

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

HEMISPHERX BIOPHARMA INC

Form 10-K/A

March 30, 2004

FORM 10-K/A

SECURITIES AND EXCHANGE COMMISSION

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

For the fiscal year ended December 31, 2003

OR

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

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

HEMISPHERX BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware 52-0845822 \_

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

1617 JFK Boulevard Philadelphia, Pennsylvania 19103 \_

(Address of principal executive offices) (Zip Code)

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

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

Common Stock, \$.001 par value

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

NONE

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

Yes (X) No ( )

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

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

The aggregate market value of Common Stock held by non-affiliates at June 30, 2003, the last business day of the registrant's most recently completed second fiscal quarter, was \$71,603,879. For purposes of this calculation, it was assumed that all Common Stock is valued at the closing price as of such date of \$1.88 per share.

The number of shares of the registrant's Common Stock outstanding as of February 27, 2004 was 40,835,199.

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		37
Item 3. Legal Proceedings		38
Item 4. Submission of Matters to a Vote of Security Holders		39
PART II		
Item 5. Market for the Registrant's Common Equity and Related Stockholder Matters		39
Item 6. Selected Financial Data		41
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations		42
Item 7A. Quantitative and Qualitative Disclosure About Market Risk		60
Item 8. Financial Statements and Supplementary Data		60
Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure		61
Item 9A. Controls and Procedures		61
PART III		
Item 10. Directors and Executive Officers of the Registrant		62
Item 11. Executive Compensation		65
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters		72
Item 13. Certain Relationships and Related Transactions		74

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

Item 14. Principal Accountant Fees and Services 75

## PART IV

Item 15. Exhibits, Financial Statement Schedules,  
and Reports on Form 8-K 76

1

### SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

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

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

### PART I

#### ITEM 1. Business.

##### GENERAL

We were founded in the early 1970s as a contract researcher for the National Institutes of Health (NIH). Dr. William A. Carter, M.D., joined us in 1976 and ultimately become our CEO in 1988. He has focused us 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

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

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 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 the open label

2  
portion of phase III clinical trials in the U.S. for use in treatment of ME/CFS and is in Phase IIb clinical development in the U.S. for the treatment of patients with HIV infection.

In March, 2003, we 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 intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. 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.

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.

3

### AMPLIGEN (R)

Our proprietary drug technology includes Ampligen(R) and utilizes specially configured ribonucleic acid ("RNA") and is protected by more than 300 patents worldwide with over 50 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, and May 6, 2011, respectively; Hepatitis treatment coverage is conveyed by U.S. patent #5593973 which expires on October 5, 2014. The U.S. Ampligen(R) Trademark (#1,515,099) expires on December 6, 2008 and can be renewed thereafter for an additional 10 years. The U.S. FDA has granted us "orphan drug status" for our nucleic acid-derived therapeutics for ME/CFS, HIV, and renal cell carcinoma and malignant melanoma. Orphan drug status grants us protection against competition for a period of seven years following FDA approval, as well as certain federal tax incentives, and other regulatory benefits.

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

Nucleic acid compounds represent a potential new class of pharmaceutical products that are designed to act at the molecular level for treatment of human diseases. There are two forms of nucleic acids, DNA and RNA. DNA is a group of naturally occurring molecules found in chromosomes, the cell's genetic machinery. RNA is a group of naturally occurring informational molecules which orchestrate a cell's behavior and which regulate the action of groups of cells, including the cells, which comprise the body's immune system. RNA directs the production of proteins and regulates certain cell activities including the activation of an otherwise dormant cellular defense against virus and tumors. Our drug technology utilizes specially configured RNA. Our double-stranded RNA drug product, trademarked Ampligen(R), which is administered intravenously, is (or has been) in human clinical development for various disease indications, including treatment for ME/CFS, HIV, renal cell carcinoma and malignant melanoma. Further studies are planned in cancer treatments 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 publication by independent  
4  
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 United States 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 medications, 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.

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

In February 1993, we presented results of our 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.

In 1998, we were authorized by the FDA to initiate a Phase III multicenter, placebo-controlled, randomized, double blind clinical trial to treat 230 patients with ME/CFS in the U.S. The objective of this Phase III, clinical study, denoted as Amp 516, is to evaluate the safety and efficacy of Ampligen(R) as a treatment for ME/CFS. Over the course of the study, we engaged the services of twelve (12) clinical investigators at Medical Centers in California, New Jersey, Florida, North Carolina, Wisconsin, Pennsylvania, Nevada, Illinois, Utah 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 has enrolled and randomized over 230 ME/CFS patients and is now fully enrolled. The patients complete a stage I, forty week, double-blind, randomized, placebo-controlled portion of the clinical trial. This stage I has now been completed with the final patients receiving their last blinded dose in February 2004. Following Stage I, the 14 remaining patients then move into the stage II or the open label treatment portion of the clinical trial. We anticipate that this segment should be completed by June, 2004. To date there have been no reported serious adverse events definitely related to the study medication. The next stage in our program is the completion of Stage II and the 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.

5

### Human Immunodeficiency Virus (HIV)

Over fifteen antiviral drugs are currently approved by the FDA for the treatment of HIV infection. Most target the specific HIV enzymes, reverse transcriptase ("RT") and protease. The use of various combinations of three or more of these drugs is often referred to as Highly Active Anti-Retroviral Therapy ("HAART"). HAART involves the utilization of several antiretrovirals with different mechanisms of action to decrease viral loads in HIV-infected patients. The goal of these combination treatments is to reduce the amount of HIV in the body ("viral load") to as low as possible. Treatments include different classes of drugs, but they all work by stopping parts of the virus so the virus cannot reproduce. Experience has shown that using combinations of drugs from different classes is a more effective strategy than using only one or two drugs. HAART has provided dramatic decreases in morbidity and mortality of HIV infection. Reduction of the viral load to undetectable levels in patients with wild type virus (i.e., non-drug-resistant virus) is routinely possible with the appropriate application of HAART. HIV mainly infects important immune system cells called CD4 cells. After HIV has infected a CD4 cell, the CD4 cell becomes damaged and is eventually destroyed. Fewer CD4 cells means more damage to the immune system and, ultimately, results in AIDS. Originally, reduction of HIV loads was seen as possibly allowing the reconstitution of the immune system and led to early speculation that HIV might be eliminated by HAART.

Subsequent experience has provided a more realistic view of HAART and the realization that chronic HIV suppression using HAART, as currently practiced, would require treatment for life with resulting significant cumulative toxicities. The various reverse transcriptase and protease inhibitor

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

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 reverse transcriptase and protease genes as well as new HIV targets, such as HIV integrase and HIV fusion inhibitors, the problem of drug toxicities, the complex interactions between these drug classes, and the likelihood of life-long therapy will remain a serious drawback to their usage.

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

We believe that the concept of Strategic Therapeutic Interruption ("STI") of HAART provides a unique opportunity to minimize the current deficiencies of HAART while retaining the HIV suppression capacities of HAART. STI is the cessation of HAART until HIV again becomes detectable (i.e., rebounds) followed by resumption of HAART with subsequent suppression of HIV. By re-institution of HAART, HIV may be suppressed before it can inflict damage to the immune system of the patient. Based on recent publications (AIDS 2001,15: F19-27 and AIDS 2001, 15:1359-1368) in peer reviewed medical literature, it is expected that in just 30 days after stopping HAART approximately 80% to 90%, of the patients will suffer a relapse evidencing detectable levels of HIV. We believe that Ampligen(R) combined with the STI approach may offer a unique opportunity to retain HAART's superb ability to suppress HIV while potentially minimizing its deficiencies. All present approved drugs block certain steps in

6

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. Our minimum expectation is that Ampligen(R) has potential to lengthen the HAART-free time interval with a resultant decrease in HAART-induced toxicities. The ultimate potential, which of course requires full clinical testing to accept or reject the hypothesis, is that Ampligen(R) may potentiate STI of HAART to the point that the cell mediated immune system will be sufficient to eliminate requirement for HAART. Clinical results of using our technology has been presented at several International AIDS Scientific Forums in 2003, including the XVI International Conference on Antiviral Research in Savannah, Georgia in April 2003 and the 2nd IAS Conference on HIV Pathogenesis and Treatment in Paris, France in July 2003.

Our AMP 720 HIV clinical trial is being conducted 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 anti-viral drug showing therapeutic synergy with Ampligen(R) based on a recently reported ex vivo study in a peer-reviewed scientific journal (Reference: Robinson W, McDougall B and Essay R. Mixed Dose Effect Analysis of a Biological Response Modifier (Ampligen) with 14 FDA-approved anti-HIV Agents. Antiviral Res, 46:A48, No. 46, 2000). All patients are chronically HIV infected and will have been receiving the indicated HAART regimen prior to starting the STI. The trial applies strategic treatment interruption of HAART based on the hypothesis that careful management of HIV rebound following STI may have potential to result in the development of

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

protective immune responses to HIV in order to achieve control of HIV replication. We believe that the addition of Ampligen(R), with its potential immunomodulatory properties, may reasonably achieve this outcome. Half of the participants in the trial are given 400 mg of Ampligen(R) twice a week and once they start the STI will remain off of HAART until such time as their HIV rebounds. The other half of the participants (the control group) are on STI, but they are given no Ampligen(R) during the "control" portion of the clinical test.

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

### Other Diseases

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

We have acquired a series of patents on Oragen(TM), potentially a set of oral broad spectrum antivirals, immunological enhancers through a licensing agreement with Temple University in Philadelphia, PA. We were granted an exclusive worldwide license from Temple for the Oragen(TM) products. Pursuant to the arrangement, we are obligated to pay royalties of 2% on sales of Oragen(TM), depending on how much technological assistance is required of Temple. We

7  
currently pay minimum royalties of \$30,000 per year to Temple. These compounds have been evaluated in various academic laboratories for application to chronic viral and immunological disorders. Research and development of Oragen(TM) may start in 2004 dependent on the availability of funding provided by various branches of the U.S. Government, including the Department of Defense where oral forms of broad spectrum immunotherapeutics may have high value.

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

### ALFERON N INJECTION(R)

Interferons are a group of proteins produced and secreted by cells to combat diseases. Researchers have identified four major classes of human interferon: alpha, beta, gamma and omega. The ALFERON N Injection(R) product contains a multi-species form of alpha interferon. The worldwide market for injectable alpha interferon-based products has experienced rapid growth and various alpha interferon injectable products are approved for many major medical uses worldwide.

Alpha interferons are manufactured commercially in three ways: by genetic engineering, by cell culture, and from human white blood cells. All



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

three of these types of alpha interferon are or were approved for commercial sale in the U.S. Our natural alpha interferon is produced from human white blood cells.

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

On October 10, 1989, the FDA approved ALFERON N Injection(R) 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  
8  
approximately eight million new and recurrent causes of genital warts occur annually in the United States alone.

Basically, our interest in acquiring Alferon N Injection(R) was driven by two factors;

- (1) Our belief that the use of Alferon N in combination with Ampligen(R) has the potential to increase the positive therapeutic responses in chronic life threatening viral diseases. Combinational therapy is evolving to the standard of acceptable medical care based on a detailed examination of the Biochemistry of the body's natural antiviral immune response; and
- (2) New knowledge about the competitive products in the interferon arena that we believe implies a large untapped market and potential new therapeutic indication for Alferon N Injection(R) which could accelerate its revenues in the near term. Specifically, the recombinant DNA derived alpha interferons are now reported to have decreased effectiveness after one year, probably due to antibody formation and other severe toxicities. These detrimental effects have not been reported with Alferon N Injection, 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 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.

The Alferon N Injection(R) targeted market consists of urologists, proctologists, dermatologists, and Obstetricians/Gynecologists. These physicians normally see patients with papilloma concondylomas (genital warts) in their

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

practice. For our marketing plans, see "Marketing/Distribution" below.

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 March 2004.

### ALFERON N Injection(R) -Other Applications

ALFERON N Injection(R) has been approved by the U.S. FDA for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older 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(R), has conducted clinical trials with regard to the use of ALFERON N Injection(R) in the treatment of HIV and Hepatitis C. While ISI found the results to be encouraging, in both instances,<sup>9</sup> the FDA determined that additional trials were necessary.

We anticipate initiating clinical trials to evaluate the use of Alferon N Injection(R) to treat West Nile Virus infections and SARS that is dependent on NIH providing the funds needed.

### ALFERON LDO

ALFERON LDO is an experimental 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. We are entering an active phase of Alferon LDO research. The FDA has recently authorized a new Phase II clinical study designed to investigate the activity and safety of Alferon LDO(R) in HIV positive subjects in early stage disease. The endpoints of the study include an increase or upregulation of expression of genes known to be mediators of the natural immune response using cutting edge gene chip technology, as well as, absolute CD4 cell counts and plasma HIV RNA level.

There can be no assurance that any of these proposed products will be cost-effective, safe, and effective or that we 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 us.

### 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(R), as well.

Our European operations have assisted the growth of a number of patient/physician educational associations. The French Chronic Fatigue Syndrome

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

Association has grown from 10 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. Although no applications are on file currently with the EEU, we are exploring various ways to accelerate the commercial availability of our products in the various nations of the EEU, including potential appreciation of the "foreign import" rule for accepting products already approved in the U.S.

10

Limited numbers of ME/CFS patients were treated during 2003 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 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 presented results of one these programs (AMP 720) at the LAS Conference on HIV Pathogenesis and Treatment in Paris, France, in July 2003.

The efforts of our European operation have 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) following regulatory approval. 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.

We executed a Memorandum of Understanding in January 2004 with Fujisawa

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

Deutschland GmbH, ("Fuji") a major pharmaceutical corporation, granting them an exclusive option for a limited number of months to enter a Sales and Distribution Agreement with exclusive rights to market Ampligen(R) for ME/CFS in Germany, Austria and Switzerland. The option period ends 12 weeks after Fuji has had a chance to review the report on the results of our Amp 516 clinical trial and meet with the trial's principal investigators. We received an initial fee of 400,000 Euros (approximately \$500,000US). If we do not provide Fuji with the full report by May 31, 2004 we will be required to repay half of this fee and if we do not provide them with the report by December 31, 2004, we will be required to refund the entire fee. If Fuji exercises the option, Fuji would be required to pay us an additional 1,600,000 Euros upon execution of the Sales and Distribution agreement, purchase Ampligen(R) exclusively from us and meet

11

certain annual minimum purchase quotas. We would be required to file an application with the EMEA for commercial sale of Ampligen(R) for ME/CFS on or before December 31, 2005. Upon our filing of that application, we would receive an additional 1,000,000 Euros and, upon approval by the EMEA, an additional 2,000,000 Euros. If we failed to meet the December 31, 2005 filing deadline, we would be required to return 40% of all payments that we had received from Fuji. We would be required to sell Ampligen(R) to Fuji at a 20% price discount until the aggregate amount of the discount reached \$1,000,000 Euros (representing 50% of the initial 2,000,000 fee paid to us on and prior to execution of the definitive agreement). The foregoing is a summary of the memorandum of understanding. We cannot assure that we can prepare and issue the AMP 516 report within the time frames noted or that Fuji will exercise the option or that the proposed terms of the Sales and Distribution Agreement will not change materially.

We continue negotiations with other prospective partners for the marketing and distribution of Ampligen(R) in other European territories.

### MANUFACTURING

Historically, we outsourced the manufacturing of Ampligen(R) to certain contractor facilities in the United States and South Africa while maintaining full quality control and supervision of the process. Nucleic Acid polymers constitute the raw material used in the production of Ampligen(R). We acquired our raw materials from Ribotech, Ltd. ("Ribotech") located in South Africa. Ribotech, is jointly owned by us (24.9%) and Bioclones (Proprietary), Ltd. (75.1%). Bioclones manages and operates Ribotech. There are a limited number of manufacturers in the United States available to provide the polymers if Ribotech is unable to supply our needs based on product specifications and pricing. Sourcing our needs from U.S. 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.

Bioclones (PTY) Ltd. is headquartered in South Africa and is the majority owner in Ribotech, Ltd. (we own 24.9%) which produces most of the polymers used to date in manufacturing Ampligen(R). The licensing agreement with Bioclones presently includes Africa, South America, Ireland, Australia, New Zealand and the United Kingdom; the agreement imposes certain clinical trial requirements on Ribotech, as well as, certain GMP standards on their facilities. We plan to consult and work with Bioclones in 2004 to assure GMP compliance of a

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

new manufacturing facility. Bioclones has conducted limited clinical studies in patients with ME/CFS in Australia and South Africa.

We currently occupy and use the New Brunswick, New Jersey laboratory and production facility owned by ISI. We expect to acquire title to these facilities pursuant to our second asset acquisition agreement with ISI by March 31, 2004 (see "Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity And Capital Resources" for more details). This facility operates in compliance to Good Manufacturing Practices (GMP's) and is approved by the FDA for the manufacture of Alferon N Injection(R).

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

In Europe, we plan to adopt a country-by-country and, in certain cases, an indication-by-indication marketing strategy due to the heterogeneity regulation and alternative distribution systems in these areas. We also plan to adopt an indication-by-indication strategy in Japan. Subject to receipt of regulatory approval, we plan to seek strategic partnering arrangements with pharmaceutical companies to facilitate introductions in these areas. The relative prevalence of people from target indications for Ampligen(R) varies significantly by geographic region, and we intend to adjust our clinical and marketing planning to reflect the specialty of each area. We have a marketing agreement with Bioclones pursuant to the Bioclones Agreement that covers South America, the United Kingdom, Ireland, Africa, Australia, Tasmania, New Zealand, and certain other countries and territories. In Spain, Portugal and Andorra we have entered into a Sales and Distribution Agreement with Esteve, and in Germany, Austria and Switzerland we have entered into a memorandum of understanding with Fuji (see "European Operations" above).

Our marketing and distribution plan for Alferon N Injection(R) is focused on increasing the sales of Alferon N Injection(R) 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 population through several media and health organizations. Different regional meetings and seminars are scheduled during

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

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, mailings and publications. We also have engaged a contract sales organization in order to build up a nationwide network of dedicated representatives in the U.S. Upon obtaining the foreign marketing rights to Alferon N Injection(R) at the second asset closing now

13

expected to take place in March, 2004 we expect to amend the current marketing/distribution agreements with Biovail, Esteve, Bioclones and Fujisawa to include Alferon N Injection(R). For more information about our arrangements with Accredo Health Services, Inc., Bioclones, Esteve and Biovails, see "Research And Development/Collaborative Agreements" below.

In August 2003, we entered into a non exclusive Sales and Marketing agreement with Engitech, a pharmaceutical contract sales organization, to launch Alferon N Injection(R) on a nationwide scale in the United States. The agreement stipulates that Engitech will deploy a sales force of 100 sales representatives within one year in the U.S. domestic market and further expand the sales team up to 250 sales representatives in the second year and after that as many as it takes to continually drive market share. As of February 25, 2004 Engitech has 93 sales representatives on board, leading us to believe that Engitech will reach the target of 100 sales representatives as stated in the agreement. Engitech will also develop and implement a strategic and tactical marketing action plan as well as organize a scientific and educational program towards a targeted audience of physicians and consumers. Engitech has been in business since 1987. This privately held company has several clients in the pharmaceutical industry.

### COMPETITION

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

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

The major competitors with drugs to treat HIV diseases include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs, Glaxo Smithkline, Merck and Schering-Plough Corp. ("Schering"). ALFERON N Injection(R) currently competes with a product produced by Schering for treating genital warts. 3M Pharmaceutical also has received FDA approval for its immune response modifier product for the treatment of genital and perianal warts.

### GOVERNMENT REGULATION

Regulation by governmental authorities in the U.S. and foreign countries is and will be a significant factor in the manufacture and marketing of ALFERON N products and our ongoing research and product development activities. Ampligen(R) and the products developed from the ongoing research and

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

product development activities will require regulatory clearances prior to commercialization. In particular, new human drug products for humans are subject  
14

to rigorous preclinical and clinical testing as a condition for clearance by the FDA and by similar authorities in foreign countries. The lengthy process of seeking these approvals, and the ongoing process of compliance with applicable statutes and regulations, has required, and will continue to require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect the marketing of any products developed by us and our ability to receive product or royalty revenue. We have received orphan drug designation for certain therapeutic indications, which might, under certain conditions, accelerate the process of drug commercialization. ALFERON N Injection(R) is only approved for use in intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection(R) for other applications requires regulatory approval.

