercial application. Possible losses may fluctuate from quarter to quarter as a result of differences in the timing of significant expenses incurred and receipt of licensing fees and/or cost recovery treatment revenues in Europe, Canada and in the United States.

ITEM 2. Properties.

We currently lease and occupy a total of approximately 18,850 square feet of laboratory and office space in two states and some office space in Paris, France. Our headquarters is located in Philadelphia, Pennsylvania consisting of a suite of offices of approximately 15,000 square feet. We also lease space of approximately 3,850 square feet in Rockville, Maryland for research & development, our pharmacy, packaging, quality assurance and quality control laboratories, as well as additional office space. Approximately 2,000 square feet are dedicated to the pharmacy, packaging, quality assurance and control functions. The Company believes that its Rockville facilities will meet its requirements, for planned clinical trials and treatment protocols, through 2004 and possibly longer after which time it may need to increase its Rockville facilities either through third parties or by building or acquiring commercial-scale facilities.

We currently occupy and use the New Brunswick, New Jersey laboratory and production facility owned by ISI. We are in the process of acquiring title to these facilities pursuant to our second asset acquisition agreement with ISI (see Financial and Asset Acquisition in Item 1 above for more details). This acquisition consists of two buildings located on 2.8 acres. One building is a two story facility consisting of a total of 31,300 square feet. This facility has offices, laboratories, production space, and shipping & receiving area. Building Two has 11,670 square feet consisting of offices, laboratories and warehouse space. The property has parking space for approximately 100 vehicles.

We also have a 24.9% interest in Ribotech, Ltd. located in South Africa. Ribotech was established by Bioclones to develop and operate a manufacturing facility. Manufacturing at the pilot facility commenced in 1996. We expect that Ribotech will start construction on a new commercial production facility in the future, although no assurance can be given that this will occur. The Company has no obligation to fund this construction. Our interest in Ribotech, is a result of the marketing and manufacturing agreement executed with Bioclones in 1994.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

ITEM 3. Legal Proceedings.

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

In June 2002, a former ME/CFS clinical trial patient and her husband filed a claim in the Superior Court of New Jersey, Middlesex County, against us, one of our clinical trial investigators others, alleging that she was harmed in the ME/CFS clinical trial as a result of negligence and breach of warranties. We believe the claim is without merit and we are defending the claim against us through our product liability insurance carrier.

In June 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 July 2002, we filed suit in the United States District Court for the Eastern District of Pennsylvania against Federal Insurance Company ("Federal") seeking (1) a judicial order declaring our rights and the obligations of Federal under the insurance policy Federal sold to us (2) monetary damage for breach of contract resulting from Federal's refusal to fully defend us in connection with the Asensio litigation (3) monetary damages to compensate us for Federal's breach of its fiduciary duty faith and dealing and (4) monetary damages, interest, costs, and attorneys fees to compensate us for Federal's violation of the Pennsylvania Bad Faith Statute. On March 31, 2003 we settled our outstanding Federal relating to reimbursement of expenses in connection with our Asensio law suits. The net settlement amount of approximately \$1,050,000 is recorded as a reduction in General and Administrative expenses in our Statement of Operations for the year ended December 31, 2002.

In March 2003, the law firm of Schnader, Harrison, Segal & Lewis, LLP filed a complaint in the Court of Common Pleas of Philadelphia County against us for alleged legal fees in the sum of \$65,051. We believe the claim is without merit and we are defending the claim.

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

No matters were submitted to a vote of the security holders during the last quarter of the year ended December 31, 2002.

PART II

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

ITEM 5. Market for Registrant's Common Equity and Related Stockholder Matters. In the year 2002, we acquired 27,500 shares of common stock on the open market at an average cost of \$1.82 per share. The acquisition of the shares was authorized under a stock buy-back program authorized by the Board of Directors.

In fiscal 2002, we issued 11,300 new shares of common stock to warrant holders exercising non-public warrants at an average exercise price of \$3.30. The warrants exercised were granted by us in the period covering 1993 through 1996. In addition, we issued 48,392 shares in settlement of debt of \$154,000.

In addition, as discussed in greater detail in "RECENT FINANCING AND ASSET ACQUISITIONS" above in Item 1. Business, we 1) issued convertible debentures and warrants to two investors for cash, we issued shares to ISI for assets, 2) issued shares to an affiliate of Esteve in exchange for convertible preferred equity certificates of our Luxembourg subsidiary and 3) we plan to issue shares of common stock to ISI and to two creditors of ISI for additional assets. Cardinal Securities LLC was placement agent on the sale of the debentures and warrants and received a placement fee equal to 7% of the proceeds from that offering (up to 1.75% of which is payable in company common stock) and common stock purchase warrants to purchase 25,000 shares for each \$1,000,000 received by the Company.

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.

Since October 1997 our common stock and Class A warrants have been listed and traded on the American Stock Exchange ("AMEX") under the symbol HEB and HEBws, respectively. The Class A Warrants expired on November 2, 2001. The following table sets forth the high and low list prices for our common stock for the last two fiscal years and the first quarter of fiscal 2003 as reported by the AMEX. Such prices reflect inter-dealer prices, without retail markup, markdowns or commissions and may not necessarily represent actual transactions.

COMMON STOCK	High	Low
	----	---
Time Period:		
January 1, 2001 through March 31, 2001	\$5.75	\$3.01
April 1, 2001 through June 30, 2001	7.15	3.96
July 1, 2001 through September 30, 2001	6.85	3.89
October 1, 2001 through December 31, 2001	5.29	3.41
Time Period:		
January 1, 2002 through March 31, 2002	4.76	3.45
April 1, 2002 through June 30, 2002	3.97	2.50
July 1, 2002 through September 30, 2002	2.63	.80
October 1, 2002 through December 31, 2002	2.86	1.40

As of March 27, 2003 there were approximately 259 holders of record of our Common Stock. This number was determined from records maintained by the Company's transfer agent and does not include beneficial owners of the Company's securities whose securities are held in the names of various dealers and/or clearing agencies.

As of April 4, 2003, the last sale price for our common stock on the AMEX was \$1.35 per share.

We have not paid any dividends on our common stock in recent years. It is

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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 the Company's 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, 2002.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities Remaining available For future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders:	294,665	\$ 3.57	258,293
Equity compensation plans not approved by security holders:			
Total	294,665	\$ 3.57	258,293

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

Year Ended December 31 -----	1998 ----	1999 ----	2000 ----
Statement of Operations Data			
Revenues and License Fee Income	\$401	\$678	\$788
Net loss	(7,324)	(12,298)	(8,552)
Basic and diluted loss per share	(0.32)	(0.47)	(0.29)
Shares used in computing basic and diluted net loss per share.	22,724,913	26,380,351	29,251,846
Balance Sheet Data			
Total Assets	\$ 16,327	\$14,168	\$ 13,067
Common Stockholders' Equity	15,185	12,657	11,572
Other Cash Flow Data			
Cash used in operating activities	(5,751)	(6,990)	(8,074)

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Capital expenditures (151) (251) (171)

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

The following discussion and analysis is related to our financial condition and results of operations for the three years ended December 31, 2002. This information should be read in conjunction with Item 6 - "Selected Financial Data" and our Consolidated Financial Statements and related Notes thereto beginning on page F-1 of this Form 10-K/A.

Statement of Forward-Looking Information

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

Background

We have reported net income only from 1985 through 1987. Since 1987, we have incurred, as expected, substantial operating losses due to our conducting clinical testing. Prior to completing an Initial Public Offering ("IPO") in November 1995, we financed operations primarily through the private placement of equity and debt securities, equipment lease financing, interest income and revenues from licensing, royalty agreements and cost recovery treatment programs.

We have established a strong foundation of laboratory, pre-clinical data with respect to the development of nucleic acid 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 approval 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. Ampligen(R) is currently in Phase III clinical trials in the U.S. for use in treatment of ME/CFS and is in Phase IIb Clinical trials in the U.S. for the treatment of newly emerged 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 350 patents worldwide, with over 80 additional patents application pending to provide further proprietary protection in various international markets. Certain patents apply to the use of Ampligen(R) alone and certain patent 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.

In March, 2003, the Company acquired from ISI, all of ISI's raw materials, work-in-progress and finished product of ALFERON N Injection(R), together with a limited license for the production, manufacture, use, marketing and sale of the product. ALFERON N Injection(R) [interferon alfa- n3 (human derived)] is a natural alpha interferon that has been approved by the U.S. Food and Drug Administration ("FDA") for commercial sale for the treatment of certain types of genital warts. We intend to market this product in the US through sales facilitated via third party marketing agreements. Additionally, we intend to implement studies, beyond those conducted by ISI, for testing the potential treatment of HIV, Hepatitis C and other indications, including multiple

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

sclerosis. This acquisition notwithstanding, our primary focus remains the development of Ampligen(R) for treating ME/CFS and HIV diseases.

We were incorporated in Maryland in 1996 under the name HEM Research, Inc., and originally served as a supplier of research support products. Our business was redirected in the early 1980's to the development of nucleic acid pharmaceutical technology and the commercialization of RNA drugs. We were reincorporated in Delaware and changed our name to Hem Pharmaceutical Corp. in 1991 and to Hemispherx Biopharma, Inc., in June 1995. We have three domestic subsidiaries BioPro Corp., BioAegean Corp., and Core BioTech Corp., all of which are incorporated in Delaware. Our foreign subsidiaries include Hemispherx Biopharma Europe N.V./S.A. established in Belgium in 1998 and Hemispherx Biopharma Europe S.A. incorporated in Luxembourg in 2002.

Result of Operations

Year Ended December 31, 2002 vs. 2001

Net loss

Our net loss was approximately \$7,424,000 for the year ended December 31, 2002 versus a net loss of \$9,083,000 in 2001. Per share losses in 2002 was 23 cents versus a per share loss of 29 cents in 2001. This year-to-year decrease in losses of \$1,659,000 is primarily due to higher revenues and lower costs in 2002. Revenues were up \$514,000 in 2002 and total expenses were down by \$2,231,000 offset by a write down in the carrying value of our investments in the amount of \$1,366,000 for a net cost decrease of \$865,000.

Revenues

Our revenues have come from our ME/CFS cost recovery treatment programs principally underway in the U.S., Canada and Europe. These clinical programs allow us to provide Ampligen(R) therapy at our cost to severely debilitated ME/CFS patients. Under this program the patients pay for the cost of Ampligen(R) doses infused. These costs total approximately \$7,200 for a 24 weeks treatment program. Revenues from cost recovery treatment programs totaled some \$341,000 in 2002. In 2001, these revenues were \$390,000 or 14% higher than 2002 revenues. We expected revenues in the U.S. to decline due to the focus of our clinical resources on conducting and completing the AMP 516 ME/CFS Phase III clinical trial as well as the start up of the AMP 719 and AMP 720 HIV clinical trials. The clinical data collected from treating patients under the cost recovery treatment programs will augment and supplement the data collected in the U.S. Phase III ME/CFS trial.

We received a licensing fee of 625,000 Euros (us \$563,000) from Esteve pursuant to a Sales and Distribution Agreement in which Esteve was granted the exclusive right to market Ampligen(R) in Spain, Portugal and Andorra for the treatment of ME/CFS. In turn we provided to Esteve technical, scientific, and commercial information. The agreement terms require no additional performance by us. Our total revenues, including this licensing fee, in 2002 were \$904,000 compared to revenues of \$390,000 in 2001.

Revenues for non-refundable license fees are recognized under the performance method. This method recognizes revenue to the extent of performance to date under a licensing agreement. In computing earned revenue, it considers only the amount of non-refundable cash actually received to date. This method considers future payments to be contingent and thus ignores the possibility of future milestone payments when computing the amount of revenue earned in a current period.

Research and Development Costs

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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

Ampligen is currently being tested in a Phase III clinical trial, in the U.S., for use in treatment of ME/CFS, the so-called AMP-516 study. Ampligen is also currently in two Phase IIb studies for the treatment of HIV to overcome multi-drug resistance, virus mutation and toxicity associated with current HAART therapies. One study, the AMP-719, is a Salvage Therapy, conducted in the U.S. and evaluating the potential synergistic efficacy of Ampligen in multi-drug resistant HIV patients for immune enhancement. The second study, the AMP-720, is a clinical trial designed to evaluate the effect of Ampligen under Strategic Treatment Intervention and is also conducted in the U.S.

AMP 516

As of December, 2002 the study was fully enrolled and we have patients in excess of the full enrollment in order to potentially compensate for "drop outs". More than 230 patients have been randomized into the trial and we expect to complete dosing the current group by the end of 2003. The next stage of the program is final data collection, quality assurance of the data to insure its accuracy and analysis of the data according to regulatory guidelines to facilitate the New Drug Application (NDA), expected to be filed in the first or second quarter of 2004. The date of potential commercial approval depends on whether the Company receives Fast Track Status or not by the FDA. In case of Fast Track the FDA approval time is maximum six months. If the Company is not granted Fast Track Designation, the approval time can take substantially longer, depending on the progress made by the FDA in review of the application. The FDA may deny full commercial approval to the drug at any time, including after Fast Track Status has been awarded.

Expenses related to the ME/CFS Phase III are expected to decrease in 2003 because of fewer patients to be treated as the trial nears completion. The remaining patients are treated at only two investigational sites, which makes data collection and monitoring more cost effective. Accordingly, the estimated cost for completion of the study and data analysis is estimated to be approximately \$500,000 to \$600,000. In the event significant numbers of patients were to prematurely leave the clinical trial, any potential FDA approval of an NDA could be indefinitely delayed which would have a materially adverse effect on the Company's ability to receive potential revenues in the next 2-3 years from this therapeutic indication.

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

AMP 719 and AMP 720

As of December 2002 approximately 55 patients have been enrolled in both studies combined and they are being treated in approximately 10 different active sites around the U.S. The Company expects the enrollment in these clinical trials to

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

accelerate as we recruit more investigators based on the open-label analysis and presentation of promising results in Prague, Barcelona, Spain and Naples.

