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FORM 10-K
SECURITIES AND EXCHANGE COMMISSION

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 (FEE REQUIRED)
For the fiscal year ended December 31, 2000
OR
[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 (NO FEE REQUIRED)
For the transition period from _____ to _____
Commission File No. 0-27072

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

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

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

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

Common Stock, $.001 par value
Class A Common Stock Redeemable
Purchase Warrant

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.

The aggregate market value of Common Stock held by non-affiliates at March 27, 2001 was $125,958,609. For purposes of this calculation, it was assumed that all Common Stock is valued at the closing price of the stock as of March 27, 2001.

The number of shares of the registrant's Common Stock outstanding as of December 31, 2000 was 29,972,242.

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DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement to be used in connection with the Registrant's 2000 Annual Meeting of Stockholders, to be held on July 12, 2001, are incorporated by reference into Part III of this Annual Report on Form 10-K.

PART I

ITEM 1. Business

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K (this "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 necessary 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. 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. The Company does 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.

GENERAL

We are a pharmaceutical research and development company using Nucleic Acid technologies to develop therapeutic products for the treatment of certain viral diseases and cancers. Our proprietary drug technology utilizes specifically configured ribonucleic acid (RNA). Over the years, we have established a strong base of laboratory, pre-clinical and clinical data to support the successful commercialization of our lead compound, Ampligen , for use in treating immune

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system dysfunction, viral diseases and certain cancers. Ampligen is presently undergoing phase II/III clinical trials in the United States and Europe for the treatment of Myalgic Encephalomyelitis/Chronic Fatigue syndrome ("ME/CFS").

We have focused on the treatment of diseases for which adequate treatment is not currently available and for which the antiviral and immunostimulatory properties of Ampligen may be beneficial. Such diseases include ME/CFS, Hepatitis, HIV and certain cancers. In recent years, the understanding of ME/CFS has grown substantially. The Centers for Disease Control and Prevention (CDC) estimates that the prevalence rate of this disease in the United States is in excess of 500,000 cases. Other medical researchers have reported evidence that ME/CFS is related to viral infection and systemic disorders. These findings led the Company to focus on pursuing the clinical development of Ampligen for regulatory approval to use in the treatment of those people afflicted with ME/CFS.

Over the years, we have secured a significant patent estate consisting of 24 patents issued in the United States and over 300 international filings. These patents primarily cover our technology platform that involves nucleic acid polymers that have specifically configured base pairs. Our policy is to file or license existing patent applications on a worldwide basis to protect technology and improvements that are considered important in the development of our business.

As an emerging, biopharmaceutical Company, we depend on accessing external resources for manufacturing, distribution and research and development. A large portion of our research and development is provided under contract with scientists and technicians who are not employed by us, and are employed by various health care and academic institutions.

We expect to continue our research and clinical efforts for the next several years with some financial benefit accruing as a result of certain revenues expected from various cost recovery treatment programs, notably in Canada, Europe and the United States. However, we may continue to incur losses over the next several years due to clinical costs incurred in the continued development of Ampligen for commercial application. Possible losses may fluctuate from quarter to quarter as a result of differences in the timing of significant expenses incurred and receipt of licensing fees and/or cost recovery treatment revenues in Europe, Canada and in the United States. We are also pursuing similar programs in other countries, especially within the European Union,

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where resources have been expanded with respect to pursuing regulatory approvals.

We were incorporated in Maryland in 1966 under the name HEM Research, Inc., and originally served as a supplier of research support products. Our business was redirected in the early 1980's to the development of nucleic acid pharmaceutical technology and the commercialization of RNA drugs. We were reincorporated in Delaware and changed our name to HEM Pharmaceuticals 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 subsidiary, Hemispherx BioPharma Europe, N.V./S.A. was established in Belgium in 1998. Our principal executive offices are located at One Penn Center, 1617 JFK Boulevard, Philadelphia, Pennsylvania 19103, and its telephone number is (215) 988-0080.

AMPLIGEN

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.

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. The Company's drug technology utilizes specially-configured RNA. Our double-stranded RNA drug product, trademarked Ampligen , which is administered intravenously, is in or has been in human clinical development for various disease indications, including treatment for ME/CFS, HIV, renal cell carcinoma and malignant melanoma.

Based on the result of pre-clinical studies and clinical trials, the Company believes that Ampligen may have broad-spectrum anti-viral and anti-cancer properties. Over 500 patients have received Ampligen in clinical trials authorized by the Food and Drug Association ("FDA") at over twenty clinical trial sites across the U.S., representing the administration of more than 41,000 doses of this drug.

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MYALGIC ENCEPHALOMYELITIS/CHRONIC FATIGUE SYNDROME (ME/CFS)

ME/CFS, also known as Chronic Fatigue and Immune Dysfunctional Syndrome (CFIDS) or, in Europe, Myalgic Encephalomyelitis (ME) is a debilitating disease that has been difficult to diagnose and for which, at present, there is no cure. Although the etiology of ME/CFS is unknown, a segment of the medical community believes that it may be caused by a virus as the onset of the condition is usually characterized by flu-like symptoms followed by chronic tiredness that, in some cases, can continue for years. ME/CFS is also often accompanied by a disturbance of the patient's immune system, as measured by lower levels of natural killer cell activity and/or lower lymphocyte counts. 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 without fever, depression, difficulty in concentrating on tasks, and tender lymph glands. Central nervous system symptoms may include memory loss. Because there may be both viral and immune components to this disease, we

believe, although it has not yet been clinically proven, that Ampligen may be well suited as a treatment for ME/CFS. There is no drug specifically approved by the FDA for this disorder and physicians typically prescribe analgesics and anti-inflammatory drugs to combat the painful symptoms. Since the early 1990's the Company has clinically studied the use of Ampligen in the treatment of ME/CFS patients in four (4) separate clinical trials. Three studies in the United States were approved by the FDA and the one study that is ongoing in Belgium was approved by Belgian regulatory authorities.

In 1998, we initiated, with FDA authorization, a confirmatory, double-blind, placebo-controlled clinical study with Poly I:Poly C12U (Ampligen) in treatment of 230 patients in the U.S. with severely debilitating ME/CFS. The objective of this confirmatory Phase III clinical study is to further evaluate the safety and efficacy of Ampligen as a treatment for ME/CFS.

As of February, 2001 we have engaged the services of eleven (11) clinical investigators at Medical Centers in California, New Jersey, Florida, North Carolina, Wisconsin, Nevada, Illinois and Connecticut. These clinical investigators are Medical Doctors with some knowledge of ME/CFS and usually are treating the symptoms of several ME/CFS patients. These investigators have recruited, prescreened and enrolled an aggregate of 236 ME/CFS patients for inclusion in the Phase II/III ME/CFS clinical trial. Over 60% of the enrolled ME/CFS patients have completed the stage I, forty week, double-blind, randomized, placebo-controlled portion of the clinical trial and moved into the stage II or the open label treatment portion of the

clinical trial. There have been no serious adverse events reported related to the study medication. Additional ME/CFS patients are being recruited by the clinical investigators.

In April, 1999 the FDA authorized us to expand our ME/CFS Cost Recovery Treatment Program to provide therapy to 100 active patients in the U.S. Under this clinical program, the enrolled patients may pay for the cost of the Ampligen doses infused. This cost totals approximately $7,200 for a 24 week treatment program. Approximately 82% of the patients who enter the program opt to extend their therapy by an additional 24 weeks with the consent of their health care providers. During the twelve months ended December 31, 2000, we received $506,000 in reimbursement for Ampligen used under this plan from the U.S. component of ME/CFS treatment protocols. Overall revenue from these programs, including Europe, was $788,000 for the twelve month period.

We have established relationships with three other companies to provide clinical/pharmacy support services and to facilitate the conduct of our clinical studies according to Good Clinical Practice ("GCP") standards. Two entities, Gentiva Health Services (formerly Olsten Health Services) and Clinical Studies Management Group provide clinical monitors who verify the accuracy of the data collected by the clinical investigators for ultimate analysis by the Company. Additionally, a third entity, WorkWell, provides exercise physiologists to conduct standardized exercise tolerance and oxygen consumption tests at the various clinical facilities across the United States. We believe that we have various corporate relationships and programs in place to insure the quality of data collection to a high international regulatory standard.

Our ME/CFS Cost Recovery Treatment Program in Belgium was started in 1994 with the approval of the Belgian regulatory authorities. Since its inception, over 100 patients have enrolled in this program. Clinical data collected in the treatment of these ME/CFS patients will be used to support our European Medical Evaluation Agency ("EMEA") Drug Approval Application and in applications in other regulatory jurisdictions. This program is being extended to several other affiliated hospitals in the Brussels area and clinical experts in this disease category have been identified in other European countries to establish similar clinical research/treatment centers for ME/CFS. A similar program in Austria is undergoing expansion. Recently, the physicians involved in this program were brought together for a three day conference to share clinical results and to plan further clinical collaborations in the U.S., Canada and Europe.

HIV/AIDS

Today, patients infected with HIV receive a number of different combinations of anti-retroviral compounds (so called "Cocktails") that target two essential viral enzymes; reverse transcriptase and protease. However, it appears that after some period of time, the AIDS virus may become resistant to these antiviral cocktails and that drug resistance is a critical obstacle to the long-term efficacy of present (cocktail) therapies for HIV.

HIV strains which are resistant to essentially all of the currently available anti-retroviral drugs are now being increasingly reported in patients in the U.S. who have received highly active anti-retroviral therapy, termed "HAART." Many HIV patients who receive HAART (including a protease inhibitor) may encounter virologic failure. According to independent sources, of an estimated 100,000 new patients in the U.S.A. initiating HAART last year, there were approximately 150,000 "treatment switches," evidencing significant problems with the regimens. Moreover, the presence of latently infected, resting immune cells termed CD4+ T cells, carrying replication-competent HIV has been demonstrated in patients receiving HAART.

Ampligen may have certain potential, as an adjunct to HAART, to restore certain functional components of the immune process which becomes deficient in HIV disease. Second, Ampligen may have potential to mitigate the deterioration in CD4 count when patients are failing HAART therapy. Third, Ampligen may have potential to assist HAART therapy because of its apparent synergistic activity with AZT and other cocktail components of HAART. These presumptive benefits have been evaluated by us in in vivo studies and will be evaluated in in vivo clinical programs. The molecular basis of the putative drug synergism has not yet been established at the clinical level and will require clinical studies which have now been authorized by the FDA.

Alone, or in conjunction with AZT, Ampligen infusion therapy has been historically well tolerated in the initial clinical tests, some of which have been published in peer review journals. Thus, overall safety assessments supported a reasonable safety profile of this drug alone or in combination with

the antiretroviral agent (AZT). Clinical studies are now being designed to combine Ampligen with certain other reverse transcriptase inhibitors of HIV as well as protease inhibitors of HIV. Ex vivo tests which have been conducted at various academic and industrial laboratories around the U.S. via research agreements and corporate partnerships support this combination approach.

The Company has received two (2) authorizations from the FDA to commence clinical studies using Ampligen to treat patients affected with HIV that are now involved in existing HAART protocols.

The objective of the first study protocol, designated as AMP 719, is to evaluate the effects of adding Ampligen (or no Ampligen) to the HAART treatment of HIV patients for evidence of reductions in the HIV-1 viral load in plasma.

The objective of the second study protocol, designated as AMP 720, is to evaluate the potential activity of Ampligen to increase the HAART-free time interval before HIV rebound during a strategic therapeutic intervention ("STI") of the HAART protocols.

Each study will be multi-center, randomized and controlled consisting of 120 patients. Each study will consist of two arms, one arm of 60 patients will receive Ampligen in connection with HAART and one arm of 60 patients will receive no Ampligen in connection with their HAART treatment.

Protocol AMP 719 has 24 weeks of randomized Ampligen /HAART treatment plus 24 weeks of open label treatment. Protocol AMP 720 consist of eight weeks of randomized Ampligen /HAART treatment followed by the STI and weekly monitoring to determine HIV rebound. Following HIV rebound, HAART will be restarted. This sequence will be replicated for a duration of 64 weeks.

Reasonably rapid clinical results are expected because the efficacy determination, or end points, of the clinical study are a series of well-established virus measurements. The virology will be performed at a national reference laboratory. Potential patients for these studies are now being screened in California and Connecticut.

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HEPATITUS C VIRUS (HCV)

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

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

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

We currently have a research and development arrangement with the California Institute of Molecular Medicine ("CIMM") to collaborate and fund the replication of human Kuffer's cells obtained from HCV infected patients. This proprietary CIMM approach would involve the in vitro growth of hepatic macrophages (called Kuffer's cells) from the failing liver of a patient and reinfusion of liver cells into the same patient. This would not raise the question of immunological incompatibility. CIMM is also developing a process for maintaining and propagating Kuffer's cells ("KC") reproducibly in defined

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cell cultures from fine needle liver aspirates from living human volunteers with potential for patients with failing liver due to a variety of etiologies.

We have a 30% equity position in CIMM, which is located in California and recently opened a new state-of-the-art research lab.

EUROPEAN OPERATIONS

While we cannot market Ampligen in Europe until approval is obtained from the European Medical Evaluation Authority ("EMEA"), we are allowed to deliver Ampligen on a cost recovery basis to ME/CFS patients through an expanded access program. Each country has different requirements for authorizing and allowing these programs.