A "Fast-Track" designation by the FDA, while not affecting any clinical development time per se, has the potential effect of reducing the regulatory review time by fifty percent (50%) from the time that a commercial drug application is actually submitted for final regulatory review. Regulatory agencies may apply a "Fast Track" designation to a potential new drug to accelerate the approval and commercialization process. Criteria for "Fast Track" include: a) a devastating disease without adequate therapy and b) laboratory or clinical evidence that the candidate drug may address the unmet medical need. As of this date, we have not received a Fast-Track designation for any of our potential therapeutic indications although we have received "Orphan Drug Designation" for both ME/CFS and HIV/AIDS in the U.S. We will continue to present data from time to time in support of obtaining accelerated review. We have not yet submitted any New Drug Application (NDA) for Ampligen(R) or any other drug to a North American regulatory authority. Assuming the results are positive, we expect to finalize the data of our double-blind, placebo controlled AMP 516 ME/CFS Phase III clinical trial and submit an NDA by year end 2004. 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 our drug is combined with certain presently available antiretroviral agents. Interim results were presented in 2002 and 2003 at various international scientific meetings.

We are subject to various federal, state and local laws, regulations and recommendations relating to such matters as safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use of and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. 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. The ISI laboratory and production facility in New Brunswick, New Jersey, which we are currently using and are in the process of acquiring title to, is approved for the manufacture of Alferon N Injection(R) and we believe it is in substantial compliance with all material regulations. However, we cannot give assurances that facilities owned and operated by third parties, including those operated by  
15

Bioclones Ltd., and Ribotech, Ltd., that are utilized in the manufacture of our

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

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; Cape Town, South Africa; Columbia, Maryland, and Melbourne, Australia.

### RESEARCH AND DEVELOPMENT/COLLABORATIVE AGREEMENTS

In 1994, we entered into a licensing agreement with Bioclones (Proprietary) limited ("Bioclones") for manufacturing and international market development in Africa, Australia, New Zealand, Tasmania, the United Kingdom, Ireland and certain countries in South Africa, of Ampligen(R) and Oragen(TM). Bioclones is to pursue regulatory approval in the areas of its franchise and is required to conduct Hepatitis clinical trials, based on international GMP and GLP standards. Thus far, these Hepatitis studies have not yet commenced to a meaningful level. Bioclones has been given the first right of refusal, subject to pricing, to manufacture that amount of polymers utilized in the production of Ampligen(R) sufficient to satisfy at least one-third of the worldwide sales requirement of Ampligen(R) and other nucleic acid-derived drugs. Pursuant to this arrangement, we received: 1) access to worldwide markets, 2) commercial-scale manufacturing resources, 3) a \$3 million cash payment in 1995 from Bioclones, 4) a 24.9% ownership in Ribotech, Ltd., a company set up by Bioclones to develop and manufacture RNA drug compounds, and 5) royalties of 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 Accredo to develop certain marketing and distribution capacity for Ampligen(R) in the United States. Accredo is one of the nation's largest home health care companies with over 400 offices and sixty thousand caregivers nationwide. Pursuant to the agreement, Accredo assumed certain responsibilities for distribution of Ampligen(R) for which they received a fee. Through this arrangement, Hemispherx may mitigate the necessity of incurring certain up-front costs. Accredo has also worked with us in connection with the Amp 511 ME/CFS cost recovery treatment program, Amp 516 ME/CFS Phase III clinical trial and the Amp 719 (combining Ampligen with other antiviral drugs in HIV-salvage therapy and Amp 720 HIV Phase IIb clinical trials now under way). There can be no assurances that this alliance will develop a significant commercial position in any of its targeted chronic disease markets. The agreement had an initial one year term from February 9, 1998 with successive additional one year terms unless either party notifies the other not less than 180 days prior to the anniversary date of its intent to terminate the agreement. Also, the agreement may be terminated for 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 Accredo or another major drug distributor. There were no initial fees and subsequent fees paid under this agreement total approximately \$15,000 for services performed in 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. We were granted an exclusive worldwide license from Temple for the Oragen(TM) products. Pursuant to the arrangement, we are

16

obligated to pay royalties of 2% to 4% on sales of Oragen(TM), depending on how much technological assistance is required of Temple. There were no initial fees and we currently pay minimum royalties of \$30,000 per year to Temple. These compounds have been evaluated in various academic laboratories for application



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

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 at the appropriate time. Biovail invested \$2,250,000 in Hemispherx equity at prices above the then current market price and agreed to make an additional investment of \$1,750,000 based on receiving approval to market Ampligen(R) in Canada from the appropriate regulatory authorities in Canada. The agreement requires Biovail to buy exclusively from us and penetrate certain market segments at specific rates in order to maintain market exclusivity. The agreement terminates on December 15, 2009, subject to successive two year extensions by the parties and subject to earlier termination by the parties for uncured defaults under the agreement, bankruptcy or insolvency of either party, or withdrawal of our product from Canada for a period of more than ninety days for serious adverse health or safety reasons.

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

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

17

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

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

by Chronix on or before September 14, 2012 for treating Chronic Fatigue Syndrome, Gulf War Syndrome and Human Herpes Virus-6 associated diseases. During the quarter ended December 31, 2002, 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 its then 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 our investment. Additionally, during 2001 we reduced our investment in CIMM based on our percentage interest in CIMM's continued operating losses. Our remaining investment at December 31, 2001 in CIMM, representing our 30% interest in CIMM's equity at such date, was not deemed to be permanently impaired, but was completely written off during 2002. Such amount was not material. These charges are reflected in the Consolidated Statements of Operations under the caption "Equity loss in unconsolidated affiliate". We still believe CIMM will succeed in their efforts to advance therapeutic treatment of HCV. We believe that CIMM's Hepatitis C diagnostic technology has great promise and will fill a long-standing global void in the collective abilities to diagnose and treat Hepatitis C infection at an early stage of the disorder.

In March 2002, our European subsidiary Hemispherx S.A. entered into a Sales and Distribution agreement with Esteve. Pursuant to the terms of the Agreement, Esteve was granted the exclusive right to market Ampligen(R) in Spain, Portugal and Andorra for the treatment of ME/CFS. In addition to other terms and other projected payments, Esteve agreed to conduct certain clinical trials using Ampligen(R) in the patient population coinfecting with hepatitis C and HIV viruses. The Agreement runs for the longer of ten years from the date of the first arms-length sale in the Territory, the expiration of the last Hemispherx patent exploited by Esteve or the period of regulatory data protection for Ampligen(R) in the applicable territory. Pursuant to the terms of the agreement Esteve is to conduct clinical trials using Ampligen(R) to treat patients with both HCV and HIV and is required to purchase certain minimum annual amounts of Ampligen(R) following regulatory approval. We expect Esteve to start HIV clinical trials in Spain in 2004. The agreement is terminable by either party if Ampligen(R) is withdrawn from the territory for a specified period due to serious adverse health or safety reasons; bankruptcy, insolvency or related issues of one of the parties; or material breach of the agreement. Hemispherx may transform the agreement into a non-exclusive agreement or terminate the agreement in the event that Esteve does not meet specified percentages of its annual minimum purchase requirements under the agreement.

18

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 \$13,876,000 in research and development, of which

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

approximately \$3,150,000 was expended in the year ended December 31, 2003. 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 February 27, 2004, we had 38 personnel working on the development of Ampligen(R) consisting of 19 full time employees, 6 regulatory/research medical personnel on a part-time basis, and 13 clinical investigators. Part time personnel are paid on a per diem or monthly basis. 22 personnel are engaged in our research, development, clinical, and manufacturing effort. 5 of our personnel perform regulatory, general administration, data processing, including bio-statistics, financial and investor relations functions.

In addition to the foregoing personnel, pursuant to our agreement with ISI, we added personnel from ISI to our payroll consisting of 5 part-time and 12 full-time employees.

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

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

### SCIENTIFIC ADVISORY BOARD

We reestablished a Scientific Advisory Board in October, 2003, consisting of individuals who we believe have particular scientific and medical expertise in Virology, Cancer, Immunology, Biochemistry and related fields. These individuals will advise us about current and long term scientific planning including research and development. The Scientific Advisory Board will hold periodic meetings as needed by the clinical studies in progress by us. In addition, individual Scientific Advisory Board Members sometimes will consult

19  
with, and meet informally with our employees. All members of the Scientific Advisory Board are employed by others and may have commitments to and/or consulting agreements with other entities, including our potential competitors. Members of the Scientific Advisory Board are compensated at the rate of \$1,000 per meeting attended or per day devoted to our affairs.

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

### RECENT FINANCING AND ASSET ACQUISITIONS

On March 12, 2003, we issued an aggregate of \$5,426,000 in principal

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

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

The March Debentures were convertible at the option of the investors at any time through January 31, 2005 into shares of our common stock. The conversion price under the March Debentures 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 was to reset to the lesser of the exercise price then in effect or a price equal to the average of the daily price of the common stock between March 13, 2003 and March 11, 2004 (but in no event less than \$1.176 per share). The exercise price (and the reset price) under the Warrants also was subject to similar adjustments for anti-dilution protection. All of these warrants have been exercised.

On June 25, 2003, we issued to each of the March 12, 2003 Debenture holders a warrant to acquire at any time through June 25, 2008 an aggregate of 500,000 shares of common stock at a price of \$2.40 per share. On June 25, 2004, the exercise price of these June 2008 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 June 26, 2003 and June 24, 2004 (but in no event

20  
less than \$1.68 per share). The exercise price (and the reset price) under the June 2008 Warrants also is subject to adjustments for anti-dilution protection similar to those in the July 2008 Warrants. Pursuant to our agreement with the Debenture holders, we have registered the shares issuable upon exercise of these June 2008 Warrants for public sale.

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

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

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

On July 10, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due July 31, 2005 (the "July Debentures") and an aggregate of 507,102 Warrants (the "July 2008 Warrants") to the same investors who purchased the March 12, 2003 Debentures, in a private placement for aggregate anticipated gross proceeds of \$4,650,000. Pursuant to the terms of the July Debentures, \$1,550,000 of the proceeds from the sale of the July Debentures were to have been held back and were to be released to us if, and only if, we acquired ISI's facility within a set timeframe. Although we had not acquired ISI's facility yet, these funds were released to us in October 2003. The July Debentures mature on July 31, 2005 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date.

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

The July 2008 Warrants received by the investors, as amended, are to acquire at any time commencing on July 26, 2004 through January 31, 2009 an aggregate of 507,102 shares of common stock at a price of \$2.46 per share. On July 10, 2004, the exercise price of these July 2008 Warrants will reset to the lesser of the exercise price then in effect or a price equal to the average of the daily price of the common stock between July 11, 2003 and July 9, 2004 (but in no event less than \$2.14 per share). The exercise price (and the reset price) under the July 2008 Warrants is also 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 July Debentures and the July 2008 Warrants.

21

The Registration Rights Agreement requires that we register on behalf of the holders the shares of common stock issuable upon conversion of the Debentures, as interest shares under the Debentures and upon exercise of the July 2008 Warrants. These shares have been registered for public sale.

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

Upon completing the sale of the October Debentures, we received \$3,275,000 in net proceeds consisting of \$1,725,000 from the October Debentures

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

and \$1,550,000 that had been withheld from the July Debentures. As noted above, \$1,550,000 of the proceeds from the October Debentures have been held back pending our completing the acquisition of the ISI facility.

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

The October 2008 Warrants, as amended, received by the investors are to acquire at any time commencing on July 26, 2004 through April 30, 2009 an aggregate of 410,134 shares of common stock at a price of \$2.32 per share. On October 29, 2004, the exercise price of these October 2008 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 October 29, 2003 and October 27, 2004 (but in no event less than \$2.19 per share). The exercise price (and the reset price) under the October 2008 Warrants is also subject to similar adjustments for anti-dilution protection.

As of February 27, 2004, the investors had converted \$9,589,300 of debt from the March and July Debentures into 5,894,137 shares of our common stock. The March Debentures have been fully converted. The remaining principal balance on the remaining debentures is convertible into shares of our stock at the option of the investors at any time, through the maturity date. In addition, we have paid \$1,300,000 into the debenture cash collateral account as required by the terms of the October Debentures. The amounts paid through December 31, 2003 have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of December 31, 2003. The cash collateral

22  
account provides partial security for repayment of the July and October 2003 and January 2004 Debentures in the event of default.

We entered into a Registration Rights Agreement with the investors in connection with the issuance of the October Debentures and the October 2008 Warrants. The Registration Rights Agreement requires that we register on behalf of the holders the shares of common stock issuable upon conversion of the October Debentures, as interest shares under the October Debentures and upon exercise of the 2008 Warrants. If, subject to certain exceptions, sales of all shares required to be registered cannot be made pursuant to the registration statement, then we will be required to pay to the investors their pro rata share of \$3,635 for each day such conditions exists.

On January 26, 2004, we issued an aggregate of \$4,000,000 in principal amount of 6% Senior Convertible Debentures due January 31, 2006 (the "January 2004 Debentures"), an aggregate of 790,514 warrants (the "2009 Warrants") and 158,103 shares of common stock, and Additional Investment Rights (to purchase up to an additional \$2,000,000 principal amount of January 2004 Debentures commencing in six months) in a private placement for aggregate anticipated net proceeds of \$3,695,000. The January 2004 Debentures mature on January 31, 2006 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Commencing six months after issuance, the Company is required to start repaying the then outstanding principal amount under the January 2004 Debentures in monthly installments amortized over 18 months in cash or, at the Company's option, in shares of common stock. Any shares of common stock issued to the investors as installment payments shall be valued at 95% of the average closing price of the common stock during the 10-day trading period

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

commencing on and including the eleventh trading day immediately preceding the date that the installment is due.

The January 2004 Debentures are convertible at the option of the investors at any time through January 31, 2006 into shares of our common stock. The conversion price under the January 2004 Debentures is fixed at \$2.53 per share, subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect.

There are two classes of July 2009 warrants received by the Investors: Class A and Class B. The Class A warrants are to acquire any time from July 26, 2004 through July 26, 2009 an aggregate of up to 395,257 shares of common stock at a price of \$3.29 per share. The Class B warrants are to acquire any time from July 26, 2004 through July 26, 2009 an aggregate of up to 395,257 shares of common stock at a price of \$5.06 per share. On January 27, 2005, the exercise price of these July 2009 Class A and Class B Warrants will reset to the lesser of their respective exercise price then in effect or a price equal to the average of the daily price of the common stock between January 27, 2004 and January 26, 2005 (but in no event less than \$2.58 per share with regard to the Class A warrants and \$3.54 per share with regard to the Class B warrants). The exercise price (and the reset price) under the July 2009 Warrants also is subject to similar adjustments for anti-dilution protection.

The Company also issued to the investors Additional Investment Rights pursuant to which the investors have the right to acquire up to an additional

23

\$2,000,000 principal amount of January 2004 Debentures from the Company. These Debentures are identical to the January 2004 Debentures except that the conversion price is \$2.58. The Additional Investment Rights are exercisable commencing on July 26, 2004 (the "Trigger" date) for a period of 90 days from the Trigger Date or 90 days from the date which the registration statement registering the shares issuable upon the conversion of the January 2004 Debentures to be issued pursuant to the Additional Investment Rights is declared effective, whichever is longer.

The Company entered into a Registration Rights Agreement with the investors in connection with the issuance of the January 2004 Debentures (including any Debentures issued pursuant to the Additional Investment Rights), the shares, and the January 2009 Warrants. The Registration Rights Agreement requires that the Company register on behalf of the investors the shares issued to the investors and 135% of the shares issuable upon conversion of the Debentures (including payment of interest thereon) and upon exercise of the January 2009 Warrants. If the Registration Statement covering these shares is not filed within the time period required by the agreement, 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.

By agreement between the Company and the investors, the date upon which all warrants previously issued to the investors may become exercisable is now July 26, 2004 and the exercise periods of these warrants have been extended accordingly.

By agreement with Cardinal Securities, LLC, ("Cardinal") for general financial advisory services and in conjunction with the private debenture placements in March, July and October 2003 and in January 2004, we paid Cardinal an investment banking fee equal to 7% of the investments made by the two Debenture holders and issued to Cardinal certain warrants. A portion of the investment banking fee was paid with the issuance of 30,000 shares of our common

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

stock. Cardinal also received 612,500 warrants to purchase common stock, of which 112,500 are exercisable at \$1.74 per share, 112,500 are exercisable at \$2.57 per share, 200,000 are exercisable at \$2.50 per share, 87,500 are exercisable at \$2.42 per share and 100,000 are exercisable at \$3.04 per share. The \$1.74 warrants expire on July 10, 2008, the \$2.57 and \$2.50 warrants expire on March 12, 2008, the \$2.42 warrants expire on October 30, 2008 and the \$3.04 warrants expire on January 25, 2009. By agreement with Cardinal, we have registered 542,500 shares for public sale and have agreed to register the balance.

On March 11, 2003, we acquired from Interferon Sciences, Inc. ("ISI"), ISI's inventory of ALFERON N Injection(R), a pharmaceutical product used for intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older, and a limited license for the production, manufacture, use, marketing and sale of this product. As partial consideration, we issued 487,028 shares of our common stock to ISI Pursuant to our agreements with ISI, we registered these shares for public sale and, as of December 17, 2003, ISI has reported that it has sold all of these shares. We also agreed to pay ISI 6 % of the net sales of ALFERON N Injection(R).

On March 11, 2003, we also entered into an agreement to purchase from ISI all of its rights to the product and other assets related to the product

24  
including, but not limited to, real estate and machinery. For these assets, we agreed to issue to ISI an additional 487,028 shares and to issue 314,465 shares and 267,296 shares, respectively to The American National Red Cross and GP Strategies Corporation, two creditors of ISI. We 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. The termination date for these guarantees is 18 months after the date of issuance of the guaranteed shares to GP Strategies, 24 months after the date of issuance and delivery of the additional 487,028 guaranteed shares to ISI and 12 months after the date of issuance of the guaranteed shares to the American National Red Cross. We also agreed to satisfy other liabilities of ISI which are past due and secured by a lien on ISI's real estate and to pay ISI 6% of the net sales of products containing natural alpha interferon.

On May 30, 2003, we issued the shares to GP Strategies and the American National Red Cross. Pursuant to our agreements with ISI and these two creditors, we have registered the foregoing shares for public sale. As of December 31, 2003, GP Strategies has indicated to us that it has sold all of its Hemispherx shares.

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

Prior to our annual meeting of stockholders in September 2003, we had a limited number of shares of Common Stock authorized but not issued or reserved for issuance upon conversion or exercise or outstanding convertible and exercisable securities such as debentures, options and warrants. Prior to the meeting, to permit consummation of the sale of the July 2005 Debentures and the related warrants, Dr. Carter agreed that he would not exercise his warrants or options unless and until our stockholders approve an increase in our authorized shares of common stock. For Dr. Carter's waiver of his right to exercise certain options and warrants prior to approval of the increase in our authorized shares, and for Dr. Carter's entering into a \$250,000 letter of credit benefiting the Debenture holders in the event of a default, we agreed to compensate Dr. Carter. See "Executive Compensation; Employment Agreements" for details related to how Dr. Carter has been compensated with respect to these matters.

On November 6, 2003 we acquired some of the outstanding ISI property tax lien certificates in the aggregate amount of \$456,839 from certain



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

investors. These tax liens were issued for property taxes and utilities due for 2000, 2001 and 2002. For more information about our acquisition of these tax liens and our suit against ISI in Delaware, see "Item 3. Legal Proceedings."