The length of the study and the costs related to these trials cannot be determined at this time as it will be materially influenced by (a) the number of clinical investigators needed to fulfill the required number of patients, (b) the rate of accrual of patients and (c) the retention of patients on the protocol and their adherence to the protocol requirements. Under optimal conditions, the out of pocket cost of completing the studies could be approximately \$3 million. The rate of enrollment depends on patient availability and on other products being in clinical trials for the treatment of HIV, because there could be 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 by the FDA, which will decide when completion of the ongoing Phase IIb is appropriate and whether a Phase III trial will have to be conducted or not. In case of 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, the Company may obtain revenues from its HIV treatment indications.

Our overall research and development direct costs in 2002 were \$4,946,000 compared to direct research and development costs in 2001 of \$5,780,000 and \$6,136,000 in 2000. We estimate that 80% of these expenditures to be related to our ME/CFS research and development and 20% related to our HIV studies.

General and Administrative Expenses

Excluding stock compensation expense, general and administrative expenses were approximately \$1,882,000 in 2002 versus \$2,741,000 in 2001. This decrease in expenses of \$859,000 in 2002, is due to several factors including the recovery of certain legal expenses of approximately \$1,050,000 relating to the Asensio lawsuit from our insurance carrier and lower overall legal expenses due to less litigation, partially offset by higher Insurance premiums.

Stock compensation expenses was \$133,000 or \$538,000 lower than recorded in the year 2001. The compensation reflects the imputed non-cash expense recorded to reflect the cost of warrants granted to outside parties for services rendered to the Company.

Equity Loss-Unconsolidated Affiliates

During the three months ended June 2002 and December 2002, we recorded a non-cash charge of \$678,000 and \$396,000 respectively, to operations with respect to our \$1,074,000 investment in R.E.D. These charges were the result of our determination that R.E.D.'s business and financial position had deteriorated to the point that our investment had been permanently impaired. Please see "RESEARCH AND DEVELOPMENT/COLLABORATIVE AGREEMENTS" in Part 1 for more details on these transactions.

In May 2000, we acquired an equity interest in Chronix Biomedical Corp. ("CHRONIX") for \$700,000. During the quarter ended December 31, 2002, we recorded a noncash charge of \$292,000 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 their current proposed equity offerings. Please see "RESEARCH AND DEVELOPMENT/COLLABORATIVE AGREEMENTS" in Part 1 for more details on these transactions.

In April, 1999 we acquired a 30% equity position in the California Institute of Molecular Medicine ("CIMM") for \$750,000. During the fourth quarter of 2001 we recorded a non-cash charge of \$485,000 with respect to our investment in CIMM.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

This was a result of our determination that CIMM's operations have not yet evolved to the point where the full carrying value of our investment could be supported based on that Company's financial position and operating results. This amount represented the unamortized balance of goodwill included as part of our investment. During 2002, CIMM continued to suffer significant losses resulting in a deterioration of its financial condition. The \$485,000 written off during 2001 represented the un-amortized balance of goodwill included as part of the Company's investment. Additionally, during 2001 the Company reduced its investment in CIMM based on its percentage interest in CIMM's continued operating losses. The Company's remaining investment at December 12, 2002 in CIMM, representing a 30% interest in CIMM's equity at such date, was completely written off during 2002. Such amount was not material.

These charges are reflected in the Consolidated Statements of Operations under the caption "Equity loss in Unconsolidated Affiliate." Please see "RESEARCH AND DEVELOPMENT/COLLABORATIVE AGREEMENTS" in Part I for more details on these transactions.

Other Income/Expense

Interest and other income totaled \$103,000 for the year ended 2002 compared to \$284,000 recorded for the year ended in 2001. Significantly lower interest rates on money market accounts and lower cash available for investment basically account for the difference. All funds in excess of our immediate need are invested in short term high quality securities, which earned much lower interest income in 2002.

Years Ended December 31, 2001 vs. 2000

Net loss

We reported a net loss of approximately \$9,083,000 for the year ended December 31, 2001 versus a net loss of approximately \$8,552,000 for the year ended 2000. The increase in losses of \$531,000 in 2001 was basically due to lower ME/CFS Cost recovery treatment revenues and interest income. In addition we recorded a non-operating, non-cash charge of \$485,000 with respect to our investments in unconsolidated affiliates. This amount represents the unamortized balance of goodwill included in the investments. Overall operating expenses in 2001 were \$639,000 lower than operating expenses experienced in 2000. Our loss per share was \$0.29 in 2001 and 2000.

Revenues

At this time, (prior to the acquisition of ALFERON N) our revenues come from our ME/CFS cost recovery treatment programs principally underway in the U.S., Canada and Europe. These clinical programs allow us to provide Ampligen(R) therapy at our cost to severely debilitated ME/CFS patients. Under this program the patients pay for the cost of Ampligen(R) doses infused. These costs total approximately \$7,200 for a 24 weeks treatment program. Revenues from cost recovery treatment programs totaled some \$788,000 in 2000. In 2001, these revenues declined by \$398,000 or 51%. We expected revenues in the U.S. to decline due to the focus of our clinical resources on conducting and completing the AMP 516 ME/CFS Phase III clinical trial as well as the start up of the AMP 719 and AMP 720 HIV clinical trials. Revenues from the European cost recovery treatment programs were lower than expected primarily due to our European investigators spending a great deal of time in reviewing and analyzing the clinical data collected in the treatment of some 150 patients in Belgium. The clinical data collected from treating patients under the cost recovery treatment programs will augment and supplement the data collected in the U.S. Phase III

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

ME/CFS trial.

Research and Development Costs

As previously noted, our research and development is primarily directed at developing our lead product, Ampligen(R), as a therapy for use in treating various chronic illnesses as well as cancer. In 2000 and 2001, most of this effort was directed toward conducting and supporting clinical trials involving patients affected with ME/CFS. Our research and development direct costs were \$5,780,000 in 2001 compared to \$6,136,000 spent in 2000. The lower research and development costs basically reflect the net sum of less costs related to lower cost recovery treatment revenues and lower expenses related to the ME/CFS clinical trials offset by increased purchases of polymers and increased expenses relating to the HIV trials initiated in 2001. As to be expected, costs related to the cost recovery treatment programs were down approximately \$275,000 due to lower revenues recorded in 2001. Also expenses relating to the ME/CFS Phase III clinical trial were down some \$863,000 in 2001 versus 2000 due to fewer patients being treated in the cost-intensive segment of the program as the clinical trial nears completion. This clinical trial is a multicenter, placebo-controlled, randomized, double blind study to evaluate the efficacy and safety of treating 230 ME/CFS patients with Ampligen(R). As of February 2002, more than 220 patients have been enrolled. These lower costs relating to our ME/CFS programs were partially offset by an increase in polymer purchase in 2001 in the amount of \$317,000 and an increase due to spending on the new HIV clinical trials now underway. The polymer purchase increase was needed to boost our on hand inventory for the production of Ampligen(R). The HIV clinical trials were initiated to evaluate the use of Ampligen(R) in concert with other antiviral drugs in treating patients severely afflicted with AIDS. We expect levels of these clinical trials to continue throughout 2002. (See part I, Item 1 "BUSINESS" for more information on our Research and Development programs.)

General and Administrative Expenses

Excluding stock compensation expense, general and administrative expenses were approximately \$2,741,000 in 2001 versus \$3,298,000 in 2000. The decrease in expense is primary due to lower professional fees in 2001. All other general and administrative expenses were slightly less than recorded in 2000. Stock compensation expenses were \$671,000 or some \$274,000 higher than recorded in the year 2000. The compensation reflects the imputed non-cash expense recorded to reflect the cost of warrants granted to outside parties for services rendered to the Company.

Equity Loss-Unconsolidated Affiliates

During the fourth quarter of 2001, we recorded a non-cash charge of \$485,000 with respect to our investment in CIMM. The amount represents the unamortized balance of goodwill included as part of our investment. This was a result of management's determination that CIMM's operations had not yet evolved to the point where our full carrying value of its investment could be supported based on their financial position and operating results.

Other Income/Expense

Interest and other income of \$284,000 in 2001 was lower than the \$572,000 recorded in 2000. Significantly lower interest rates on money market accounts and lower cash available for investment basically account for the difference. All funds in excess of our immediate need are invested in short term high quality securities, which earned much lower interest income in 2001.

Liquidity and Capital Resources

Cash, cash equivalents and short term investments at December 31, 2002 were

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

approximately \$2,811,000. Cash used for operating activities in 2002 was \$6,409,000. Additional uses of cash included expenditures of \$176,000 for patent acquisition cost, and \$50,000 to acquire 27,500 shares of our stock.

Cash proceeds from financing activities in 2002 were approximately \$961,000. \$65,000 was received from stock subscriptions and \$946,000 was received from the issuance of preferred equity certificates of our European subsidiary.

Our net operating cash "burn rate" for the last three months of fiscal year 2002 approximated \$547,000 per month or \$6,564,000 on an annualized basis. All clinical trial drug supplies produced in 2002 were fully expensed although some costs are expected to be recovered under the expanded access cost recovery programs authorized by FDA and regulatory bodies in other countries. Our operating cash "burn rate" should decline in 2003 as the AMP 516 ME/CFS clinical trial nears completion and the cost of European market development activity is reduced.

On March 20, 2002, our European subsidiary Hemispherx Biopharma Europe, S.A. ("Hemispherx S.A.") entered into a Sales and Distribution Agreement with Laboratories Del Dr. Esteve S.A. ("Esteve"). Pursuant to the terms of the agreement, Esteve was granted the exclusive right to market Ampligen(R) in Spain, Portugal and Andorra for the treatment of Myalgic Encephal/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. FDA 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.

Also Esteve purchased 1,000,000 Euros of Hemispherx S.A.'s convertible preferred equity certificates. These securities paid a 7% dividend and were to be converted into .00114% of the outstanding common stock of Hemispherx S.A. upon the earlier of the completion of an initial public offering ("IPO") on a European stock exchange or September 30, 2003. However, at our request, on January 9, 2003, Esteve agreed to convert the preferred equity certificates into shares of our common stock and, on March 13, 2003, we issued 347,445 shares of our common stock to Provesan SA, an affiliate of Esteve, in exchange for the 1,000,000 Euros of convertible preferred equity certificates owned by Esteve. We agreed to register the shares issued to Provesan SA and we have registered these shares for public sale.

On March 12, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due March 2005 and an aggregate of \$743,288 warrants to two investors in a private placement for aggregate anticipated gross proceeds of \$4,650,000. Pursuant to the terms of the Debentures, \$1,550,000 of the proceeds from the sale of the Debentures have been held back and will be released to us if, and only if, we acquire ISI's facility within a set timeframe (see the discussion below). The Debentures mature on January 31, 2005 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Pursuant to the terms and conditions of the Senior Convertible Debentures, we have pledged all of our assets, other than our intellectual property, as collateral and are subject to comply with certain financial and negative covenants, which include but are not limited to the repayment of principal balances upon achieving certain revenue milestones.

The Debentures are convertible at the option of the investors at any time through January 31, 2005 into shares of our common stock. The conversion price under the Debentures is fixed at \$1.46 per share, subject to adjustment for

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect.

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

We entered into a Registration Rights Agreement with the investors in connection with the issuance of the Debentures and the warrants. The Registration Rights Agreement requires that we register the shares of common stock issuable upon conversion of the Debentures, as interest shares under the Debenture and upon exercise of the warrants. In accordance with this agreement, we filed a Registration Statement on Form S-3 with the Securities and Exchange Commission. The investors include Portside Growth & Opportunity Fund Ltd. and Leonardo, L.P. the debentures mature on March 12, 2005 and bear interest at 6% per annum, payable quarterly in cash or common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date.

On March 11, 2003, we acquired from Interferon Sciences, Inc. ("ISI") ISI's inventory of ALFERON N Injection(R), a pharmaceutical product used for the treatment of certain types of genital warts, and a limited license for the production, manufacturing, use, marketing and sale of this product. As partial consideration, we issued 487,028 shares of our common stock to ISI. Pursuant to our agreements with ISI, we are in the process of registering the foregoing shares for public sale.

On March 11, 2003, we also entered into an agreement to purchase from ISI all of its rights to the product and other assets related to the product including, but not limited to, real estate and machinery. For these assets, we have agreed to issue to ISI an additional 487,028 shares and to issue 314,465 shares and 267,296 shares, respectively to the American National Red Cross and GP Strategies Corporation, two creditors of ISI. The Company also will be required to satisfy real estate taxes and utility expenses of ISI which totaled \$520,751 as of December 31, 2002 and which are secured by a lien on the real estate to be acquired by the Company. We have guaranteed the market value of all but 62,500 of these share on terms substantially similar to those for the initial acquisition of the ISI assets.

As of December 31, 2002, we had approximately \$2,811,000 in cash and short term investments. We believe that these funds plus 1) the anticipated infusion of approximately \$4.4 million in net proceeds from the Debenture placement, 2) projected net cash flow from the acquisition of the ALFERON N business and 3) the funds received from the insurance settlement, should be sufficient to meet our operating requirement during the next 12 months. Also, we have the ability to curtail discretionary spending, including research and development activities, if required to conserve cash.

Because of our long-term capital requirements, we may seek to access the public equity market whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. We may also need additional funding earlier than anticipated, and our cash requirements, in

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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.

Contractual Obligations

(dollars in thousands)				
Obligations Expiring by Period				
	Total	2003	2004-2005	2006-2007
	=====	=====	=====	=====
Operating leases	\$ 1,063	\$ 279	\$ 526	\$ 258
2687:	=====	=====	=====	=====
Total	\$ 1,063	\$ 279	\$ 526	\$ 258
2691:	=====	=====	=====	=====

NEW ACCOUNTING PRONOUNCEMENTS

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities" ("Interpretation No. 46"), that clarifies the application of Accounting Research Bulletin No. 51, Consolidated Financial Statements, "to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. Interpretation No. 46 is applicable immediately for variable interest entities created after January 31, 2003. For variable interest entities created to January 31, 2003, the provisions of Interpretation No. 46 are applicable no later than July 1, 2003. The Company does not expect this Interpretation to have an effect on the Consolidated Financial Statements.