Through Hemispherx Biopharma-Europe, N.V./S.A. we are developing an organization and infrastructure to expand access to Ampligen while under clinical development. This will allow us to have a basic marketing and distribution system in place pending approval from EMEA. Initial efforts include recruiting staff to establish potential distribution and marketing processes with the immediate focus on setting up Expanded Access Cost Recovery Treatment Programs of ME/CFS patients in France, Italy, Spain and Germany. If successful, this program will allow certain severely disabled ME/CFS patients in those countries to have access to Ampligen prior to the completion of the full commercial registration process. During this time, we may realize

revenues from our expanded access programs.

In France and Italy, the use of a drug before registration is possible under special circumstances (serious illness, no alternative treatment, likelihood of efficacy and tolerance of the drug) either on a named patient basis or for a group of patients. For a named patient authorization, the request is made by a physician and the prescription will be his or her responsibility. For a group of patients, the request is normally initiated by a drug company and by an institution (e.g. a hospital) or a scientific body. In Germany and Spain, only clinical trials are possible before registration, but they can be open-label with relaxed inclusion/exclusion criteria. In Spain, Expanded Use Clinical Trials are possible if a controlled clinical trial is already being implemented with the test drug.

In all four countries, the drug can be sold to patients pursuant to the applicable expanded access criteria, but the reimbursement of the cost may not

be possible in some situations. In France, patients are likely to be reimbursed if the drug is provided for a group of patients, not on a named patient basis; and some regional health insurance bodies can decline the reimbursement. In Germany, reimbursement is possible but again, depends on regional health authorities. In Spain, reimbursement may be possible for Expanded Use/Cost recovery Clinical Trials.

We plan to support different tax exempt educational based organizations and physicians who seek to increase scientific/medical insight into the potential treatment of ME/CFS. A number of such advocacy groups are already organized in Germany, Italy, the Benelux, the United Kingdom, France, and other countries. We are also assisting physicians/advocacy groups to establish a Pan European Web site to enable them to hold scientific forums and exchange medical information and clinical experiences to enable a better understanding of the morbidity of ME/CFS.

In November 1998 we conducted a scientific meeting in Rome, assembling 35 physicians (internists) and (specialists concentrating on viral infections and chronic diseases) from 10 different European countries. We plan to conduct a similar convention in 2001.

The expanded access program will be organized using Approved Clinical Centers ("ACC"). Each ACC is expected to be a clinic or hospital service in which a physician is ready to diagnosis and treat selected patients with Ampligen under an approved protocol designed by the Company. Our target will be eventually to have a network of approximately 30 ACCs set up throughout Europe starting with an initial goal of 12. Once this network is established and developed we intend to move on a country by country basis to helping develop home care treatments under the supervision and responsibility of approved specialists and general practitioners.

In April 2000 we withdrew our ME/CFS treatment application that was originally filed with the EMEA in December, 1998. The application was withdrawn for two economically compelling reasons. First of all, subsequent to the original filing, we executed a manufacturing agreement with a multinational company to manufacture Ampligen in an easier to use, more economic, liquid form. Secondly, in December, 1999, the European Parliament established new regulations for orphan medicinal products which creates various important economic incentives for certain manufacturers including, a ten (10) year period of marketing exclusivity, financial support of research, waiver of various

administrative fees as well as regulatory assistance in developing certain new drug products. Under current European Union ("EU") laws, pending marketing applications cannot be amended, either with respect to a change in manufacturing format to reflect the application of new orphan drug regulations, without withdrawal and resubmission. The overall economic advantages of submitting the application with a new manufacturing format and the possibility of qualifying under the new regulations offered economic advantages which outweigh any attendant delays in the overall review process. In August 2000 we filed an application for orphan drug designation for potential treatment of several forms of ME/CFS with our investigational drug Ampligen . In

December 2000, a group within EMEA determined that the prevalence of ME/CFS may be 10 to 50 times higher than originally reported. An EU subcommittee, whose mandate is to evaluate and designate rare (also called "orphan") diseases in the EU, found the current number of potential CFS cases as high as 8,000,000 in the European Union. The committee relied in part on the Year 2000 British Journal of Medicine, which reported projected prevalence ratios within the entire EU population of 320,000,000. Under recently enacted laws of the European Parliament, a rare disease cannot exceed 160,000 total cases in the entire EU or 5 cases per 10,000 population. The clinical studies cited used the EU based "Oxford criteria" for ME/CFS diagnosis and were conducted in both health communities and primary care-based facilities within the EU. These findings rule out any orphan drug designation for ME/CFS therapies in the European Union. The orphan designation for ME/CFS was received several years earlierfor the United States pharma market, before the dramatic increase in prevalence of this worldwide disorder.

In July 2000 we entered into a pharmaceutical marketing/licensing agreement with AOP Orphan Pharmaceuticals headquartered in Vienna, Austria. The new licensee is well established in a territory which includes Austria, the Czech Republic, Slovakia, Poland and Hungary.

INTERNATIONAL

Our licensee partner, Bioclones (PTY) Ltd ("Bioclones") located in the Republic of South Africa, has initiated Ampligen treatment of patients severely affected by ME/CFS on a cost recovery basis in South Africa, Australia and Great Britain. Bioclones announced planned collaborative research with British ME/CFS research centers in order to further evaluate ME/CFS treatment and diagnosis.

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In December 2000 we entered the first phase of a new relationship with Ie Sung International of Seoul, Korea and Tokyo, Japan to facilitate accelerated development of its clinical programs in chronic viral diseases in selected Pacific Rim markets. Ie Sung International maintains a team of chemists, regulatory experts and clinicians who tailor the positioning of promising new drug candidates to maximize their potential entrance into emerging markets.

COMPETITION

There are several publicly held companies that place emphasis on nucleic acid technology such as ours. Gilead Sciences, Inc. (Foster City, California; GILD/NASDAQ) is developing nucleotide as well as other innovative antiviral technologies and is pursuing pre-clinical and clinical development of a number of therapeutic product candidates for treating certain viral diseases including, without limitation, cytomegalovirus retinitis, HIV and Hepatitis B. Gilead reports that they have investigational drug products in Phase II clinical trials for treating Hepatitis B and Phase III for treating HIV. The FDA recently granted a Fast Track designation to a Gilead product, but marketing approval of this product was subsequently withdrawn.

ISIS Pharmaceuticals, Inc. (Carlsbad, California; ISIS/NASDAQ). has devoted substantially all of its resources to research, drug discovery and development programs. Isis currently has one product, Vitravene, a treatment for CMV Retinitis in AIDS patients, which has achieved limited market acceptance in a small commercial market with significant competition. Isis reports that most of their resources are being dedicated to applying molecular biology and medicinal chemistry to discovery and development of drug candidates based upon antisense technology.

These 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, many of our competitors have significantly greater experience than us in preclinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, Health Protection Branch ("HPB") and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA 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.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we have. In addition, many of these competitors may have significantly greater experience than we do in undertaking certain aspects of research, preclinical studies and human clinical trials of new pharmaceutical products, obtaining FDA and other regulatory approvals, and manufacturing and marketing such products. Accordingly, our competitors may succeed in commercializing the products more rapidly or more effectively than the Company.

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 our proposed products and our ongoing research and product development activities. Our existing product and the products of the ongoing research and product development activities will require regulatory clearances prior to commercialization. In particular, human new drug products are subject to rigorous preclinical and clinical testing as a condition of clearances by the FDA and by similar authorities in foreign countries. The lengthy process of seeking these approvals, and the ongoing process of compliance with applicable statutes and regulations, has required and will continue to require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect the marketing of any products developed by the Company and its ability to receive product or royalty revenue. We have received orphan drug designation for certain therapeutic indications which might, under certain conditions, accelerate the process of drug commercialization.

As of December 31, 2000, we have not received a "Fast-Track" designation for any of our potential therapeutic indications. 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 50 percent (50%) from the time that a commercial drug application is actually submitted for final regulatory review. We will continue to present data in support of obtaining a Fast-Track designation. We have not yet submitted any New Drug Application (NDA) to a North American regulatory authority. There are no

assurances that such designation will be granted, or if granted, there are no assurances that such designation will materially increase the prospect of a successful commercial application. We have 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 emergency treatments will be granted by any regulatory authority or that the resultant treatments, if any, will support drug efficacy and safety. We also have FDA authorization for two phase II/III HIV treatment protocols in which the Company's drug is combined with certain presently available antiretroviral agents.

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 the our research work. We believe that our Rockville, Marylandmanufacturing and quality assurance/control facility is in substantial compliance with all material regulations applicable to these activities. However, we cannot give assurances that facilities owned and operated by third parties, that are utilized in the manufacture of our products, are in substantial compliance, or if presently in substantial compliance, will remain so. These facilities include manufacturing operations in San Juan, Puerto Rico, Capetown, South Africa, Columbia, Maryland, and Melbourne, Australia.

RESEARCH AND DEVELOPMENT/COLLABORATIVE AGREEMENTS

In 1994, we formed a strategic alliance with 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 and Oragen . 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.

Bioclones has been given the first right of refusal, subject to pricing, to manufacture at least one-third of the worldwide sales requirement of Ampligen and other nucleic acid-derived drugs. Pursuant to this arrangement, we received access to worldwide markets and commercial-scale manufacturing resources, as well as a $3 million cash payment in 1995 from Bioclones, a 24.9%

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ownership in a company set up by Bioclones to develop and manufacture RNA drugs, and royalties of 8% on Bioclones nucleic acid-derived drug sales in the licensed territories. We regularly conduct quality control audits of the facility.

In the United States, the Company has entered into a strategic alliance with Gentiva Health Services (formerly known as Olsten Health Care Services) to develop certain marketing and distribution capacity for Ampligen to patients suffering from ME/CFS, both in the cost recovery treatment program as well as the home infusion market upon commercialization. Gentiva is one of the nation's largest home health care companies with over 400 offices and sixty thousand caregivers nationwide. Pursuant to the agreement, Gentiva will be responsible for marketing, distribution, billing and collecting. Through this arrangement, Hemispherx mitigates the necessity of incurring significant up-front marketing and distribution costs. There can be no assurances that this alliance will develop a significant commercial position in any of its targeted chronic disease markets.

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

In December, 1999, we entered into an agreement with Biovail Corporation International ("Biovail"). Biovail is an international full service pharmaceutical company engaged in the formulation, clinical testing, registration and manufacture of drug products utilizing advanced drug delivery systems. Biovail is headquartered in Toronto, Canada. The agreement grants Biovail the exclusive distributorship of our product in the Canadian territories subject to certain terms and conditions. In return, Biovail agrees to conduct certain pre-marketing clinical studies and market development programs, including without limitation, expansion of the Emergency Drug Release Program in Canada with respect to our products. In addition, Biovail agrees to work with us in preparing and filing a New Drug Submission with Canadian Regulatory Authorities. Biovail invested several million dollars in Hemispherx equity at prices above the then current market price and agreed to make further

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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.

In May 2000, we acquired an interest in Chronix Biomedical Corp. ("CHRONIX"). Chronix focused upon the development of diagnostics for chronic diseases. 100,000 shares of common stock were issued from the treasury 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 chronic fatigue syndrome. The strategic alliance agreement provides us certain royalty rights with respect

to certain diagnostic technology developed from this research and a right of first refusal to license certain therapeutic technology developed from this research.

HUMAN RESOURCES

As of February 28, 2001 we had 48 employees consisting of 23 full time, three (3) part-time employees and 22 regulatory/research medical personnel on a part-time basis. Such parties are paid on a per diem or monthly basis. 27 personnel are engaged in our research, development, clinical, manufacturing effort, including 5 individuals in Europe. 14 of our personnel perform regulatory, general administration, data processing, including bio-statistics, financial and investor relations functions. We consider our relationship with our employees to be good and believe that this arrangement provides the most efficient approach to drug development at this point in time. While we have been successful in attracting skilled and experienced scientific personnel, there can be no assurance that the Company will be able to attract or retain the necessary qualified employees and/or consultants in the future.

FINANCING

The development of the our 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 spent approximately $15,435,000 in research and development, of which approximately $6,136,000 was expended in the year ended December 31, 2000.

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At the present time, we are funding our European subsidiary from our cash flows. These costs could be substantial over the next several years. The European expanded access program (cost recovery) should provide some funds to offset costs and, other funding will be provided by us as required.

Our European subsidiary has an exclusive license on all the technology and support from us concerning Ampligen for the use of ME/CFS and other applications for all countries of the European Union (excluding the UK wherein Bioclones has a marketing license) and Norway, Switzerland, Hungry, Poland, the Balkans, Russia, Ukraine, Romania, Bulgaria, Slovakia, Turkey, Iceland and Liechtenstein. There is also an agreement between us and our European subsidiary to ensure that the commercialization of future technologies can take place under conditions which would provide proper incentives to Hemispherx Biopharma Europe.

As of December 31, 2000, we had approximately $8,378,000 in cash and short term investments. Based on our current operating plan, we expect that these funds and anticipated receipt of revenues from the cost recovery treatment protocols and interest income on unused funds will be sufficient to meet our operating requirements well into 2002. In addition, we may receive proceeds in the form of equity from the exercise of shareholder warrants. For the fiscal year 2000, the Company received $9,985,000 in equity from shareholders exercising warrants. The amount of additional funding required, if any, will depend on the timing of regulatory approval and commercialization of Ampligen .