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

As of December 31, 2003, we had approximately \$5,260,000 in cash and short term investments. We believe that these funds plus the net proceeds of approximately \$3.7 million from the recently placed January 2004 Debentures, 2) the receipt of the \$1.55 million of proceeds held back pending the acquisition of the ISI facility, 3) potential licensing fee income, 4) the \$2,000,000 in proceeds we expect when the investors exercise their additional investment rights in connection with the January 2004 Debenture, and 5) and the projected  
25  
revenue from the acquisition of the ALFERON N Injection(R) business should be sufficient to meet our operating requirements for the 2004 fiscal year.

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. Among the key factors that have a direct bearing on our results of operations are:

No assurance of successful product development

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

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

## 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(R) are investigational and must receive prior regulatory approval by appropriate regulatory authorities for general use and are currently legally available only through clinical trials with specified disorders. At present, ALFERON N Injection(R) is only approved for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of ALFERON N Injection(R) for other indications will require regulatory approval. In this regard, Interferon Sciences, Inc. ("ISI"), the company from which we obtained our rights to ALFERON N Injection(R), conducted clinical trials related to use of ALFERON N Injection(R) for treatment of HIV and Hepatitis C. In both instances, the FDA determined that additional studies

26

were necessary in order to fully evaluate the efficacy of ALFERON N Injection(R) in the treatment of HIV and Hepatitis C diseases. We have no obligation or immediate plans to conduct these additional studies at this time.

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

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

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses, as we pursued our clinical trial effort and expanded our efforts in Europe. As of December 31, 2003, our accumulated deficit was \$113,843,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

We may require additional financing which may not be available.

The development of our products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of December 31, 2003, we had approximately \$5.3 million

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

in cash and short term investments. We believe that these funds plus 1) the \$3,695,000 in net proceeds from the January Debenture placement, 2) the anticipated infusion of approximately \$1.55 million in remaining net proceeds from the October Debentures, 3) the projected net cash flow from the sale of ALFERON N Injection(R), 4) the proceeds from licensing agreements and/or the expected infusion of \$2,000,000 in proceeds from our investors exercising their additional investment rights should be sufficient to meet our operating cash requirements including debt service during the 2004 fiscal year. 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 adverse effect on our ability to develop our products.

27

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. asset acquisition, our ability to generate revenues from the sale of ALFERON N Injection(R) and our financial condition will be adversely affected.

In March, 2003 we executed two agreements with 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). If we are unable to generate sustained revenues from the sale of this product, our financial condition could be materially and adversely affected.

In addition, pursuant to terms of the October Debentures, we are required to acquire ISI's facility within 90 days from January 26, 2004 and, unless and until we acquire the facility, \$1,550,000 of the proceeds from the sale of the October Debentures will be held back. The same condition was in the July Debentures and in the debentures issued in March 2003; however, the holders waived this condition in both debentures. Consummation of the second agreement requires, among other things, approval by ISI's stockholders. On March 9, 2004 ISI's stockholders approved the second asset acquisition.

Due to ongoing delays on the part of ISI, on September 23, 2003, we commenced an action against ISI in Delaware seeking specific performance and declaratory and injunctive relief related to the first and second asset acquisition agreements. Our primary objectives are to compel ISI to complete the second asset acquisition and to prevent ISI from terminating the second asset acquisition agreement due to the passage of time. For more information on this action, see "Item 3. Legal Proceedings." It is possible that that this lawsuit could further delay the closing of the second asset acquisition.

Our failure to complete the acquisition within the 90 day period will result in a technical default of the terms of the October Debentures and, absent consent from the holders of these debentures for additional time, might result in our having to redeem the securities. If we do not receive the additional funds from the October Debentures as planned and, especially if we are required to redeem these 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. In addition, although we have not yet completed the acquisition, we issued an aggregate of 581,761 shares to GP Strategies and the American National Red Cross, two

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

creditors of ISI, as partial consideration for the acquisition and we may be required to repurchase some of the shares in the future at \$1.59 per share (see the risk factor "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 24 months after the dates of issuance of the guaranteed shares, our financial condition could be adversely affected" below). If we do not complete the acquisition, we will look to ISI to pay us the value of the shares that we issued to these two creditors. No assurance can be given that we will be able to so recoup the value of these shares.

28

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 24 months after the dates of issuance of the guaranteed shares, our financial condition could be adversely affected.

Upon the consummation of the second ISI asset acquisition, we will issue an additional 487,028 shares to ISI. In May 2003 we issued an aggregate of 581,761 shares to two creditors of ISI. We anticipate, but cannot assure, that we will close the second ISI asset acquisition sometime in March 2004. We have guaranteed the value of all but 62,500 of these shares to be issued to ISI and the creditors, to be \$1.59 per share on the termination date. As of February 10, 2004, GP Strategies has sold all of its guaranteed shares. The termination dates are 24 months after the dates of issuance and delivery of the guaranteed shares to ISI, 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 ISI and the American National Red Cross 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 remaining 738,993 shares are still held on the relevant termination dates and the holders requested that we honor the guarantees, we would be obligated to pay to ISI and the American National Red Cross an aggregate of \$1,174,999. The reported last sale price for our common stock on the American Stock Exchange on February 18, 2004 was \$4.05 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 guaranteed shares still outstanding on the relevant termination dates might be a factor of the market price and sales volume of our common stock during the 24, and 12 month periods 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(R), 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

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

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

29  
patent which affords protection on the use of Ampligen(R) in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of Ampligen(R) as a sole treatment for any of the cancers, which we have sought to target. With regard to ALFERON N Injection(R), 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 patent and intellectual property rights. Such litigation could require substantial resources from us and we may not have the financial resources necessary to enforce the patent rights that we hold. No assurance can be made that our patents will provide competitive advantages for our products or will not be successfully challenged by competitors. No assurance can be given that patents do not exist or could not be filed which would have a materially adverse effect on our ability to develop or market our products or to obtain or maintain any competitive position that we may achieve with respect to our products. Our patents also may not prevent others from developing competitive products using related technology.

30

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

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

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

not adversely affect the value of our license.

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

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

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

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

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

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

A number of essential materials are used in the production of ALFERON N Injection(R), including human white blood cells. We do not have long-term agreements for the supply of any of such materials. There can be no assurance we can enter into long-term supply agreements covering essential materials on commercially reasonable terms, if at all. If we are unable to obtain the required raw materials, we may be required to scale back our operations or stop manufacturing ALFERON N Injection(R). The costs and availability of products and materials we need for the commercial production of ALFERON N Injection(R) and other products which we may commercially produce are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, and FDA and other governmental regulations and there can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all.

31

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

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

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 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(R) is manufactured in ISI's facility and ALFERON N Injection(R) is formulated and packaged at a production facility operated by Abbott Laboratories located in Kansas. If and when we close on the second ISI asset acquisition, we will acquire their New Brunswick, NJ facility. We still will be dependent upon Abbott Laboratories and/or another third party for product formulation and packaging.

32

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. Also, each production lots of Alferon N Injection(R) is subject to FDA review and approval prior to releasing the lots to be sold. This review and approval process could take considerable time, which would delay our having product in inventory to sell. Alferon N Injection(R) has a shelf life of 18 months after having been bottled.

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.

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

Most of these entities have significantly greater research and development capabilities than us, as well as substantial marketing, financial and managerial resources, and represent significant competition for us. There can be no assurance that developments by others will not render our products or technologies obsolete or noncompetitive or that we will be able to keep pace with technological developments.

Our products may be subject to substantial competition.

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

33

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

General. Other companies may succeed in developing products earlier than we do, obtaining approvals for such products from the FDA more rapidly than we do, or developing products that are more effective than those we may develop. While we will attempt to expand our technological capabilities in order to



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

remain competitive, there can be no assurance that research and development by others or other medical advances will not render our technology or products obsolete or non-competitive or result in treatments or cures superior to any therapy we develop.

Possible side effects from the use of Ampligen(R) or ALFERON N Injection(R) could adversely affect potential revenues and physician/patient acceptability of our product.

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

34

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

We may be subject to product liability claims from the use of Ampligen(R) or other of our products which could negatively affect our future operations.

We face an inherent business risk of exposure to product liability claims in the event that the use of Ampligen(R) or other of our products results in adverse effects. This liability might result from claims made directly by patients, hospitals, clinics or other consumers, or by pharmaceutical companies or others manufacturing these products on our behalf. Our future operations may be negatively affected from the litigation costs, settlement expenses and lost 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 and clinical trials. The loss of Dr. Carter's

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

services could have a material adverse effect on our operations and chances for success. We have secured key man life insurance in the amount of \$2 million on the life of Dr. Carter and we have an employment agreement with Dr. Carter that, as amended, runs until May 8, 2008. However, Dr. Carter has the right to terminate his employment upon not less than 30 days prior written notice. The loss of Dr. Carter or other personnel, or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

Uncertainty of health care reimbursement for our products.

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

35  
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

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

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, 2003, the price of our common stock has ranged from \$1.33 to \$2.96. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if without merit or unsuccessful, it would result

36

in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

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

As of February 10, 2004, approximately 556,523 shares of our common stock constituted "restricted securities" as defined in Rule 144 under the Securities Act of 1933. Substantially all of these shares have been or will be registered pursuant to agreements between us and the holders of these shares. In addition, we have registered 10,160,362 shares issuable (i) upon conversion of approximately 135% of the January 2004 Debentures, October Debentures, July Debentures and the January 2004 Debentures (issuable upon exercise of Additional Investment Rights issued in conjunction with the January 2004 Debentures); (ii) as payment of 135% of the interest on all of the Debentures; (iii) upon exercise of 135% of the 2009 Warrants, October 2008 Warrants, July 2008 Warrants and June 2008 Warrants; (iv) upon exercise of certain other warrants and stock options and (v) shares issued to certain suppliers. Registration of the shares permits the sale of the shares in the open market or in privately negotiated transactions without compliance with the requirements of Rule 144. To the extent the exercise price of the warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the conversion price and exercise price of these securities are adjusted pursuant to anti-dilution protection, the securities could be exercisable or convertible for even more shares of common stock. Moreover, we anticipate that we will be issuing and registering for public resale 487,028 shares if and when we close the second ISI asset acquisition. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock. Sales of substantial amounts of our common stock in the public market could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and

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

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

37

initially entitles holders to buy one unit of preferred stock for \$30.00. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Dr. Carter, our chief executive officer, who already beneficially owns 12.8% 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 and 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. We believe that our Rockville facilities will meet our requirements, for planned clinical trials and treatment protocols through 2004 and possibly longer after which time we may need to increase our 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. These assets consist of two buildings located on 2.8 acres. One building is a two story facility consisting of a total of 31,300 square feet. This facility

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

has offices, laboratories and production space, and shipping and receiving areas. Building Two has 11,670 square feet consisting of offices, laboratories and warehouse space. The property has parking space for approximately 100 vehicles.

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.

38

We have no obligation to fund this construction. Our interest in Ribotech, is a result of the marketing and manufacturing agreement executed with Bioclones in 1994.

### ITEM 3. Legal Proceedings.

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

On September 16, 2003, we filed and subsequently served and moved for expedited proceedings on, a complaint filed in the Court Of Chancery of the State of Delaware, New Castle County, against ISI. The Complaint seeks specific performance, and declaratory and injunctive relief related to the first and second asset acquisition agreements with ISI. Specifically, we allege that ISI has delayed its performance pursuant to the agreements and, as a result, the second asset purchase did not close within 180 days of the date of the agreements. Paragraph 7.7 of the second asset purchase agreement states that either party to the agreement may terminate the agreement if there is no closing within 180 days of the date of the agreement. We request that the Court require

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

ISI to specifically perform its obligations under the agreement or, in the alternative, that paragraph 7.7 of the agreement be eliminated or reformed to eliminate ISI's ability to terminate pursuant to that paragraph. We also request that ISI, as a result of its conduct, not be permitted to terminate the agreements pursuant to paragraph 7.7 or due to the passage of time. At a hearing held on September 29, 2003, the Court set a trial of our case for January 6-7, 2004, which was postponed until March 4-5, 2004, and accepted the agreement of

39  
the parties pursuant to which the date on which ISI may exercise its termination right is extended until no earlier than two weeks following trial. In response to our complaint, ISI has filed a motion to dismiss. In February, we notified the Court to remove the trial from the docket in light of the pending ISI stockholder meeting to approve the transaction.

On November 5, 2003 we purchased for the sum of \$476,839 from M.D. Sass Municipal Finance Partners II, L.P. ("SASS") certain tax lien certificates evidencing liens on the ISI facility in New Brunswick, New Jersey. By this purchase we also succeeded to the position of SASS and became the plaintiff in the Complaint For Foreclosure Of Tax Sale Certificate(s) now pending in the Superior Court Of New Jersey Chancery Division, Middlesex County, Docket No. F-11766-03.

#### 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, 2003.

## PART II

#### ITEM 5. Market for Registrant's Common Equity and Related Stockholder Matters.

In 2003, we issued 6,756,942, shares of common stock consisting of 1) 1,068,789 shares related to the ISI Asset Acquisition, 2) 4,334,916 shares for debt conversion and interest payments related to the 6% convertible debentures, 3) 790,745 shares for exercise of warrants, 4) 215,047 shares for payment of debt and 5) 347,445 shares for conversion of minority interest of subsidiary.

See "RECENT FINANCING AND ASSET ACQUISITIONS" above in Item 1. Business, for information on our private issuance of securities.

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

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

COMMON STOCK	High	Low
	----	---
Time Period:		
January 1, 2002 through March 31, 2002	\$4.95	\$3.40
April 1, 2002 through June 30, 2002	4.00	2.30
July 1, 2002 through September 30, 2002	2.89	0.75
October 1, 2002 through December 31, 2002	2.95	1.10

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

Time Period:

January 1, 2003 through March 31, 2003	2.19	1.33
April 1, 2003 through June 30, 2003	3.35	1.33
July 1, 2003 through September 30, 2003	2.35	1.85
October 1, 2003 through December 31, 2003	2.94	1.83

As of February 27, 2004 there were approximately 258 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 February 27, 2004, the last sale price for our common stock on the AMEX was \$3.91 per share.

We have not paid any dividends on our Common Stock in recent years. It is management's intention not to declare or pay dividends on our Common Stock, but to retain earnings, if any, for the operation and expansion of 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, 2003.

41

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 Remain futur equit plans secur colum  -----
	(a)	(b)	
Equity compensation plans approved by security holders:	433,134	\$ 3.16	
Equity compensation plans not approved by security holders:	-	-	

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

Total 433,134 \$ 3.16

In September, 2003 our Board of Directors changed the non-employee Board Member compensation to be 50% cash and 50% stock. The Board's stock compensation is to be paid on the first day of each calendar quarter. The number of shares paid shall have a value of \$12,500 with the value of the shares being determined by the closing price of our common stock on the American Stock Exchange on the last trading day of the preceding quarter. In no event shall the number of shares issued under this plan exceed 1,000,000 shares over a ten year period.

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

Year Ended December 31 -----	1999 ----	2000 ----	2001 ----	2002 ----
Statement of Operations Data:				
Revenues and License fee Income				
	\$678	\$788	\$390	\$904
Total Costs and Expenses(1)				
	13,458	9,831	9,192	6,961
Interest Expense and Financing Costs(3)				
	-	-	-	-
42				
Net loss	(12,298)	(8,552)	(9,083)	(7,424)
Basic and diluted net loss per share				
	(0.47)	(0.29)	(0.29)	(0.23)
Shares used in computing basic and diluted net loss per share				
	26,380,351	29,251,846	31,433,208	32,085,776
Balance Sheet Data:				
Working Capital				
	\$9,507	\$7,550	\$7,534	\$2,925
Total Assets				
	14,168	13,067	12,035	6,040
Common Stockholders Equity				
	12,657	11,572	10,763	3,630
Other Cash Flow Data:				
Cash used in operating activities				
	\$(6,990)	\$(8,074)	\$(7,281)	\$(6,409)
Capital expenditures				
	(251)	(171)	-	-

(1) General and Administrative expenses include stock compensation expense totaling \$4,618, \$397, \$673, \$132, \$237 for the years ended December 31, 1999, 2000, 2001, 2002, and 2003, respectively.

(2) For information concerning recent acquisitions of certain assets of ISI and related financing see notes 1, 4 and 7 to our consolidated financial statements for the year ended December 31, 2003.

(3) In accounting for the March 12, 2003, July 10, 2003, and October 29, 2003 issuances of 6% Senior Convertible Debentures in the principal amounts of \$5,426,000, \$5,426,000, and \$4,142,357, respectively, and related embedded conversion features and warrant issuances, we recorded debt discounts of approximately \$11.3 million which, in effect, reduced the carrying value of the debt to \$1.6 million. Excluding the application of related accounting standards, our debt outstanding as of December 31, 2003 totaled approximately \$6.6 million.



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

Through December 31, 2003, we have recorded charges of approximately \$7.3 million for amortization of original issue discount and other related debt costs. Such amounts have been reflected as financing costs in the statement of operations. For additional information refer to note 7 to our consolidated financial statements for the year ended December 31, 2003.

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, 2003. This information should be read in conjunction with Item 6 - "Selected Financial

43

Data" and our consolidated financial statements and related notes thereto beginning on F-1 of this Form 10-K.

### Statement of Forward-Looking Information

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

### Background

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

We have established a strong foundation of laboratory and 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 the therapeutic products for the treatment of chronic disease. 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 Syndrome (ME/CFS"), HIV, hepatitis C ("HCV") and hepatitis B ("HBV") in the U.S., Canada, Europe and Japan. In February, 2004, we completed the double-blind segment of the AMP 516 Phase III clinical trial for use of Ampligen(R) in treating ME/CFS. The 14 remaining patients are enrolled in the open label portion of the trial and should complete this segment by June, 2004. With the conclusion of the double-blind segment we can finalize data collection and start data analysis in anticipation of preparing the NDA for submission to the FDA. Ampligen(R) is also 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 cocktail.

Our proprietary drug technology utilizes specifically configured ribonucleic acid ("RNA") and is protected by more than 350 patents worldwide as well as 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 patent apply to the use of Ampligen(R) in combination with certain other drugs. Some composition of matter patents pertain to other new medication, which have a similar mechanism of action.

In March, 2003, we 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

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

genital warts. We intend to market this product in the United State 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 sclerosis.

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

44  
reincorporated in Delaware and changed our name to Hem Pharmaceutical Corp. in 1991 and to Hemispherx Biopharma, Inc., in June 1995. We have three domestic subsidiaries BioPro Corp., BioAegean Corp., and Core BioTech Corp., all of which are incorporated in Delaware. Our foreign subsidiaries include Hemispherx Biopharma Europe N.V./S.A. established in Belgium in 1998 and Hemispherx Biopharma Europe S.A. incorporated in Luxembourg in 2002.

### Result of Operations

Years Ended December 31, 2003 vs. 2002

During the year ended December 31, 2003, we 1) acquired certain assets and patent rights to ALFERON N Injection(R), 2) privately placed the March 2005, the July 2005, and October 2005, 6% convertible debentures with an aggregate maturity value of \$14,994,357 (gross proceeds of \$12,850,000), 3) continued our efforts to develop Ampligen(R) for the treatment of patients afflicted with ME/CFS and HIV, 4) activated the ISI New Brunswick production facility to process doses of Alferon N and 5) produced some 21,000 doses of Alferon N for sale in 2003.