In August 2001, the FASB issued Statement No. 143, "Accounting for Asset Retirement Obligation" ("SFAS 143"), which provides the accounting requirements for retirement obligation associated with tangible long-lived assets. SFAS 143 requires entities to record the fair value of the liability for an asset retirement obligation in the period in which it is incurred and is effective for the Company's 2003 fiscal year. The adoption of SFAS 143 is not expected to have a material impact on the Company's consolidated results of operations, financial position or cash flows.

In October 2001, the FASB issued Statement No. 144, "Accounting for the Impairment or Disposal of Long-lived Assets" ("SFAS 144"). SFAS 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This statement supersedes SFAS Statement No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of, and the accounting and reporting provision of APB Opinion No. 30, "Reporting the

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and transactions. This new pronouncement also amends Accounting Research Bulletin (ARB) No. 51 "Consolidated Financial Statements, to eliminate the exception to consolidation for a subsidiary for which control is likely to be temporary. SFAS 144 required that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired and also broadens the presentation of discontinued operation to include more disposal transactions. SFAS 144 is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years. Adoption of SFAS 144 on January 1, 2002, did not have impact on the Company's financial position, cash flows or results of operation for the year ended December 31, 2002.

In June 2002, the FASB issued Statement No. 146, "Accounting for Cost Associated with Exit or Disposal Activities" ("SFAS 146"), which addresses financial accounting and reporting for costs associated with exit or disposal activities, and nullifies Emerging Task Force (ETF) Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit and Activity (including Certain Costs Incurred in a Restructuring)" which previously governed the accounting treatment for restructuring activities. SFAS 146 applies to costs associated with an exit activity that does not involve an entity newly acquired in a business combination or with disposal activity covered by SFAS 144. Those costs include, but are not limited to, the following: (1) termination benefits provided to current employees that are involuntarily terminated under the terms of a benefit arrangement that, in substance, is not an ongoing benefit arrangement or individual deferred-compensation contract, (2) costs to terminate a contract that is not a capital lease, and (3) costs to consolidated facilities or relocated employees. SFAS 146 does not apply to costs associated with the retirement of long-lived assets covered by SFAS 143. SFAS 146 will be applied prospectively and is effective for exit or disposal activities after December 31, 2002.

In December 2002, the FASB issued Statement No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure", and amendment of FASB Statement No. 123. SFAS 148 amends FASB Statement No. 123, "Accounting for Stock-Based Compensation", to provide alternative method of transition for an entity that voluntarily changes to the fair value based of accounting for stock-based employee compensation. It also amends the disclosure provisions of that Statement to require prominent disclosure about the effects on reported net income of an entity's accounting policy decisions with respect to stock-based employee compensation. Finally, this Statement amends (APB) Opinion No. 28, "Interim Financial Reporting" to require disclosure about those effects in interim financial information. SFAS 148 is effective for financial statements for fiscal years ending after December 15, 2002. The Company will continue to account for stock-based compensation using the intrinsic value method of APB Opinion No. 25, "Accounting for Stock Issued to Employees", but has adopted the enhance disclosure requirements of SFAS 148 (See Note 10).

Critical Accounting Policies

Financial Reporting Release No. 60., which was recently released by the Securities and Exchange Commission, requires all companies to include a discussion of critical accounting policies or method used in the preparation of financial statements. Our significant accounting policies are described in Notes to the Consolidated Financial Statements. The significant accounting policies that we believe are most critical to aid in fully understanding our reported financial results are the following:

Revenue

Revenues for non-refundable license fees are recognized under the performance method. This method recognizes revenue to the extent of performance

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

to date under a licensing agreement. In computing earned revenue, it considers only the amount of non-refundable cash actually received to date. This method considers future payments to be contingent and thus ignores the possibility of future milestone payments when computing the amount of revenue earned in a current period.

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

Patents and Trademarks

Effective October 1, 2001, we adopted a 17 year estimated useful life for the amortization of our patents and trademark rights in order to more accurately reflect their useful life. Prior to October 1, 2001, we were using a ten year estimated useful life.

Patents and trademarks are stated at cost (primarily legal fees) and are amortized using the straight line method over the life of the assets. 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 ultimate revenue and profitability potential on an undiscounted cash basis to support the realizability of its respective capitalized cost. In addition, management's review addresses whether each patent continues to fit into the Company's strategic business plans.

Research and Developments Costs

Research and development costs are direct costs related to both future and present products and are charged to operations as incurred. The Company recognized research and development costs of \$6,136,000 \$5,780,000 and \$4,946,000 in 2000, 2001 and 2002, respectively.

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.

ITEM 7a. Quantitative and Qualitative about Market Risk.

Market Risk

We had \$2.8 million in cash, cash equivalents and short term investments at December 31, 2002. To the extent that our cash and cash equivalents exceed our near term funding requirements, the excess cash was invested in three to six month high quality financial instruments. We employ established policies and procedures to manage any risks with respect to any investment exposure.

ITEM 8. Financial Statements and Supplementary Data.

The consolidated balance sheets as of December 31, 2001 and 2002, and our Consolidated Statements of Operations, changes in stockholders' equity (deficit) and comprehensive loss and cash flows for each of the years in the three year period ended December 31, 2002, together with the reports of BDO Seidman, LLP, independent 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.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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

None.

PART III

ITEM 10. Directors and Executive Officers of the Registrant.

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 filing:

Name	Age	Position
William A. Carter, M.D.	65	Chairman, Chief Executive Officer, and President
Robert E. Peterson	65	Chief Financial Officer
David R. Strayer, M.D.	55	Medical Director, Regulatory Affairs
Carol A. Smith, Ph.D.	51	Director of Manufacturing and Process Development
Richard C. Piani	76	Director
William M. Mitchell, M.D.	67	Director
Ransom W. Etheridge	63	Director and Secretary
Eraj Kiani	58	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.

WILLIAM A. CARTER, M.D., the co-inventor of Ampligen, joined Hemispherx in 1978, and has served as: (a) Hemispherx's Chief Scientific Officer since May 1989; (b) the Chairman of Hemispherx's Board of Directors since January 1992; (c) Hemispherx's Chief Executive Officer since July 1993; (d) Hemispherx's President since April, 1995; and (e) a director since 1987. From 1987 to 1988, Dr. Carter served as Hemispherx's 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 Hemispherx's 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.

ROBERT E. PETERSON has served as Chief Financial Officer of the Company since April, 1993 and served as an Independent Financial Advisor to the Company 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.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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

CAROL A. SMITH, Ph.D. has served as the Company's 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 of Hemispherx 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 Hemispherx in 1993, with respect to general business strategies for Hemispherx's 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 of Hemispherx since October 1997, and presently serves as our Secretary. Mr. Etheridge first became associated with Hemispherx in 1980 when he provided consulting services to Hemispherx and participated in negotiations with respect to Hemispherx's initial private placement through Oppenheimer & Co., Inc. Mr. Etheridge has been practicing law since 1967, specializing in transactional law. Mr. Etheridge is a member of the Virginia State Bar, a Judicial Remedies Award Scholar, and has served as President of the Tidewater Arthritis Foundation. He is a graduate of Duke University, and received his Law degree from the University of Richmond School of Law.

WILLIAM M. MITCHELL, M.D. has been a director of Hemispherx 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 a director of Hemispherx from 1987 to 1989.

IRAJ E. 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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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 the Company's 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, 2002, all of our officers, directors and ten percent stockholders complied with all applicable Section 16(a) filing requirements on a timely basis.

Audit Committee Expert

Our Audit Committee of the Board of Directors consists of Richard Piani, Committee Chairman, William Mitchell, MD and Ransom Etheridge. Mr. Piani and Dr. Mitchell are Independent Directors. Mr. Etheridge is Secretary of our Company and is considered to be an insider. We do not have a financial expert on the committee in the true sense of the description. However, Mr. Piani is a businessman and has 40 years of experience working with budgets, analyzing financials and dealing with financial institutions.

Code of Ethics

Our Board of Directors have not yet adopted a Code of Ethics that would apply to the Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer. However, we are in the process of preparing a Code of Ethics to be presented to the Board of Directors at the next meeting.

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, 2002, 2001 and 2000 to (i) our Chief Executive Officer and (ii) our four 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	Warrants & Options Awards	All Other Compensation (1)
William A. Carter	2002	\$468,830	-	(8) 1,000,000	\$25,747
Chairman of	2001	(4) 456,608	-	(2) 386,650	22,917

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

the Board and CEO	2000	(4) 539,620	-	(5) 100,000	17,672
Robert E. Peterson	2002	\$151,055	-	(8) 200,000	-
Chief Financial Officer	2001	146,880	-	(3) 40,000	-
	2000	145,944	-	-	-
David R. Strayer, M.D.	2002	\$178,594	-	(8) 50,000	-
Medical Director	2001	174,591	-	(7) 10,000	-
	2000	(6) 172,317	-	-	-
Carol A. Smith, Ph.D.	2002	\$128,346	-	(8) 20,000	-
Director of Manufacturing	2001	124,800	-	(7) 10,000	-
	2000	124,800	-	-	-

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

(2) Consists of 188,325 warrants to purchase common stock at \$6.00 per share and 188,325 warrants to purchase common stock at \$9.00 per share. Also includes a stock option grant of 10,000 shares exercisable at \$4.03 per share.

(3) Consists of a stock option grant of 10,000 shares exercisable at \$4.03 per share and 30,000 warrants to purchase common stock at \$5.00 per share.

(4) Includes a bonus of \$90,397 paid in 2000. Also includes funds previously paid to Dr. Carter by Hahnemann Medical University where he served as a professor until 1998. This compensation was continued by the Company and totaled \$79,826 in 2000 and 2001, and \$82,095 in 2002.

(5) Represents warrants to purchase common stock exercisable at \$6.25 per share.

(6) Includes \$98,926 paid by Hahnemann Medical University where Dr. Strayer served as a professor until 1998. This compensation was continued by the Company in 2000, 2001 and 2002.

(7) Consists of a stock option grant of 10,000 shares exercisable at \$4.03 per share.

(8) Represents number of warrants to purchase shares of common stock at \$2 per share.

The following table sets forth certain information regarding stock warrants granted during 2002 to the executive officers named in the Summary Compensation Table.

INDIVIDUAL GRANTS

NAME	NUMBER OF SECURITIES UNDERLYING WARRANTS GRANTED (1)	PERCENTAGE OF TOTAL WARRANTS GRANTED TO EMPLOYEES IN FISCAL YEAR 2002 (2)	EXERCISE PRICE PER SHARE (3)	EXPIRATION DATE	PO A APP
------	--	--	---------------------------------	-----------------	----------------

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Carter, W.A.	1,000,000	61.6%	\$2	8/13/07
Peterson, R.	200,000	12.3%	\$2	8/13/07
Smith, C.	20,000	1.2%	\$2	8/13/07
Strayer, D.	50,000	3.1%	\$2	8/13/07

(1) Warrants vest over a period ranging from two to four years.

(2) Total warrants issued to employees in 2002 were 1,622,000.

(3) The exercise price is equal to the closing price of the Company's common stock at the date of issuance.

(4) 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 the Company's estimate of future stock price appreciation.

The following table sets forth certain information regarding the stock options held as of December 31, 2002 by the individuals named in the above Summary Compensation Table.

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

Name	Shares Acquired on Exercise (#)	Value Realized (\$)	Securities Underlying Unexercised Options at Fiscal Year End Numbers		Value In-the- (1) Dollar Exerci
			Exercisable	Unexercisable	
William Carter	-	-	3,552,044 (2)	753,334 (3)	\$209
Robert Peterson	-	-	314,240 (4)	103,334 (5)	6
David Strayer	-	-	101,666 (6)	28,334 (7)	3
Carol Smith	-	-	28,457 (8)	13,334 (9)	1

(1) Computation based on \$2.13, the December 31, 2002 closing bid price for the common stock on the American Stock Exchange.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

(2) Consist of (i) 250,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007 (ii) 188,325 warrants exercisable at \$6.00 per share expiring on February 22, 2006 (iii) 188,325 warrants exercisable at \$9.00 per share expiring on February 22, 2006 (iv) 100,000 warrants exercisable at \$6.25 per share expiring on April 8, 2004 (v) 25,000 warrants exercisable at \$6.50 per share expiring on September 17, 2004 (vi) 25,000 warrants exercisable at \$8.00 per share expiring on September 17, 2004 and 6,666 stock option exercisable at \$4.03 per share expiring on January 3, 2011. Also include 2,768,728 warrants and options held in the name of Carter Investments, L.C. of which W.A. Carter in the principal beneficiary. These securities consist of (i) 340,000 warrants exercisable at \$4.00 per share expiring on January 1, 2008, (ii) 170,000 warrants exercisable at \$5.00 per share expiring on January 1, 2005, (iii) 300,000 warrants exercisable at \$6.00 per share expiring on January 1, 2005 (iv) 20,000 warrants exercisable at \$4.00 per share expiring on 2008, (v) 465,000 warrants exercisable at \$1.75 expiring on June 3, 2005, (vi) 1,400,000 warrants exercisable at \$3.50 per share expiring on October 16, 2004 and 73,728 stock options exercisable at \$2.71 per share until exercised.

(3) Consists of (i) 750,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007 and (ii) 3,334 start options exercisable at \$4.03 per share expiring on January 3, 2011.