Accordingly, we may raise substantial additional funds through additional equity or debt financing, collaborative arrangements with corporate partners, off balance sheet 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.

RISK FACTORS

All of our drugs and associated technologies 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. Our principal development efforts are currently focused on Ampligen , which has not been approved for commercial use in the U.S. or elsewhere. Our products, including Ampligen , are subject to extensive

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regulation by numerous governmental authorities in the U.S. and other countries, including, but not limited to, the Food and Drug Administration in the U.S., the Health Protection Branch of Canada, and the European Medical Evaluation Agency 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 our products and receive product revenues or royalties. No regulatory agency has approved the full commercial sale of any of our products. We cannot assure that the drug will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligen is authorized for use in clinical trials in the United States and other countries, we cannot assure 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. Moreover, we cannot assure that Ampligen will be commercially successful in any country that may approve its use. If Ampligen or one of our other products does not receive regulatory approval in the U.S. or elsewhere, our operations will be significantly affected.

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

Our drug and related technologies are investigational and subject to regulatory approval

All of our drugs and associate technologies 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. Our principal development efforts are currently focused on Ampligen , which has not been approved for commercial use. Our products, including Ampligen are subject to extensive regulation by numerous governmental authorities in the U.S. and other countries, including, but not limited to, the Food and Drug Administration in the U.S., the Health Protection Branch of Canada, and the European Medical Evaluation Agency in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory

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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 cannot assure you that the drug will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligen 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 or one of our other products does not receive regulatory approval in the U.S. or elsewhere, our operations will be materially adversely effected.

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

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses. As of December 31, 2000 our accumulated deficit was approximately $82,566,000. 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 profitability.

Additional financing requirements.

The development of our products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. Based on our current operating plan, we anticipate receipt of limited revenues form the sales of Ampligen under the Cost Recovery Clinical Programs and investors exercising our Class A Redeemable Warrants, which we believe will be sufficient to meet our capital requirements for the near future. The Company may need to raise substantial 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 its products. There can be no assurances that our Class A Redeemable Warrants will be exercised or that we will raise any proceeds from possible equity financing, which may

have a material effect on our ability to develop our products.

No regulatory agency has approved the full commercial sale of any of the our products.

We cannot assure you that Ampligen will ultimately be demonstrated to be safe or efficacious. While Ampligen 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 or one of our other products does not receive regulatory approval in the United States or elsewhere, our operations will be significantly affected.

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

We need to acquire enforceable patents covering the use of Ampligen for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen for such disease. Our success depends, in large part, on our ability to obtain patent protection for our products and to obtain and preserve our trade secrets and expertise. We have been issued certain patents on the use of Ampligen and Ampligen in combination with certain other drugs for the treatment of HIV. We have also been issued patents on the use of Ampligen in combination with certain other drugs for the treatment of chronic hepatitis B virus, chronic hepatitis C virus, and a patent which affords protection on the use of Ampligen in patients with chronic fatigue syndrome. We have not been issued any patents in the United States for the use of Ampligen as a sole treatment for any of the cancers which we have sought to target. Our applications for United States patents for the use of Ampligen in the treatment of renal cell carcinoma and lung cancer are currently pending. 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 Ampligen in combination with various other agents, including AZT, for a particular target indication prior to us. If we cannot protect our patents covering the use of Ampligen for a particular disease, or obtain additional pending patents, we may not be able to successfully market Ampligen .

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 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 requires substantial resources from us. 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 market our products or to obtain or maintain any competitive position the we may achieve with respect to our products. Our patents also may not prevent others from developing competitive products using related technology.

There can be no assurance that we will have the financial resources necessary to enforce patent rights we may hold.

If we cannot enforce the patent rights we currently hold we may be required to obtain licenses from others to develop, manufacture or market our products. There can be no assurance that we would be able to obtain any such licenses on commercially reasonable terms, if at all. We currently license certain proprietary information from third parties, some of which may have been developed with government grants under circumstances where the government maintained certain rights with respect to the proprietary information developed. No assurances can be given that such third parties will adequately enforce any rights they may have or that the rights, if any, retained by the government will not adversely affect the value of our license. Certain of our know-how and technology is not patentable, particularly the procedures for the manufacture of our drug product which are carried out according to standard operating procedure manuals.

We may not be profitable unless we can produce Ampligen in commercial quantities at costs acceptable to us.

We have never produced Ampligen or any other products in large commercial quantities. Ampligen is currently produced only for use in clinical trials. We must manufacture our products in compliance with regulatory requirements in commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are

unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen or enter into third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected.

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

We have limited marketing and sales capability. We need to enter into marketing agreements and third party distribution agreements for our products in order to generate significant revenues and become profitable. To the extent that we enter into co-marketing or other licensing arrangements, any revenues received by us will be dependent on the efforts of third parties, and there is no assurance that these efforts will be successful. Our agreement with Gentiva Health Services offers the potential to provide significant marketing and distribution capacity in the United States while licensing and marketing agreements with certain foreign firms should provide an adequate sales force in South America, Africa, United Kingdom, Australia and New Zealand, Canada and Austria.

Gentiva Health Services is able to deliver treatment and services to chronic disease patients including infusion services, home nursing and other medical services through a national network of more than 500 locations. We cannot assure that Gentiva Health Services or our foreign marketing partners will be able to successfully distribute our products, or that we will be able to establish future marketing or third party distribution agreements on terms acceptable to us, or that the cost of establishing these arrangements will not exceed any product revenues. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a materially adverse effect on us. We are dependent upon certain third party suppliers for key components of the proposed products and for substantially all of the production process. If we cannot enter into future marketing and distribution agreements at terms acceptable to us, or if these distributors cannot effectively market and distribute our products, our operations will be negatively affected.

No assurance of successful product development of Ampligen .

The development of Ampligen and our other products is subject to a number of significant risks. Ampligen may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale, be uneconomical to market or be precluded from commercialization by proprietary rights of third parties. Our

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products are in various stages of clinical and pre-clinical development and, require further clinical studies and appropriate regulatory approval processes before any such products can be marketed. We do not know when, or if ever, Ampligen will be generally available for commercial sale for any indication for at least the next several years, if at all. Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale.

Ampligen safety profile.

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

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 and other such 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 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 ofpre-clinical and clinical research quantities to production of commercial quantities of our products will involve distinct management and technical challenges and will require additional management and technical personnel and capital to the extent such manufacturing is not handled by third parties. There can be no assurance that our efforts will be successful or that

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any given product will be determined to be safe and effective, capable of being manufactured economically in commercial quantities or successfully marketed.

Rapid technological change.

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

Substantial competition.

Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these 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 will 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 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.

Limited manufacturing experience and capacity.

Ampligen is currently produced only in limited quantities for use in our clinical trials. 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 Good Manufacturing Practices ("GMP") regulations. There can be no assurance that such facilities can be used, built, or acquired on commercially acceptable terms, that such facilities, if used, built, or acquired, will be adequate for our long-term needs.

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

We face an inherent business risk of exposure to product liability claims in the event that the use of Ampligen or other of our products results in adverse effects. This liability might result from claims made directly by patients, hospitals, clinics or other consumers, or by pharmaceutical companies or others manufacturing these products on our behalf. Our future operations may be negatively effected 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 worldwide product liability insurance coverage in the amount of $1,000,000, there can be no assurance that this insurance will provide adequate coverage against product liability claims. While no product liability claims are pending or threatened against us to date, a successful product liability claim against us in excess of our insurance coverage could have a negative effect on our business and financial condition.

Members of our Scientific Advisory Board may have conflicting interests and may disclose data and technical know how to our competitors.

All of our Scientific Advisory Board members are employed by other entities, which may include our competitors. Although we require each of our Scientific Advisory Board members to sign a non-disclosure and non-competition agreement with respect to the data and information that he or she receives from us, we cannot assure you that members will abide by them. If a member wereto reveal this information to outside sources, accidentally or otherwise, our operations could be negatively effected. Since our business depends in large part on our ability to keep our technical expertise confidential, any revelation of this information to a competitor or other source could have an adverse effect on our operations.

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.

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

Our success is dependent on the continued efforts of Dr. William A. Carter. The loss of Dr. Carter's services could have a material adverse effect on our operations. While we have an employment agreement with Dr. William A. Carter, and have secured key man life insurance in the amount of $2 million on the life of Dr. Carter, the loss of Dr. Carter or other key personnel, such as Dr. David Strayer or Dr. Carol Smith, 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 and potential legislation.

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

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. The company does not maintain insurance coverage against such liabilities.

Exercise of Class A Redeemable Warrants may have dilutive effect on market.

Holders of the Class A Redeemable Warrants may exercise the Class A Redeemable Warrants and purchase the underlying Common Stock at a time when we may be able to obtain capital by a new offering of securities on terms more favorable than that provided by such Class A Redeemable Warrants, in which event our ability to obtain additional capital would be affected adversely.

Litigation in Pennsylvania involving us and Manuel Asensio and Asensio & Company,Inc.

In 1998, we filed a multi-count complaint against Manuel P. Asensio, Asensio & Company, Inc., and others in the United States District Court for the Eastern District of Pennsylvania. The action presently includes claims of defamation, disparagement, tortious interference with existing and prospective business relations and conspiracy, arising out of the current defendants' false and defamatory statements. The complaint further alleges that defendants defamed and disparaged the Company in furtherance of a manipulative, deceptive and unlawfulshort-selling scheme between August, 1998, and the present.

In 1999, Manuel P. Asensio, and Asensio & Company, Inc., and others filed an answer and counterclaim against the Company. The counterclaim alleges that in or around September 1998, and in response to defendants' strong sell recommendation and other press releases about the Company and its officers and directors, the Company made defamatory statements about defendants, including statements that defendants' attack and manipulative short-selling scheme may have constituted criminal wrongdoing on the part of defendants. The Company has denied the material allegations of the counterclaim and is vigorously defending against the counterclaim. The action has been transferred to Pennsylvania State Court and is presently listed for trial in August 2001.

Litigation in New York involving us and Manuel Asensio, Asensio & Company Inc., and Asensio.com Inc.

In May 2000, we received notice of a claim by Manuel P. Asensio and Asensio & Company, Inc., in the Supreme Court of the State of New York against the Company, the Chairman and Chief Executive Officer, William A. Carter, and our prior auditors (the "first New York Action") in which they allege that defendants defamed them in oral and written communications made in March 2000.

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The allegations of Manuel P. Asensio and Asensio & Company, Inc. in the first New York Action are similar in substance to the alleged defamation which are the subject of the counterclaims filed by them in the action presently pending in Pennsylvania State Court.

In June 2000, Manuel P. Asensio, Asensio & Company, Inc. and Asensio.com Inc.,("Asensio plaintiffs") filed a second action against the Company and Dr. William Carter, the Company's Chairman and Chief Executive Officer in the Supreme Court of the State of New York. (the "second New York Action"). In September 2000, we were served with a complaint in this action. The second New York Action purports to seek a declaratory judgment that Asensio plaintiffs statements regarding the Company constituted protected speech, and that they did not engage in any actionable interference with our existing or prospective business relations. We intend to vigorously defend against the claims asserted in both the First and Second New York Actions. However, this litigation could subject us to significant liability for damage and, even if it does not subject us to liability for damage, it could be time-consuming and expensive to defend, and could result in the diversion of management time and attention.

ITEM 2. Properties

We currently lease and occupy a total of approximately 18,850 square feet of laboratory and office space in two states. 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 our pharmacy, packaging, quality assurance and quality control laboratories, as well as additional office space. Approximately 2,000 square feet are dedicated to the pharmacy, packaging, quality assurance and control functions. The Company believes that its Rockville facilities will meet its requirements, for planned clinical trials and treatment protocols, through 2001, after which time it may need to increase its Rockville facilities either through third parties or by building or acquiring commercial-scale facilities.

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

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result of the marketing and manufacturing agreement executed with Bioclones in 1994.

ITEM 3. Legal Proceedings

In September, 1998, we filed a multi-count complaint against Manuel P. Asensio, ("Asensio") Asensio & Company, Inc., ("ACI") and others in the United States District Court for the Eastern District of Pennsylvania. On October 22, 1998,

we amended the complaint to add additional counts and to conform the complaint to agreed upon dismissals without prejudice as to certain of the defendants. In August, 1999, we amended and supplemented the complaint for a second time to conform the complaint to court ordered dismissals of certain counts of the complaint and parties, to add Asensio.com, Inc. (formerly known as Asensio Holdings, Inc.), the holding company of defendant ACI and to add a conspiracy charge against the remaining defendants and certain unnamed John Does.

As amended, our complaint seeks recovery on common law theories of intentional interference with existing and prospective business relations, defamation, commercial disparagement, and conspiracy on account of defendants' short selling of our stock and the publication, by defendants Asensio and ACI, of defamatory statements regarding the Company. In April 1999, defendants Asensio and ACI answered the complaint and asserted defamation and disparagement counterclaims against us seeking damages in an unspecified amount. Defendants' counterclaims allege that we, through our officers, defamed Asensio in oral and written communications accusing Asensio and ACI of having engaged in possibly criminal behavior with respect to the short selling of our stock and the subsequent publication of various defamatory statements regarding us . In May 1999, we filed an answer, including affirmative defenses, to these counterclaims.