### Net loss

Our net loss was approximately \$14,770,000 for the year ended December 31, 2003 versus a net loss of \$7,424,000 in 2002. Per share loss in 2003 was \$0.42 cents versus a per share loss of \$0.23 in 2002. This year-to-year increase in losses of \$7,346,000 is primarily due to non-cash financing costs of \$7,345,000 relating to our March 2005, July 2005, and October 2005 6% convertible debentures. These non-cash charges account for 48% of our net losses for the year ended December 31, 2003. In addition, our losses during this period include \$957,000 in operating expenses relating to our new Alferon division. Solely for comparison purposes, excluding our 2003 losses for these two factors, our losses were \$6,775,000 in 2003 compared to \$7,424,000 in 2002 or a reduction totaling \$649,000. This was primarily due to a decrease in research and development direct costs of \$1,800,000 in 2003 due to reduced costs associated with the development of Ampligen(R) to treat ME/CFS patients. During 2002, our AMP 516 ME/CFS Phase III clinical trial was in full force and effect therefore increasing our manufacturing and clinical support expenses during that period (See "Research and Development Costs" below). This was offset by the recovery of certain legal expenses in 2002 of approximately \$1,050,000 related to the Asensio lawsuit and trial from our insurance carrier. This recovery produced a one-time reduction in G&A Expenses for 2002 (See "General and Administrative Expenses" below).

### Revenues

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

Revenues from our ME/CFS cost recovery treatment programs principally

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

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

45

Revenues from the cost recovery treatment programs in 2002 were \$341,000 or 57% higher than 2003 revenues. We expected revenues in the U.S. to decline due to our efforts to complete the AMP 516 ME/CFS Phase III trials and the focus of our clinical resources on the start up of the AMP 719 and AMP 720 HIV clinical trials. The clinical data collected from treating patients under the cost recovery treatment programs will augment and supplement the clinical data collected in the U.S. AMP 516 Phase III ME/CFS trial.

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

Since acquiring the right to manufacture and market Alferon N in March 2003, we have focused on converting the work-in-progress inventory into finished goods. This work-in-progress inventory included three production lots totaling the equivalent of approximately 55,000 vials (doses) at various stages of the manufacturing process. In August 2003, we released the first lot of product to Abbott Laboratories for bottling and realized some 21,000 vials of ALFERON N. Preliminary work has started on completing the second lot of approximately 16,000 vials. Our production and quality control personnel in the New Brunswick facility are involved in the extensive process of manufacturing and validation required by the FDA. Plans are underway for completing the third lot of some 18,000 vials now in very early stages of production.

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

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

### Production costs

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

Research and Development costs

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

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

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

AMP 516

Over 230 patients have participated in our ME/CFS Phase III clinical trial. Approximately 14 patients are in the open label phase of the clinical process. We have completed the randomized placebo controlled phase of this study and expect to complete data collection and start the data analysis process with the expectation of filing an NDA (New Drug Application) with the FDA by the end of 2004. As with any experimental drug being tested for use in treating human diseases, the FDA must approve the testing and clinical protocols employed and must render their decision based on the safety and efficacy of the drug being tested. Historically this is a long and costly process. Our ME/CFS AMP 516 clinical study is a Phase III study, which based on favorable results, will serve as the basis for us to file a new drug application with the FDA. The FDA review process could take 18-24 months and result in one of the following events; 1) approval to market Ampligen(R) for use in treating ME/CFS patients, 2) required more research, development, and clinical work, 3) approval to market as well as conduct more testing, or 4) reject our application. Given these variables, we are unable to project when material net cash inflows are expected to commence from the sale of Ampligen(R).

AMP 719 and AMP 720

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

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

Our AMP 719 HIV clinical trial has been put on hold at this time.

In July 2003, Dr. Blick, a principal investigator in our HIV studies, presented updated results on our Amp 720 HIV study at the 2nd IAS CONFERENCE ON HIV PATHOGENESIS AND TREATMENT in Paris France. In this study using Strategic Treatment Interruption (STI), patients' antiviral HAART regimens are interrupted and Ampligen(R) is substituted as mono-immunotherapy. Ampligen(R) is an experimental immunotherapeutic designed to display both antiviral and immune enhancing characteristics. Prolonged use of Highly Active Antiretroviral Therapy (HAART) has been associated with long-term, potentially fatal, toxicities. The clinical study AMP 720 is designed to address these issues by evaluating the administration of our lead experimental agent, Ampligen(R), a double stranded RNA drug acting potentially both as an immunomodulator and antiviral. Patients, who have completed at least nine months of Ampligen(R) therapy, were able to stay off HAART for a total STI duration with a mean time of 29.0 weeks whereas the control group, which was also taken off HAART, but not given Ampligen(R), had earlier HIV rebound with a mean duration of 18.7 weeks. Thus, on average, Ampligen(R) therapy spared the patients excessive exposure to HAART, with its inherent toxicities, for more than 11 weeks. As more patients are enrolled, the related clinical costs will continue to increase with some offset to our overall expenses due to the diminishing cost of the ME/CFS clinical trial. It is difficult to estimate the duration or projected costs of these two clinical trials due to the many variables involved, i.e.: patient drop out rate, recruitment of clinical investigators, etc. The length of the study and costs related to our clinical trials cannot be determined at this time as such will be materially influenced by (a) the number of clinical investigators needed to recruit and treat the required number of patients, (b) the rate of accrual of patients and (c) the retention of patients in the studies and their adherence to the study protocol requirements. Under optimal conditions, the cost of completing the studies could be approximately \$2.0 to \$3.0 million. The rate of enrollment depends on patient availability and on other products being in clinical trials for the treatment of HIV, as there is competition for the same patient population. At present, more than 18 FDA approved drugs for HIV treatment may compete for available patients. The length, and subsequently the expense of these studies, will also be determined by an analysis of the interim data, which will determine when completion of the ongoing Phase IIb is appropriate and whether a Phase III trial be conducted or not. In case a Phase III study is required; the FDA might require a patient population exceeding the current one which will influence the cost and time of the trial. Accordingly, the number of "unknowns" is sufficiently great to be unable to predict when, or whether, we may obtain revenues from our HIV treatment indications.

### General and Administrative Expenses

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

### Equity Loss-Unconsolidated Affiliates

In the year ended December 31, 2002, we recorded a non-cash charge of \$1,470,000 to operations with respect to our investments in unconsolidated affiliates. \$1,074,000 of these charges were related to our investment in R.E.D.

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

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

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

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

### Other Income/Expense

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

### Interest Expense and Financing Costs

Interest expense and financing costs were \$7,598,000 in 2003. Non-cash financing costs consist of \$581,000 for the amortization of debenture closing costs, \$1,066,000 for the amortization of Original Issue Discounts and \$5,698,000 for the amortization of costs associated with beneficial conversion features of the debentures and the fair value of the warrants relating to the January 2005, July 2005 and October 2005 6% convertible debentures. These charges are reflected in the Consolidated Statements of Operations under the caption "Financing Costs." Please see Note 16 in the consolidated financial statements contained herein for more details on these transactions.

### Years 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 loss in 2002 was \$0.23 versus a per share loss of \$0.29 in 2001. This year to year decrease in losses of \$1,659,000 was 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 came 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

49  
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.

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

We received a licensing fee of 625,000 Euros (some \$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 was \$904,000 compared to revenues of \$390,000 in 2001.

### Research and Development costs

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.

At December 31, 2002, Ampligen was 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. It also was 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 AMP 516 clinical trial was fully enrolled with more than the targeted 230 patients in order to potentially compensate for "drop outs". The last patients completed the randomized segment of this clinical trial in February, 2004. 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 by the end of 2004. The date of potential commercial approval depends on whether we receive Fast Track Status from the FDA. In case of Fast Track the FDA approval time is maximum six months. If we are 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.

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,

50  
2) require 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 had been enrolled in both studies combined and they were being treated in approximately 10 different active sites around the U.S.

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

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. See "AMP 719 and AMP 720" in "Result of Operations; Years Ended December 31, 2003 vs. 2002; Research and Development costs" above.

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 us.

### 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 its then proposed equity offerings. Please see "RESEARCH AND DEVELOPMENT/COLLABORATIVE AGREEMENTS" in Part 1 for more details on these transactions.

51

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. 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 our investment. Additionally, during 2001 we reduced our investment in CIMM based on our percentage interest in CIMM's continued operating losses. Our remaining investment at December 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.



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

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 1 for more details on these transactions.

### Interest and Other Income

Interest and other income totaled \$103,000 in 2002 compared to \$284,000 recorded 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.

### Liquidity And Capital Resources

Cash used in operating activities for the twelve months ended December 31, 2003 was \$7,022,000. Cash provided by financial activities for twelve months ended December 31, 2003 amounted to \$10,317,000, substantially from proceeds from debentures (see below). As of December 31, 2003, we had approximately \$5,260,000 in cash, cash equivalents and short term investments. We believe that these funds plus the net proceeds of approximately \$3.7 million from the recently placed January 2004 Debentures, 2) the potential receipt of the \$1.55 million of proceeds held back pending the acquisition of the ISI facility, 3) potential licensing fee income, 4) the \$2,000,000 in proceeds we expect when the investors exercise their additional investment rights, and 5) and the projected revenue from the acquisition of the ALFERON N Injection(R) business will be sufficient to meet our operating requirements including debt service during the 2004 fiscal year. Sales of ALFERON N Injection(R) could be greater than expected which would improve our cash position during the next twelve months. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash. If we do not timely complete the second ISI asset acquisition, our financial condition could be adversely affected (see the risk factor "If we do not complete the second Interferon Sciences asset acquisition, our ability to generate revenues from the sales of ALFERON N Injection(R) and our financial condition will be adversely affected").

On March 12, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due January 2005 (the "March Debentures") and an aggregate of 743,288 warrants to two investors in a private

52  
placement for aggregate proceeds of \$4,650,000. Pursuant to the terms of the March Debentures, \$1,550,000 of the proceeds from the sale of the March Debentures were to have been held back and were to be released to us if, and only if, we acquired ISI's facility within a set timeframe. Although we had not acquired ISI's facility, these funds were released to us in June 2003. The March Debentures were to mature on January 31, 2005 and bore interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest were valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Pursuant to the terms and conditions of the March Debentures, we pledged all of our assets, other than our intellectual property, as collateral and were subject to comply with certain financial and negative covenants, which include but were not limited to the repayment of principal balances upon achieving certain revenue milestones.

The March Debentures were convertible at the option of the investors at any time through January 31, 2005 into shares of our common stock. The

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

conversion price under the March Debentures was fixed at \$1.46 per share, subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect.

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

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

As of December 31, 2003 the investors had converted the total \$5,426,000 principal of the March Debentures into 3,716,438 shares of our common stock. The total interest on the debenture was \$111,711 of which \$17,290 was paid in cash and \$94,421 was paid by the issuance of shares of our common stock. The investor exercised 742,288 warrants in July 2003 which produced proceeds in the amount of \$1,248,724.

On July 10, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due July 31, 2005 (the "July Debentures") and an aggregate of 507,103 Warrants (the "July 2008 Warrants") to the same investors who purchased the March 12, 2003 Debentures, in a private placement for aggregate anticipated proceeds of \$4,650,000. Pursuant to the terms of the July Debentures, \$1,550,000 of the proceeds from the sale of the July Debentures were to have been held back and were to be released to us if, and only if, we acquired ISI's facility within a set timeframe. Although we have not acquired ISI's facility, these funds were released to us in October 2003. The July Debentures mature on July 31, 2005 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date.

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

The July 2008 Warrants received by the investors, as amended, are to acquire at any time commencing on July 26, 2004 through January 31, 2009 an aggregate of 507,102 shares of common stock at a price of \$2.46 per share. On July 10, 2004, the exercise price of these July 2008 Warrants will reset to the lesser of the exercise price then in effect or a price equal to the average of the daily price of the common stock between July 11, 2003 and July 9, 2004 (but in no event less than \$2.14 per share). The exercise price (and the reset price) under the July 2008 Warrants also is subject to similar adjustments for

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

anti-dilution protection.

We entered into a Registration Rights Agreement with the investors in connection with the issuance of the July Debentures and the July 2008 Warrants. The Registration Rights Agreement requires that we register on behalf of the holders the shares of common stock issuable upon conversion of the Debentures, as interest shares under the Debentures and upon exercise of the July 2008 Warrants. These shares have been registered for public sale.

On June 25, 2003, we issued to each of the March 12, 2003 Debenture holders a warrant to acquire at any time through June 25, 2008 an aggregate of 500,000 shares of common stock at a price of \$2.40 per share. On June 25, 2004, the exercise price of these June 2008 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 June 26, 2003 and June 24, 2004 (but in no event less than \$1.68 per share). The exercise price (and the reset price) under the June 2008 Warrants also is subject to adjustments for anti-dilution protection similar to those in the July 2008 Warrants. Pursuant to our agreement with the Debenture holders, we have registered the shares issuable upon exercise of these June 2008 Warrants for public sale.

On October 29, 2003, we issued an aggregate of \$4,142,357 in principal amount of 6% Senior Convertible Debentures due October 31, 2005 (the "October Debentures") and an aggregate of 410,134 Warrants (the "October 2008 Warrants") in a private placement for aggregate anticipated gross proceeds of \$3,550,000. Pursuant to the terms of the October Debentures, \$1,550,000 of the proceeds from the sale of the October Debentures have been held back and will be released to us if, and only if, we acquired ISI's facility within 90 days of January 26, 2004 and provide a mortgage on the facility as further security for the October Debentures. The October Debentures mature on October 31, 2005 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on 54 the third business day immediately preceding the applicable interest payment date.

Upon completing the sale of the October Debentures, we received \$3,275,000 in net proceeds consisting of \$1,725,000 from the October Debentures and \$1,550,000 that had been withheld from the July Debentures. As noted above, \$1,550,000 of the proceeds from the October Debentures have been held back pending our completing the acquisition of the ISI facility.

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

The October 2008 Warrants, as amended, received by the investors are to acquire at any time commencing on July 26, 2004 through April 30, 2009 an aggregate of 410,134 shares of common stock at a price of \$2.32 per share. On October 29, 2004, the exercise price of these October 2008 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 October 29, 2003 and October 27, 2004 (but in no event less than \$2.19 per share). The exercise price (and the reset price) under the October 2008 Warrants also is subject to similar adjustments for anti-dilution protection.

As of February 27, 2004, the investors had converted \$9,589,300 of debt

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

from the March, July and October Debentures into 5,894,137 shares of our common stock. The remaining principal balance on the debentures is convertible into shares of our stock at the option of the investors at any time, through the maturity date. In addition, we have paid \$1,300,000 into the debenture cash collateral account as required by the terms of the October Debentures. The amounts paid through December 31, 2003 have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of December 31, 2003. The cash collateral account provides partial security for repayment of the March, July and October 2003 and January 2004 Debentures in the event of default.

We entered into a Registration Rights Agreement with the investors in connection with the issuance of the October Debentures and the October 2008 Warrants. The Registration Rights Agreement requires that we register on behalf of the holders the shares of common stock issuable upon conversion of the October Debentures, as interest shares under the October Debentures and upon exercise of the 2008 Warrants. These shares have been registered for public sale. If, subject to certain exceptions, sales of all shares required to be registered cannot be made pursuant to the registration statement, then we will be required to pay to the investors their pro rata share of \$3,635 for each day such conditions exists.

On January 26, 2004, we issued an aggregate of \$4,000,000 in principal amount of 6% Senior Convertible Debentures due January 31, 2006 (the "January 2004 Debentures"), an aggregate of 790,514 warrants (the "2009 Warrants") and 158,103 shares of common stock, and Additional Investment Rights (to purchase up to an additional \$2,000,000 principal amount of January 2004 Debentures commencing in six months) in a private placement for aggregate net proceeds of \$3,695,000. The January 2004 Debentures mature on January 31, 2006 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction

55

of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Commencing six months after issuance, we are required to start repaying the then outstanding principal amount under the January 2004 Debentures in monthly installments amortized over 18 months in cash or, at our option, in shares of common stock. Any shares of common stock issued to the investors as installment payments shall be valued at 95% of the average closing price of the common stock during the 10-day trading period commencing on and including the eleventh trading day immediately preceding the date that the installment is due.

The January 2004 Debentures are convertible at the option of the investors at any time through January 31, 2006 into shares of our common stock. The conversion price under the January 2004 Debentures is fixed at \$2.53 per share, subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect.

There are two classes of July 2009 warrants received by the Investors: Class A and Class B. The Class A warrants are to acquire any time from July 26, 2004 through July 26, 2009 an aggregate of up to 395,257 shares of common stock at a price of \$3.29 per share. The Class B warrants are to acquire any time from July 26, 2004 through July 26, 2009 an aggregate of up to 395,257 shares of common stock at a price of \$5.06 per share. On January 27, 2005, the exercise price of these July 2009 Class A and Class B Warrants will reset to the lesser of their respective exercise price then in effect or a price equal to the average of the daily price of the common stock between January 27, 2004 and January 26, 2005 (but in no event less than \$2.58 per share with regard to the Class A warrants and \$3.54 per share with regard to the Class B warrants). The exercise price (and the reset price) under the July 2009 Warrants also is

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

subject to similar adjustments for anti-dilution protection.

We also issued to the investors Additional Investment Rights pursuant to which the investors have the right to acquire up to an additional \$2,000,000 principal amount of January 2004 Debentures from us. These Debentures are identical to the January 2004 Debentures except that the conversion price is \$2.58. The Additional Investment Rights are exercisable commencing on July 26, 2004 (the "Trigger" date) for a period of 90 days from the Trigger Date or 90 days from the date which the registration statement registering the shares issuable upon the conversion of the January 2004 Debentures to be issued pursuant to the Additional Investment Rights is declared effective, whichever is longer.

We entered into a Registration Rights Agreement with the investors in connection with the issuance of the January 2004 Debentures (including any Debentures issued pursuant to the Additional Investment Rights), the shares, and the January 2009 Warrants. The Registration Rights Agreement requires that we register on behalf of the investors the shares issued to the investors and 135% of the shares issuable upon conversion of the Debentures (including payment of interest thereon) and upon exercise of the January 2009 Warrants. If the Registration Statement containing these shares is not filed within the time period required by the agreement, 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

56

pro rata share of \$3,635 for each day any of the above conditions exist with respect to this Registration Statement.

By agreement between us and the investors, the date upon which all warrants previously issued to the investors may become exercisable is now July 26, 2004 and the exercise periods of these warrants have been extended accordingly.

By agreement with Cardinal Securities, LLC, for general financial advisory services and in conjunction with the private debenture placements in March, July and October 2003 and in January 2004, we paid Cardinal Securities, LLC an investment banking fee equal to 7% of the investments made by the two Debenture holders and issued to Cardinal certain warrants. A portion of the investment banking fee was paid with the issuance of 30,000 shares of our common stock. Cardinal also received 612,000 warrants to purchase common stock, of which 112,500 are exercisable at \$1.74 per share, 112,500 are exercisable at \$2.57 per share, 200,000 are exercisable at \$2.50 per share, 87,500 are exercisable at \$2.42 per share and 100,000 are exercisable at \$3.04 per share. The \$1.74 warrants expire on July 10, 2008, the \$2.57 and \$2.50 warrants expire on March 12, 2008, the \$2.42 warrants expire on October 30, 2008 and the \$3.04 warrants expire on January 5, 2009. By agreement with Cardinal, we have registered 542,500 shares for public sale and have agreed to register the balance.

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

On March 11, 2003, we acquired from ISI, ISI's inventory of ALFERON N Injection(R), a pharmaceutical product used for intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older, and a limited license for the production, manufacture, use, marketing and sale of this product. As partial consideration, we issued 487,028 shares of our common stock to ISI Pursuant to our agreements with ISI, we have registered these shares for public sale. ISI has sold all of these shares. We also agreed to pay ISI 6 % of the net sales of ALFERON N Injection(R).

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

On March 11, 2003, we also entered into an agreement to purchase from ISI all of its rights to the product and other assets related to the product including, but not limited to, real estate and machinery. For these assets, we agreed to issue to ISI an additional 487,028 shares and to issue 314,465 shares and 267,296 shares, respectively to The American National Red Cross and GP Strategies Corporation, two creditors of ISI. We have guaranteed the market value of all but 62,500 of these shares to be \$1.59 per share on the termination date. The termination date for these guarantees is 18 months after the date of issuance of the guaranteed shares to GP Strategies, 24 months after the date of issuance and delivery of the 487,028 guaranteed shares to ISI and 12 months after the date of issuance of the guaranteed shares to the American National Red Cross. These stockholders are permitted to periodically sell certain amounts of their shares. If, within 30 days after the respective termination date, one or more of these stockholders requests that we honor the guarantee, we will be obligated to reacquire their remaining guaranteed shares and pay them \$1.59 per share. Please see "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 24 months after the dates of issuance of the guaranteed shares, our financial condition could be adversely affected" in "Risk Factors," above.