(4) Consists of (i) 6,666 stock options exercisable at \$4.03 per share expiring on January 3, 2011 (ii) 13,750 stock options exercisable at \$3.50 per share expiring on January 22, 2007, (iii) 13,824 stock option exercisable at \$4.34 per share expiring on July 17, 2003, (iv) 100,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007, (v) 50,000 warrants exercisable at \$3.50 expiring on March 1, 2006, (vi) 100,000 warrants exercisable at \$5.00 per share expiring on April 14, 2006 and (vii) 30,000 warrants exercisable at \$5.00 per share expiring on February 28, 2009.

(5) Consists of (i) 100,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007 and (ii) 3,334 stock options exercisable at \$4.03 per share expiring on January 3, 2011.

(6) Consists of (i) 25,000 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) 6,666 stock options exercisable at \$4.08 expiring on January 3, 2011 and (iv) 20,000 stock options exercisable at \$3.50 per share expiring on January 22, 2007.

(7) Consists of 25,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007 and 3,334 stock options exercisable at \$4.03 per share expiring on August 13, 2007.

(8) Consists of (i) 10,000 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) 6,666 stock options exercisable at \$4.03 per share expiring on January 3, 2016, and (iv) 6,791 stock options exercisable at \$3.50 per share expiring on January 22, 2007.

(9) Consists of 10,000 warrants exercisable at \$2.00 per share and 3,334 stock options exercisable at \$4.03 per share expiring on January 3, 2004.

Employment Agreements

Hemispherx entered into an amended and restated employment Agreement with its President and Chief Executive Officer, Dr. William A. Carter, dated as of December 3, 1998, which provided for his employment until May 8, 2004 at an initial annual base salary of \$361,586, subject to annual cost of living increases. In addition, Dr. Carter could receive an annual performance bonus of up to 25% of his base salary, at the sole discretion of the Board of Directors.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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 Hemispherx from any joint venture or corporate partnering arrangement, up to an aggregate maximum incentive bonus of \$250,000 for all such transactions. Dr. Carter's agreement also provides that he be paid a base salary and benefits through May 8, 2004 if he is terminated without "cause", as that term is defined in the agreement. This agreement was extended to May 8, 2008. Pursuant to his original agreement, as amended on August 8, 1991, Dr. Carter was granted options to purchase 73,728 shares of Hemispherx's common stock at an exercise price of \$2.71 per share.

Hemispherx entered into an amended and restated Engagement Agreement with Robert E. Peterson dated April 1, 2001 which provides for Mr. Peterson's employment as Hemispherx's Chief Financial Officer until December 31, 2003 at an annual base salary of \$155,988 per year, subject to annual cost of living increases. In addition, Mr. Peterson shall receive bonus compensation upon FDA approval of Ampligen(R) based on the number of years of his employment by Hemispherx up to the date of such approval. During 2002, Mr. Peterson also received 200,000 warrants to purchase shares of common stock with an exercise price of \$2.00.

Compensation of Directors

The existing compensation package was put in place in 2000. Board members' compensation consists of an annual retainer to \$35,000 plus \$1,000 per meeting attended. Committee chairmen each receive an additional retainer of \$5,000 per year and committee members each receive an additional retainer of \$3,000 per year. All non-employee directors received some compensation in 2001 for special project work performed on behalf of Hemispherx. All directors have been granted options to purchase common stock under Hemispherx's 1990 Stock Option Plan and/or Warrants to purchase common stock. Hemispherx believes such compensation and payments are necessary in order for Hemispherx to attract and retain qualified outside directors.

1993 Stock Option Plan

Hemispherx's 1993 Stock Option Plan ("1993 Plan"), provides for the grant of options for the purchase of up to an aggregate of 138,240 shares of common stock to Hemispherx's employees, directors, consultants and others whose efforts are important to the success of Hemispherx. The 1993 Plan is administered by the Compensation Committee of the Board of Directors, which has complete discretion to select the eligible individuals to receive and to establish the terms of option grants. The 1993 Plan provides for the issuance of either non-qualified options or incentive stock options, provided that incentive stock options must be granted with an exercise price of not less than fair market value at the time of grant and that non-qualified stock options may not be granted with an exercise price of less than 85% of the fair market value at the time of grant. The number of shares of common stock available for grant under the 1993 Plan is subject to adjustment for changes in capitalization. This plan terminates as of July 7, 2003. To date, no options have been granted under the 1993 Plan.

1992 Stock Option Plan

Hemispherx's 1992 Stock Option Plan ("1992 Plan"), provides for the grant of options for the purchase of up to an aggregate of 92,160 shares of common stock to Hemispherx's employees, directors, consultants and others whose efforts are important to the success of Hemispherx. The 1992 Plan is administered by the Compensation Committee of the Board of Directors, which has complete discretion to select the eligible individuals to receive and to establish the terms of option grants. The 1992 Plan provides for the issuance of either non-qualified options or incentive stock options, provided that incentive stock options must be granted with an exercise price of not less than fair market value at the time of grant and that non-qualified stock options may not be granted with an

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

exercise price of less than 50% of the fair market value at the time of grant. The number of shares of common stock available for grant under the 1992 Plan is subject to adjustment for changes in capitalization. This plan expired as of December 3, 2002. No options were granted under the 1992 Plan.

1990 Stock Option Plan

Hemispherx's 1990 Stock Option Plan, as amended ("1990 Plan"), provides for the grant of options to employees, directors, officers, consultants and advisors of Hemispherx 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, 2001, options to acquire an aggregate of 154,535 shares of the common stock were available for grants under the 1990 Plan. This plan remains in effect until terminated by the Board of Directors or until all options are issued.

401(K) Plan

In December 1995, Hemispherx established a defined contribution plan, effective January 1, 1995, entitled the Hemispherx Biopharma Employees 401(K) Plan and Trust Agreement. All full-time employees of Hemispherx 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 Hemispherx contributions will vest over one year. In 2002 Hemispherx provided matching contributions to each employee for up to 6% of annual pay for a total of \$38,000 for all employees.

Compensation Committee Interlocks and Insider Participation

During the fiscal year ended December 31, 2002, the members of Hemispherx's Compensation Committee were Ransom W. Etheridge and Richard Piani. Mr. Etheridge serves as the Company's Secretary and he is an attorney in private practice and has rendered legal services to Hemispherx for which he received a fee. Mr. Piani received fees for certain consulting work performed in Europe on behalf of the Company. Refer to Item 13. "Certain Relationships and Related Transactions" for more information.

Compensation Committee Report on Compensation

The Compensation Committee makes recommendations concerning salaries and compensation for employees of and consultants to Hemispherx.

The following report of the Compensation Committee discusses the company's executive compensation policies and the basis of the compensation paid to our executive officers in 2002.

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 Hemispherx's executive total compensation program, all determined by individual and corporate performance as specified in the

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

various employment agreements; base salary, annual compensation, and long-term incentives.

Base Salary

The Summary Compensation Table shows amounts earned during 2002 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. The Company established the base salaries for Chief Executive Officer, Dr. William A. Carter under an employment agreement in December 3, 1998 (to be amended on August 14, 2003), which provides for a base salary of \$361,586 until May 8, 2008. Also the Company entered into an extended employment agreement with Robert E. Peterson, Chief Financial Officer for a base salary of \$155,988 until December 31, 2003. Dr. Carter and Mr. Peterson's agreements allow for annual cost of living increases. Dr. Carter's compensation also includes funds previously paid to Dr. Carter by Hahneman Medical University where he served as a professor until 1998. This compensation was continued by the Company and totaled \$79,826 in each of 2000 and 2001, and \$82,095 in 2002.

Annual Incentive

Our Chief Executive Officer and our Chief Financial Officer are entitled to an annual incentive bonus as determined by the Compensation Committee based on such executive officers' performance during the previous calendar year. The cash bonus awarded to the Company's Chief Executive Officer in 1999 and 2000 was determined based on this provision of his employment agreement.

Performance Graph

Company Name / Index	ANNUAL RETURN PERCENTAGE				
	Years Ending				
	Dec98	Dec99	Dec00	Dec01	Dec02
HEMISPHERX BIOPHARMA INC	69.25	44.55	-52.20	-5.26	-52.67
S&P SMALLCAP 600 INDEX	-1.31	12.40	11.80	6.54	-14.63
PEER GROUP	6.85	13.61	54.46	63.31	-7.96

Company Name / Index	INDEXED RETURNS					
	Base Years Ending					
	Period					
	Dec97	Dec98	Dec99	Dec00	Dec01	Dec02
HEMISPHERX BIOPHARMA INC	100	169.25	244.65	116.94	110.78	52.44
S&P SMALLCAP 600 INDEX	100	98.69	110.94	124.03	132.13	112.80
PEER GROUP	100	106.85	121.39	187.50	306.22	281.85

Peer Group Companies

 GILEAD SCIENCES INC
 ISIS PHARMACEUTICALS INC

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

The following table sets forth as of April 1, 2003, the number and percentage of outstanding shares of common stock beneficially owned by each of the Company directors and the Named Executives, and all of our executive officers and directors as a group. As of December 31, 2002, there were no other persons, individually or as a group, known to Hemispherx to be deemed the beneficial owners of five percent or more of the issued and outstanding common stock.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

OFFICERS, DIRECTORS AND PRINCIPAL STOCKHOLDERS	SHARES BENEFICIALLY OWNED	% OF SHARES BENEFICIALLY OWNED (1)
---	---------------------------	---------------------------------------

William A. Carter, M.D.	4,246,034 (2)	11.4
Robert E. Peterson	314,074 (3)	*
Ransom W. Etheridge	214,316 (4)	*
Richard C. Piani	196,747 (5)	*
William M. Mitchell, M.D.	175,640 (6)	*
David R. Strayer, M.D.	87,246 (7)	*
Carol A. Smith, Ph.D	28,457 (8)	*
Araj-Eghbal Kiani	12,000 (9)	
All directors and executive officers as a group (8 persons)	5,274,514	13.7

* Less than 1%

(1) For purposes of this table, a person or group of persons is deemed to have "beneficial ownership" of any shares of common stock, which such person has the right to acquire within 60 days of April 1, 2003. For purposes of computing the percentage of outstanding shares of common stock held by each person or group of persons named above, any security which such person or persons has or have the right to acquire within such date is deemed to be outstanding but is not deemed to be outstanding for the purpose of computing the percentage ownership of any other person. Except as indicated in the footnotes to this table and pursuant to applicable community property laws, Hemispherx believes based on information supplied by such persons, that the persons named in this table have sole voting and investment power with respect to all shares of common stock which they beneficially own.

(2) Includes (i) an option to purchase 73,728 shares of common stock from Hemispherx at an exercise price of \$2.71 per share and expiring on August 8, 2004, (ii) Rule 701 warrants to purchase 1,400,000 shares of common stock at a price of \$3.50 per share, originally expiring on September 30, 2002 was extended to September 30, 2007; (iii) warrants to purchase 465,000 shares of common stock at \$1.75 per share issued in connection with the 1995 Standby Financing Agreement and expiring on June 30, 2005; (iv) 340,000 common stock warrants exercisable at \$4.00 per share and originally expiring on January 1, 2003 was extended to January 1, 2008; (v) 170,000 common stock warrants exercisable at \$5.00 per share and expiring on January 2, 2005; (vi) 25,000 warrants to purchase common stock at \$6.50 per share and expiring on September 17, 2004; (vii) 25,000 warrants to purchase common stock at \$8.00 per share and expiring on September 17, 2004; (viii) 100,000 warrants to purchase common stock at \$6.25 per share and expiring on April 8, 2004; (ix) 20,000 warrants to purchase common stock at \$4.00 per share originally expiring January 1, 2003 was extended to January 1, 2008, (x) 188,325 common stock warrants exercisable at \$6.00 per share and expiring on February 22, 2006; (xi) 188,325 common stock warrants exercisable at \$9.00 per share and expiring on February 22, 2006 (xii) 300,000 common stock warrants granted in 1998 that are exercisable at \$6.00 per share and expiring on January 1, 2006 (xiii) options to purchase 6,666 shares of common stock at \$4.03 per share and expiring on January 3, 2011 (XIV) 250,000 warrants exercisable at \$2.00 per share in August 13, 2007 and 693,990 shares of common stock.

(3) Includes (i) 27,574 options to purchase common stock at an average exercise price of \$3.92 per share, expiring on July 17, 2003; (ii) warrants to purchase 50,000 shares of common stock at and exercise price of \$3.50 per share, expiring on March 1, 2006; (iii) warrants to purchase 100,000 shares of common stock at \$5.00 per share, expiring on April 14, 2006; (iv) 30,000 warrants to purchase

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

common stock at \$5.00 per share an expiring on February 28, 2009 (v) options to purchase 6,000 shares at \$4.03 per share that expire on January 3, 2011 (VI) 200,000 warrants exercised at \$2.00 per share expiring on November 13, 2007 and (v) 500 shares of common stock expiring.

(4) Includes 20,000 warrants to purchase common stock at \$4.00 per share, originally expiring on January 1, 2003 and was extended to January 1, 2008; 25,000 warrants to purchase common stock at \$6.50 per share; 25,000 warrants to purchase common stock at \$8.00 at expiring per share, all expiring on September 12, 2004; 100,000 warrants exercisable \$2.00 per share expiring on August 13, 2007 and 44,316 shares of common stock.

(5) Includes (i) 20,000 warrants to purchase common stock at \$4.00 per share; (ii) warrants to purchase 25,000 shares of common stock at \$6.50 per share; (iii) 25,000 warrants to purchase common stock at \$8.00 per share, all expiring on September 17, 2004; (vi) 100,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007, (vi) 8,847 shares of common stock owned by Mr. Piani (vi) 12,900 shares of common stock owned jointly by Mr. and Mrs. Piani; and (vii) 5000 shares of common stock owned by Mrs. Piani expire.