In June 2000, the United States District Court dismissed the Company's complaint and the defendants' counterclaims for lack of federal subject matter jurisdiction over the action. In July 2000, we transferred the action to the Pennsylvania State Court. In September 2000 defendants in the action filed preliminary objections seeking the dismissal of the transferred action on various grounds. Those objections were disposed of and the case in scheduled for trial is August 2001. In August 2000, we filed a Notice of Appeal from the decision of the United States District Court dismissing the action. The appeal is presently pending, although it has been stayed pending the determination of the case in the Pennsylvania State Court.

In May 2000, Asensio and ACI filed a separate action in the Supreme Court of the State of New York against our company, our Chairman and Chief Executive Officer, William A. Carter and our prior auditors ("the first New York action"). The action was commenced by Summons. In July 2000, Asensio and ACI filed a Complaint in which they allege that the defendants defamed them in oral and written communications made in March 2000. Plaintiff's allegations in the first New York action are similar in substance to the alleged defamations which are the subject of the counterclaim filed by them in the action presently pending in Pennsylvania State Court. In August 2000, we filed an answer, including affirmative defenses to these claims, and Dr. Carter moved to dismiss the claims. In October 2000, the Company and Dr. Carter moved to dismiss the action.

In June 2000, Asensio, ACI and Asensio.Com, Inc. filed a second action against us and Dr. Carter in the Supreme Court of the State of New York ("the second New York action"). The action was commenced by Summons. In September 2000,plaintiffs filed a Complaint in the second New York action which purports to seek a declaratory judgment that the statements of Asensio, ACI and Asensio.com, Inc. about the Company constituted protected speech, and that plaintiffs did not engage in any actionable interference with existing or prospective business relations of the Company. In essence, the second New York action seeks to establish the validity of the affirmative defenses asserted by the defendants in the action now listed for trial in August 2001 in the Pennsylvania State Court.

We intend to vigorously defend against the "claims" asserted by Asensio, ACI and Asensio.com, Inc. in the New York actions and we have moved to consolidate and dismiss the first New York actions.

Cook Imaging Corp. ("Cook") commenced action against us in March 2000, which is presently pending in the United States District Court for the Eastern District of Pennsylvania. From approximately 1997 through 1999, Cook manufactured the drug Ampligen (as well as Ampligen placebo) for us. Cook has sued for approximately $250,000 in unpaid invoices related to four Ampligen batches manufactured by
Cook and delivered to us in 1999. Cook contends that the four batches at issue were deemed to be sterile by us and had been released for clinical use. The Company has denied that the such amounts are owed and has asserted a counterclaim for approximately $1 million. The basis of counterclaim is Cook's

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failure to consistently manufacture Ampligen in strict conformance with federal regulations known as current good manufacturing practices ("cGMP"). We are seeking the costs we have incurred as a result of Cook's cGMP deviations, as well as the market value of raw materials (supplied by us) that were lost or destroyed due to Cook's cGMP deviations. Discovery in the action in ongoing, and on December 22, 2000, the court denied Cook's motion for summary judgment on its claims. The case is presently scheduled for trial in April 2001. We are unable at this time to express any opinion as to likely outcome of the action.

In October 1998, the Company contacted the Securities and Exchange Commission ("SEC") regarding what it believed may have been illegal short selling and unlawful market manipulation in furtherance of the short selling of Manuel P. Asensio and others. Thereafter, in July 1999, the Company was advised by the SEC of a private investigation authorized by the SEC on April 1, 1999 into various allegations of misrepresentations by the Company and its officers. In general, the SEC sought information relating to allegations about the Company's investigational drug application for treatment of various diseases, results of clinical research, incidence of ME/CFS in the United States, the Company's patents, and Ampligen's safety and efficacy. These allegations had also been included by Asensio & Co. in its various "research reports" which the Company considers defamatory and for which the Company has sued Asensio and his company. In October 2000, the SEC brought forth certain specific concerns with respect to certain alleged omissions in the Company's public statements to which the Company replied in November. The Company has had no further contact with the SEC on this matter.

The Company has also been advised that the NASD has initiated an investigation into the short selling of Hemispherx Securities (Enf-303). Asensio has admitted, in deposition testimony in the Company's litigation against him, that he and his company was the subject of such an investigation. In November 2000, Asensio and his Company were censured and fined $ 75,000 by the NASD. The censure and fine were based on short selling violations and advertising violations between September 1996 and July 1999. By consenting to the NASD sanction and censure, Asensio was further required to hire an independent compliance officer and discontinue the conduct sanctioned by NASD.

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

No matters were submitted to a vote of the security holders during the year ended December 31, 2000.

PART II

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

In the year 2000, we acquired 350,800 shares of common stock on the open market at an average cost of $ 10.24 per share. The acquisition of the shares was authorized under a stock buy-back program authorized by the board of directors. Certain of the acquired shares were utilized to fund strategic alliances and obtain equity positions in other companies in order to potentially increase the breadth and depth of our drug technology portfolio.

In October 2000 we filed a registration statement on form S-3 with the SEC registering certain warrants and underlying common stock on behalf of certain warrant holders. In addition, we registered 500,000 shares of our common stock to be used in pursuit of our business objectives.

In fiscal 2000, we issued 830,879 new shares of common stock to warrant holders exercising non-public warrants at an average exercise price of $4.495. The warrants exercised were granted by us in the period covering 1995 through 1998. In addition, we issued 1,562,502 new shares of common stock to warrant holdersexercising publicly traded Class A Redeemable Warrants at $4.00 per share.

The foregoing private offerings were private transactions and exempt from registration under section 4(2) and 4(6) of the Securities Act and/or

regulation D rule 506 promulgated under the Securities Act. Investors in these transactions are accredited.

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

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COMMON STOCK	High	Low
Time Period:		
January 1, 1999 through March 31, 1999	$ 7.375	$ 4.688
April 1, 1999 through June 30, 1999	10.063	5.563
July 1, 1999 through September 30, 1999	8.125	5.875
October 1, 1999 through December 31, 1999	10.500	6.000
January 1, 2000 through March 31, 2000	18.538	8.625
April 1, 2000 through June 30, 2000	11.125	5.250
July 1, 2000 through September 30, 2000	7.938	7.500
October 1, 2000 through December 31, 2000	5.875	4.438
WARRANTS		
Time Period:		
January 1, 1999 through March 31, 1999	$ 3.750	$ 1.750
April 1, 1999 through June 30, 1999	6.188	2.250
July 1, 1999 through September 30, 1999	4.125	2.250
October 1, 1999 through December 31, 1999	6.500	4.125
January 1, 2000 through March 31, 2000	14.938	4.875
April 1, 2000 through June 30, 2000	6.750	1.750
July 1, 2000 through September 30, 2000	4.188	2.125
October 1, 2000 through December 31, 2000	3.500	0.875

As of December 31, 2000 there were approximately 330 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 areheld in the names of various dealers and/or clearing agencies.

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As of December 31, 2000, we had approximately 3,917,808 Class A Redeemable Warrants registered and outstanding at an exercise price of $4.00 per share. As of March 27, 2001, our common stock was trading at $ 4.50 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.

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

Year Ended December 31	1996	1997	1998	RESTATED(1) 1999	2000
Statement of Operations Data					
Net revenues	$32	$259	$401	$678	$788
Net loss	(4,554)	(6,107)	(7,324)	(12,298)	(8,552)
Basic and diluted loss per share	(0.29)	(0.35)	(0.32)	(0.47)	(0.29)
Shares used in computing basic and diluted net loss per share.	15,718,136	17,275,994	22,724,913	26,380,351	29,251,846
Balance Sheet Data					
Total Assets	6,999	11,543	16,327	14,168	13,067
Common Stockholders Equity	5,853	10,745	15,185	12,657	11,572
Other Cash Flow Data					
Cash used in operating activities	(6,098)	(4,642)	(5,751)	(6,990)	(8,074)
Capital expenditures	(86)	(15)	(151)	(251)	(171)

(1) See note 1 to the consolidated financial statements.

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, 2000. This information should be read in conjunction with the Item 6 "Selected consolidated financial data" and our consolidated financial statements and related notes thereto beginning on F-1 of this Form 10-K.

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

Background

We are actively engaged in various clinical efforts and market development strategies in the United States, European Union, Canada, Australia and South Africa. Disease categories under active development include ME/CFS, Hepatitis and HIV. We maintain offices and clinical operations in both the United States and the European Union. We also have ownership interests in R.E.D. Laboratories a European based diagnostic company and Ribotech Ltd. a South African manufacturing entity, which produces our raw drug materials.

We have reported net income only from 1985 through 1987. Since 1987, we have incurred substantial operating losses. Prior to completing an Initial Public Offering ("IPO") in November 1995, we financed operations primarily

through the private placement of equity and debt securities, equipment lease financing, interest income and revenues from licensing and royalty agreements.

Our consolidated financial statements include the financial statements of Hemispherx BioPharma, Inc. and its four wholly-owned subsidiaries, BioPro Corp., BioAegean Corp., Core BioTech Corp. and Hemispherx Biopharma-Europe N.V./S.A. The U.S. subsidiaries were incorporated in September 1994 for the purpose of developing technology for ultimate sale into certain non-pharmaceutical specialty consumer markets. The European subsidiary was formed for the purpose of serving our needs with respect to pursuing clinical trials and regulatory approval in the European Union. The U.S. subsidiaries are inactive at this time. All significant intercompany balances and transactions have been eliminated in consolidation.

In 1998, we initiated a Phase III clinical study of using Ampligen to treat 230 patients affected by ME/CFS at various medical centers in the United States. ME/CFS patients that are not eligible for the Phase III clinical study may seek treatment under a ME/CFS Cost Recovery Treatment Program that has been authorized by the FDA. Under the cost recovery program, enrolled patients pay for the cost of Ampligen administered, which totals $7,200 for a 24 week

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treatment program. Patients are also treated in Belgium and Austria under similar cost recovery programs.

In March 2001, we discovered that we should have recorded a non-cash charge for stock compensation expense in our 1999 financial statements. This change is related to the extension of the expiration date of certain Rule 701 warrants in February 1999. The $3,097,000 adjustment does not affect our cash or our shareholder net worth, but it does affect the 1999 net loss and earnings per share. All references to the 1999 financial statements in this form 10K, have been adjusted to reflect this change.

We expect to continue our research and clinical efforts for the next several years with some benefit of certain revenues from our cost recovery treatment programs. These cost recovery treatment sales were approximately $ 788,000 in fiscal year 2000. We may continue to incur losses over the next several years due to clinical and operating costs which may be partially offset by cost recovery treatment revenues and potential licensing fees. Such 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 revenues. Acquisition of full or conditional marketing approval in any major market would significantly affect our cash flow. There are no assurances that such approvals will ever happen in any major pharmaceutical market.

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RESULTS OF OPERATIONS

The Company is restating its consolidated financial statements as of and for the year ended December 31, 1999 and for the first quarter of 1999. The restated financial statements now reflect a non-cash charge for the extension of the lives of certain Section 701 warrants on February 19, 1999, as described in note 7 to the financial statements. The following discussion of results has been amended for the $3.1 million non-cash charge.

Years Ended December 31, 2000 vs. 1999

Net loss
We reported a net loss of approximately $8,552,000 for the year ended December 31, 2000 versus a net loss of approximately $12,298,000 for the same period in 1999. Several factors contributed to the $3,746,000 decrease.

Revenues
Overall revenues from the Cost Recovery Treatment Programs in the United States, Canada and Europe increased by $110,000 in 2000 compared to 1999. Cost recovery revenues in the United States were up $ 115,000 or 29.5%. European cost recovery revenues declined by $5,000 or 18%. The Company expects the European operations to expand significantly in 2001. The Company's European operations received a $97,000 research grant in 2000 from a France based pharmaceutical company.

Research and Development costs
In 2000, research and development costs increased $1,399,000 primarily due to a major increase in patients entering the AMP 516 ME/CFS clinical trial initiated by us in 1998 and our efforts in Europe to increase the expanded ME/CFS access program in European countries other than Belgium. By year end 2000 we had engaged the services of eleven (11) clinical investigators located throughout the United States to enroll eligible ME/CFS patients in the Amp 516 program. As of December 31, 2000 some 212 patients were involved in the clinical study. Cost incurred in producing Ampligen and other drugs for clinical studies were $919,000 in 2000 compared to $1,503,000 in 1999. The 1999 production costs reflect the build-up of drug supplies needed to support clinical trials and other research and development efforts expected in 2000 and 2001. At present, we charge all raw material and related production costs to research and development expense as incurred.

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General and Administrative Expenses

General and administrative expenses were down $5,026,000 in 2000 compared to 1999. Lower stock compensation expense accounted for $4,221,000 of this decrease. This expense was $397,000 in 2000 versus $4,618,000 in 1999. Stock compensation expense is a non-cash expense that reflects the fair value of our common stock and warrants granted to non-employees of our Company for services or benefits provided. The decrease in 2000 reflects fewer warrants granted to consultants and other service providers. Legal and related expenses in 2000 were lower by $ 354,000 compared to 1999, primarily due to lower costs from litigation associated with the Asensio & Company lawsuit, and other legal matters. Legal expenses associated with the Company's defense of the Asensio countersuit are mostly paid by our Company's liability insurance 3 carrier. Expenses associated with stock transactions, the filing of registration statements and financing costs were lower by $173,000. The cost of evaluating the feasibility of the proposed spin-off of the Company's wholly owned subsidiary, Core Biotech Corp., was $124,000 in 1999 which did not occur in 2000. We have not decided whether to spin-off Core BioTech Corp.