57

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

On May 30, 2003, we issued the shares to GP Strategies and the American National Red Cross. Pursuant to our agreements with ISI and these two creditors, we have registered the foregoing shares for public sale. As of February 10, 2004 GP Strategies had sold all of its shares

In addition, as of December 31, 2003, we have \$200,000 in restricted cash under other letter of credit agreements required by our insurance carrier. Prior to our annual meeting of stockholders in September 2003, we had a limited number of shares of Common Stock authorized but not issued or reserved for issuance upon conversion or exercise or outstanding convertible and exercisable securities such as debentures, options and warrants. Prior to the meeting, to permit consummation of the sale of the July 2005 Debentures and the related warrants, Dr. Carter agreed that he would not exercise his warrants or options unless and until our stockholders approve an increase in our authorized shares of common stock. For Dr. Carter's waiver of his right to exercise certain options and warrants prior to approval of the increase in our authorized shares, we agreed to compensate Dr. Carter. See "Executive Compensation; Employment Agreements" for details related to how Dr. Carter has been compensated with respect to this matter.

On November 6, 2003 we acquired some of the outstanding ISI property tax lien certificates in the aggregate amount of \$456,839 from certain investors. These tax liens were issued for property taxes and utilities due for 2000, 2001 and 2002.

Because of our long-term capital requirements, we may seek to access the public equity market whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. We may also need additional funding earlier than anticipated, and our cash requirements, in general, may vary materially from those now planned, for reasons including, but not limited to, changes in our research and development programs, clinical trials, competitive and technological advances, the regulatory process, and higher than anticipated expenses and lower than anticipated revenues from certain of our clinical trials for which cost recovery from participants has been approved.

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

Contractual Obligations

Contractual Cash Obligations	(dollars in thousands)		
	Total	2004	2005-2006
Operating Leases	\$784	\$286	\$433
Convertible Debentures			
July 10, 2003 5,426,000 6% Senior Convertible Debenture	4,257	-	4,257
October 29, 2003 \$4,142,000 6% Senior Convertible Debenture	2,334	-	2,334
<b>Total</b>	<b>\$7,375</b>	<b>\$286</b>	<b>\$7,024</b>

58

NEW ACCOUNTING PRONOUNCEMENTS

In November, 2002, the FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others" ("Interpretation No. 45"). Interpretation No. 45 elaborates on the existing disclosure requirements for most guarantees, including loan guarantees such as standby letters of credit. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair market value of the obligations it assumes under the guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and measurement provisions of Interpretation No. 45 apply on a prospective basis to guarantees issued or modified after December 31, 2002. Interpretation No. 45 did not have an effect on our financial statements.

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"). 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 Accounting Principles Board ("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. We 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 have adopted the enhanced disclosure requirements of SFAS 148.

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

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

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 prior to January 31, 2003, the provisions of Interpretation No. 46 have been deferred to the first quarter of 2004. This Interpretation did not have an effect on our consolidated financial statements.

In May 2003, the FASB issued Statement No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity" ("SFAS 150"). SFAS 150 requires an issuer to classify certain financial instruments, such as mandatory redeemable shares and obligations to repurchase the issuers equity shares, as liabilities. The guidance is effective for financial instruments entered into or modified subsequent to May 31, 2003, and is otherwise effective at the beginning of the first interim period after June 15, 2003. SFAS 150 did not have an impact on our financial condition or results of operations.

59

### Disclosure About Off-Balance Sheet Arrangements

Prior to our annual meeting of stockholders in September 2003, we had a limited number of shares of Common Stock authorized but not issued or reserved for issuance upon conversion or exercise of outstanding convertible and exercisable securities such as debentures, options and warrants. Prior to the meeting, to permit consummation of the sale of the July 2005 Debentures and the related warrants, Dr. Carter agreed that he would not exercise his warrants or options unless and until our stockholders approve an increase in our authorized shares of common stock. For Dr. Carter's waiver of his right to exercise certain options and warrants prior to approval of the increase in our authorized shares, we have agreed to compensate Dr. Carter. See "Executive Compensation; Employment Agreements" for details related to how Dr. Carter has been compensated with respect to this matter.

In connection with the debenture agreements, HEB has outstanding letters of credit of \$1,000,000 as additional collateral.

### Critical Accounting Policies

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

#### Revenue

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

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



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

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

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

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

60

### 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. We review our patents and trademark rights periodically to determine whether they have continuing value. Such review includes an analysis of the patent and trademark's ultimate revenue and profitability potential on an undiscounted cash basis to support the realizability of our respective capitalized cost. In addition, management's review addresses whether each patent continues to fit into our strategic business plans.

### Concentration of Credit Risk

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

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

Concentration of credit risk, with respect to receivables, is limited through our credit evaluation process. We do not require collateral on our receivables. Our receivables consist principally of amounts due from wholesale drug companies as of December 31, 2003.

### ITEM 7a. Quantitative and Qualitative Market Risk.

#### Market Risk

We had \$5.2 million in cash, cash equivalents and short term investments at December 31, 2003. To the extent that our cash and cash equivalents exceed our near term funding requirements, the excess cash was invested in three (3) to six (6) 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, 2002, and 2003, and our consolidated statements of operations, changes in stockholders' equity and

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

comprehensive loss and cash flows for each of the years in the three year period ended December 31, 2003, together with the report 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.

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

None.

61

ITEM 9A. Controls and Procedures.

Our Chairman of the Board (serving as the principal executive officer) and the Chief Financial Officer performed an evaluation of our disclosure controls and procedures, which have been designed to permit us to effectively identify and timely disclose important information. They concluded that the controls and procedures were effective as of December 31, 2003 to ensure that material information was accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. During the quarter ended December 31, 2003, we have made no change in our internal controls over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

62

### 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 Agreement:

Name	Age	Position
William A. Carter, M.D.	66	Chairman, Chief Executive Officer, and President
Robert E. Peterson	66	Chief Financial Officer
David R. Strayer, M.D.	58	Medical Director, Regulatory Affairs
Mei-June Liao, Ph.D.	53	Vice President of Regulatory Affairs, Quality Control and Research and Development
Robert Hansen	60	Vice President of Manufacturing
Carol A. Smith, Ph.D.	54	Director of Process Development
Richard C. Piani	77	Director
William M. Mitchell, M.D., Ph.D.	69	Director
Ransom W. Etheridge	64	Director, Secretary, and General Counsel
Eraj Kiani, M.B.A., Ph.D.	58	Director
Antoni Esteve, Ph.D.	45	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

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

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

63

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

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

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

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

CAROL A. SMITH, Ph.D. is Director of Process Development and has served as our Director of Manufacturing and Process Development since April 1995, as Director of Operations since 1993 and as the Manager of Quality Control from 1991 to 1993, with responsibility for the manufacture, control and chemistry of Ampligen(R). Dr. Smith was Scientist/Quality Assurance Officer for Virotech International, Inc. from 1989 to 1991 and Director of the Reverse Transcriptase

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

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 our European operations and markets. Mr. Piani served as Chairman of Industrielle du Batiment-Morin, a building materials corporation, from 1986 to 1993. Previously Mr. Piani was a Professor of International Strategy at Paris Dauphine University from 1984 to 1993. From 1979 to 1985, Mr. Piani served as Group Director in Charge of International and

64  
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 and general counsel. Mr. Etheridge first became associated with Hemispherx in 1980 when he provided consulting services to us and participated in negotiations with respect to our initial private placement through Oppenheimer & Co., Inc. Mr. Etheridge has been practicing law since 1967, specializing in transactional law. Mr. Etheridge is a member of the Virginia State Bar, a Judicial Remedies Award Scholar, and has served as President of the Tidewater Arthritis Foundation. He is a graduate of Duke University, and received his Law degree from the University of Richmond School of Law.

WILLIAM M. MITCHELL, M.D., Ph.D. has been a director 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 years. Dr. Kiani is a planning and logistic specialist who is now applying his knowledge and experience to build a worldwide immunology network, which will use our proprietary technology. Dr. Kiani received his Ph.D. degree from the University of Warwick in England.

ANTONI ESTEVE, Ph.D. became a member of our Board of Directors in November 2003. Dr. Esteve is a Member of the Executive Committee and Director of Scientific and Commercial Operations for Laboratorios del Dr. Esteve S.A. He has been engaged at Laboratorios del Dr. Esteve since 1984. Since 1986 he is Professor at the Autonomous University of Barcelona, School of Pharmacy. In 2001 he was elected as member of the Advisory Board for R&D of the Spanish Ministry of Science and Technology. Since 2002 he also has been President of Centre de

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

Transfussio i Banc de Teixits (the Transfusion and Tissues Bank Center of Catalonia). Dr. Esteve received a degree in Pharmacy from the University of Barcelona, Faculty of Pharmacy, in 1981 and a Ph.D. in Pharmaceutical Science in 1990.

65

### 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, 2003, all of our officers, directors and ten percent stockholders complied with all applicable Section 16(a) filing requirements on a timely basis, except that Dr. Carter, Dr. Mitchell and Mr. Piani each filed a Form 5 late in which each reported one transaction that should have been reported on a Form 4 during 2003; Mr. Etheridge filed a Form 5 late in which he reported two transactions that should have been reported on a Form 4 during 2003; and Dr. Esteve and Mr. Kiani, we have been informed, are each in the process of filing a Form 3.

### Audit Committee and Audit Committee Expert

Audit Committee. Our Audit Committee of the Board of Directors consists of Richard Piani, Committee Chairman, William Mitchell, M.D. and Iraj Eghbal Kiani, M.B.A., Ph.D. Mr. Piani, Dr. Mitchell and Dr. Iraj Eghbal Kiani are Independent Directors. We do not have a financial expert as defined in Securities and Exchange Commission rules on the committee in the true sense of the description. However, Mr. Piani is a businessman and has 40 years of experience working with budgets, analyzing financials and dealing with financial institutions. We believe Mr. Piani, Dr. Mitchell and Iraj Eghbal Kiani to be independent of management and free of any relationship that would interfere with their exercise of independent judgment as members of this committee. The principal functions of the Audit Committee are to recommend our independent auditors, review the scope of their engagement, consult with the auditors, review the results of their examination, act as liaison between the Board of Directors and the auditors and review various company policies, including those relating to accounting and internal controls.

### Code of Ethics

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

### Item 11. Executive Compensation.

The summary compensation table below sets forth the aggregate compensation paid or accrued by us for the fiscal years ended December 31, 2003, 2002 and 2001 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 & Opti Awards
William A. Carter Chairman of the Board and CEO	2003	(4) \$582,561	-	(5) 1,450,000
	2002	(4) 565,514	-	(8) 1,000,000
	2001	(4) 551,560	-	(2) 386,650
Robert E. Peterson Chief Financial Officer	2003	(9) \$230,450	-	-
	2002	151,055	-	(8) 200,000
	2001	146,880	-	(3) 40,000
David R. Strayer, M.D. Medical Director	2003	(6) \$190,096	-	-
	2002	(6) 178,594	-	(8) 50,000
	2001	(6) 174,591	-	(7) 10,000
Carol A. Smith, Ph.D. Director of Manufacturing	2003	\$140,576	-	-
	2002	128,346	-	(8) 20,000
	2001	124,800	-	(7) 10,000
Robert Hansen, V.P. of Manufacturing	2003	(10) \$104,500	-	-
	2002	-	-	-
	2001	-	-	-

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

(2) 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) Consist 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 \$94,952, \$96,684, and \$99,481 in 2001, 2002 and 2003, respectively. 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 us and totaled \$79,826 in 2001, \$82,095 in 2002 and \$84,776 in 2003.

67

(5) Represents warrants to purchase common stock exercisable at \$2.20 per share.

(6) Includes \$98,926 paid by Hahnemann Medical University where Dr. Strayer

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

served as a professor until 1998. This compensation was continued by us in 2001, 2002 and 2003.

(7) Consist of 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.

(9) 2003 includes a bonus of \$74,464 paid in 2004.

(10) Compensation since March 2003. Employed by ISI prior to that. The following table sets forth certain information regarding stock warrants granted during 2003 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	POTENTIAL ASSUMED APPRECIATION (4)
Carter, W.A.	1,450,000	100%	\$2.20	9/8/08	\$4,071,5%

(1) Warrants vest upon execution of the second ISI asset closing or the filing by us with the U.S. Food and Drug Administration of a new drug application, whichever happens first.

(2) Total warrants issued to employees in 2003 were 1,450,000.

(3) The exercise price is equal to the closing price of our 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 our estimate of future stock price appreciation.

68

The following table sets forth certain information regarding the stock options held as of December 31, 2003 by the individuals named in the above Summary Compensation Table.

### AGGREGATED OPTION EXERCISES IN LAST FISCAL YEAR

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

## AND FISCAL YEAR-END OPTION VALUE

Name	Shares Acquired on Exercise (#)	Value Realized (\$)	Securities Underlying Unexercised Warrants/ Options at Fiscal Year End Numbers		Value of Unexercised In-the-Money-Options Year End (1)
			Exercisable	Unexercisable	Dollars Exercisable
William Carter	-	-	3,805,378 (2)	1,950,000 (3)	\$367,150
Robert Peterson	-	-	403,750 (4)	0	52,000
David Strayer	-	-	130,000 (5)	0	13,000
Carol Smith	-	-	41,791 (6)	0	5,200

(1) Computation based on \$2.26, the December 31, 2003 closing bid price for the common stock on the American Stock Exchange.

(2) Consist of (i) 500,000 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 (vii) 10,000 stock option exercisable at \$4.03 per share expiring on January 3, 2011, (viii) 73,728 stock options exercisable at \$2.71 per share until exercised. Also include 2,695,000 warrants and options held in the name of Carter Investments, L.C. of which W.A. Carter is the principal beneficiary. These securities consist of (i) 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, and 1,400,000 warrants exercisable at \$3.50 per share expiring on October 16, 2004.

69

(3) Consists of (i) 500,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007 and (ii) 1,450,000 warrants exercisable at \$2.20 per share expiring on September 8, 2008.

(4) Consists of (i) 10,000 stock options exercisable at \$4.03 per share expiring on January 3, 2011 (ii) 13,750 stock options exercisable at \$3.50 per share expiring on January 22, 2007, (iii) 200,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007, (iv) 50,000 warrants exercisable at \$3.50 expiring on March 1, 2006, (v) 100,000 warrants exercisable at \$5.00 per share expiring on April 14, 2006 and (vi) 30,000 warrants exercisable at \$5.00 per share expiring on February 28, 2009.

(5) Consists of (i) 50,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007, (ii) 50,000 warrants exercisable at \$4.00 per share expiring on February 28, 2008, (iii) 10,000 stock options exercisable at \$4.03 expiring on



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

January 3, 2011 and (iv) 20,000 stock options exercisable at \$3.50 per share expiring on January 22, 2007.

(6) Consists of (I) 20,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007, (ii) 5,000 warrants exercisable at \$4.00 per share expiring on June 7, 2008, (iii) 10,000 stock options exercisable at \$4.03 per share expiring on January 3, 2016, and (iv) 6,791 stock options exercisable at \$3.50 per share expiring on January 22, 2007.

### Employment Agreements

We entered into an amended and restated employment agreement with our President and Chief Executive Officer, Dr. William A. Carter, dated as of December 3, 1998, as amended in August 2003, which provided for his employment until May 8, 2008 at an initial base annual 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. Dr. Carter will not participate in any discussions concerning the determination of his annual bonus. Dr. Carter is also entitled to an incentive bonus of 0.5% of the gross proceeds received by us from any joint venture or corporate partnering arrangement, 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 our common stock at an exercise price of \$2.71 per share.

We entered into an amended and restated engagement agreement with Robert E. Peterson dated April 1, 2001 which provides for Mr. Peterson's employment as our Chief Financial Officer until December 31, 2003 which has been extended six months, 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 Federal Drug Administration approval of Ampligen based on the number of years of his employment by us up to the date of such approval. Mr. Peterson's agreement also contains a provision for severance pay equal to nine months compensation.

### Compensation of Directors

The compensation package for Members of the Board of Directors was changed on September 9, 2003. Board member compensation consists of an annual  
70  
retainer of \$100,000 to be paid 50% in cash and 50% in Company common stock. In addition, all non-employee directors received some compensation in 2003 for special project work performed on our behalf. All directors have been granted options to purchase common stock under our 1990 Stock Option Plan and/or Warrants to purchase common stock. We believe such compensation and payments are necessary in order for us to attract and retain qualified outside directors.

### 1990 Stock Option Plan

Our 1990 Stock Option Plan, as amended ("1990 Plan"), provides for the grant of options to our employees, directors, officers, consultants and advisors for the purchase of up to an aggregate of 460,798 shares of common stock. The 1990 plan is administered by the Compensation Committee of the board of directors, which has complete discretion to select eligible individuals to receive and to establish the terms of option grants. The number of shares of common stock available for grant under the 1990 Plan is subject to adjustment for changes in capitalization. As of December 31, 2003, no options were available for grants under the 1990 plan. This plan remains in effect until

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

terminated by the Board of Directors or until all options are issued.

### 401(K) Plan

In December 1995, we established a defined contribution plan, effective January 1, 1995, entitled the Hemispherx Biopharma employees 401(K) Plan and Trust Agreement. All of our full time employees are eligible to participate in the 401(K) plan following one year of employment. Subject to certain limitations imposed by federal tax laws, participants are eligible to contribute up to 15% of their salary (including bonuses and/or commissions) per annum. Participants' contributions to the 401(K) plan may be matched by Hemispherx at a rate determined annually by the board of directors. Each participant immediately vests in his or her deferred salary contributions, while our contributions will vest over one year. In 2003 we provided matching contributions to each employee for up to 6% of annual pay for a total of \$34,000 for all eligible employees.

### Compensation Committee Interlocks and Insider Participation

During the fiscal year ended December 31, 2003, the members of our Compensation Committee were Ransom W. Etheridge and Richard Piani. Mr. Etheridge serves as our Secretary and he is an attorney in private practice and has rendered legal services to us for which he received a fee. Mr. Piani received fees for certain consulting work performed in Europe on our behalf. Refer to Item 13. "Certain Relationships and Related Transactions" for more information.

### Compensation Committee Report on Compensation

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

The following report of the compensation committee discusses our executive compensation policies and the basis of the compensation paid to our executive officers in 2003.

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.

71

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

### Base Salary

The Summary Compensation Table shows amounts earned during 2003 by our executive officers. The base compensation of such executive officers is set by terms of the employment agreement entered into with each such executive officer. We established the base salaries for Chief Executive Officer, Dr. William A. Carter under an employment agreement in December 3, 1998 (as amended on August 14, 2003), which provides for a base salary of \$361,586 until May 8, 2008. Also we entered into an extended employment agreement with Robert E. Peterson, Chief Financial Officer for a base salary of \$155,988 until December 31, 2003, which was extended six months. 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 us and totaled \$79,826 in 2001, \$82,095 in 2002 and \$84,776 in 2003.

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

### Annual Incentive

Our Chief Executive Officer and our Chief Financial Officer are entitled to an annual incentive bonus as determined by the compensation committee based on such executive officers' performance during the previous calendar year. The cash bonus awarded to our Chief Executive Officer in 2003 and the cash bonus awarded to the Chief Financial Officer in 2003 were determined based on this provision in their employment agreements.

### Long-Term Incentives

We grant long-term incentive awards periodically to align a significant portion of the executive compensation program with stockholder interest over the long-term through encouraging and facilitating executive stock ownership. Executives are eligible to participate in our incentive stock option plans. Our Chief Executive Officer and President, Dr. William Carter, received a grant of 1,450,000 warrants in 2003. These warrants are exercisable at \$2.20 per share and expire on September 8, 2008, unless previously exercised. These Warrants vest upon consummation of the second ISI asset closing or the filing by us with the U.S. Food and Drug Administration of a new drug application, whichever happens first. The warrants vested on March 17, 2004, when the second ISI asset closing was consummated.