(6) Includes (I) warrants to purchase 12,000 shares of common stock at \$6.00 per share, expiring on August 25, 2003; (ii) 25,000 warrants to purchase common stock at \$6.50 per share; (iii) 25,000 warrants to purchase common stock at \$8.00 per share all expiring on September 17, 2004; (iv) 100,000 warrants exercisable at \$2.00 per share expiring in August 13, 2007 and 13,640 shares of common stock expire.

(7) Includes (i) stock options to purchase 20,000 shares of common stock at \$3.50 per share; (ii) 50,000 warrants to purchase common stock at \$4.00 per share; (iii) 2,500 stock options exercisable at \$4.03 per share and expiring on January 3, 2011 and; (iv) 14,746 shares of common stock expire.

(8) Consists of 5,000 warrants to purchase common stock at \$4.00 per share expiring June 7, 2003; 6,791 stock options exercisable at \$3.50 expiring January 22, 2007 10,000 warrants exercisable at \$2.00 per share expiring in August 13, 2007 and options to purchase 6,666 shares of common stock at \$ 4.03 per share expiring on January 3, 2011.

(9) Consist of 12,000 warrants exercisable at \$3.86 per share expiring on April 30, 2005.

ITEM 13. Certain Relationships and Related Transactions.

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

Ransom W. Etheridge, a Director of the Company, is an attorney in private practice who has rendered corporate legal services to us from time to time, for which he has received fees. Richard Piani, a Director of the Company, lives in Paris, France and assists our European subsidiary in their dealings with medical institutions and the European Medical Evaluation Authority. William Mitchell, M.D. a Director of the Company, works with David Strayer, M.D. (our Medical Director) in establishing clinical trial protocols as well as performs other scientific work for us from time to time. For these services, these Directors were paid an aggregate of \$170,150 in the year 2002. No individual Director was paid in excess of \$60,000.00.

William A. Carter, Chief Executive Officer of the Company, received an aggregate of \$12,486 in short-term advances which were repaid as of December 31, 2001. All

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

advances bear interest at 6% per annum. The Company loaned \$60,000 to Ransom W. Etheridge, a Director of the Company in November, 2001 for the purpose of exercising 15,000 class A redeemable warrants. This loan bears interest at 6% per annum. Dr. Carter's short term advances and Mr. Etheridge's loan was approved by the Board of Directors.

The Company paid \$33,450 to Carter Realty for the rent of property used at various times in 2002 by the Company. The property is owned by others and managed by Carter Realty. Carter Realty is owned by Robert Carter, the brother of William A. Carter.

ITEM 14. Controls and Procedures.

The Company management, including the Chairman of the Board (serving as the principal executive officer) and the Chief Financial Officer, have conducted an evaluation of the effectiveness of disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based on that evaluation, the Chairman of the Board and the Chief Financial Officer concluded that the disclosure controls and procedures are effective in ensuring that all material information required to be filed in this Annual Report has been made known to them in a timely fashion. There have been no significant changes in internal controls, or in other factors that could significantly affect internal controls, subsequent to the date the Chairman of the Board and Chief Financial Officer completed their evaluation.

ITEM 15. Principal Accountant Fees and Services.

All work to be performed by our independent accountants is put forth in engagement letters, which also includes estimates of the cost of performing the work. All engagement letters are presented to the Audit Committee for review and approval.

During 2002 our Independent Accountants, BDO Seidman, LLP have billed us \$102,707 for services consisting of the annual audit and reviews of the Company's quarterly financial statements and \$4,435 for the review of the Company's proxy materials, other SEC filings and other services.

The Company did not retain BDO Seidman, LLP for any professional services relating to financial information system design or implementation.

PART IV

ITEM 16. Exhibits, Financial Statement Schedules and Reports on Form 8-K

- (a) (1) (2) Financial Statements and Schedules - See index to financial statements on page F-1 of this Annual Report.
- (a) (3) Exhibits - See exhibit index below.
- (b) Exhibits and Reports on Form 8K

During the fourth quarter 2002, we filed the following Current Reports on Form 8-K: Report filed on March 12, 2003, concerning events that occurred on March 11, 2003.

(c) As of the date of the filing of this Annual Report on Form 10-K/A no proxy materials have been furnished to security holders. Copies of all proxy materials will be sent to the Commission in compliance with its rules. Except as disclosed

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

in the footnotes, the following exhibits were filed with the Securities and Exchange Commission as exhibits to the Company's 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.*
2.2	Second Asset Purchase Agreement dated March 11, 2003, by and between the Company and ISI.*
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	Form of Class A Redeemable Warrant Certificate
4.3	Form of Underwriter's Unit Option Purchase Agreement
4.4	Form of Class A Redeemable Warrant Agreement with Continental Stock and Transfer and Trust Company
4.5	Rights Agreement, dated as of November 19, 2002, between the Company and Continental Stock Transfer & Trust Company. The Rights 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.**
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
10.8	Employment Agreement by and between the Registrant and Harris Freedman, dated August 1, 1994
10.9	Employment Agreement by and between the Company and Sharon Will dated August 1, 1994
10.10	License Agreement by and between the Company and The Johns Hopkins University, dated December 31, 1980
10.11	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
10.12	Pharmaceutical Use Agreement, by and between the Company and Temple University, dated August 3, 1988
10.13	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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

- 10.14 Lease Agreement between the Company and Red Gate Limited Partnership, dated November 1, 1989, relating to the Company's Rockville, Maryland facility
- 10.15 Agreement between the Company and Bioclones (Proprietary) Limited
- 10.16 Amendment, dated August 3, 1995, to Agreement between the Company and Bioclones (Proprietary) Limited (contained in Exhibit (10.46)
- 10.17 Amended employment agreement by and between the Company and Robert E. Peterson dated April 1, 2001
- 10.18 Forbearance Agreement dated March 11, 2003, by and between ISI, the American National Red Cross and the Company.*
- 10.19 Forbearance Agreement dated March 11, 2003, by and between ISI, GP Strategies Corporation and the Company.*
- 10.20 Securities Purchase Agreement, dated March 12, 2003, by and among the Company and the Buyers named therein.*
- 10.21 Form of 6% Convertible Debenture of the Company.*
- 10.22 Form of Warrant for Common Stock of the Company.*
- 10.23 Registration Rights Agreement, dated March 12, 2003, by and among the Company and the Buyers named therein.*
- 10.24 Agreement with Esteve.
- 10.25 Agreement with Gentiva Health Services.
- 10.26 Agreement with Biovail Corporation International.
- 21 Subsidiaries of the Registrant
- 23.01 BDO Seidman, LLP consent
- 99.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.***
- 99.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.***

* Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 0-27072) dated March 12, 2003 and is hereby incorporated by reference.

** 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) dated March 12, 2003 and is hereby incorporated by reference.

*** Filed herewith.

SIGNATURES

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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

HEMISPHERx BIOPHARMA, INC.

By: /S/William A. Carter, M.D.

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

May 20, 2003

We, the undersigned officers and directors of Hemispherx Biopharma, Inc. hereby severally constitute William A. Carter, our true and lawful attorney with full power to him, and to him singly, to sign for us and in our names in the capacities indicated below, any and all reports (including any amendments thereto), with all exhibits thereto and any and all documents in connection therewith, and generally do all such thing in our name and on our behalf in such capacities to enable Hemispherx Biopharma, Inc. to comply with the applicable provision of Securities Exchange Act of 1934, as amended, and all requirements of the Securities and Exchange Commission, and we hereby ratify and confirm our signatures as they may be signed by our said attorneys, to any and all such reports (including any Amendments thereto) and other documents in connection therewith.

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

/S/William A. Carter Chairman of the Board, Chief Executive

William A. Carter, M.D. Officer and Director September 9, 2003

/s/Richard Piani Director September 9, 2003

Richard Piani

/S/Robert E. Peterson Chief Financial Officer September 9, 2003

Robert E. Peterson

/S/Ransom Etheridge Secretary And Director September 9, 2003

Ransom Etheridge

/s/William Mitchell Director September 9, 2003

William Mitchell, M.D., Ph.D.

CERTIFICATIONS

Certifications pursuant to Securities and Exchange Act of 1934 Rule 13a-14 as

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002:

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

1. I have reviewed this amendment to the Annual Report on 10-K of the Registrant;
2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operation and cash flow of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to filing date of this annual report (the "Evaluation Date"); and
 - c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weakness.

Date: September 9, 2003

/s/_William A. Carter

William A. Carter
Chief Executive Officer

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

1. I have reviewed this amendment to the annual report on Form 10-K of the Registrant;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operation and cash flow of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have;

- a. Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
- b. Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to filing date of this annual report (the "Evaluation Date"); and
- c. Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

- a. All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
- b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

internal controls: and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weakness.

Date: September 9, 2003

/s/ Robert E. Peterson

Robert E. Peterson
Chief Financial Officer

F-1

HEMISPHERx BIOPHARMA, INC AND SUBSIDIARIES

Index to Consolidated Financial Statements

	Page
Report of Independent Certified Public Accountants.	F-2
Consolidated Balance Sheets at December 31, 2001 and 2002. . .	F-3
Consolidated Statements of Operations for each of the years in the three-year period ended December 31, 2002.	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, 2002	F-5
Consolidated Statements of Cash Flows for each of the years in the three-year period ended December 31, 2002	F-6
Notes to Consolidated Financial Statements	F-8

F-2

Report of Independent Certified Public Accountants

The Board of Directors and Stockholders
Hemispherx Biopharma, Inc.

We have audited the accompanying consolidated balance sheets of Hemispherx Biopharma, Inc. and subsidiaries as of December 31, 2001 and 2002 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, 2002. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Hemispherx Biopharma, Inc. and subsidiaries as of December 31, 2001 and 2002 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2002 in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO SEIDMAN, LLP

Philadelphia, Pennsylvania

March 13, 2003, except for note 12, which is as of March 31, 2003

F-3

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2001 and 2002
(in thousands)

	December 31,	
	2001	2002
ASSETS		
Current assets:		
Cash and cash equivalents	\$3,107	\$ 2,256
Short term investments (Note 3)	5,310	555
Other receivables (Note 12)	8	1,507
Prepaid expenses and other current assets	381	71
	8,806	4,389
Property and equipment, net	246	155
Patent and trademark rights, net	1,025	995
Investments in unconsolidated affiliates	1,878	408
Other assets	80	93
	\$12,035	\$ 6,040
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 979	\$ 786
Accrued expenses (Note 4)	293	678
	1,272	1,464
Commitments and contingencies (Notes 7,9, 10 and 12)		
Minority Interest in subsidiary (Note (5c))	-	946

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Stockholders' equity (Note 5):		
Common stock	33	33
Additional paid-in capital	106,832	107,155
Accumulated other comprehensive income (Note 2i)	17	35
Accumulated deficit	(91,649)	(99,073)
Treasury stock	(4,470)	(4,520)
	-----	-----
Total stockholders' equity	10,763	3,630
	-----	-----
Total liabilities and stockholders' equity	\$12,035	\$ 6,040
	=====	=====

See accompanying notes to consolidated financial statements.

F-4

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations For each of the years
in the three-year period ended December 31, 2002
(in thousands, except share and per share data)

	December 31,		
	2000	2001	2002
	-----	-----	-----
Revenue:	\$788	\$390	\$341
License Fee income (Note 9)	-	-	563
	-----	-----	-----
	788	390	904
Costs and expenses:			
Research and development	6,136	5,780	4,946
General and administrative	3,695	3,412	2,015
	-----	-----	-----
Total costs and expenses	9,831	9,192	6,961
Equity loss and write offs of investments in unconsolidated affiliates (Note 2c)	(81)	(565)	(1,470)
Interest and other income	572	284	103
	-----	-----	-----
Net loss	\$ (8,552)	\$ (9,083)	\$ (7,424)
	=====	=====	=====
Basic and diluted loss per share	\$ (.29)	\$ (.29)	\$ (.23)
	=====	=====	=====
Weighted average shares outstanding	29,251,846	31,433,208	32,085,776
	=====	=====	=====

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

See accompanying notes to consolidated financial statements.