Years Ended December 31, 1999 vs. 1998

Net loss
We reported a net loss of approximately $12,298,000 (including a non-cash loss of $4,618,000 for stock compensation expense) for the year ended December 31, 1999 as compared to a net loss of approximately $7,324,000 for the same period in 1998. Several factors contributed to the $4,974,000 increase in net losses in 1999. In general, non-cash stock compensation expense, increased clinical costs and legal fees account for the increase in net losses in 1999.

Revenues

Revenues from our Cost Recovery Treatment Program in the United States and Europe were up by $277,000 in 1999 compared to 1998. Cost recovery treatment protocols were approved for severely affected ME/CFS patients in the United States in 1998. The cost recovery treatment program in Belgium was approved by regulatory authorities in 1994.

Research and Development Cost
In 1999, research and development costs increased $175,000 basically due to increased activity in the AMP 516 ME/CFS clinical trial initiated by us in October 1998. Drug production and related costs were $1,503,000 in 1999 versus $1,923,000 in 1998. The 1998 costs reflects the build-up of drug supplies

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needed to support clinical trials and other research and development efforts. At present, the Company charges all raw material and related production costs to research and development as incurred.

General and Administrative Expenses

General and administrative expenses were up $4,968,000 in 1999 compared to 1998. Legal expenses for attorneys increased $603,000 primarily due to litigation associated with the Asensio & Company lawsuit, the ELL & Co. lawsuit,

settlement of the VMW lawsuit and other legal matters. Expenses associated with stock transactions, registration statement filing and financing expenses were up $156,000 The cost of funding the European operation was up by $187,000 in 1999 due to establishing and staffing of our European subsidiary. The cost of evaluating the feasibility of the spin-off of the Company's wholly owned subsidiary Core BioTech Corp. was $116,000 more than expensed in 1998.

Stock compensation expense, included in general and administrative expense, was $4,618,000 for 1999 versus $795,000 recorded for 1998. This non-cash expense reflects the fair value of the common stock including the warrants granted to non-employees of our Company and the extension of the lives of our Rule 701 warrants. The increase in 1999 reflects warrants granted to consultants for various types of assistance and professional services provided to us.

LIQUIDITY AND CAPITAL RESOURCES

Cash, cash equivalents and short term investments at December 31, 2000 were approximately $8,378,000. Cash used for operating activities in 2000 was approximately $8,074.000. Cash used for investing and financing activities totaled $4,404,000 and consists of expenditures of $171,000 for capital expenditures $197,000 for patent acquisition cost, $411,000 investments in unconsolidated subsidiaries, $34,000 in other investments and $3,591,000 to acquire 350,800 shares of our company stock which will be used to acquire interest in companies and biotechnologies that may benefit our purposes. In addition, purchases of short term investments exceeded maturities of these investments by $230,000.

Cash proceeds from financing activities in 2000 were approximately $12,235,000. $2,250,000 was received from the collection of stock subscriptions and $9,985,000 was generated from the exercise of warrants to acquire 2,386,625 shares of our stock.

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Our operating cash burn rate for the last six months of fiscal year 2000 was approximately $603,000 per month or $7,236,000 on an annualized basis. All clinical trial drug products produced in 2000 were fully expensed and some costs are expected to be recovered under the expanded access, cost recovery programs authorized by FDA and regulatory bodies in other countries. As the clinical testing efforts in the United States moderates and the European market development activity increases cost recovery revenues, the operating cash burn rate should decline somewhat in 2001. Also, certain of the operating, as well as the non-operating cash outlays are of a one-time nature and are expected to decline.

We also expect warrant holders to continue exercising the Class A redeemable warrants and private warrants from time to time depending on the trading price of our common stock. As of December 31, 2000, we had 3,866,518 Class A Redeemable Warrants outstanding. These warrants are exercisable at $4.00 per share. In addition, there are 462,000 Class A Redeemable Warrants outstanding at an exercise price of $6.60 per share. Private warrants outstanding total 7,295,650 with a weighted average exercise price of $4.05.

Based on cash, cash equivalents and short term investments on hand at December 31, 2000 and projected operating cash needs, we expect to have sufficient cash to fund operations through at least the second quarter of 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.

NEW ACCOUNTING PRONOUNCEMENTS

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities. "SFAS No.133"

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requires companies to recognize all derivative contracts at their fair values, as either assets or liabilities on the balance sheet. If certain conditions are met, a derivative may be specifically designated as a hedge, the objective of which is to match the timing of gain or loss recognition on the hedging derivative with the recognition of (1) the changes in the fair value of the hedged asset or liability that are attributable to the hedged risk, or (2) the earnings effect of the hedged forecasted transaction. For a derivative not designated as a hedging instrument, the gain or loss is recognized in income in the period of change. SFAS No. 133, as amended by SFAS No. 137, is effective for fiscal years beginning January 1, 2001. Historically, the Company has not entered into derivative contracts either to hedge existing risks or for speculative purpose. Accordingly, the Company does not expect adoption of the new standard to affect its financial statements.

In March 2000, the FASB issued Interpretation No. 44 ("FIN 44"),"Accounting for Certain Transactions Involving Stock Compensation, an interpretation of Accounting Principle Board ("APB") Opinion No. 25."FIN 44" clarifies the application of APB No. 25 for (a) the definition of employee for purposes of applying APB 25, (b) the criteria for determining whether a plan qualifies as a noncompensatory plan, (c) the accounting consequences of various modifications to the previously fixed stock option or award, and (d) the accounting for an exchange of stock compensation awards in a business combination. FIN 44 became effective July 1, 2000 but certain conclusions cover specific events that occur after either December 15, 1998 or January 12, 2000. The Company adopted FIN 44 in fiscal 2000 and it did not have a material effect on the Company's financial statements.

In December 1999, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 101 which summarizes certain of the SEC staff's views in applying generally accepted accounting principles to revenue recognition in financial statements. The Staff Accounting bulletin is effective for 2000. The initial adoption of this guidance did not have a material impact on the Company's results of operations or financial position.

ITEM 7a. Quantitative and Qualitative Market Risk

Market Risk

We had $8.4 million in cash, cash equivalents and short term investments at December 31, 2000. To the extent that our cash and cash equivalents exceed our near term funding requirement, we invest the excess cash 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.

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ITEM 8. Financial Statements and Supplementary Data

The consolidated balance sheets as of December 31, 1999 and 2000, and our consolidated statements of operations, changes in stockholder's equity (deficit) and comprehensive loss and cash flows for each of the years in the three year period ended December 31, 2000, together with the reports of BDO Seidman, LLP and KPMG LLP, independent public accountants, are included elsewhere herein. Reference is made to the "Index to Financial Statements and Financial Statement Schedule" on page F-1 which follows page 47.

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

On May 3, 2000, KPMG LLP ("KPMG") resigned from the client-auditor relationship with our Company. On May 3, 2000, pursuant to the prior decision of our Board Of Directors and Audit Committee of the Board of Directors to seek and retain the services of an independent accounting firm other than KPMG, we accepted the resignation of KPMG and confirmed that the client-auditor relationship with us had ceased.

KPMG's reports on our financial statements for the fiscal years ended

December 31, 1998, and December 31, 1999, did not contain any adverse opinion or any disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles.

During our two most recent fiscal years ended December 31, 1998, and December 31, 1999, and the subsequent interim period through May 3, 2000, there were no "reportable events" as described in Items 304(a) (1) (iv) and (v) of Regulation S-K and no disagreements between the Registrant and KPMG on any matter of accounting principles or practice, financial statement disclosure or auditing scope of procedure which, if not resolved to the satisfaction of KPMG would have caused KPMG to make a reference to the subject matter thereof in connection with its reports.

On June 5, 2000, we engaged the services of BDO Seidman, LLP as our Independent Certified Public Accountants.

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PART III

The information called for by this Part III (items 10,11,12 and 13) is not set forth herein because we intend to file with the SEC no later than 120 days after the end of this fiscal year ended December 31, 2000 the Definitive Proxy Statement for the 2000 Annual Meeting of Stockholders to be held on July 12, 2001. Such information to be included in the Definitive Proxy Statement is hereby incorporated into items 10,11,12 and 13 by this reference.

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PART IV

ITEM 14. 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 which follows page 47 of this Annual Report.

(a)(3) Exhibits - See exhibit index below.

(b) Exhibits and Reports on Form 8K

NONE in the fourth quarter 2000.

(c) As of the date of the filing of this Annual Report on From 10K no proxy materials have been furnished to security holders, Copies of all proxy materials will be sent to the Commission in compliance with its rules. 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. Exhibits marked with a star are filed herewith:

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended, along with Certificates of Designations
3.1.1	Series E Preferred Stock
3.2	By-laws of Registrant, as amended
4.1	Specimen certificate representing our Common Stock
4.2	Form of Class A Redeemable Warrant Certificate
4.3	Form of Underwriter's Unit Option Purchase Agreement
4.4	Form of Class A Redeemable Warrant Agreement with Continental Stock and transfer and Trust Company
10.1	1990 Stock Option Plan
10.2	1992 Stock Option Plan
10.3	1993 Employee Stock Purchase Plan
10.4	Form of Confidentiality, Invention and Non-Compete Agreement
10.5	Form of Clinical Research Agreement
10.6	Form of Collaboration Agreement
10.7	Amended and Restated Employment Agreement by and between the

Company and Dr.
William A. Carter, dated as of July 1, 1993

10.8 Employment Agreement by and between the Registrant and Harris Freedman, dated August 1, 1994

10.9 Employment Agreement by and between the Company and Sharon Will, dated August 1, 1994

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10.10 License Agreement by and between the Company and The Johns Hopkins University, dated December 31, 1980

10.11 Technology Transfer, Patent License and Supply Agreement by and between the Company, Pharmacia LKB Biotechnology Inc., Pharmacia P-L Biochemicals Inc. and E.I. du Pont de Nemours and Company, dated November 24, 1987

10.12 Pharmaceutical Use Agreement, by and between the Company and Temple University, dated August 3, 1988

10.13 Assignment and Research Support Agreement by and between the Company, Hahnemann University and Dr. David Strayer, Dr. lsadore Brodsky and Dr. David Gillespie, dated June 30, 1989

10.14 Lease Agreement between the Company and Red Gate Limited Partnership, dated November 1, 1989, relating to the Company's Rockville, Maryland facility

10.15 Agreement between the Company and Bioclones (Proprietary) Limited

10.16 Amendment, dated August 3, 1995, to Agreement between the Company and Bioclones (Proprietary) Limited (contained in Exhibit (10.46)

21 Subsidiaries of the Registrant

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SIGNATURES

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

HEMISPHERx BIOPHARMA, INC.
By: /S/William A. Carter, M.D.
William A. Carter, M.D.
Chief Executive Officer

March 30, 2001

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

Pursuant to the requirements of Section 13 or (d) of the Securities Exchange 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		March 30,2001
William A. Carter, M.D.	Chairman of the Board, Chief Executive Officer and Director	
/S/ Richard Piani		March 26,2001
Richard Piani	Director	

/S/ Robert E. Peterson Robert E. Peterson	Chief Financial Officer	March 26,2001
/S/ Ransom Etheridge Ransom Etheridge	Secretary And Director	March 29,2001
/S/ William Mitchell William Mitchell,M.D.,Ph.D.	Director	March 26,2000
/S/ Josephine Dolhancryk Josephine Dolhancryk	Assistant Secretary and Treasurer	March 27,2001

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HEMISPHERx BIOPHARMA, INC AND SUBSIDIARIES

Index to Consolidated Financial Statements

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Reports of Independent Certified Public Accountants:
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Consolidated Statements of Operations for each of the years in the three-year period ended December 31, 2000. . . . . F-5

Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Income (Loss) for each of the years in the three-year period ended December 31, 2000 . . . . . F-6

Consolidated Statements of Cash Flows for each of the years in the three-year period ended December 31, 2000 . . . . . .F-7

Notes to Consolidated Financial Statements F-9

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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, 2000, and the related consolidated statements of operations, changes in stockholders' equity and comprehensive loss and cash flows for the year then ended. 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 audit.

We conducted our audit 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 audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Hemispherx Biopharma, Inc. and subsidiaries as of December 31, 2000, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO SEIDMAN, LLP

February 23, 2001,
Philadelphia, Pennsylvania

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Independent Auditors' Report

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, 1998 and 1999 (as restated for 1999), and the related consolidated statements of operations, changes in stockholders' equity and comprehensive loss and cash flows for each of the years then ended (as restated for 1999). 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 misstatements. 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, 1998 and 1999, and the results of their operations and their cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

As discussed in note 1 to the consolidated financial statements, the Company has restated its financial statements as of December 31, 1999 and for the year then ended.

/s/ KPMG LLP

Philadelphia, Pennsylvania

February 19, 2000, except as to the seventh paragraph of note 15, which is as of March 6, 2000 and as to note 1, which is as of March 30, 2001.