### Performance Graph

Total Return to Shareholders  
(Includes reinvestment of dividends)

Company Name / Index	ANNUAL RETURN PERCENTAGE Years Ending			
	Dec99	Dec00	Dec01	Dec02
HEMISPHERX BIOPHARMA INC	44.55	-52.20	-5.26	-52.20
S&P SMALLCAP 600 INDEX	12.40	11.80	6.54	-14.20
PEER GROUP	-23.18	-33.76	48.39	-45.20

Company Name / Index	Base Years Ending Period	INDEXED RETURNS			
		Dec99	Dec00	Dec01	Dec02
HEMISPHERX BIOPHARMA INC	100	144.55	69.09	65.45	30.20
S&P SMALLCAP 600 INDEX	100	112.40	125.67	133.88	114.20
PEER GROUP	100	76.82	50.88	75.51	40.20

72

#### Peer Group Companies

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

[GRAPHIC OMITTED] [GRAPHIC OMITTED]

GRAPH OF TOTAL SHAREHOLDER RETURNS

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

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

The following table sets forth as of February 15, 2004 the number and percentage of outstanding shares of common stock beneficially owned by each of our Directors and the Named Executives, and all of our executive officers and directors as a group. As of December 31, 2003, there were no other persons, individually or as a group, known to the Hemispherx to be deemed the beneficial owners of five percent or more of the issued and outstanding common stock.

OFFICERS, DIRECTORS AND PRINCIPAL STOCKHOLDERS	SHARES BENEFICIALLY OWNED	% OF SHARES BENEF
William A. Carter, M.D.	4,392,028	(2)
Robert E. Peterson	404,250	(3)
Ransom W. Etheridge	414,316	(4)
73		
Richard C. Piani	196,747	(5)
William M. Mitchell, M.D.	196,861	(6)
Antoni Esteve, M.D.	347,446	(7)
David R. Strayer, M.D.	144,746	(8)
Carol A. Smith, Ph.D	41,791	(9)
Iraj-Eghbal Kiani	12,000	(10)
Mei-June Liao, Ph.D.	0	
Robert Hansen	0	
All directors and executive officers as a group (11 persons)	6,150,185	

\* 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 February 15, 2004. 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

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

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 10,000 shares of common stock at \$4.03 per share and expiring on January 3, 2011 (XIV) 500,000 warrants exercisable \$2.00 per share in August 13, 2007, and 586,650 shares of common stock. Does not include 1,950,000 warrants that are not vested consisting of 500,000 warrants exercisable at \$2.00 per share expiring on August 13, 2007 and 1,450,000 warrants exercisable at \$2.20 per share expiring on September 9, 2008.

(3) Includes (i) 13,750 options to purchase common stock at an exercise price of \$3.50 per share, expiring on January 7, 2007; (ii) warrants to purchase 50,000 shares of Common stock at an exercise price of \$3.50 per share, expiring on March 1, 2006; (iii) warrants to purchase 100,000 shares of common stock at

74  
\$5.00 per share, expiring on April 14, 2006; (iv) 30,000 warrants to purchase common stock at \$5.00 per share an expiring on February 28, 2009 (v) options to purchase 10,000 shares at \$4.03 per share that expire on January 3, 2011 (VI) 200,000 warrants exercised at \$2.00 per share expiring on November 13, 2007 and (v) 500 shares of common stock.

(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 per share, all expiring on September 12, 2004; 100,000 warrants exercisable \$2.00 per share expiring on August 13, 2007; 200,000 stock options exercisable at \$2.75 per share and expiring on December 4, 2013 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.

(6) Includes (I) warrants to purchase 12,000 shares of common stock at \$6.00 per share, expiring on August 25, 2008; (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 34,861 shares of common stock.

(7) Consists of 347,446 shares of our common stock owned by Provesan S.A., an affiliate of Laboratorios del Dr. Esteve S.A. Dr. Antoni Esteve is a member of the executive committee and director of Scientific and Commercial Operations of Laboratorios del Dr. Esteve S.A.

(8) 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) 10,000 stock options exercisable at \$4.03 per share and expiring on January 3, 2011; 50,000 warrants to purchase common stock at \$2.00 per share and expiring on August 13, 2007 and; (iv) 14,746 shares of common stock.

(9) Consists of 5,000 warrants to purchase common stock at \$4.00 per share expiring June 7, 2008; 6,791 stock options exercisable at \$3.50 expiring January 22, 2007 20,000 warrants exercisable at \$2.00 per share expiring in August 13,

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

2007 and options to purchase 10,000 shares of common stock at \$ 4.03 per share expiring on January 3, 2011.

(10)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 options and warrants to purchase our common stock, as discussed under the headings, "Item 11. Executive Compensation," and "Item 12. Security Ownership of Certain Beneficial Owners and Management," above.

75

Ransom W. Etheridge, one of our directors, 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, another of our director, 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. another of our directors, 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 \$100,100 in the year 2003. Mr. Etheridge was the only Director to exceed \$60,000 for his professional services.

William A. Carter, our Chief Executive Officer, received an aggregate of \$12,106 in short term advances which were repaid as of December 31, 2002. We loaned \$60,000 to Ransom W. Etheridge, one of our directors 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.

We paid \$57,750, \$33,450, and \$18,800 for the years ending December 31, 2001, 2002 and 2003 respectively to Carter Realty for the rent of property used at various times in years 2001, 2002 and 2003 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.

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

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

All audit and professional services provided by BDO Seidman, LLP are approved by the Audit Committee. The total fees billed by BDO Seidman, LLP were \$178,429 in 2002 and \$313,992 in 2003. The following table shows the aggregate fees billed to us by BDO Seidman, LLP for professional services rendered during the year ended December 31, 2003.

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

	Amount (\$)
Description of Fees	2002
Audit Fees	\$173,929
Audit-Related Fees	4,500
Tax Fees	-
All Other Fees	-
Total	\$178,429 =====

76

Audit Fees

Represents fees for professional services provided for the audit of our annual financial statements and review of our financial statements included in our quarterly reports and services in connection with statutory and regulatory filings.

Audit-Related Fees

Represents the fees for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements, including those in 2002 and 2003 related to the acquisition of ISI.

The Audit Committee has determined that BDO Seidman, LLP's rendering of these non-audit services is compatible with maintaining auditors independence. The Board of Directors considers BDO Seidman, LLP to be well qualified to serve as our independent public accountants. The committee also approved the charges for services performed in 2003.

PART IV

ITEM 15. 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) Reports on Form 8-K

During the fourth quarter of 2003, we filed the following Current Reports on Form 8-K:

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

Report dated October 30, 2003, reporting Item 5. "Other Events". No financial statements were filed with the report.

Report dated October 30, 2003, reporting Item 5. "Other Events". No financial statements were filed with the report.

Report dated September 12, 2003, reporting Item 5. "Other Events". No financial statements were filed with the report.

(c) Except as disclosed 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.(1)
2.2	Second Asset Purchase Agreement dated March 11, 2003, by and between the Company and ISI.(1)
77	
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended, along with Certificates of Designations.
3.1.1	Series E Preferred Stock.
3.2	By-laws of Registrant, as amended.
4.1	Specimen certificate representing our Common Stock.
4.2	Rights Agreement, dated as of November 19, 2002, between the Company and Continental Stock Transfer & Trust Company. The Right Agreement includes the Form of Certificate of Designation, Preferences and Rights of the Series A Junior Participating Preferred Stock, the Form of Rights Certificate and the Summary of the Right to Purchase Preferred Stock.(2)
4.3	Form of 6% Convertible Debenture of the Company issued in March 2003.(1)
4.4	Form of Warrant for Common Stock of the Company issued in March 2003.(1)
4.5	Form of Warrant for Common Stock of the Company issued in June 2003.(3)
4.6	Form of 6% Convertible Debenture of the Company issued in July 2003.(4)
4.7	Form of Warrant for Common Stock of the Company issued in July 2003.(4)
4.8	Form of 6% Convertible Debenture of the Company issued in October 2003.(5)
4.9	Form of Warrant for Common Stock of the Company issued in October 2003.(5)
4.10	Form of 6% Convertible Debenture of the Company issued in January 2004.(6)
4.11	Form of Warrant for Common Stock of the Company issued in January 2004.(6)
10.1	1990 Stock Option Plan.
10.2	1992 Stock Option Plan.
10.3	1993 Employee Stock Purchase Plan.



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

- 10.4 Form of Confidentiality, Invention and Non-Compete Agreement.
- 10.5 Form of Clinical Research Agreement.
- 10.6 Form of Collaboration Agreement.
- 10.7 Amended and Restated Employment Agreement by and between the Company and Dr. William A. Carter, dated as of July 1, 1993. (7) 10.8 Employment Agreement by and between the Registrant and Robert E. Peterson, dated April 1, 2001.
- 10.9 License Agreement by and between the Company and The Johns Hopkins University, dated December 31, 1980.
- 10.10 Technology Transfer, Patent License and Supply Agreement by and between the Company, Pharmacia LKB Biotechnology Inc., Pharmacia P-L Biochemicals Inc. and E.I. du Pont de Nemours and Company, dated November 24, 1987.
- 10.11 Pharmaceutical Use Agreement, by and between the Company and Temple University, dated August 3, 1988.
- 10.12 Assignment and Research Support Agreement by and between the Company, Hahnemann University and Dr. David Strayer, Dr. Isadore Brodsky and Dr. David Gillespie, dated June 30, 1989.
- 10.13 Lease Agreement between the Company and Red Gate Limited Partnership, dated November 1, 1989, relating to the Company's Rockville, Maryland facility.
- 10.14 Agreement between the Company and Bioclones (Proprietary) Limited.
- 10.15 Amendment, dated August 3, 1995, to Agreement between the Company and Bioclones (Proprietary) Limited (contained in Exhibit 10.14).
- 10.16 Licensing Agreement with Core BioTech Corp.
- 10.17 Licensing Agreement with BioPro Corp.
- 10.18 Licensing Agreement with BioAegean Corp.
- 10.19 Agreement with Esteve.
- 10.20 Agreement with Accredo (formerly Gentiva) Health Services.
- 10.21 Agreement with Biovail Corporation International.
- 10.22 Forbearance Agreement dated March 11, 2003, by and between ISI, the American National Red Cross and the Company.(1)
- 10.23 Forbearance Agreement dated March 11, 2003, by and between ISI, GP Strategies Corporation and the Company.(1)
- 78
- 10.24 Securities Purchase Agreement, dated March 12, 2003, by and among the Company and the Buyers named therein.(1)
- 10.25 Registration Rights Agreement, dated March 12, 2003, by and among the Company and the Buyers named therein.(1)

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

10.26 Securities Purchase Agreement, dated July 10, 2003, by and among the Company and the Buyers named therein.(4)

10.27 Registration Rights Agreement, dated July 10, 2003, by and among the Company and the Buyers named therein.(4)

10.28 Securities Purchase Agreement, dated October 29, 2003, by and among the Company and the Buyers named therein.(5)

10.29 Registration Rights Agreement, dated October 29, 2003, by and among the Company and the Buyers named therein.(5)

10.30 Securities Purchase Agreement, dated January 26, 2004, by and among the Company and the Buyers named therein.(6)

10.31 Registration Rights Agreement, dated January 26, 2004, by and among the Company and the Buyers named therein.(6) 10.32 Memorandum of Understanding with Fujisawa. (8)

21 Subsidiaries of the Registrant.

23.1 BDO Seidman, LLP consent.(9)

31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer.(9)

31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer.(9)

32.1 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer.(9)

32.2 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer.(9)

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

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

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

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

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

79

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

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

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

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

(9) Filed herewith.

80

### SIGNATURES

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

HEMISPHERx BIOPHARMA, INC.

By: /s/ William A. Carter

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

March 29, 2004

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 ----- William A. Carter, M.D.	Chairman of the Board, Chief Executive Officer and Director	March 29, 2004
---	---	----------------

/s/ Richard Piani ----- Richard Piani	Director	March 29, 2004
---	----------	----------------

/s/ Robert E. Peterson ----- Robert E. Peterson	Chief Financial Officer	March 29, 2004
---	-------------------------	----------------

/s/ Ransom Etheridge ----- Ransom Etheridge	Secretary And Director	March 29, 2004
---	------------------------	----------------

/s/ William Mitchell ----- William Mitchell, M.D., Ph.D.	Director	March 29, 2004
--	----------	----------------

F1

HEMISPHERx BIOPHARMA, INC AND SUBSIDIARIES

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

## Index to Consolidated Financial Statements

	Page
Report of Independent Certified Public Accountants. . . . .	F-2
Consolidated Balance Sheets at December 31, 2002 and 2003. . .	F-3
Consolidated Statements of Operations for each of the years in the three-year period ended December 31, 2003. . . . .	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, 2003 . . . . .	F-5
Consolidated Statements of Cash Flows for each of the years in the three-year period ended December 31, 2003 . . . . .	F-7
Notes to Consolidated Financial Statements . . . . .	F-8

F2

### 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, 2002 and 2003 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, 2003. 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 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, 2002 and 2003 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO SEIDMAN, LLP

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

Philadelphia, Pennsylvania  
February 13, 2004

F3

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES  
Consolidated Balance Sheets  
December 31, 2002 and 2003  
(in thousands)

	December 31,	
	2002	2003
	-----	-----
ASSETS		
Current assets:		
Cash and cash equivalents . . . . .	\$ 2,256	\$ 3,764
Short term investments (Note 5) . .	555	1,495
Inventory (Note 3)	-	2,896
Accounts and other receivables (Note 15)	1,507	282
Prepaid expenses and other current assets . . . . .	71	170
	-----	-----
Total current assets . . . . .	4,389	8,607
Property and equipment, net . . . . .	155	94
Patent and trademark rights, net . .	995	1,027
Investment	408	408
Deferred acquisition costs (Note 4)	-	1,546
Deferred financing costs	-	393
Advance receivable (Note 7)	-	1,300
Other assets . . . . .	93	29
	-----	-----
Total assets . . . . .	\$ 6,040	\$ 13,404
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable . . . . .	\$ 786	\$ 488
Accrued expenses (Note 6) . . . . .	678	1,119
	-----	-----
Total current liabilities . . .	1,464	1,607
	-----	-----
Long-Term Debt-net of current portion (Note 7)	-	2,058
Commitments and contingencies (Notes 10, 12, 13 and 15)		
Minority Interest in subsidiary (Note 8c)	946	-
Redeemable common stock (Note 4)	-	491
Stockholders' equity (Note 8):		
Common stock . . . . .	33	39
Additional paid-in capital . . . . .	107,155	123,054
Accumulated other comprehensive income . . . . .	35	-
Accumulated deficit . . . . .	(99,073)	(113,843)
Treasury stock . . . . .	(4,520)	(2)
	-----	-----
Total stockholders' equity . . .	3,630	9,248

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

Total liabilities and stockholders' equity . . . . .	\$ 6,040	\$ 13,404
	=====	=====

See accompanying notes to consolidated financial statements.

F4

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES  
Consolidated Statements of Operations For each of the years  
in the three-year period ended December 31, 2003  
(in thousands, except share and per share data)

	December 31,		
	2001	2002	2003
Revenues:	-----	-----	-----
Sales of product net	\$ -	\$ -	\$509
Clinical treatment programs . . . . .	390	341	148
License Fee income (Note 12)	-	563	-
	-----	-----	-----
Total Revenues:	390	904	657
Costs and expenses:			
Production/cost of goods sold . . . .	-	-	502
Research and development . . . . .	5,780	4,946	3,150
General and administrative . . . . .	3,412	2,015	4,257
	-----	-----	-----
Total costs and expenses . . . . .	9,192	6,961	7,909
Equity loss and write offs of investments in unconsolidated affiliates (Note 2c)	(565)	(1,470)	-
Interest and other income . . . . .	284	103	80
Interest expense	-	-	(253)
Financing costs (Note 7)	-	-	(7,345)
	-----	-----	-----
Net loss . . . . .	\$ (9,083)	\$ (7,424)	\$ (14,770)
	=====	=====	=====
Basic and diluted loss per share. . . . .	\$ (.29)	\$ (.23)	\$ (.42)
	=====	=====	=====
Weighted average shares outstanding . . . . .	31,433,208	32,085,776	35,234,526
	=====	=====	=====

See accompanying notes to consolidated financial statements.

F5

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

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 -----	Accumulated other Comprehensive Income (loss) -----	Accumulated deficit -----
Balance at December 31, 2000	30,367,888	\$30	\$97,984	\$34	\$(82,500)
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	-	-
Net comprehensive (loss)	-----	-----	-----	(17)	(9,000)
Balance at December 31, 2001	32,575,986	33	106,832	17	(91,600)
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)
Debt conversion and interest payments	4,334,916	4	6,741	-	-
Fair value ascribed to debenture beneficial conversion features and related warrants issued	-	-	9,363	-	-
Warrants exercised	790,745	1	1,234	-	-
Common stock issued in connection with ISI acquisition (Note 4)	1,068,789	1	1,667	-	-
Reclassification of redeemable Common Stock in connection with ISI acquisition (Note 4)	-	-	(491)	-	-
Treasury stock purchased	-	-	-	-	-
Treasury Stock retired	(339,543)	-	(4,272)	-	-
Conversion of minority interest of subsidiary into common stock (Note (8c))	347,445	-	946	-	-
Stock issued in settlement of debt	215,047	-	474	-	-
Stock warrant compensation expense	-	-	237	-	-
Net comprehensive loss	-----	-----	-----	(35)	(14,700)
Balance December 31, 2003	39,067,577	\$39	\$123,054	\$ -	\$(113,800)
	=====	===	=====	===	=====

See accompanying notes to consolidated financial statements

F6

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

Flows for each of the years in the three-year period  
ended December 31, 2003  
(in thousands)

	December 31,		
	----- 2001 -----	----- 2002 -----	----- 2003 -----
Cash flows from operating activities:			
Net loss . . . . .	\$(9,083)	\$(7,424)	\$(14,770)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of property and equipment. . . . .	127	91	80
Amortization of patent and trademark rights . . . . .	397	206	122
Amortization of deferred financing costs. . .	-	-	7,345
Equity loss and write offs of investments in unconsolidated affiliates. .	565	1,470	-
Stock option and warrant compensation and service expense . . . . .	673	132	237
Changes in assets and liabilities:			
Inventory . . . . .	-	-	(1,429)
Accounts and other receivables. . . . .	52	(1,293)	1,225
Prepaid expenses and other current assets. . .	202	104	(98)
Accounts payable . . . . .	(271)	(67)	(298)
Accrued expenses . . . . .	139	385	558
Other assets. . . . .	(82)	(13)	6
	-----	-----	-----
Net cash used in operating activities. . . . .	(7,281)	(6,409)	(7,022)
	-----	-----	-----
Cash flows from investing activities:			
Purchase of property and equipment .	-	-	(19)
Additions to patent and trademark rights .	(218)	(176)	(154)
Maturity of short term investments .	4,613	5,293	520
Purchase of short term investments.	(5,293)	(520)	(1,496)
Investments in unconsolidated affiliates	(22)	-	-
Deferred acquisition cost. . . . .	-	-	(638)
	-----	-----	-----
Net cash (used in) provided by investing activities. .	(920)	4,597	(1,787)
	-----	-----	-----

F7

(CONTINUED)

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

	December 31,		
	----- 2001 -----	----- 2002 -----	----- 2003 -----
Cash flows from financing activities:			
Proceeds from stock subscriptions and issuance			



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

of common stock, net. . . . .	\$ 72	\$ 65	-
Deferred financing costs . . . . .	-	-	(835)
Proceeds from issuance of preferred stock certificates of Subsidiary	-	946	-
Proceeds from long-term borrowing . . .	-	-	11,300
Advance receivable	-	-	(1,300)
Proceeds from exercise of stock warrants . . . . .	8,075	-	1,235
Purchase of treasury stock . . . . .	(560)	(50)	(83)
	-----	-----	-----
Net cash provided by financing activities. . . . .	7,587	961	10,317
	-----	-----	-----
Net increase (decrease) in cash and cash equivalents. . . . .	(614)	(851)	1,508
Cash and cash equivalents at beginning of year. . . . .	3,721	3,107	2,256
	-----	-----	-----
Cash and cash equivalents at end of year . . . . .	\$ 3,107	\$2,256	\$3,764
	=====	=====	=====
Supplemental disclosures of cash flow information:			
Issuance of common stock for accrued expenses. . . . .	\$ 91	\$ 154	\$ 931
	=====	=====	=====
Issuance of common stock for note receivable . . . . .	\$ 60	\$ -	\$ -
	=====	=====	=====
Issuance of Common Stock for Acquisition of ISI assets, including deferred acquisition costs	\$ -	\$ -	\$1,668
	=====	=====	=====
Common Stock Issued for Compensation	\$ 637	\$ 132	\$ 237
	=====	=====	=====
Issuance of Common Stock for Debt Conversion and Interest Payments	\$ -	\$ -	\$6,741
	=====	=====	=====
Common Stock Issued for Conversion of Minority Interest in Subsidiary	\$ -	\$ -	\$ 946
	=====	=====	=====

See accompanying notes to consolidated financial statements.