F-5

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
 Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Income
 For each of the years in the three-year period ended December 31,

(in thousands except share data)

	Common Stock ----- Shares -----	Common Stock .001 Par Value	Additional paid in capital	Deferred Compensation	Accumulated other Comprehensive Income (loss)	Accumul Deficit
Balance at December 31, 1999	27,974,507	\$ 28	\$ 87,972	\$ (310)	\$ -	\$ (74,01
Common stock issued	2,393,381	2	9,860	-	-	-
Purchase of equity investment	-	-	67	-	-	-
Treasury stock purchased	-	-	-	-	-	-
Treasury stock issued in settlement of debt	-	-	8	-	-	-
Stock compensation and service expense, net	-	-	87	310	-	-
Registration costs	-	-	(10)	-	-	-
Net comprehensive (loss)	-	-	-	-	34	(8,55
Balance at December 31, 2000	30,367,888	30	97,984	-	34	(82,56
Common stock issued	2,155,900	3	8,072	-	-	-
Purchase of equity investment	12,000	-	72	-	-	-
Treasury stock purchased	-	-	-	-	-	-
Note issued for purchase of stock	-	-	(60)	-	-	-
Stock issued in settlement of debt	21,198	-	91	-	-	-
Stock and stock warrant compensation expense	19,000	-	673	-	-	-

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Net comprehensive (loss)	-	-	-	-	(17)	(9,083)
Balance at December 31, 2001	32,575,986	33	106,832	-	17	(91,600)
4175:						
Common stock issued	25,800	-	37	-	-	-
Treasury stock Purchased	-	-	-	-	-	-
Stock issued in settlement of debt	48,392	-	154	-	-	-
Stock and stock warrant compensation expense	-	-	132	-	-	-
Net comprehensive (loss)	-	-	-	-	18	(7,400)
Balance at December 31, 2002	32,650,178	\$ 33	\$ 107,155	\$ -	\$35	\$ (99,000)

F-5

4175: See accompanying notes to consolidated financial statements

F-6

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash
Flows for each of the years in the three-year period
ended December 31, 2002
(in thousands)

	December 31		
	2000	2001	2002
Cash flows from operating activities:			
Net loss	\$ (8,552)	\$ (9,083)	\$ (7,424)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of property and equipment	131	127	91
Amortization of patent and trademark rights	356	397	206
Equity loss and write offs of investments in unconsolidated affiliates.	81	565	1,470
Stock compensation and service expense	397	673	132
Changes in assets and liabilities:			
Other receivables.	15	52	(1,293)
Prepaid expenses and other current assets.	(463)	202	104
Accounts payable	210	(271)	(67)
Accrued expenses	(266)	139	385
Security deposits.	17	(82)	(13)
Net cash used in operating activities.	(8,074)	(7,281)	(6,409)

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Cash flows from investing activities:			
Purchase of property and equipment	(171)	-	-
Additions to patent and trademark rights	(197)	(218)	(176)
Maturity of short term investments	2,157	4,613	5,293
Purchase of short term investments.	(4,589)	(5,293)	(520)
Investments in unconsolidated affiliates	(411)	(22)	(-)
Other investments.	(34)	-	-
	-----	-----	-----
Net (used in) cash provided by investing activities.	(3,245)	(920)	4,597
	-----	-----	-----

F-7

(CONTINUED)

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

	December 31,		
	2000	2001	2002
	-----	-----	-----
Cash flows from financing activities:			
Proceeds from stock subscriptions and issuance of common stock, net.	2,250	72	\$ 65
Proceeds from issuance of preferred stock of subsidiary	-	-	946
Proceeds from exercise of stock warrants	9,985	8,075	-
Purchase of treasury stock	(3,591)	(560)	(50)
	-----	-----	-----
Net cash provided by financing activities.	8,644	7,587	961
	-----	-----	-----
Net decrease in cash and cash equivalents.	(2,675)	(614)	(851)
Cash and cash equivalents at beginning of year.	6,396	3,721	3,107
	-----	-----	-----
Cash and cash equivalents at end of year	\$ 3,721	\$ 3,107	\$2,256
	=====	=====	=====
Supplemental disclosures of cash flow information:			
Issuance of treasury stock for Investment	\$ 618	\$ -	\$ -
	=====	=====	=====
Issuance of common stock for accrued expenses.	\$ 34	\$ 91	\$ 154
	=====	=====	=====
Issuance of common stock for note receivable	\$ -	\$ 60	\$ -
	=====	=====	=====

See accompanying notes to consolidated financial statements.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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

(1) Business

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

The consolidated financial statements include the financial statements of Hemispherx BioPharma, Inc. and its wholly-owned subsidiaries BioPro Corp., BioAegean Corp. and Core BioTech Corp. which were incorporated in September 1994, and are inactive, and Hemispherx Biopharma-Europe N.V./S.A. which was incorporated in 1998 and Hemispherx Biopharma Europe S.A., which was incorporated during 2002. All significant intercompany balances and transactions have been eliminated in consolidation. The Company also has investments in unconsolidated affiliates which are accounted for on the equity or cost method of accounting (see note 2c).

On March 11, 2003, we acquired from Interferon Sciences, Inc. ("ISI") ISI's inventory of ALFERON N Injection(R), a pharmaceutical product used for the treatment of certain types of genital warts, and a limited license for the production, manufacturing, use, marketing and sale of this product. As partial consideration, we issued 487,028 shares of our common stock to ISI. Pursuant to our agreements with ISI, we are in the process of registering the foregoing shares for public sale. Except for 62,500 of the shares issued to ISI, we have guaranteed the market value of the shares retained by ISI through March 11, 2005 to be \$1.59 per share.

On March 11, 2003, we also entered into an agreement to purchase from ISI all of its rights to the product and other assets related to the product including, but not limited to, real estate and machinery. This purchase is contingent on us receiving appropriate Governmental approval for the real estate transaction. For these assets, we have agreed to issue to ISI an additional 487,028 shares and to issue 314,465 shares and 267,296 shares, respectively to two creditors of ISI. The Company will be required to satisfy other liabilities of ISI which aggregate approximately \$521,000 and which are secured by a lien on ISI's real estate. We have guaranteed the market value of all but 62,500 of these shares on terms substantially similar to those for the initial acquisition of the ISI assets.

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

On May 1, 1997, the Company received permission from the U.S. Food and Drug Administration ("FDA") to recover the cost of Ampligen(R) from patients enrolled in the Company's AMP-511 ME/CFS open-label treatment protocol. The cost of Ampligen(R) to the patient is \$2,100 for the first eight weeks of treatment and \$2,400 for each additional eight-week period thereafter.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

In 1998, the Company initiated the recruitment of clinical investigators to enroll ME/CFS patients in the confirmatory Phase III double blind placebo-controlled clinical study of Ampligen(R). This clinical trial was approved by the FDA in 1998 and is designed to test the safety and efficiency of Ampligen(R) in treating ME/CFS.

The ME/CFS Cost Recovery Treatment Program in Belgium was started in 1994 with the approval of the Belgian Regulatory authorities. Since its inception, over 150 patients have participated in this program. Clinical data collected in the treatment of these ME/CFS patients will be used to support the Company's European Medical Evaluation Agency ("EMEA") Drug Approval Application and in applications in other regulatory jurisdictions. A similar program underway in Austria is undergoing expansion.

(2) Summary of Significant Accounting Policies

(a) Cash and Cash Equivalents

Cash equivalents consist of money market certificates and overnight repurchase agreements collateralized by money market securities with original maturities of less than three months, with both a cost and fair value of \$2,552,000 and \$1,404,000 at December 31, 2001 and 2002, respectively.

(b) Short-term Investments

Investments with original maturities of more than three months and marketable equity securities are considered available for sale. The investments classified as available for sale include debt securities and equity securities carried at estimated fair value of \$5,310,000 and \$555,000 at December 31, 2001 and 2002 respectively. The unrealized gains and losses are recorded as a component of shareholders' equity.

(c) Investments in unconsolidated affiliates

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

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

In 1998, the Company invested \$1,074,000 for a 3.3% equity interest in R.E.D. Laboratory ("R.E.D."). R.E.D. is a privately held biotechnology company for the development of diagnostic markers for Chronic Fatigue Syndrome and other chronic immune diseases. We have a research collaboration agreement with R.E.D. to assist in this development. R.E.D. is headquartered in Belgium. The investment was recorded at cost. During the three months ended June 30, 2002 and December 31, 2002 we recorded non-cash charges of \$678,000 and \$396,000 respectively, to operations with respect to our investment in R.E.D. These charges were the result of our determination that R.E.D.'s business and financial position had deteriorated to the point that our investments had been permanently impaired.

In April, 1999 we acquired a 30% equity position in the California Institute of Molecular Medicine ("CIMM") for \$750,000 and entered into a research and development arrangement. CIMM'S research is focused on developing therapies for use in treating patients affected by Hepatitis C ("HCV"). We use the equity method of accounting with respect to this investment. During the fourth quarter of 2001 we recorded a non-cash charge of \$485,000 with respect to our investment in CIMM. This was a result of our determination that CIMM's operations have not yet evolved to the point where the full carrying value of our investment could

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

be supported based on that company's financial position and operating results. During 2002, CIMM continued to suffer significant losses resulting in a deterioration of its financial condition. The \$485,000 written off during 2001 represented the unamortized balance of goodwill included as part of the Company's investment. Additionally, during 2001 the Company reduced its investment in CIMM based on its percentage interest in CIMM's continued operating losses. The Company's remaining investment at December 31, 2001 in CIMM, representing its 30% interest in CIMM's equity at such date, was not deemed to be permanently, but was completely written off during 2002. Such amount was not material. These charges are reflected in the Consolidated Statements of Operations under the caption "Equity loss in unconsolidated affiliates". We still believe CIMM will succeed in their efforts to advance therapeutic treatment of HCV. We believe that CIMM's Hepatitis C diagnostic technology has great promise and fills a long-standing global void in the collective abilities to diagnose and treat Hepatitis C infection at an early stage of the disorder.

The Company's investment in Ribotech, Ltd. is also accounted for using the equity method of accounting. The Company received 24.9% of Ribotech, Ltd. as partial compensation under the license agreement described in Note 10. Ribotech, Ltd. has incurred net losses since inception. The Company does not share in those losses in accordance with the licensing agreement and is not obligated to fund such losses. The net investment in Ribotech is zero as of December 31, 2001 and 2002. During 2000, the Company prepaid \$500,000 to Ribotech, Ltd. for raw material purchases. \$110,000 of materials were delivered in 2000 and the balance of \$390,000 was applied towards the purchase of materials during 2001.

Investments in unconsolidated affiliates also includes an equity investment in Chronix Biomedical ("Chronix"). Chronix focuses upon the development of diagnostics for chronic diseases. The initial investment was made in May 31, 2000 through the issuance of 50,000 shares of Hemispherx Biopharma, Inc. common stock from the treasury. On October 12, 2000 an additional 50,000 shares of common stock were issued from the treasury for a total investment of approximately \$678,000. During 2001 additional shares of common stock plus cash were given to Chronix for a total investment of \$700,000. The percentage ownership in Chronix is approximately 5.4% and is accounted for under the cost method of accounting. During the quarter ended December 31, 2002, we recorded a noncash charge of \$292,000 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 their current proposed investment offerings.

Pursuant to a Strategic Alliance Agreement, the Company provided Chronix with \$250,000 during 2000 to conduct research in an effort to develop intellectual property on potential new products for diagnosing and treating various chronic illnesses including Chronic Fatigue Syndrome. 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 payment of \$250,000 was charged to research and development expense during 2000.

(d) Property and Equipment	(000 omitted) December 31,	
	2001	2002
	-----	-----
Furniture, fixtures, and equipment	\$ 1,178	\$ 760
Leasehold improvements	96	85
	-----	-----
Total property and equipment	1,274	845
Less accumulated depreciation	1,028	690
	-----	-----
Property and equipment, net	\$ 246	\$ 155

=====

Property and equipment consists of 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 seven years. Depreciation and amortization expense was \$131,000, \$127,000 and \$91,000 for 2000, 2001 and 2002, respectively. In 2002, fully depreciated equipment in the amount of \$418,000 and fully depreciated leasehold improvements in Europe in the amount of \$12,000 were written-off due to the closing of European offices.

(e) Patent and Trademark Rights

Effective October 1, 2001, the Company adopted a 17 year estimated useful life for amortization of its patent and trademark rights in order to more accurately reflect their useful life. Prior to October 1, 2001, the Company was using a 10 year estimated useful life. The adoption of the 17 year life had been accounted for as a change in accounting estimate.

Patents and trademarks are stated at cost (primarily legal fees) and are amortized using the straight line method over the life of the assets. The Company reviews its patents and trademark rights periodically to determine whether they have continuing value. Such review includes an analysis of the patent and trademark's ultimate revenue and profitability potential on an undiscounted cash flow basis to support the realizability of its respective capitalized cost. Management's review addresses whether each patent continues to fit into the Company's strategic business plans. During the years ended December 31, 2000, 2001 and 2002, the Company decided not to pursue the technology in certain countries for strategic reasons and recorded charges of \$32,000, \$38,000 and \$5,000, respectively. Amortization expense was \$324,000, \$359,000 and \$201,000 in 2000, 2001 and 2002, respectively. The accumulated amortization as of December 31, 2001 and 2002 is \$2,096,000 and \$1,996,000, respectively.

(f) Revenue

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.

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

The agreement also requires the licensee to pay of 1,000,000 Euros after FDA approval of Ampligen(R) for the treatment of ME/CFS and a fee of 1,000,000 after issuance in Spain of final marketing approval authorization for Ampligen(R) for the treatment of ME/CFS. See Note 6 for more detailed information.

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

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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

cash earned (including the upfront payment).

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

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

During the periods ending December 31, 2000, 2001 and 2002 the Company did not receive any grant monies from local, state and or Federal Agencies.

(g) Net Loss Per Share

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Equivalent common shares, consisting of stock options and warrants, are excluded from a calculation of diluted net loss per share 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 Income (loss)

On January 1, 1998, the Company adopted SFAS No. 130, Reporting Comprehensive Income. Statement of Financial Accounting Standards (SFAS) No. 130 establishes standards for reporting and presentation of the Company's comprehensive income (loss) and its components in a full set of financial statements. Comprehensive income (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 income (loss).

(j) Use of Estimates

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

(k) Foreign Currency translations

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Assets and liabilities of the Company's foreign operations are generally translated into U.S. dollars at current exchange rates as of the 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.

(1) Recent Accounting Standard and Pronouncements

In January 2003, the Financial Accounting Standards Board (FASB) issued Interpretation No. 46, "Consolidation of Variable Interest Entities" ("Interpretation No. 46"), that clarifies the application of Accounting Research Bulletin No. 51, Consolidated Financial Statements, "to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. Interpretation No. 46 is applicable immediately for variable interest entities created after January 31, 2003. For variable interest entities created to January 31, 2003, the provisions of Interpretation No. 46 are applicable no later than July 1, 2003. The Company does not expect this Interpretation to have an effect on the consolidated financial statements.

In August 2001, the FASB issued Statement No. 143, "Accounting for Asset Retirement Obligation" ("SFAS 143"), which provides the accounting requirements for retirement obligation associated with tangible long-lived assets. SFAS 143 requires entities to record the fair value of the liability for an asset retirement obligation in the period in which it is incurred and is effective for the Company's 2003 fiscal year. The adoption of SFAS 143 is not expected to have a material impact on the Company's consolidated results of operations, financial position or cash flows.

In October 2001, the FASB issued Statement No. 144, "Accounting for the Impairment or Disposal of Long-lived Assets" ("SFAS 144"). SFAS 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This statement supersedes SFAS Statement No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," and the accounting and reporting provision of APB Opinion No. 30, "Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions. "This new pronouncement also amends Accounting Research Bulletin (ARB) No. 51 "Consolidated Financial Statements, "to eliminate the exception to consolidation for a subsidiary for which control is likely to be temporary. SFAS 144 requires that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired and also broadens the presentation of discontinued operation to include more disposal transactions. SFAS 144 is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years. Adoption of SFAS 144 on January 1, 2002, did not have an impact on the Company's financial position, cash flows or results of operation for the year ended December 31, 2002.