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HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 1999 and 2000
(in thousands)

<TABLE>
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	December 31,	
	1999	2000
<S>	<C>	<C>
ASSETS	(RESTATED)	
Current assets:		
Cash and cash equivalents.	$6,396	$ 3,721
Short term investments (Note 4). .	2,153	4,657
Accounts receivable	75	60
Stock subscription receivable (Note 7c)	2,250	-
Prepaid expenses and other current assets	144	607
Total current assets	11,018	9,045
Property and equipment, net	333	373
Patent and trademark rights, net. .	1,363	1,204
Investments in unconsolidated affiliates	1,413	2,421
Others assets	41	24
Total assets.	$14,168	$ 13,067
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,091	$ 1,341
Accrued expenses (Note 6).	420	154
Total current liabilities . . .	1,511	1,495
Commitments and contingencies (Notes 7, 10, 12, 13 and 15)		
Stockholders' equity (Notes 7 and 8):		
Preferred stock.	-	-
Common stock.	28	30
Additional paid-in capital. . . .	87,972	97,984
Deferred compensation	(310)	-
Accumulated other comprehensive income (Note 3j).	-	34
Accumulated deficit	(74,014)	(82,566)
Treasury stock	(1,019)	(3,910)
Total stockholders' equity. . .	12,657	11,572
Total liabilities and stockholders' equity	$14,168	$ 13,067

</TABLE>
See accompanying notes to consolidated financial statements.

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HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations
For each of the years in the three-year period ended December 31, 2000
(in thousands, except share and per share data)

<TABLE>
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	December 31,		
	1998	1999	2000
		(RESTATED)	
<S>	<C>	<C>	<C>
Revenue:	$401	$678	$788

Costs and expenses:			
Research and development	4,562	4,737	6,136
General and administrative	3,753	8,721	3,695
Total costs and expenses . . .	8,315	13,458	9,831
Equity loss in unconsolidated affiliate	-	-	(81)
Interest and other income	590	482	572
Net loss.	$(7,324)	$(12,298)	$(8,552)
Basic and diluted loss per share. .	$(.32)	$(.47)	$(.29)
Weighted average shares outstanding.	22,724,913	26,380,351	29,251,846

</TABLE>

See accompanying notes to consolidated financial statements.

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HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Income (Loss)
For each of the years in the three-year period ended December 31, 2000
(in thousands except share data)

<TABLE>
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<S>	<C> Preferred stock shares	<C> Preferred stock	<C> Common stock shares	<C> Common Stock .001 ParValue	<C> Additional paid-in capital
Balance at December 31, 1997	3,650	$37	21,042,606	$21	$65,256
Common stock issued	-	-	3,294,434	3	11,059
Preferred stock converted	(3,650)	(37)	1,825,000	2	(2)
Stock issue costs	-	-	-	-	(16)
Payout of stock guarantees	-	-	-	-	(80)
Stock compensation expense, net	-	-	-	-	1,842
Net comprehensive loss	-	-	-	-	-
Balance at December 31, 1998	-	-	26,162,040	26	78,059
Purchase of treasury stock	-	-	-	-	-
Common stock issued	-	-	1,812,467	2	6,267
Purchase of public warrants	-	-	-	-	(98)
Stock compensation and services expense, net	-	-	-	-	3,744

Net comprehensive loss, as restated	-	-	-	-	-
Balance at December 31, 1999, as restated	-	-	27,974,507	28	87,972
Common stock issued	-	-	2,393,381	2	9,860
Purchase of equity investment	-	-	-	-	67
Treasury stock purchased	-	-	-	-	-
Treasury stock issued in settlement of debt	-	-	-	-	8
Stock compensation and service expense, net	-	-	-	-	87
Registration costs	-	-	-	-	(10)
Net comprehensive loss	-	-	-	-	-
Balance at December 31, 2000	-	-	30,367,888	$30	$97,984

</TABLE>

<PAGE>
<PAGE> F-6B

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Income (Loss)- Continued
For each of the years in the three-year period ended December 31, 2000
(in thousands except share data)

<TABLE>
<CAPTION>
<S>

	<C> Deferred compensation	<C> Accumulated other Comprehensive Income (Loss)	<C> Accumulated deficit	<C> Treasury stock shares	<C> Treasury Stock	<C> Total stockholders equity
Balance at December 31, 1997	$(137)	$(2)	$(54,392)	-	-	$10,746
Common stock issued	-	-	-	-	-	11,062
Preferred stock converted	-	-	-	-	-	-
Stock issue costs	-	-	-	-	-	(16)
Payout of stock guarantees	-	-	-	-	-	(80)
Stock compensation expense, net	(1,047)	-	-	-	-	795
Net comprehensive loss	-	3	(7,324)	-	-	(7,321)
Balance at December 31, 1998	(1,184)	1	(61,716)	-	-	15,186
Purchase of treasury stock	-	-	-	290,811	(1,967)	(1,967)
Common stock issued	-	-	-	(122,876)	948	7,217
Purchase of public warrants	-	-	-	-	-	(98)

Stock compensation and services expense, net	874	-	-	-	-	4,618
Net comprehensive loss, as restated	-	(1)	(12,298)	-	-	(12,299)
Balance at December 31, 1999, as restated	(310)	-	(74,014)	167,935	(1,019)	12,657
Common stock issued	-	-	-	(20,000)	123	9,985
Purchase of equity investment	-	-	-	(100,000)	551	618
Treasury stock purchased	-	-	-	350,800	(3,591)	(3,591)
Treasury stock issued in settlement of debt	-	-	-	(3,089)	26	34
Stock compensation and service expense, net	310	-	-	-	-	397
Registration costs	-	-	-	-	-	(10)
Net comprehensive loss	-	34	(8,552)	-	-	(8,518)
Balance at December 31, 2000	$-	$34	$ (82,566)	395,646	$ (3,910)	$ 11,572

</TABLE>

See accompanying notes to consolidated financial statements

<PAGE>
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HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
for each of the years in the three-year period ended December 31, 2000

(in thousands)

<TABLE>
<CAPTION>

	December 31,		
	1998	1999	2000
		(RESTATED)	
<S>	<C>	<C>	<C>
Cash flows from operating activities:			
Net loss	$(7,324)	$(12,298)	$(8,552)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of property and equipment	39	99	131
Amortization of patent and trademark rights	310	220	356
Equity in loss of unconsolidated affiliate	-	-	81
Stock compensation and service expense	795	4,618	397
Stock issued in settlement of debt	-	126	-
Changes in assets and liabilities:			
Accounts receivable	(24)	(18)	15
Prepaid expenses and other current assets	10	(88)	(463)
Accounts payable	337	289	210
Accrued expenses	7	80	(266)
Security deposits	(3)	(18)	17
Net cash used in operating activities	(5,853)	(6,990)	(8,074)

Cash flows from investing activities:			
Purchase of property and equipment .	(151)	(251)	(171)
Additions to patent and trademark rights .	(278)	(227)	(197)
Maturity of short term investments .	1,004	1,591	2,157
Purchase of short term investments .	(1,591)	(2,153)	(4,589)
Investments in unconsolidated affiliates	(1,038)	(375)	(411)
Other investments.	-	-	(34)
Net cash used in investing activities . .	$(2,054)	$(1,415)	$(3,245)

</TABLE>

(CONTINUED)

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

<TABLE>
<CAPTION>

	December 31,		
	1998	1999	2000
		(RESTATED)	
<S>	<C>	<C>	<C>
Cash flows from financing activities:			
Proceeds from stock subscriptions and issuance of common stock, net. . . .	2,234	1,969	2,250
Repayment of stock guarantee	(80)	-	-
Proceeds from exercise of stock warrants	8,812	1,923	9,985
Purchase of treasury stock	-	(1,966)	(3,591)
Sale of treasury stock	-	948	-
Purchase of public warrants.	-	(98)	-
Net cash provided by financing activities.	10,966	2,776	8,644
Net increase (decrease) in cash and cash equivalents.	3,059	(5,629)	(2,675)
Cash and cash equivalents at beginning of year. . . .	8,966	12,025	6,396
Cash and cash equivalents at end of year . .	$ 12,025	$ 6,396	$ 3,721
Supplemental disclosures of cash flow information:			
Issuance of treasury stock for Investment	$ -	$ -	$ 618
Issuance of common stock for accrued expenses.	$ -	$ 126	$ 34

</TABLE>

See accompanying notes to consolidated financial statements.

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

(1) Restatement of Financial Statements

The Company is restating its financial statements as of and for the year ended December 31, 1999, and for the first quarter of 1999. The restated financial statements now reflect a non-cash charge for the extension of the lives of

certain Section 701 warrants on February 19, 1999, as described in note 7 to the consolidated financial statements.

The effect of the restatement on the accompanying consolidated financial statements from amounts previously reported in 1999 Annual Report on Form 10-K are summarized as follows:

	(OOO's omitted)		
	As Filed	Adjustment	As Restated
Revenue	$678	-	$678
Research and development	4,737	-	4,737
General and administrative	5,624	3,097	8,721
Total costs	10,361	3,097	13,458
Net loss	$(9,201)	3,097	$(12,298)
Basic and diluted loss per share	$(.35)		$(.47)
Weighted average outstanding shares	26,380,351		26,380,351

The restatement did not effect the December 31, 1999 reported assets and liabilities. The effect on stockholders' equity is shown below.

Preferred Stock	-	-	-
Common Stock	28		28
Additional Paid-in Capital	84,875	3,097	87,972
Deferred Compensation	(310)	-	(310)
Accumulated Other Comprehensive Income	-	-	-
Accumulated Deficit	(70,917)	(3,097)	(74,014)
Treasury Stock	(1,019)	-	(1,019)
Total Stockholders' Equity	$12,657		$12,657

(2) 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 , is in human clinical development for various therapeutic indications. The potential efficacy and safety of Ampligen is being evaluated clinically for three anti-viral indications: myalgic encephalomyelitis, also known as chronic fatigue syndrome ("ME/CFS"), human immunodeficiency virus (HIV) associated disorders, and chronic hepatitis C (HVC) virus infection. The Company also has clinical experience

with Ampligen in patients with certain cancers including renal cell carcinoma (kidney cancer) and metastatic malignant melanoma. The Company has other compounds to be evaluated.

The consolidated financial statements include the financial statements of Hemispherx BioPharma, Inc. and its wholly-owned subsidiaries BioPro Corp., BioAegean Corp. and Core BioTech Corp. which were incorporated in September 1994, and are inactive, and Hemispherx Biopharma-Europe N.V./S.A. which was incorporated in August 1998. All significant intercompany balances and transactions have been eliminated in consolidation. The Company also has investments in unconsolidated affiliates which are accounted for on the equity or cost method of accounting (see note 3d).

On May 1, 1997, the Company received permission from the U.S. Food and Drug Administration ("FDA") to recover costs from ME/CFS patients in the Company's AMP-511 open-label treatment protocol. The cost of Ampligen to the patient is $2,100 for the first eight weeks of treatment and $2,400 for each additional eight-week period thereafter. Approximately 100 ME/CFS patients have been treated under this protocol at various clinical centers in the U.S as

of February 13, 2001.

In 1998, the Company initiated the recruitment of clinical investigators to enroll ME/CFS patients in the confirmatory Phase III placebo-controlled clinical study of Ampligen in the treatment of patients severely suffering from ME/CFS. The Company is presently enrolling patients in this study. This clinical trial was approved by the FDA in 1998 and is designed to test the safety and efficiency of Ampligen in treating ME/CFS.

The ME/CFS Cost Recovery Treatment Program in Belgium was started in 1994 with the approval of the Belgian Regulatory authorities. Since its inception, over 100 patients have enrolled 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. This program is being extended to several other affiliated hospitals in the Brussels area and clinical experts in this disease category have been identified in other European countries to establish similar clinical research/treatment centers for ME/CFS. A similar program in Austria is undergoing expansion.

(3) Summary of Significant Accounting Policies

(a) Reclassification

Prior years amounts have been reclassified to conform to current year presentation.

(b) 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 $6,396,000 and $2,895,000 at December 31, 1999 and 2000, respectively.

(c) 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 with unrealized gains and losses recorded as a component of shareholders' equity.

(d) Investments in unconsolidated affiliates

In 1998, the Company acquired 3.3% of the issued and outstanding common stock of R.E.D. Laboratories at a cost of $1,074,000. R.E.D. Laboratories is developing a diagnostic test for the ME/CFS disease. This investment is accounted for under the cost method of accounting.

In 1999, the Company acquired 15% of the stock of the California Institute of Molecular Medicine ("CIMM") for $375,000. During 2000, the Company acquired an additional 15% of the stock of CIMM for $375,000. CIMM is conducting research toward a treatment for Hepatitis C virus. This investment is accounted forunder the equity method of accounting beginning in 2000 because the Company's ownership increased beyond the 20% threshold. The Company's net investment of $669,000 at December 31, 2000 includes unamortized goodwill of approximately $521,000. The goodwill is being amortized over its estimated usefull life of 15 years.

The Company's investment in Ribotech, Ltd. is also accounted for using the equity method of accounting. The Company received 24.9% of Ribotech, Ltd. as partial compensation under the license agreement described in note 12. Ribotech, Ltd. has incurred net losses since inception. The Company does not share in those losses in accordance with the licensing agreement and is not obligated to fund such losses. The net investment in Ribotech is zero as of December 31, 1999 and 2000. 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 is recorded in prepaid and other current assets in the accompanying balance sheet at December 31, 2000.