F8

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

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

(HVC) virus infection. The Company also has clinical experience with Ampligen(R) used in treating patients with certain cancers including renal cell carcinoma (kidney cancer) and metastatic malignant melanoma. The Company has other compounds to be evaluated.

On March 11, 2003, we acquired from Interferon Sciences, Inc. ("ISI") ISI's inventory of ALFERON N 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.

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 ISI shareholder approval for the real estate transaction.

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.

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.

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.

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

### F9

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 \$2,256,000 and

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

\$3,764,000 at December 31, 2002 and 2003, 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 \$555,000 and \$1,495,000 at December 31, 2002 and 2003 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 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

F10 Company's investment. Additionally, during 2001 the Company reduced its investment in CIMM based on its percentage interest in CIMM's continued operating losses. The Company's remaining investment at December 31, 2001 in CIMM, representing its 30% interest in CIMM's equity at such date, was not deemed to be permanently impaired, but was completely written off during 2002. Such amount was not material. These charges are reflected in the Consolidated Statements of Operations under the caption "Equity loss in unconsolidated affiliates". 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 12. Ribotech, Ltd. has incurred net losses since inception. The Company does not share in

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

those losses in accordance with the licensing agreement and is not obligated to fund such losses. The net investment in Ribotech is zero at all year end periods presented. 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 include an initial equity investment of \$290,625 in Chronix Biomedical ("Chronix"). Chronix focuses upon the development of diagnostics for chronic diseases. This initial investment was made in May 31, 2000 by the issuance of 50,000 shares of Company common stock from the treasury. On October 12, 2000, the Company issued an additional 50,000 shares of its common stock and on March 7, 2001 the Company issued 12,000 more shares of its common stock from the treasury to Chronix for an aggregate equity investment of \$700,000. The percentage ownership in Chronix is approximately 5.4% and is accounted for under the cost method of accounting. During the quarter ended December 31, 2002, we recorded a non cash 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 its then proposed investment offerings.

During 2000, pursuant to a strategic alliance agreement, the Company provided Chronix with \$250,000 to conduct research in an effort to develop intellectual property on potential new products for diagnosing and treating various chronic illnesses 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,	
	-----	
	2002	2003
	-----	
Furniture, fixtures, and equipment	\$ 760	\$ 779
Leasehold improvements	85	85
	-----	
Total property and equipment	845	864
Less accumulated depreciation	690	770
	-----	
Property and equipment, net	\$ 155	\$ 94
	=====	

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 \$127,000, \$91,000 and \$80,000 for 2001, 2002 and 2003, 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 has been accounted for as a change in accounting estimate.

Patents and trademarks are stated at cost (primarily legal fees) and are

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

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, 2001, 2002 and 2003, the Company decided not to pursue the technology in certain countries for strategic reasons and recorded charges of \$38,000, \$5,000, and \$5,000 respectively. Amortization expense was \$359,000, \$201,000 and \$122,000 in 2001, 2002 and 2003, respectively. The accumulated amortization as of December 31, 2002 and 2003 is \$2,096,000 and \$2,150,000, respectively.

As of December 31, 2003, the weighted average remaining life of the patents and trademarks was 8.6 years. Amortization of patents and trademarks for each of the next five is as follows: 2004 - \$96,000, 2005 - \$94,000, 2006 - \$90,000, 2007 - \$89,000 and 2008 - \$87,000.

### (f) Revenue and License Fee Income

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

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

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

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

#### F12

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

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

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

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

to the total non-refundable cash received to date of approximately \$563,000.

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

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

During the years ending December 31, 2001, 2002 and 2003 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 the 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 (loss)

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

### (j) Use of Estimates

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

F13

### (k) Foreign currency translations

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

### (l) Recent Accounting Standard and Pronouncements:

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

In November, 2002, the FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others" ("Interpretation No. 45"). Interpretation No. 45 elaborates on the existing disclosure requirements for most guarantees, including loan guarantees such as standby letters of credit. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair market value of the obligations it assumes under the guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and measurement provisions of Interpretation No. 45 apply on a prospective basis to guarantees issued or modified after December 31, 2002. Interpretation No. 45 did not have an effect on our financial statements.

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"). 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 Accounting Principles Board ("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 enhanced disclosure requirements of SFAS 148.

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 prior to January 31, 2003, the provision of Interpretation No. 46 have been deferred to the first quarter of 2004. This Interpretation did not have an effect on the consolidated financial statements.

In May 2003, the FASB issued Statement No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity" ("SFAS 150"). SFAS 150 requires an issuer to classify certain financial instruments, such as mandatory redeemable shares and obligations to repurchase the issuers equity shares, as liabilities. The guidance is effective for financial instruments entered into or modified subsequent to May 31, 2003, and

F14  
is otherwise effective at the beginning of the first interim period after June 15, 2003. SFAS 150 did not have an impact on our financial condition or results of operations.

### (m) Research and Development Costs

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

### (n) Stock Based Compensation

The Company follows Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock-Based Compensation." We chose to apply Accounting

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

Principal Board Opinion 25 and related interpretations in accounting for stock options granted to our employees. The Company provides pro forma disclosures of compensation expense under the fair market value method of SFAS No. 123, "Accounting for Stock-Based Compensation," and SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure."

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

	2001 ----	December 31, 2002 ----	2003 ----
Risk-free interest rate	4.23%	5.23%	5.23%
Expected dividend yield	-	-	-
Expected lives	3.0 yrs	2.5 yrs	2.5 yrs
Expected volatility	74.9%	63.17%	98.07%

Had compensation cost for the Company's option plan been determined using the fair value method at the grant dates, the effect on the Company's net loss and loss per share for the years ended December 31, 2001, 2002, and 2003 would have been as follows:

(In Thousands except for per share data)

For the years ended December 31, -----	2001 -----	2002 -----	2003 -----
Net (loss) as reported	\$ (9,083)	\$ (7,424)	\$ (14,770)
 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	 (632)	 (1,085)	 (1,825)
	-----		
Pro forma - net loss	\$ (9,715)	\$ (8,509)	\$ (16,595)
	=====		
Basic and diluted loss per share - as reported	\$ (.29)	\$ (.23)	\$ (.42)
	=====		
Basic and diluted loss per share - pro forma	\$ (.31)	\$ (.27)	\$ (.47)
	=====		

### F15

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 25 on the date of the grant.



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

### (0) Accounts Receivable

Concentration of credit risk, with respect to accounts receivable, is limited due to the Company's credit evaluation process. The Company does not require collateral on its receivables. The Company's receivables primarily consist of amounts due from the wholesale drug companies as of December 31, 2003.

### (3) Inventories

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

Inventories consist of the following:

	December 31, 2003
Raw materials and work in process	\$1,729
Finished goods	1,167
	-----
	\$2,896
	=====

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

On March 11, 2003, we acquired from Interferon Sciences, Inc.'s ("ISI") inventory of ALFERON N Injection, a pharmaceutical product used for the treatment of certain types of genital warts, and a limited license for the production, manufacture, use, marketing and sale of this product. As consideration, we issued 487,028 shares of our common stock, assumed certain liabilities and agreed to pay ISI 6% of the net sales of product. Pursuant to our agreements with ISI, we have registered 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 as of March 11, 2005, the termination date, to be \$1.59 per share. ISI is permitted to periodically sell certain amounts of its shares. If, within 30 days after the termination date, holders of the guaranteed shares request that we honor the guarantee, we will be obligated to reacquire the holders' remaining guaranteed shares and pay the holders \$1.59 per share for a total of \$675,000. Accordingly, certain shares issued in connection with this transaction were initially recorded as redeemable common stock outside of stockholders' equity. As of February 10, 2004, ISI had sold the 427,528 guaranteed shares at prices in excess of \$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. For these assets, we agreed to issue

F16 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, two creditors of ISI, to continue to pay royalties of 6% on net sales of Alferon N and other consideration, e.g., paying off a third creditor and paying a real estate tax liability.

On May 30, 2003, we issued the shares to GP Strategies and the American National Red Cross. Pursuant to our agreements with ISI and these two creditors, we have agreed to register the foregoing shares for public sale. The acquisition of the real estate and machinery is contingent on our receiving appropriate ISI stockholder approval. The value of these guaranteed shares totaled \$925,000 and these shares are redeemable under certain conditions, accordingly they were initially reflected as redeemable common stock and deferred acquisition costs on

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

the accompanying financial statements as of December 31, 2003. As of February 10, 2004 GP Strategies had sold their 247,296 shares. Additionally other liabilities associated with the real estate in the amount of \$621,000 have been recorded as deferred acquisition costs. It is expected that ISI stockholder approval will be obtained in March 2004 with substantially the entire amount of the deferred purchase price being allocated to real estate.

As of December 31, 2003 all but 314,465 guaranteed shares had been sold. As a result, the remaining liability for redeemable stock was \$491,000.

Except for 62,500 of the 487,028 shares to be issued to ISI at closing of this second asset acquisition, we have guaranteed the market value of the shares retained by ISI on terms substantially similar to those for the guaranteed shares issued to ISI on the first acquisition of ISI assets. Pursuant to our agreement with ISI, we plan to register the foregoing shares for public sale.

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

As a result of the first agreement, the following table summarizes the estimated fair value of the assets and liabilities assumed at the initial acquisition date.

At March 11, 2003

Inventory	\$1,840,762
Fair Value of liabilities	
Assumed	(1,081,041)
	-----
Fair Value of Common Shares	
Issued	\$759,721
	=====

The following table represents the Unaudited pro forma results of operations as though the acquisition, described in the first agreement, of certain net assets of ISI occurred on January 1, 2002.

	Years Ended December 31,	
	2002	2003
	----	----
	(in thousands except for share data)	
Net revenues	\$2,830	\$899
Expenses	(14,699)	(16,215)
	-----	-----
Net Loss	\$(11,869)	\$(15,316)
	=====	=====
Basic and diluted loss per share	\$ (.36)	\$ (.43)
	=====	=====
Weighted average shares outstanding	32,572,804	35,326,594
	=====	=====

F17

In giving effect to the additional shares that would be issued as a result of the second agreement with ISI the weighted average shares outstanding during the Years Ending December 31, 2002 and 2003 would have been 33,641,593 and 36,055,994 resulting in a pro forma loss per share as adjusted of \$(.36) and

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

\$(.45) for said periods respectively.

(5) Short-term investments:

Securities classified as available for sale consisted of General Motors commercial paper at December 31, 2003 where its cost approximated its market value of \$1,495,000 and matures in April and May 2004, and Calamos Mutual Market at December 31, 2002 where its carrying value of \$555,000 exceeded its cost by \$34,000.

(6) Accrued Expenses

Accrued expenses at December 31, 2002 and 2003 consists of the following:

	(000's omitted)	
	December 31,	
	-----	-----
	2002	2003
	-----	-----
Compensation . . . . .	\$ 6	\$ 366
Interest	-	158
Commissions and royalties	-	100
Professional fees	-	126
Other expenses . . . . .	222	369
Fees associated with litigation settlement.	450	-
	-----	-----
	\$ 678	\$ 1,119
	=====	=====

(7) Debenture Financing

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

F18

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

The investors also received Warrants to acquire at any time through March 12, 2008 an aggregate of 743,288 shares of common stock at a price of \$1.68 per share. On March 12, 2004, the exercise price of the Warrants was to reset to the lesser of the exercise price then in effect or a price equal to the average of the daily price of the common stock between March 13, 2003 and March 11, 2004

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

(but in no event less than \$1.176 per share). The exercise price (and the reset price) under the Warrants also was subject to similar adjustments for anti-dilution protection. All of these warrants have been exercised.

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

As of December 31, 2003 the investors had converted the \$5,426,000 principal of the March Debentures into 3,716,438 shares of our common stock. The total imputed interest on the debenture was \$111,711 of which \$17,290 was paid in cash and \$94,421 was paid by the issuance of 39,080 shares of common stock. The investors exercised the 743,288 warrants in July 2003 which produced proceeds in the amount of \$1,248,724

On July 10, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due July 31, 2005 (the "July Debentures") and an aggregate of 507,102 Warrants (the "July 2008 Warrants") to the same investors who purchased the March 12, 2003 Debentures, in a private placement for aggregate anticipated gross proceeds of \$4,650,000. Pursuant to the terms of the July Debentures, \$1,550,000 of the proceeds from the sale of the July Debentures were to have been held back and will be released to us if, and only if, we acquired ISI's facility within a set timeframe. Although we had not acquired ISI's facility, these funds were released to us in October 2003. The July Debentures mature on July 31, 2005 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date.

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

F19

The July 2008 Warrants received by the investors, as amended, are to acquire at any time commencing on July 26, 2004 through January 31, 2009 an aggregate of 507,102 shares of common stock at a price of \$2.46 per share. On July 10, 2004, the exercise price of these July 2008 Warrants will reset to the lesser of the exercise price then in effect or a price equal to the average of the daily price of the common stock between July 11, 2003 and July 9, 2004 (but in no event less than \$2.14 per share). The exercise price (and the reset price) under the July 2008 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 July Debentures and the July 2008 Warrants. The Registration Rights Agreement requires that we register on behalf of the holders the shares of common stock issuable upon conversion of the Debentures, as interest shares under the Debentures and upon exercise of the July 2008 Warrants. These shares have been registered for public sale.

On June 25, 2003, we issued to each of the March 12, 2003 Debenture holders a warrant to acquire at any time through June 25, 2008 an aggregate of 500,000

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

shares of common stock at a price of \$2.40 per share. On June 25, 2004, the exercise price of these June 2008 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 June 26, 2003 and June 24, 2004 (but in no event less than \$1.68 per share). The exercise price (and the reset price) under the June 2008 Warrants also is subject to adjustments for anti-dilution protection similar to those in the July 2008 Warrants. Pursuant to our agreement with the Debenture holders, we have registered the shares issuable upon exercise of these June 2008 Warrants for public sale.

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

Upon completing the sale of the October Debentures, we received \$3,275,000 in net proceeds consisting of \$1,725,000 from the October Debentures and \$1,550,000 that had been withheld from the July Debentures. As noted above, \$1,550,000 of the proceeds from the October Debentures have been held back pending our completing the acquisition of the ISI facility.

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

F20

The October 2008 Warrants, as amended, received by the investors are to acquire at any time commencing on July 26, 2004 through April 30, 2009 an aggregate of 410,134 shares of common stock at a price of \$2.32 per share. On October 29, 2004, the exercise price of these October 2008 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 October 29, 2003 and October 27, 2004 (but in no event less than \$2.19 per share). The exercise price (and the reset price) under the October 2008 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 October Debentures and the October 2008 Warrants. The Registration Rights Agreement requires that we register on behalf of the holders the shares of common stock issuable upon conversion of the October Debentures, as interest shares under the October Debentures and upon exercise of the 2008 Warrants. If, subject to certain exceptions, sales of all shares required to be registered cannot be made pursuant to the registration statement, then we will be required to pay to the investors their pro rata share of \$3,635 for each day such conditions exist.

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

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

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

The January 2004 Debentures are convertible at the option of the investors at any time through January 31, 2006 into shares of our common stock. The conversion price under the January 2004 Debentures is fixed at \$2.53 per share, subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect.

There are two classes of July 2009 warrants received by the Investors: Class A and Class B. The Class A warrants are to acquire any time from July 26, 2004 through July 26, 2009 an aggregate of up to 395,257 shares of common stock at a price of \$3.29 per share. The Class B warrants are to acquire any time from July 26, 2004 through July 26, 2009 an aggregate of up to 395,257 shares of common stock at a price of \$5.06 per share. On January 27, 2005, the exercise price of these July 2009 Class A and Class B Warrants will reset to the lesser of their respective exercise price then in effect or a price equal to the average of the daily price of the common stock between January 27, 2004 and January 26, 2005

F21

(but in no event less than \$2.58 per share with regard to the Class A warrants and \$3.54 per share with regard to the Class B warrants). The exercise price (and the reset price) under the July 2009 Warrants also is subject to similar adjustments for anti-dilution protection.

The Company also issued to the investors Additional Investment Rights pursuant to which the investors have the right to acquire up to an additional \$2,000,000 principal amount of January 2004 Debentures from the Company. These Debentures are identical to the January 2004 Debentures except that the conversion price is \$2.58. The Additional Investment Rights are exercisable commencing on July 26, 2004 (the "Trigger" date) for a period of 90 days from the Trigger Date or 90 days from the date which the registration statement registering the shares issuable upon the conversion of the January 2004 Debentures to be issued pursuant to the Additional Investment Rights is declared effective, whichever is longer.

The Company entered into a Registration Rights Agreement with the investors in connection with the issuance of the January 2004 Debentures (including any Debentures issued pursuant to the Additional Investment Rights), the shares, and the January 2009 Warrants. The Registration Rights Agreement requires that the Company register on behalf of the investors the shares issued to the investors and 135% of the shares issuable upon conversion of the Debentures (including payment of interest thereon) and upon exercise of the January 2009 Warrants. If the Registration Statement containing these shares is not filed within the time period required by the agreement, not declared effective within the time period required by the agreement or, after it is declared effective and subject to

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

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.

By agreement between the Company and the investors, the date upon which all warrants previously issued to the investors may become exercisable is now July 26, 2004 and the exercise periods of these warrants have been extended accordingly.

By agreement with Cardinal Securities, LLC, for general financial advisory services and in conjunction with the private debenture placements in March, July and October 2003 and in January 2004, we paid Cardinal Securities, LLC an investment banking fee equal to 7% of the investments made by the two Debenture holders and issued to Cardinal certain warrants. A portion of the investment banking fee was paid with the issuance of 30,000 shares of our common stock. Cardinal also received 612,500 warrants to purchase common stock, of which 112,500 are exercisable at \$1.74 per share, 112,500 are exercisable at \$2.57 per share, 200,000 are exercisable at \$2.50 per share, 87,500 are exercisable at \$2.42 per share and 100,000 are exercisable at \$3.04 per share. The \$1.74 warrants expire on July 10, 2008, the \$2.57 and \$2.50 warrants expire on March 12, 2008, the \$2.42 warrants expire on October 30, 2008 and the \$3.04 warrants expire on January 25, 2009. By agreement with Cardinal, we have registered 542,500 shares for public sale and have agreed to register the balance.

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

As of December 31, 2003, the investors have converted \$6,595,000 of debt from the March and July Debentures into 4,334,916 shares of our common stock. The March Debentures have been fully converted. The remaining principal balance on the remaining debentures is convertible into shares of our stock at the option of the investors at any time, through the maturity date. In addition, we have F22 paid \$1,300,000 into the debenture cash collateral account as required by the terms of the October Debentures. The amounts paid through December 31, 2003 have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of December 31, 2003. The cash collateral account provides partial security for repayment of the July and October 2003 and January 2004 Debentures in the event of default.