In June 2002, the FASB issued Statement No. 146, "Accounting for Cost Associated with Exit or Disposal Activities" ("SFAS 146"), which addresses financial accounting and reporting for costs associated with exit or disposal activities, and nullifies Emerging Task Force (EITF) Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit and Activity (including Certain Costs Incurred in a Restructuring)" which previously governed the accounting treatment for restructuring activities. SFAS 146 applies to costs associated with an exit activity that does not involve an entity newly acquired in a business combination or with disposal activity covered by SFAS 144. Those costs include, but are not limited to, the following: (1) termination benefits provided to current employees that are involuntarily terminated under the terms of a benefit arrangement that, in substance, is not an ongoing benefit

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

arrangement or individual deferred-compensation contract, (2) costs to terminate a contract that is not a capital lease, and (3) costs to consolidated facilities or relocated employees. SFAS 146 does not apply to costs associated with the retirement of long-lived assets covered by SFAS 143. SFAS 146 will be applied prospectively and is effective for exit or disposal activities after December 31, 2002.

In December 2002, the FASB issued Statement No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure", and amendment of FASB Statement No. 123 ("SFAS"148). SFAS 148 amends FASB Statement No. 123, Accounting for Stock-Based Compensation, to provide alternative method of transition for an entity that voluntarily changes to the fair value based on accounting for stock-based employee compensation. It also amends the disclosure provisions of that Statement to require prominent disclosure about the effects on reported net income of an entity's accounting policy decisions with respect to stock-based employee compensation. Finally, this Statement amends (APB) Opinion No. 28, "Interim Financial Reporting" to require disclosure about those effects in interim financial information. SFAS 148 is effective for financial statements for fiscal years ending after December 15, 2002. The Company will continue to account for stock-based compensation using the intrinsic value method of APB Opinion No. 25, "Accounting for Stock Issued to Employees", but has adopted the enhance disclosure requirements of SFAS 148 (See Note 10).

F-31

(m) Research and Development Costs

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

(n) Stock Compensation

The Company applies the intrinsic value method in accordance with APB Opinion No. 25, "Accounting for Stock Issued to Employees" in accounting for stock-based compensation of its employees and, accordingly, no compensation cost has been recognized for stock purchase warrants and options issued to employees. Had the Company determined compensation cost based on the fair value at the grant date for its stock-based compensation of its employees in accordance with FASB 123, the Company's net loss would have been increased to the pro forma amounts indicated below:

(in thousands except for per share data)

For the years ended December 31,	2000	2001	2002
-----	----	----	----
Net loss-as reported	\$(8,552)	\$(9,083)	\$(7,424)
 Add: Stock based compensation included in net loss as reported, net of related tax effects	-	-	-
 Deduct: Stock based compensation determined under fair value based method for all awards, net of related tax effects	(237)	(632)	(1,085)

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Net loss - pro forma	\$ (8,789)	\$ (9,715)	\$ (8,509)
Basic and diluted loss per share - as reported	\$ (.29)	\$ (.29)	\$ (.23)
Basic and diluted loss per share - pro forma	\$ (.30)	\$ (.31)	\$ (.27)

In 1999, the Company granted 275,000 warrants to employees in recognition of services performed and services to be performed. The fair value of the stock purchase warrants granted during 1999 was also determined using the Black-Scholes option pricing model with a rate of 5.18%, volatility of 135.4%-294.31%, and expected lives of two years. These warrants are included in the 2,633,000 non-public warrants outstanding as of December 31, 2000 as described in Footnote 5 (ii). On page 62 there were no warrants granted to employees during 2000. During 2001 the Company granted 406,650 warrants to employees. The Company granted to employees 8,000 options in 2000 and 94,000 options in 2001. See Footnote 5(i) on page 62. The fair value of stock options and warrants granted during 2001 was determined using Black Scholes Option Pricing Model with a rate of 4.23%, volatility of 69.7% to 74.9% and expected life of three years. In 2002 1,622,000 warrants were issued to employees in recognition of services performed and services to be performed. The fair value of the warrants granted during 2002 was determined using Black Scholes Option Pricing model with a rate of 5.23%, volatility of 63.17%, and expected life of two and one half & four years. The weighted average fair value of those options and warrants granted during the years ended December 31, 2002, 2001 and 2000, were estimated as \$0.62, \$1.57 and \$1.09, respectively.

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

The exercise price of all stock warrants granted was equal to the fair market value of the underlying common stock as defined by APB opinion No. 25 on the date of the grant.

(3) Short-term investments:

Securities classified as available for sale are summarized below:

(000's omitted)

	Adjusted Cost	December 31, 2001		Carrying Value
		Unrealized Gains	Unrealized (Losses)	
General Motors Commercial Paper	\$ 3,977	\$ 13	\$ -	\$ 3,990
Ford Motors Commercial Paper	795	1	-	796
Calamos Mutual Market	521	3	-	524

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Total	\$ 5,293	\$ 17	\$ -	\$ 5,310
	=====	=====	=====	=====

December 31, 2002

Unrealized

	Adjusted Cost	Gains	(Losses)	Carrying Value
	-----	-----	-----	-----
Calamos Mutual Market	\$ 521	\$ 34	\$ -	\$ 555
	-----	-----	-----	-----
Total	\$ 521	\$ 34	\$ -	\$ 555
	=====	=====	=====	=====

(4) Accrued Expenses

Accrued expenses at December 31, 2001 and 2002 consists of the following:

	(000's omitted)	
	December 31,	
	-----	-----
	2001	2002
Salaries	\$ 85	\$ 6
Other Accrued Expenses	208	222
Fees Associated with Litigation Settlement.	-	450
	-----	-----
	\$ 293	\$ 678
	=====	=====

(5) Stockholders' Equity

(a) Preferred Stock

The Company is authorized to issue 5,000,000 shares of \$.01 per value preferred stock with such designations, rights and preferences as may be determined by the Board of Directors. There were no preferred shares issued and outstanding at December 31, 2001 and 2002.

(b) Common Stock and Exercise of Stock Warrants

The Company is authorized to issue 50,000,000 shares of \$.001 par value Common stock. As of December 31, 2001 and 2002, 32,060,280 and 32,106,972 shares, net of shares held in the treasury, were outstanding, respectively.

The exercise of stock warrants generated \$9,985,000 and \$8,075,000 in net proceeds to the Company in 2000 and 2001, respectively. There were no exercises during 2002.

(c) New Equity Financing

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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

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

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

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

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

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

(d) 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 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 ten 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.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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

	<u>2000</u>			<u>2001</u>			Shares
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	
Outstanding, beginning of year	294,000	\$1.06-6.00	\$ 3.60	218,567	\$1.06-6.81	\$3.45	306,263
Granted	8,000	\$3.00-6.81	\$ 4.88	94,000	\$4.03	\$4.03	
Canceled	(76,677)	\$3.50-4.34	\$ 4.09	(6,304)	\$4.34-6.81	\$5.91	(11,608)
Exercised	(6,756)	\$1.06-3.50	\$ 2.75	-	-	-	
Outstanding, end of year	<u>218,567</u>	\$1.06-6.81	\$ 3.45	<u>306,263</u>	\$1.06-4.34	\$3.58	<u>294,655</u>
Exercisable	<u>198,717</u>	\$1.06-6.81	\$ 3.48	<u>234,263</u>	\$1.06-4.34	\$4.67	<u>252,861</u>
Weighted average remaining contractual life (years)	<u>3.83 years</u>			<u>3.57 years</u>			<u>3.68 years</u>
Exercised in current and prior years	<u>(37,791)</u>			<u>(37,791)</u>			<u>(37,791)</u>
Available for future grants	<u>204,440</u>			<u>116,744</u>			<u>170,064</u>

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

In December 1992, the Board of Directors approved the 1992 Stock Option Plan (see page 57 "1992 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, advisers, 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 ten years and one month from the date as of which an option agreement is executed. To date, no options have been granted under the 1992 stock option Plan.

The Company's 1993 Stock option Plan ("1993 Plan") was approved by the Board of Directors in July 1993. The outline of the 1993 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 Plan is administered by the Compensation Committee of the Board of Directors. Under the 1993 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 Plan to date and no shares of common stock have been issued thereunder.

(ii) Stock Warrants

Number of warrants exercisable into shares of common stock

	<u>2000</u>			<u>2001</u>		
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price
Outstanding, beginning of year	14,058,010	\$1.75-10.85	\$3.90	11,624,168	\$1.75-12.00	\$4.05
Granted	293,800	\$6.00-12.00	6.40	856,650	\$5.00-16.00	\$9.89
Canceled	(341,017)	\$2.00-10.85	6.01	(3,396,508)	\$2.50-4.00	\$3.89
Exercised	(2,386,625)	\$1.75-4.00	4.19	(2,157,200)	\$1.75-4.00	\$3.75
Outstanding, end of year	<u>11,624,168</u>	<u>\$1.75-12.00</u>	<u>\$4.05</u>	<u>6,927,110</u>	<u>\$1.75-16.00</u>	<u>\$4.77</u>
Exercisable	<u>11,624,168</u>	<u>\$1.75-12.00</u>	<u>\$4.05</u>	<u>6,927,110</u>	<u>\$1.75-16.00</u>	<u>\$4.77</u>

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

Weighted average remaining contractual life (years)	2.66 years =====	4.05 years =====	4. ==
Years exercisable	2001-2006 =====	2002-2006 =====	2 =

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

Warrants Issued to Stockholders

In 2000, 149,807 warrants expired and 147,000 warrants were converted to common stock. At December 31, 2000, there were 305,160 warrants remaining. In 2001, 73,000 warrants were converted to common stock. At December 31, 2001 there were 232,160 warrants remaining. In 2002, 10,000 warrants were converted to common stock. At December 31, 2002 there were 222,160 warrants remaining. These warrants have an exercise price of \$3.50 per share and expire in October 2004.

Other Stock Warrants

In addition, the Company has other issued warrants outstanding - totaling 7,745,650 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. This extension resulted in a non-cash charge of approximately \$3,097,000. In 1999, 235,000 warrants were exercised and 5,000 warrants were exercised in 2000. At December 31, 2000, there were 1,840,000 Rule 701 warrants remaining. In 2001, 20,000 of these warrants expired, leaving a balance of 1,820,000 in warrants outstanding at December 31, 2001. During 2002, 420,000 warrants expired and the Company extended the expiration date of the remaining balance of 1,400,000 stock warrants 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 if as the extension date exceeded the fair value of the underlying common stock.

In May 1995, the Company and certain officers, directors and shareholders entered into a Standby Finance Agreement pursuant to which the parties agreed to provide an aggregate of \$5,500,000 in financing to the Company during 1995 in the event that existing and additional financing was insufficient to cover the cash needs of the Company through December 31, 1996. In exchange, the Company issued warrants to purchase an aggregate of 2,750,000 shares of Common stock at \$1.75 per share to the parties. In 1999, 290,000, in 2000, 216,500, in 2001, 200,000 and in 2002, 1,300 of these warrants were exercised, leaving a balance of 1,450,200 warrants. These warrants expire June 30, 2005.

In connection with the stock issued in September, 1997, the Company issued 385,067 warrants to several entities to purchase common stock at \$4 per share, 149,034 of these warrants were exercised in 1998, 173,300 were exercised in 1999, and 34,333 were exercised in 2000. The remaining 28,400 warrants expired December 31, 2001.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

In the years 2000, 2001 and 2002 the Company issued 293,800, 450,000 and 25,000 warrants, respectively, to investment banking firms for services performed on behalf of the Company. Accordingly, the Company recorded stock compensation expense of \$397,000, \$673,000 and \$133,000 for the years 2000, 2001 and 2002, respectively. These warrants have various vesting dates and exercise prices ranging from \$4.00 to \$16.00 per share. In 2000, 75,000 of these warrants were exercised. December 31, 2002 1,193,800 warrants were outstanding. These warrants are exercisable in five years from the date of issuance.

In 2000, 2001, and 2002, the Company had non-public warrants outstanding of 2,633,000, 2,254,650, and 3,701,650 respectively. These warrants are exercisable at rates of \$2.50 to \$10.00 per share of common stock. The exercise price was equal to the fair market value of the stock on the date of grant. During 2002, the Company granted 1,777,000 warrants to employees for services performed. These warrants have a weighted average exercise price of \$2.07 per share, and have been included in the proforma loss calculation in Note 2(n)1982. During 2001, 370,000 of the non-public warrants were exercised and 415,000 expired without being exercised. 2,254,650 of the non-public warrants were outstanding. During 2002, none of these warrants were exercised and 750,000 expired. 3,701,650 of the non-public warrants were outstanding at December 31, 2002. During 2002 the Company also extended the expiration date of 322,000 of these warrants for a period of five years to now expire in the years ending 2007 and 2008. These stock warrants have exercise prices ranging from \$3.50 to \$4.00. In accordance FASB 44, no compensation expense was recognized as the exercise price at the extension date exceeded the fair value of the underlying common stock.

(e) Stock Repurchase

On February 19, 1999, the Board of Directors authorized the repurchase of up to 200,000 shares of the Company's common stock on the open market. On February 8, 2000, the Board authorized the repurchase of another 200,000 shares.

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."

(f) Rights Offering

On November 19, 2002, the Board of Directors of Hemispherx Biopharma, Inc. (the "Company") declared a dividend distribution of one Right for each outstanding share of common stock to stockholders of record at the close of business on 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) ten 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) ten

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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.

(6) Segment and Related Information

The Company operates in one segment, which is the performance of research and development activities related to Ampligen(R) and other drugs under development.