Investments in unconsolidated affiliates also includes an equity investment in Chronix Biomedical ("Chronix"). Chronix focuses upon the development of

diagnostics for chronic diseases. The initial investment was made in May 31, 2000 through the issuance of 50,000 shares of Hemispherx Biopharma, Inc. common stock from the treasury. On October 12, 2000 an additional 50,000 shares of common stock were issued from the treasury for a total investment of approximately $678,000. The percentage ownership in Chronix is approximately 5.4% and is accounted for under the cost method of accounting.

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.

(e) Property and Equipment

	(000 omitted) December 31, 1999	2000
Furniture, fixtures, and equipment	$ 1,018	$ 1,178
Leasehold improvements	85	96
Total property and equipment	1,103	1,274
Less accumulated depreciation	770	901
Property and equipment, net	$ 333	$ 373

Property and equipment consist of furniture, fixtures, office equipment, and leasehold improvements 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 expense was $39,000, $99,000 and $131,000 for 1998, 1999 and 2000, respectively.

(f) Patent and Trademark Rights

Patents and trademarks are stated at cost (primarily legal fees) and are amortized using the straight line method over the life of the assets, generally 10 years. The Company reviews its patents and trademark rights periodically to determine whether they have continuing value. Such review includes an analysis of the patent and trademark's ultimate revenue and profitability potential on an undiscounted cash flow basis to support the realizability of its respective capitalized cost. In addition, management's review addresses whether each patent continues to fit into the Company's strategic business plans. During the years ended December 31, 1998, 1999 and 2000, the Company decided not to pursue the technology in certain countries for strategic reasons and wrote down $120,000, $59,000 and $32,000, respectively of these patents to research and development. Amortization expense was $190,000, $161,000 and $324,000 in 1998, 1999 and 2000, respectively. Accumulated amortization as of December 31, 1999 and 2000 is $1,377,000 and $1,699,000, respectively.

(g) Revenue

Revenue is recognized immediately for nonrefundable license fees, if any, when agreement terms require no additional performance with respect to such on the part of the Company.

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

(h) 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 consist of stock options and warrants, using the treasury stock method, and are excluded from a calculation of diluted net loss per share since their effect is antidilutive.

(i) 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.

(j) Comprehensive Income

On January 1, 1998, the Company adopted SFAS No. 130, Reporting Comprehensive Income. SFAS No. 130 establishes standards for reporting and presentation of the Company's comprehensive loss and its components in a full set of financial statements. Comprehensive loss consists of net loss and net unrealized gains (losses) on securities and is presented in the consolidated statements of changes in stockholder's equity and comprehensive loss.

(k) 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.

(l) 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.

(m) Recent Accounting Standard and Pronouncements:

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities."SFAS No.133" requires companies to recognize all derivative contracts at their fair values, as either assets or liabilities on the balance sheet. If certain conditions are met, a derivative may be specifically designated as a hedge, the objective of which is to match the timing of gain or loss recognition on the hedging derivative with the recognition of (1) the changes in the fair value of the

hedged asset or liability that are attributable to the hedged risk, or (2) the earnings effect of the hedged forecasted transaction. For a derivative not designated as a hedging instrument, the gain or loss is recognized in income in the period of change. SFAS No. 133, as amended by SFAS No. 137, is effective for all fiscal years beginning after January 1, 2001. Historically, the Company has not entered into derivative contracts either to hedge existing risks or for speculative purpose. Accordingly, the Company does not expect adoption of the new standard to affect its financial statements.

In March 2000, the FASB issued Interpretation No. 44 ("FIN 44"),"Accounting for Certain Transactions Involving Stock Compensation, an interpretation of Accounting Principle Board ("APB") Opinion No. 25."FIN 44" clarifies the application of APB No. 25 for (a) the definition of employee for purposes of applying APB 25, (b) the criteria for determining whether a plan qualifies as a noncompensatory plan, (c) the accounting consequences of various modifications

to the previously fixed stock option or award, and (d) the accounting for an exchange of stock compensation awards in a business combination. FIN 44 became effective July 1, 2000 but certain conclusions cover specific events that occur after either December 15, 1998 or January 12, 2000. The Company adopted FIN 44 in fiscal 2000 and it did not have a material effect on the Company's financial statements.

In December 1999, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 101 which summarizes certain of the SEC staff's views in applying generally accepted accounting principles to revenue recognition in financial statements. The Staff Accounting bulletin is effective for 2000. The initial adoption of this guidance did not have a material impact on the Company's results of operations or financial position.

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(4) Short-term investments:

Securities classified as available for sale are summarized below.

	(000's omitted) December 31, 1999			
		Unrealized		
	Adjusted Cost	Gains	(Losses)	Carrying Value
Federal Home Loan Bank Note	$ 681	-	-	$ 681
General Electric Note	980	-	-	980
CPML & Co. Note	492	-	-	492
Total	$ 2,153	-	-	$ 2,153

	December 31, 2000			
		Unrealized		
	Adjusted cost	Gains	(Losses)	Carrying Value
Federal Home Loan Bank Note	$ 970	$ 20	$ -	$ 990
Federal Home Loan Bank Notes	1,309	25	-	1,334
Calamos Mutual Market	51	-	(1)	50
General Electric Commercial Paper	2,259	-	-	2,259
Daxor Corp.	34	-	(10)	24
Total	$ 4,623	45	(11)	$ 4,657

(5) Stock-Based Compensation

In 1998, the Company granted 1,113,000 warrants to employees in recognition of services performed and services to be performed. For purposes of pro forma disclosure under FAS 123 the fair value of the stock purchase warrants granted during the year was determined using a rate of 6.14%, volatility of 45.67%-73.31%, and expected lives of 2-5 years. In 1999, the Company granted 275,000 warrants to employees in recognition of services performed and services to be performed. The fair value of the stock purchase warrants granted during 1999 was also determined using the Black-Scholes option pricing model with a rate of 5.81%, volatility of 135.4% - 294.31%, and expected life of 2 years. These warrants are included in the 2,633,000 non-public warrants outstanding as of December 31, 2000 as described in footnote 6(ii). There were no warrants granted to employees during 2000. The Company granted to employees 8,000 options in 2000. See footnote 7(i).

The Company applies the intrinsic value method in accordance APB Opinion No. 25, "Accounting for Stock Issued to Employees" in accounting for stock-based

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compensation of its employees and, accordingly, no compensation cost has been recognized for stock purchase warrants issued to employees. Had the Company determined compensation cost based on the fair value at the grant date for its stock-based compensation of its employees in accordance with FAS 123 the Company's net loss would have been increased to the pro forma amounts indicated below:

		(000's omitted)		
		1998	1999	2000
Net loss-	as reported	$(7,324)	$(12,298)	$ (8,552)
	Pro forma	(8,200)	(13,635)	(8,789)
Net loss per share-	as reported	$(.32)	$(.47)	$(.29)
	Pro forma	(.36)	(.52)	(.30)

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.

(6) Accrued Expenses

Accrued expenses at December 31, 1999 and 2000 consists of the following:

	(000's omitted) December 31,	
	1999	2000
Accrued Professional Fees.	182	-
Other Accrued expenses	238	154
	$ 420	$ 154

(7) 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, 1999 and 2000.

(b) Common Stock

The Company is authorized to issue 50,000,000 shares of $.001 par value Common Stock. As of December 31, 1999 and 2000, 27,806,572 and 29,972,242 shares, net of shares held in the treasury, were issued and outstanding, respectively.

(c) New Equity Financing

New equity financing in 1999 included the private placement of common stock for an aggregate of $4,219,000 in net proceeds, of which $2,250,000 was received in 2000. In addition, the exercise of stock warrants generated an additional $1,923,000 and $9,985,000 in net proceeds to the Company in 1999 and 2000, respectively.

(d) Common Stock Options and Warrants

(i) Stock Options

The 1990 Stock Option Plan provides for the grant of options to purchase up to 460,798 shares of the Company's Common Stock to employees, directors, and officers of the Company and to consultants, advisors, and other persons whose contributions are important to the success of the Company. The recipients of

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

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Information regarding the options approved by the Board of Directors under the 1990

Stock Option Plan is summarized below:

<TABLE>
<CAPTION>

	1998			1999			2000		
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price
<S>	<C>	<C>	<C>	<C>	<C>	<C>	<C>	<C>	<C>
Outstanding, beginning of year	291,256	$1.06-4.34	$3.35	294,609	$1.06-4.34	$3.56	294,000	$1.06-6.00	$3.60
Granted	20,000	$3.50-6.00	$3.50	-	-		8,000	$3.00-6.81	$4.88
Canceled	(4,482)	$3.50	$3.50	(609)	$3.50	$3.50	(76,677)	$3.50-4.34	$4.09
Exercised	(12,165)	$1.06-3.50	$2.93	-			(6,756)	$1.06-3.50	$2.75
Outstanding, end of year	294,609	$1.06-6.00	$3.56	294,000	$1.06-6.00	$3.60	218,567	$1.06-6.81	$ 3.45
Exercisable	229,523	$1.06-6.00	$3.48	250,915	$1.06-6.00	$3.55	198,717	$1.06-6.81	$ 3.48
Weighted average remaining contractual life (years)	3.81 years			3.81 years			3.83 years		
Exercised in current and prior years	(31,035)			(31,035)			(37,791)		
Available for future grants	135,154			135,763			204,440		

</TABLE>

In December 1992, the Board of Directors approved the 1992 Stock Option Plan (the 1992 Stock Option Plan) which provides for the grant of options to purchase up to 92,160 shares of the Company's Common Stock to employees, directors, and officers of the Company and to consultants, 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.

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.

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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 usedto purchase shares of Common Stock. The purchase price for such shares is equal to the lower of 85% of the fair market value of such shares on the date of grant or 85% of its fair market value of such shares on the date such right is exercised. There have been no offerings under the 1993 Purchase Plan to date and no shares of Common Stock have been issued thereunder.

(ii) Stock warrants

Number of warrants exercisable into shares of common stock

<TABLE>
<CAPTION>

	1998			1999			2000		
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price
<S>	<C>	<C>	<C>	<C>	<C>	<C>	<C>	<C>	<C>
Outstanding, beginning of year	15,630,934	$1.75 -10.85 $3.00	$3.57	14,999,910	$1.75 -10.85 $6.00	$3.71	14,058,010	$1.75 -10.85 $6.00	$3.90
Granted	1,838,000	-10.00	4.69	575,000	-10.00	7.00	293,800	-12.00 $2.00	6.40
Canceled							(341,017)	-10.85	6.01
Exercised	(2,469,024)	$1.75 -5.78	3.56	(1,516,900)	$1.75 -4.00	3.12	(2,386,625)	$1.75 -4.00	4.19
Outstanding, end of year	14,999,910	$1.75 -10.85	$3.71	14,058,010	$1.75 -10.85	$3.90	11,624,168	$1.75 -12.00	$4.05
Exercisable	14,999,910	$1.75 -10.85	$3.71	14,058,010	$1.75 -10.85	$3.90	11,624,168	$1.75 -12.00	$4.05
Weighted average remaining contractual life (years)	4.34 years			3.45 years			2.66 years		
Years exercisable	1999-2006			2000-2006			2001-2006		

</TABLE>

Warrants issued to stockholders

Certain of the stock warrants outstanding at December 31, 2000 are related to the issuance of stockholder notes payable. These warrants are subject to adjustments for stock splits and dividends. At December 31, 1998 and 1999 601,967 of these warrants were outstanding. In 2000, 149,807 warrants expired and 147,000 warrants were converted to common stock. At December 31, 2000, there were 305,160 warrants remaining. These warrants have an exercise price of $3.50 per share and expire in October 2004

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Other stock warrants

In addition, the Company has other issued warrants outstanding - totaling 11,319,008 which consists of the following:

In November 1994, the Company granted Rule 701 Warrants to purchase an aggregate of 2,080,000 shares of Common Stock to certain officers and directors. These Warrants are exercisable at $3.50 per share and, if not exercised, were to expire in September, 1999. On February 19, 1999 the Board of Directors extended the expiration date for three more years. This extension resulted in a non-cash charge of approximately $3,097,000, see note 1. 235,000 warrants were exercised in 1999 and 5,000 warrants were

exercised in 2000. At December 31, 2000, there were 1,840,000 Rule 701 warrants remaining.

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 1998, 592,000, in 1999, 290,000 and in 2000, 216,500 of these warrants were exercised, leaving a balance of these warrants of 1,651,500. These warrants expire June 30, 2005.

In June 1995, the Company entered into an agreement with The Sage Group whereby, in return for identifying certain distribution partners, The Sage Group received certain percentages of the proceeds from the first distribution agreement arising from such identification. The Company paid to The Sage Group a monthly retainer and provided warrants to purchase 100,000 shares of Common Stock at an exercise price of $1.75 share. In May, 1996, additional warrants to purchase 140,000 shares of Common Stock were issued at an exercise price of $3.50. 50,000 of these warrants were exercised in 1999. In May, 1997, additional warrants to purchase 250,000 shares of common stock were issued at an exercise price of $3.50, as part of the engagement contract. In 2000, 180,000 warrants were exercised and 191,210 warrants expired, leaving a balance of 68,790 which will expire May 15, 2001.

In connection with the IPO completed on November 7, 1995, the Company sold 6,313,000 units. Each unit consisted of one share of common stock and one Class A Redeemable Warrant exercisable at $4.00 per share. Warrant holders exercised 100 warrants during 1997, 664,090 during 1998, 168,500 in 1999, and 1,613,792 in 2000. 3,866,518 warrants were outstanding at December 31, 2000. These warrants will expire on November 2, 2001.