The March, July, and October 2003 debenture issuances of \$5,426,000, \$5,426,000, and \$4,142,357, respectively, and warrant issuances, were accounted for in accordance with EITF 98-5: Accounting for convertible securities with beneficial conversion features or contingency adjustable conversion and with EITF No. 00-27: Application of issue No. 98-5 to Certain convertible instruments. The Company determined the fair values to be ascribed to detachable warrants issued with the convertible debentures utilizing the Black-Scholes method.

As a result, the Company recorded debt discounts of approximately \$11.8 million for the 2003 debenture issuances which, in effect, reduced the carrying value of our debt. As debt is converted to common stock, the remaining unamortized debt discount is charged to finance costs. These costs were initially deferred and charged to finance costs over the life of the debentures. As of December 31, 2003, the amount of debt discount amortized to finance cost totaled approximately \$7.3 million.

Costs associated with the financings aggregated approximately \$1.3 million. These costs are also deferred and expensed as finance costs over the life of the debentures.

Excluding the application of related accounting standards, and remaining debt

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

discounts of \$4.5 million, the Company's outstanding debt as of December 31, 2003 totaled \$6.6 million and is due during 2005.

### (8) Stockholders' Equity

#### (a) Preferred Stock

The Company is authorized to issue 5,000,000 shares of \$.01 per value preferred stock with such designations, rights and preferences as may be determined by the board of directors. There were no preferred shares issued and outstanding at December 31, 2002 and 2003.

#### (b) Common Stock

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

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

F23

As of December 31, 2002 and 2003, 32,106,972 and 39,067,134 shares, net of shares held in the treasury, were outstanding, respectively.

#### (c) Minority Shareholder Interest

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

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

Esteve purchased 1,000,000 Euros of Hemispherx Biopharma Europe S.A.'s convertible preferred equity certificates on May 23, 2002. During 2002, the terms and conditions of these securities were changed so that these preferred equity certificates could be converted into the common stock of Hemispherx Biopharma, Inc. (HEB) in the event that a European IPO is not completed by



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

September 30, 2003. The conversion rate is to be 300 shares of Hemispherx Biopharma, Inc.'s common shares for each 1,000 Euro convertible preferred certificate. As a result the Company recorded approximately \$946,000 as minority interest in subsidiary on its balance sheet at December 31, 2002.

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

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

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

### (d) Common Stock Options and Warrants

#### (i) Stock Options

F24

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

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

2001			2002			
Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	Shares
-----	-----	-----	-----	-----	-----	-----

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

Outstanding, beginning of year	218,567	\$1.06-6.81	\$3.45	306,263	\$1.06-4.34	\$3.58	294,665	\$1
Granted	94,000	\$4.03	\$4.03	-	-	-	200,000	
Canceled								
	(6,304)	\$4.34-6.81	\$5.91	(11,598)	\$3.00-4.34	\$3.71	(61,531)	\$3
Exercised	-	-	-	-	-	-	-	-
Outstanding, end of year	306,263 =====	\$1.06-4.34	\$3.58	294,665 =====	\$1.06-4.34	\$3.57	433,134 =====	\$1
Exercisable	234,263 =====	\$1.06-4.34	\$4.67	252,746 =====	\$1.06-4.34	\$3.50	433,134 =====	\$1
Weighted average remaining contractual life (years)	3.57 years =====			3.68 years =====			3.37 years =====	
Exercised in current and prior years	(37,791) =====			(37,791) =====			(37,791) =====	
Available for future grants	116,744 =====			128,342 =====			-0- =====	

In December 1992, the Board of Directors approved the 1992 Stock Option Plan (the 1992 Stock Option Plan) which provides for the grant of options to purchase up to 92,160 shares of the Company's Common Stock to employees, directors, and officers of the Company and to consultants, 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 10 years and one month from the date as of which an option agreement is executed. To date, no options have been granted under the 1992 Stock Option Plan.

F25

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

The 1993 Purchase Plan is administered by the Compensation Committee of the board of directors. Under the 1993 Purchase Plan, Company employees are eligible to participate in semi-annual plan offerings in which payroll deductions may be used to purchase shares of Common Stock. The purchase price for such shares is equal to the lower of 85% of the fair market value of such shares on the date of grant or 85% of its fair market value of such shares on the date such right is

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

exercised. There have been no offerings under the 1993 Purchase Plan to date and no shares of Common Stock have been issued thereunder.

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

(ii) Stock warrants

Number of warrants exercisable into shares of common stock

	<u>2001</u>			<u>2002</u>			
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	Share
Outstanding beginning of year	11,624,168	\$1.75-12.0	\$4.05	6,927,110	\$1.75-16.0	\$4.77	7,967,
Granted	856,650	\$5.00-16.00	\$9.89	1,802,000	\$2.00-6.00	\$2.07	4,623,
Canceled	(3,396,508)	\$2.50-4.00	\$3.89	(750,000)	\$3.50-6.00	\$3.72	(276,0
Exercised	(2,157,200)	\$1.75-4.00	\$3.75	(11,300)	\$1.75-7.50	\$3.30	(812,0
Outstanding end of year	<u>6,927,110</u>	\$1.75-16.0	\$4.77	<u>7,967,810</u>	\$1.75-16.0	\$3.18	<u>11,502,</u>
Exercisable	<u>6,927,110</u>	\$1.75-16.00	\$4.77	<u>6,345,810</u>	\$1.75-16.00	\$3.48	<u>8,635,</u>
Weighted average remaining contractual life (years)	<u>4.05 years</u>			<u>4.03 years</u>			<u>4.04 ye</u>
Years exercisable	<u>2002-2006</u>			<u>2003-2008</u>			<u>2004-2</u>

The following table summarizes information about stock warrants outstanding at December 31, 2003:

Exercise price range

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

	\$1.74-\$5.00	\$6.00-\$9.00	\$10.00-\$16.00
Outstanding warrants			
Number outstanding	9,545,346	1,357,450	600,000
Weighted average remaining contractual life (years)	4.84	1.51	1.46
Weighted average exercise price	\$2.56	\$6.77	\$12.33
Exercisable warrants			
Number outstanding	6,678,110	1,357,450	600,000
Weighted average exercise price	\$2.70	\$6.77	\$12.33

F26

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

Warrants issued to stockholders

At December 31, 2000, there were 305,160 warrants remaining. In 2001, 73,000 were converted to common stock. At December 31, 2001 there were 232,160 warrants remaining. In 2002, 10,000 were converted to common stock. At December 31, 2002 and 2003 there were 222,160 warrants remaining. These warrants 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 11,280,636 which consists of the following:

In November 1994, the Company granted Rule 701 Warrants to purchase an aggregate of 2,080,000 shares of Common Stock to certain officers and directors. These Warrants are exercisable at \$3.50 per share and, if not exercised, were to expire in September, 1999. On February 19, 1999 the Board of Directors extended the expiration date for three more years. In 1999 235,000 warrants were exercised and 5,000 warrants were exercised in 2000. At December 31, 2000, there were 1,840,000 Rule 701 warrants remaining. In 2001 20,000 of these warrants expired, leaving a balance of 1,820,000 in warrants outstanding at December 31, 2001. During 2002, 420,000 warrants expired and the Company extended the expiration date of the remaining balance of 1,400,000 for a period of five years to now expire on September 30, 2007. These stock warrants have an exercise price of \$3.50. In accordance with FASB Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation, no compensation expense was recognized as the exercise price at the extension date exceeded the fair value of the underlying common stock.

In May 1995, the Company and certain officers, directors and shareholders entered into a standby finance agreement pursuant to which the parties agreed to provide an aggregate of \$5,500,000 in financing to the Company during 1995 in the event that existing and additional financing was insufficient to cover the cash needs of the Company through December 31, 1996. In exchange, the Company issued warrants to purchase an aggregate of 2,750,000 shares of Common Stock at \$1.75 per share to the parties. In 1999, 290,000, in 2000, 216,500, in 2001, 200,000, 2002, 1,300 and in 2003 35,000 of these warrants were exercised, leaving a balance of these warrants of 1,415,200. These warrants expire June 30, 2005.

In the years 2001, 2002 and 2003, the Company issued 450,000, 25,000 and no warrants, respectively, exclusive of warrants issued in connection with the Company's 2003 Debenture issuances (see below), to investment banking firms for services performed on behalf of the Company. Accordingly, the Company recorded

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

stock compensation of 637,000, 133,000 and none for the years 2001, 2002 and 2003, respectively. These warrants have various vesting dates and exercisable prices ranging from \$4.00 to \$16.00 per share. 1,193,800 warrants were outstanding at December 31, 2002. In 2003, 225,000 of these warrants expired leaving a balance of 968,800 warrants at December 31, 2003. These warrants are exercisable in five years from the date of issuance.

In 2001, 2002 and 2003 the Company had non-public warrants outstanding of 2,254,650, 3,701,650 and 5,100,650 respectively. These warrants are exercisable at rates of \$2.20 to \$10.00 per share of common stock. The exercise price was equal to the fair market value of the stock on the date of grant. During 2003 the company granted 1,450,000 warrants to employees with an exercise price of \$2.20 for services performed and 51,000 warrants expired. During 2002, the Company granted 1,777,000 warrants to employees for services performed. These warrants have a weighted average exercise price of \$2.07 per share, and have been included in the pro-forma loss calculation in note 2(n). 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 at December 31, 2001. 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 with FASB Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation, no compensation expense was recognized as the exercise price at the extension date exceeded the fair value of the underlying common stock.

In 2003 the company issued warrants to acquire 3,173,024 shares in connection with the financing of the purchase of the assets of Interferon Sciences, Inc. During 2003, 777,038 of these warrants were exercised leaving a balance of 2,395,986 at December 31, 2003.

### (e) Stock Repurchase

The Company's repurchases of shares of common stock are recorded as "Treasury Stock" and result in a reduction of "Stockholders' equity." When treasury shares are reissued, the Company uses a first-in, first-out method and the excess of repurchase cost over reissuance price is treated as a reduction of "Additional paid-in capital." At December 31, 2003 there were 443 shares in the treasury. During 2003 most of the then existing treasury shares were either re-issued or retired.

### (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,

F28

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

the Rights will separate from the Common Stock and a Distribution Date will occur upon the earlier of (i) 10 days following a public announcement that a person or group of affiliated or associated persons (an "Acquiring Person") has acquired beneficial ownership of 15% or more (or 20% or more for William A. Carter, M.D.) of the outstanding shares of Common Stock (the "Stock Acquisition Date"), other than as a result of repurchases of stock by the Company or certain inadvertent actions by institutional or certain other stockholders or (ii) 10 business days (or such later date as the Board shall determine) following the commencement of a tender offer or exchange offer that would result in a person or group becoming an Acquiring Person. Until the Distribution Date, (i) the Rights will be evidenced by the Common Stock certificates and will be transferred with and only with such Common Stock certificates, (ii) new Common Stock certificates issued after the Record Date will contain a notation incorporating the Rights Agreement by reference and (iii) the surrender for transfer of any certificates for Common Stock outstanding will also constitute the transfer of the Rights associated with the Common Stock represented by such certificate. Pursuant to the Rights Agreement, the Company reserves the right to require prior to the occurrence of a Triggering Event (as defined below) that, upon any exercise of Rights, a number of Rights be exercised so that only whole shares of Preferred Stock will be issued.

### (9) Segment and Related Information

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

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

	2001	2002	2003
	-----	-----	-----
United States	\$274	\$237	\$655
Belgium	107	74	2
Other	9	30	-
	-----	-----	-----
	\$ 390	\$ 341	\$ 657
	=====	=====	=====

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

### (10) Research, Consulting and Supply Agreements

In December, 1999, the Company entered into an agreement with Biovail Corporation International ("Biovail"). Biovail is an international full service pharmaceutical company engaged in the formulation, clinical testing, registration and manufacture of drug products utilizing advanced drug delivery systems. Biovail is headquartered in Toronto, Canada. The agreement grants Biovail the exclusive distributorship of the Company's product in the Canadian territories subject to certain terms and conditions. In return, Biovail agrees to conduct certain pre-marketing clinical studies and market development programs, including without limitation, expansion of the Emergency Drug Release

F29 Program in Canada with respect to the Company' products. Biovail agrees to work with the Company in preparing and filing of a New Drug Submission with Canadian Regulatory Authorities. Biovail invested \$2.25 million in Hemispherx equity at

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

prices above the then current market price and agreed to make further payments based on reaching certain regulatory milestones. The Agreement requires Biovail to penetrate certain market segments at specific rates in order to maintain market exclusivity.

The Company has entered into agreements for consulting services, which are performed at medical research institutions and by medical and clinical research individuals. The Company's obligation to fund these agreements can be terminated after the initial funding period, which generally ranges from one to three years or on an as-needed monthly basis. During the year ending December 31, 2001, 2002 and 2003 the Company incurred approximately \$595,000, \$395,000 and \$389,000 respectively, of consulting service fees under these agreements. These costs are charged to research and development expense as incurred.

### (11) 401(K) Plan

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

Each participant immediately vests in his or her deferred salary contributions, while Company contributions will vest over one year. In 2001, 2002 and 2003 the Company provided matching contributions to each employee for up to 6% of annual pay aggregating \$48,000, \$38,000 and \$34,000 respectively.

### (12) Royalties, License, and Employment Agreements

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

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

F30  
funding for research and development of the patents and technology licensed to the Company.

In October 1994, the Company entered into a licensing agreement with Bioclones

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

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

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

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

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

The Company has contractual agreements with two of its officers. The aggregate annual base compensation under these contractual agreements for 2001, 2002 and 2003 was \$603,000, \$620,000 and \$637,000 respectively. In addition, certain of these officers are entitled to receive performance bonuses of up to 25% of the annual base salary (in addition to the bonuses described below). In 2001 and 2002 no performance bonuses were granted. In 2003, bonuses of \$266,100 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 option to purchase 1,220,000 shares of common stock at \$2.00 - \$4.03 per share. In 2003, the Chief Executive Officer of the Company was

F31  
granted warrants to purchase 1,450,000 shares of common stock at \$2.20 per share. The Chief Executive Officer's employment agreement provides for bonuses



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

based on gross proceeds received by the Company from any joint venture or corporate partnering agreement.

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

In October 2003, in recognition of this action as well as Dr. Carter's prior and on-going efforts relating to product development securing critically needed financing and the acquisition of a new product line, the Compensation Committee determined that Dr. Carter be awarded bonus compensation in 2003 consisting of \$196,636 and a grant of 1,450,000 stock warrants with an exercise price of \$2.20 per share. This additional compensation was reviewed by an independent valuation firm and found to be fair and reasonable within the context of total compensation paid to chief executive officers of comparable biotechnology companies. These warrants vest upon the earlier of the second ISI Asset closing or the filing by the Company with the U.S. Food and Drug Administration of a new drug application. Upon the occurrence of either of these events, the Company will expense the intrinsic value, if any, of the warrants.

### (13) Leases

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

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

Year ending December 31, -----	(000's omitted) Operating leases -----
2004. . . . .	286
2005. . . . .	240
2006. . . . .	193
2007. . . . .	65
	-----
Total minimum lease payments. . . . .	\$ 784 =====

Rent expense charged to operations for the years ended December 31, 2001, 2002 and 2003 amounted to approximately \$294,000, \$307,000 and \$266,000 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.

F32

### (14) Income Taxes

As of December 31, 2003, the Company has approximately \$73,000,000 of federal net operating loss carryforwards (expiring in the years 2004 through 2024) available to offset future federal taxable income. The Company also has approximately \$17,000,000 of state net operating loss carryforwards (expiring in the years 2004 through 2008) available to offset future state taxable income. The utilization of certain state net operating loss carryforwards may be subject

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

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, 2002 and 2003.

The components of the net deferred tax asset of December 31, 2002 and 2003 consists of the following:

	(000, s omitted)	
Deferred tax assets:	2002	2003
	----	----
Net operating losses	\$22,440	\$24,700
Accrued Expenses and Other	(16)	12
Capitalized Research and development costs	3,763	2,825
	-----	-----
	26,187	27,537
Less: Valuation Allowance	(26,187)	(27,537)
	-----	-----
Balance	\$ -0-	\$ -0-
	=====	=====

### (15) Contingencies

On September 30, 1998, we filed a multi-count complaint against Manuel P. Asensio, Asensio & Company, Inc. ("Asensio"). The action included claims of defamation, disparagement, tortuous 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 F33 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

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

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 our outstanding claim with our insurance carrier for \$1,500,000 relating to reimbursement of expenses in connection with our Asensio law suits. We realized 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.

On September 16, 2003, HEB filed and subsequently served and moved for expedited proceedings on, a complaint filed in the Court Of Chancery of the State of Delaware, New Castle County, against ISI. The Complaint seeks specific performance, and declaratory and injunctive relief related to the Inventory and Asset Purchase Agreements with ISI. Specifically, HEB alleges that ISI has delayed its performance pursuant to the Inventory and Asset Purchase Agreement and, as a result, the Asset Purchase Agreement did not close within 180 days of the date of the execution of the agreements. Paragraph 7.7 of the Asset Purchase Agreement states that either party to the agreement may terminate the agreement if there is no closing within 180 days of the date of the agreement. HEB requested that the Court require ISI to specifically perform its obligations under the agreement or, in the alternative, that paragraph 7.7 of the agreement be eliminated or reformed to eliminate ISI's ability to terminate pursuant to that paragraph. HEB also requested that ISI, as a result of its conduct, not be permitted to terminate the Asset Purchase Agreement pursuant to paragraph 7.7 or due to the passage of time. At a hearing held on September 29, 2003, the Court set a trial of the case for January 6-7, 2004 which has been postponed at the request of both parties until March 4-5, 2004. The parties have agreed that neither party shall have the right to terminate the Asset Purchase Agreement

F34

pursuant to paragraph 7.7 until the date which is at least two weeks following trial, and only then, unless the Court has ruled, upon five days written notice to the other party.

The current court date of March 4 and 5, 2004 will be rescheduled to allow for the ISI shareholders to meet on March 9, 2004 as now scheduled. The results of the Shareholders Meeting and subsequent actions of ISI management will determine if we proceed with this lawsuit.

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

### (16) Related Party Transactions

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

A director of the Company, is an attorney in private practice, who has rendered corporate legal services to us from time to time, for which he has received fees and options to purchase Company stock valued at \$237,000 using the Black Scholes pricing model and recorded as stock compensation expense. 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 \$144,955, \$170,150 and \$100,100 for the years ending December 31, 2001, 2002 and 2003 respectively.

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

We paid \$57,750, \$33,450 and \$18,800 for the years ending December 31, 2001, 2002 and 2003, respectively to Carter Realty for the rent of property used at various times in years 2001, 2002 and 2003 by us. The property is owned by others and managed by Carter Realty. Carter Realty is owned by Robert Carter, the brother of William A. Carter.

### (17) Concentrations of credit risk

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

F35

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

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

(1) During the fourth quarter 2003, the Company recorded stock compensation of

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

\$237,000.

	2002 (2)				
	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)

(2) 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)

Exhibit 31.1

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

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

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

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

disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Registrant and have:

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

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

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

Date: March 29, 2004

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

Exhibit 31.2

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

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

1. I have reviewed this annual report on Form 10-KSB of the Registrant;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

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

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

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

Date: March 29, 2004

/s/ Robert E. Peterson

-----  
Robert Peterson  
Chief Financial Officer

Exhibit 32.1

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 for the fiscal year ended December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William A. Carter, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/ William A. Carter



-----  
William A. Carter, M.D.  
Chief Executive Officer  
March 29, 2004

Exhibit 32.2

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

In connection with the Annual Report of Hemispherx Biopharma, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert Peterson, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/ Robert E. Peterson

-----  
Robert Peterson  
Chief Financial Officer  
March 29, 2004