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

	(000's omitted)		
	2000	2001	2002
	-----	-----	-----
United States	\$506	\$274	\$237
Belgium	272	107	74
Other	10	9	30
	-----	-----	-----
	\$788	\$ 390	\$341
	=====	=====	=====

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

(7) Research, Consulting and Supply Agreements

In December, 1999, the Company entered into an agreement with Biovail Corporation International ("Biovail"). Biovail is an international full service pharmaceutical company engaged in the formulation, clinical testing, registration and manufacture of drug products utilizing advanced drug delivery systems. Biovail is headquartered in Toronto, Canada. The agreement grants Biovail the exclusive distributorship of the Company's product Ampligen(R) in the Canadian territories subjects 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' product. 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 the company equity at prices above the then current market price and agreed to make further payments based on reaching certain regulatory milestones. The Agreement

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

requires Biovail to penetrate certain market segments at specific rates in order to maintain market exclusivity.

The Company has entered into agreements for consulting services, which are performed at medical research institutions and by medical and clinical research individuals. The Company's obligation to fund these agreements can be terminated after the initial funding period, which generally ranges from one to three years or on an as-needed monthly basis. During the years ending December 31, 2000, 2001 and 2002, the Company incurred approximately \$924,000, \$595,000 and \$395,000 respectively, of consulting service fees under these agreements. These costs are charged to research and development expense as incurred.

(8) 401(K) Plan

The Company has a defined contribution plan, entitled the Hemispherx Biopharma Employees 401(K) Plan and Trust Agreement (the 401(K) Plan). Full-time employees of the Company are eligible to participate in the 401(K) Plan following one year of employment. Subject to certain limitations imposed by federal tax laws, participants are eligible to contribute up to 15% of their salary (including bonuses and/or commissions) per annum. Participants' contributions to the 401(K) Plan may be matched by the Company at a rate determined annually by the Board of Directors.

Each participant immediately vests in his or her deferred salary contributions, while Company contributions will vest over one year. In 2000, 2001 and 2002 the Company provided matching contributions to each employee for up to 6% of annual pay aggregating \$48,000, \$48,000 and \$38,000, respectively.

(9) Royalties, License, and Employment Agreements

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

In August 1988, the Company entered into a Pharmaceutical use License Agreement with Temple University (the "Temple Agreement"). In July 1994, Temple terminated the Temple Agreement. In November 1994, the Company filed suit against Temple in the Superior Court of the State of Delaware seeking a declaratory judgment that the agreement was unlawfully terminated by Temple and therefore remained in full force and effect. Temple filed a separate suit against the Company seeking a declaratory judgment that its agreement with the Company was properly terminated. These legal actions have now been settled. Under the settlement, the parties have entered into a new Pharmaceutical Use License Agreement ("New Temple Agreement") that is equivalent in duration and scope to the previous license. Under the terms of the New Temple Agreement, Temple granted the Company an exclusive world-wide license for the term of the agreement for the commercial sale of Oragentm products using patents and related technology held by Temple, which license is exclusive except to the extent Temple is required to grant a license to any governmental agency or non-profit organization as a condition of funding for research and development of the patents and technology licensed to the Company.

The Company has contractual agreements with two of its officers. The aggregate annual base compensation under these contractual agreements for 2000, 2001 and 2002 was \$686,000, \$603,000 and \$620,000 respectively. In addition, certain of these officers are entitled to receive performance bonuses of up to 25% of the

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

annual base salary (in addition to the bonuses described below). In 2000, 2001 and 2002, no performance bonuses were granted. In 2001, certain officers were granted warrants and options to purchase 426,650 shares of common stock at \$4.01 per share. In 2002, certain officers were granted warrants and options to purchase 1,220,000 shares of common stock at \$2.00 - \$4.03 per share. One of the employment agreements provides for bonuses based on gross proceeds received by the Company from any joint venture or corporate partnering agreement.

In October 1994, the Company entered into a licensing agreement with Bioclones (Propriety see page 13) LTD 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 provides Bioclones with an exclusive manufacturing and marketing license for certain southern hemisphere countries (including certain countries in South America, Africa and Australia as well as the United Kingdom and Ireland (the licensed territory). In exchange for these marketing and manufacturing rights, the licensing agreement provides for: (a) a \$3 million cash payment to the Company, all of which was received during the year ended December 31, 1995; (b) the formation and issuance to the Company of 24.9% of the capital stock of Ribotech, Ltd., a company which developed and operates a new manufacturing facility that produces raw material components of Ampligen(R) and (c) royalties of 6% to 8% of net sales of the licensed products in the licensed territories as defined, after the first \$50 million of sales. Bioclones will be granted a right of first refusal to manufacture and supply to the Company licensed products for not less than one third of its world-wide sales of Ampligen(R), excluding Bioclones related sales. In addition, Bioclones will have the right of first refusal for oral vaccines in the licensed territory. In 2000, the Company paid to Ribotech a total of \$500,000 for the current and future purchases and delivery of polymers. Of the \$500,000 advanced in 2000, a balance of \$390,000 was included in other assets in 2000 and was used for purchases of polymers in 2001. In 2002, \$262,000 was paid to Ribotech for delivery of Polymers.

In October 1994, the Board of Directors granted a director of the Company the right to receive 3% of gross proceeds of any licensing fees received by the Company pursuant to the Bioclones licensing agreement, a fee of .75% of gross proceeds in the event that 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 Bioclones. The Company may prepay in full its obligation to provide commissions within a ten year period.

On March 20, 2002, our European subsidiary Hemispherx Biopharma Europe, S.A. ("Hemispherx S.A.") entered into a 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/Encephalomyelitis/Chronic Fatigue Syndrome ("ME/CFS"). In addition to other terms and other projected payment, 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 two agreements entered into with Interferon Sciences, Inc. ("ISI") (See Note 1 page 76), the Company is obligated to pay ISI a 6% royalty on the net sales of the ALFERON N Injection(R) product.

(10) Leases

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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

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

Year ending December 31, -----	(000's omitted) Operating leases -----
2003.	\$ 279
2004.	286
2005.	240
2006.	193
2007.	65

Total minimum lease payments.	\$ 1,063 =====

Rent expense charged to operations for the years ended December 31, 2000, 2001 and 2002, amounted to approximately \$347,000, \$294,000 and \$307,000 respectively. The term of the lease for the Rockville, Maryland facility is through June, 2005 with an average rent of \$8,000 per month, plus applicable taxes and charges. The term of the lease for the Philadelphia, Pennsylvania offices is through April, 2007 with an average rent of \$15,000 per month, plus applicable taxes and charges.

(11) Income Taxes

As of December 31, 2002, the Company has approximately \$66,000,000 of federal net operating loss carryforwards (expiring in the years 2004 through 2022) available to offset future federal taxable income. The Company also has approximately \$15,000,000 of state net operating loss carryforwards (expiring in the years 2003 through 2007) available to offset future state taxable income. The utilization of certain state net operating loss carryforwards may be subject to annual limitations.

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

Deferred income taxes reflect the net tax effects of temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the carrying amounts used for income tax purposes. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences representing net future deductible amounts become deductible. Due to the uncertainty of the Company's ability to realize the benefit of the deferred tax asset, the deferred tax assets are fully offset by a valuation allowance at December 31, 2001 and 2002.

The components of the net deferred tax asset of December 31, 2001 and 2002 consists of the following:

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

(000,s omitted)

Deferred tax assets:	2001	2002
	----	----
Net operating losses	\$20,790	\$22,440
Accrued expenses and other	21	(16)
Capitalized research and development costs	4,634	3,763
	-----	-----
	25,445	26,187
Less: Valuation allowance	25,445	26,187
	-----	-----
Balance	\$ -0-	\$ -0-
	=====	=====

(12) Contingencies

On September 30, 1998, we filed a multi-count complaint against Manuel P. Asensio, Asensio & Company, Inc. ("Asensio"). The action included claims of defamation, disparagement, tortious interference with existing and prospective business relations and conspiracy, arising out of the 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. This appeal is now pending in the Superior Court of Pennsylvania.

In June 2002, a former ME/CFS clinical trial patient and her husband filed a claim in the Superior Court of New Jersey, Middlesex County, against us, one of our clinical trial investigators and others alleging that she was harmed in the ME/CFS clinical trial as a result of negligence and breach of warranties. We believe the claim is without merit and we are defending the claim against us through our product liability insurance carrier.

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 July 2002, we filed suit in the United States District Court for the Eastern District of Pennsylvania against our insurance company seeking (1) a judicial order declaring our rights and the obligations of our insurance carrier under the insurance policy our insurance carrier sold to us (2) monetary damage for breach of contract resulting from our insurance carrier refusal to fully defend us in connection with the Asensio litigation (3) monetary damages to compensate us for our insurance carrier breach of its fiduciary duty faith and dealing and (4) monetary damages, interest, cost, and attorneys fees to compensate us for violation of the Pennsylvania Bad Faith Statute. On March 31, 2003 we settled

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

our outstanding claim with our insurance carrier for \$1,500,000 relating to reimbursement of expenses in connection with our Asensio law suits. We expect to realize approximately \$1,050,000 of this amount after payment of expenses related to the settlement. Such amount was recorded during the fourth quarter 2002 as a reduction in General and Administrative expenses in our statement of operations.

In March 2003, one of our former law firms filed a complaint in the Court of Common Pleas of Philadelphia County against us for alleged legal fees in the sum of \$65,051. We believe the claim is without merit and are defending the matter.

(13) Related Party Transactions

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

A director of the Company is an attorney in private practice, who has rendered corporate legal services to us from time to time, for which he has received fees. A director of the Company lives in Paris, France and assists our European subsidiaries in their dealings with medical institutions and the European Medical Evaluation Authority. A director of the Company assists us in establishing clinical trial protocols as well as performs other scientific work for us from time to time. For these services, these directors were paid an aggregate of \$173,500, \$144,955 and \$170,150 for the years ending December 31, 2000, 2001 and 2002 respectively.

William A. Carter, Chief Executive Officer of the Company, received an aggregate of \$12,486 in short term advances which were repaid as of December 31, 2001. All advances bore interest at 6% per annum. The Company loaned \$60,000 to a director of the Company in November, 2001 for the purpose of exercising 15,000 class A redeemable warrants. This loan bears interest at 6% per annum.

We paid \$42,775, \$57,750 and \$33,450 for the years ending December 31, 2000, 2001 and 2002, respectively to Carter Realty for the rent of property used at various times in 2002 by us. The property is owned by others and managed by Carter Realty. Carter Realty is owned by Robert Carter, the brother of William A. Carter.

(14) Concentrations of Credit Risk

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

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

2001			

First	Second	Third	Fourth

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

	Quarter	Quarter	Quarter	Quarter	Total
	-----	-----	-----	-----	-----
Revenue	127	\$ 101	\$ 76	\$ 86	\$ 390
Costs and expenses	2,676	2,504	2,262	1,750	9,192
Net loss	(2,480)	(2,343)	(2,145)	(2,115)	(9,083)
Basic and diluted loss per share	----- \$ (.08)	----- \$ (.08)	----- \$ (.07)	----- \$ (.07)	----- \$ (.29)

2002 (1)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
	-----	-----	-----	-----	-----
Revenues and license fee income	\$ 613	\$ 134	\$ 79	\$ 78	\$ 904
Costs and expenses	2,121	2,097	1,961	782	6,961
Net loss	(1,488)	(2,634)	(1,891)	(1,411)	(7,424)
Basic and diluted loss per share	----- \$ (.05)	----- \$ (.08)	----- \$ (.06)	----- \$ (.04)	----- \$ (.23)

(1) During the fourth quarter of 2002, the Company recorded write offs of certain investments in unconsolidated affiliates of approximately \$688,000. (See Note 2(c)). Additionally, during the fourth quarter of 2002, the Company recorded, as a reduction of general and administrative expenses, an amount of \$1,050,000 representing the net settlement with its insurance carrier. (See Note 12).

(16) Debenture Financing

On March 12, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due January 31, 2005 and an aggregate of 743,288 warrants to two investors in a private placement for aggregate anticipated gross proceeds of \$4,650,000. Pursuant to the terms of the Debentures, \$1,550,000 of the proceeds from the sale of the Debentures have been held back and will be released to us if, and only if, we acquire ISI's facility within a set timeframe. The Debentures mature on January 31, 2005 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Pursuant to the terms and conditions of the Senior Convertible Debentures, we have pledged all of our assets as collateral and are subject to comply with certain financial and negative covenants, which include but are not limited to the repayment of principal balances upon achieving certain revenue milestones.

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

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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

share. On March 12, 2004, the exercise price of the warrants will reset to the lesser of the exercise price then in effect or a price equal to the average of the daily price of the common stock between March 13, 2003 and March 11, 2004 (but in no event less than \$1.176 per share). The exercise price (and the reset price) under the warrants also is subject to similar adjustments for anti-dilution protection.

We entered into a Registration Rights Agreement with the investors in connection with the issuance of the Debentures and the warrants. The Registration Rights Agreement requires that we register the shares of common stock issuable upon conversion of the Debentures, as interest shares under the Debenture and upon exercise of the warrants. In accordance with this agreement, we filed a Registration Statement on Form S-3 with the Securities and Exchange Commission. If the Registration Statement is not declared effective within the time period required by the agreement or, after it is declared effective and subject to certain exceptions, sales of all shares required to be registered thereon cannot be made pursuant thereto, then we will be required to pay to the investors their pro rata share of \$3,635 for each day any of the above conditions exist with respect to this Registration Statement.

Exhibit 99.1

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

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

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

(2) The information contained in the Report fairly presents, in all

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-K/A

material respects, the financial condition and result of operations of the Company.

/s/ William A. Carter

William A. Carter
Chief Executive Officer
September 9, 2003

Exhibit 99.2

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

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

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

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

/s/ Robert Peterson

Robert Peterson
Chief Financial Officer
September 9, 2003