As part of the underwriting agreement, the underwriter received warrants to purchase 462,000 shares of common stock at $5.775 per share, these warrants were exercised in 1998. The underwriter also received 462,000 Class A Redeemable Warrants to purchase common stock at $6.60 per share. These warrants will expire on November 2, 2001.

In connection with the stock issued in September, 1997, the company issued 385,067 warrants to several entities to purchase common stock at $4 per share, 149,034 of these warrants were exercised in 1998, 173,300 were exercised in

1999, and 34,333 were exercised in 2000. The remaining 28,400 warrants will expire December 31, 2001.

In the years 1998, 1999, and 2000 the Company issued 350,000, 350,000 and 293,800 warrants, respectively, to investment banking firms for services performed on behalf of the Company. Accordingly, the company recorded stock compensation expense of $795,000, $1,521,000 and $397,000 for the years 1998, 1999 and 2000, respectively. These warrants have various vesting dates and exercise prices ranging from $4.00 to $10.00 per share. In 1999, 150,000 of these warrants were exercised, and 75,000 were exercised in 2000. 768,800 warrants were outstanding at December 31, 2000. These warrants are exercisable in five years from the date of issuance.

In 1998, 1999, and 2000 the Company had non-public warrants outstanding of 2,898,100, 2,748,000 and 2,633,000, respectively. These warrants are exercisable at rates of $2.50 to $10.00 per share of common stock. The exercise price was equal to the fair market value of the stock on the date of grant. Of the 2,633,000 outstanding warrants at December 31, 2000, 421,000 warrants were granted to employees for services performed. These warrants granted to employees, with a weighted average exercise price of $7.14 per share, have been included in the pro-forma loss calculation in note 5.

(8) Registration Statements

The Company filed a Registration Statement with the SEC which became effective as of October 1, 1999. This filing registered 2,125,000 warrants to purchase common stock as well as 304,165 shares of common stock to be used by the Company

for various business matters. If the warrantholders exercised all warrants, the Company expects to realize approximately $ 6,900,000 in proceeds.

On October 18, 2000 the Company filed a Registration Statement with the SEC which became effective on that date. This filing registered 755,000 warrants to purchase the related underlying shares of common stock.

In addition, the Company registered 500,000 shares of common stock to be used for general corporate purposes.

(9) Segment and Related Information

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

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

	(000's omitted)		
	1998	1999	2000
United States	$195	$391	$506
Belgium	179	259	272
Other	27	28	10
	$401	$678	$ 788

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

(10) Research, Consulting and Supply Agreements

The Company has entered into various clinical research agreements for the purpose of undertaking clinical evaluations of the safety and efficacy of Ampligen . The Company's obligation under these agreements is primarily dependent on the number of actual patients enrolled in the study and may be terminated without penalty at any time. During the year ended December 31, 1998, the Company incurred approximately $179,000 of research fees under an agreement with Hahnemann Medical University in Philadelphia. Such costs were expensed as incurred. No such costs were incurred in 1999 or 2000.

In December, 1999, the Company entered into an agreement with Biovail Corporation International ("Biovail"). Biovail is an international full service pharmaceutical company engaged in the formulation, clinical testing, registration and manufacture of drug products utilizing advanced drug delivery systems. Biovail is headquartered in Toronto, Canada. The agreement grants Biovail the exclusive distributorship of the Company's product in the Canadian territories subject to certain terms and conditions. In return, Biovail agrees to conduct certain pre-marketing clinical studies and market development programs, including without limitation, expansion of the Emergency Drug Release Program in Canada with respect to the Company's products. Biovail agrees to work with the Company in preparing and filing of a New Drug Submission with Canadian Regulatory Authorities. Biovail invested $2.250 million in Hemispherx equity at prices above the then current market price and agreed to make further payments based on reaching certain regulatory milestones. The Agreement requires Biovail to penetrate certain market segments at specific rates in order to maintain market exclusivity.

The Company has entered into agreements for consulting services which are performed at medical research institutions and by medical and clinical research individuals. The Company's obligation to fund these agreements can be terminated after the initial funding period, which generally ranges from one to three

years or on an as-needed monthly basis. During the years ending December 31, 1998, 1999 and 2000, the Company incurred approximately $269,000, $664,000 and $924,000, 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 1998, 1999, and 2000, the Company provided matching contributions to each employee for up to 6% of annual pay aggregating $37,000, $47,000 and $48,000, 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 , 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 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 judgement 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 judgement 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 funding for research and development of the patents and technology licensed to the Company.

The Company had contractual agreements with three of its officers. The contract with one of the officers was terminated in 1999 and a buy-out amount of $143,000 was paid to this officer. The aggregate annual base compensation under these contractual agreements for 1998, 1999, 2000 is $623,000, $815,000 and $682,000, respectively. The 1999 amount includes the buy-out amount of $143,000 for the terminated contract. 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 1998, a performance bonus of $90,397 was granted to one officer. In 1999 and 2000 no performance bonuses were granted. Pursuant to the employment agreements, certain officers were granted Rule 701 Warrants to purchase 2,080,000 shares of Common Stock at $3.50 per share, see note 1. One of the employment agreements provides for bonuses based on gross proceeds received by the Company from any joint venture or corporate partnering agreement.

In October 1994, the Company entered into a licensing agreement with Bioclones (Propriety) Limited (SAB/Bioclones) with respect to co-development of various

RNA drugs, including Ampligen , 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 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 , excluding SAB/Bioclones related sales. In addition, SAB/Bioclones will have the right of first refusal for oral vaccines in the licensed territory. In the years ending 1998, 1999 and 2000 the Company paid to Ribotech a total of $282,000, $156,000 and $500,000, respectively, for the current and future purchase and delivery of polymers. Of the $500,000 advanced in 2000 a balance of $390,000 is included in other assets and will be used for future purchases 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.

In December, 1995, the Company retained the law firm of Akin, Gump, Strauss, Hauer & Feld, L.L.P. (Akin-Gump) to provide general legal counsel, advise and representation with respect to various United States regulatory agencies, primarily the Food and Drug Administration (FDA). This agreement expired in August, 1997. In September, 1997, the Company acknowledged a

contingent liability of $147,000 to Akin-Gump for certain fees billed and not covered by the agreement. These fees are due Akin-Gump if and only if the Company achieves regulatory approval of Ampligen in the future.

(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
2001	$ 299
2002	289
2003	279
2004	286
2005	240
2006 and later	258
Total minimum lease payments	$ 1,651

Rent expense charged to operations for the years ended December 31, 1998, 1999 and 2000 amounted to approximately $308,000, $341,000 and $347,000 respectively. The term of the lease for the Rockville, Maryland facility is through June, 2005 with an average rent of $8,000 per month, plus applicable taxes and charges. The term of the lease for the Philadelphia, Pennsylvania offices is through April, 2007 with an average rent of $15,000 per month, plus applicable taxes and charges.

(14) Income Taxes

As of December 31, 2000, the Company has approximately $57,000,000 of federal net operating loss carryforwards (expiring in the years 2003 through 2020) available to offset future federal taxable income. The Company also has approximately $8,000,000 of state net operating loss carryforwards (expiring in the years 2006 through 2010) available to offset future state taxable income. The utilization of certain state net operating loss carryforwards may be subject to annual limitations.

Under the Tax Reform Act of 1986, the utilization of a corporation's net operating loss carryforward is limited following a greater than 50% change in ownership. Due to the Company's prior and current equity transactions, the 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.

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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 ultimate goal realization of deferred tax assets is dependent uponthe 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, 1999 and 2000.

The components of the net deferred tax asset of December 31, 1999 and 2000 consists of the following:

(000,s omitted)

Deferred tax assets:	1999	2000
Net Operating Losses	$18,608	$19,520
Accrued Expenses and Other	41	86
Capitalized Research and Development Costs	3,722	4,837
	22,371	24,443
Less: Valuation Allowance	22,371	24,443
Balance	$ 0	$ 0

(15) Contingencies

In September, 1998, the Company filed a multi-count complaint against Manuel P. Asensio, Asensio & Company, Inc., and others in the United States District Court for the Eastern District of Pennsylvania. In October 1998, and August 1999, the Company amended the complaint to add additional counts and to add Asensio.com, Inc. (formerly known as Asensio Holdings, Inc.), the holding company of defendant Asensio Company Inc. The action presently includes claims of defamation, disparagement, tortious interference with existing and prospective business relations and conspiracy, arising out of the current defendants' false and defamatory statements. The complaint further alleges that defendants defamed and disparaged the Company in furtherance of a manipulative, deceptive and unlawful short-selling scheme between August 1998, and the present.

On April 19, 1999, Manuel P. Asensio Asensio & Company, Inc.,and others filed an answer and counterclaim against the Company. The counterclaim alleges that on or about September, 1998, and in response to defendants' strong sell recommendation and other press releases about the Company and its officers

and directors, the Company made defamatory statements about defendants, including statements that defendants' attacks and manipulative short-selling scheme may have constituted criminal wrongdoing on the part of defendants. The Company has denied the material allegations of the counterclaim and is vigorously defending against the counterclaim. The action is presently listed for trial in August 2001.

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On May 30, 2000, the Company received notice of a claim by Manuel P. Asensio and Asensio & Company, Inc.,in the Supreme Court of the State of New York against the Company, the Chairman, and Chief Executive Officer, William A. Carter, and the Company's predecessor auditor, (the "first New York Action") in which they allege that defendants defamed them in oral and written communications made in March 2000. The allegations of Manuel P. Asensio and Asensio & Company, Inc., in the first New York Action are similar in substance to the alleged defamations which are the subject of the counterclaims filed by them in the action presently pending in Pennsylvania state court.

On June 26, 2000, Manuel P. Asensio, Asensio & Company, Inc. and Asensio.com Inc., filed a second action against the Company its Chairman and Chief Executive Officer in the Supreme Court of the State of New York. (the "second New York Action"). On September 25, 2000, the Company was served with a complaint in this action. The second New York Action purports to seek a declaratory judgment that Asensio's statements regarding the Company constituted protected speech, and that they did not engage in any actionable interference with our existing or prospective business relations. We intend to vigorously defend against the claims asserted in both the First and Second New York Actions.

These litigations could subject the Company to significant liability for damage and, could be time-consuming and expensive to pursue, and could result in the diversion of management time and attention.

In October, 1998, the Company contacted the Securities and Exchange Commission ("SEC") regarding what it believed may have been illegal short selling and unlawful market manipulation in furtherance of the short selling of Manuel P. Asensio and others. Thereafter, in July, 1999, the Company was advised by the SEC of a private investigation authorized by the SEC on April 1, 1999 into various allegations of misrepresentations by the Company and its officers. In general, the SEC sought information relating to allegations about the Company's investigational drug application for treatment of various diseases, results of clinical research, incidence of ME/CFS in the United States, the Company's patents, and Ampligen's safety and efficacy. These allegations had also been included by Asensio & Co. in its various "research reports" which the Company considers defamatory and for which the Company has sued Asensio and his company. In October 2000, the SEC brought forth certain specific concerns with respect to certain alleged omissions in the Company's public statements to which the Company replied in November. The Company has had no further contact with the SEC on this matter.

On March 6, 2000, Cook Imaging Corp. et. al, filed a complaint against us in the United States District Court for the Eastern District of Pennsylvania. Cook Imaging Corp. asserts that the Company refused to pay for certain Ampligen manufacturing efforts by Cook. The Company has responded to the complaint and asserted a counterclaim seeking damages in excess of the claim by Cook. The Company maintains that Cook Imaging Corp. did not perform as required by the contract under Good Maintenance Practices ("GMP") conditions. On December 22, 2000, the Court denied plaintiff's motion for summary judgement and trial is presently scheduled for late April 2001.

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The Company is unable to form an opinion as to the ultimate outcomes of the preceding suits and SEC investigation and is unable to estimate the potential impact, if any, on its financial condition , results of operations or liquidity.

The Company is subject to claims and legal actions that arise in the ordinary course of their business. Management believes that the ultimate liability, if any,with respect to these claims and legal actions will not have a material effect onthe financial position or results of operations of the Company.

(16) Related Party Transactions

Certain directors performed professional services for the Company for which they were compensated over the amount paid for directors' fees. An officer of the Company received an aggregate of $65,000 in short term advances, of which the outstanding balance was repaid as of March 2, 2001. All advances bear interest at 6% per annum.

(17) Stock Repurchase

On February 19, 1999, the Board of Directors authorized the repurchase of up to 200,000 shares of the Company's common stock on the open market. The repurchased shares will eventually be used for acquisitions or other purposes. On February 8, 2000, the Board authorized the repurchase of another 200,000 shares.

The Company's repurchases of shares of common stock are recorded as "Treasury Stock" and result in a reduction of "Stockholders' equity." When treasury shares are reissued, the Company uses a first-in, first-out method and the excess of repurchase cost over reissuance price is treated as a reduction of "Additional paid-in capital."

(18) Concentrations of credit risk

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

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First quarter 1999 was restated to reflect the $3.1 million non-cash charge as noted in note 1.

(19) Quarterly Results of Operation (unaudited)

(000's omitted)

	1999				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
	(RESTATED)				
Revenues	$ 132	$ 155	$ 168	$ 223	$ 678
Costs and expenses	6,276	2,817	2,165	2,200	13,458
Net loss	$(5,997)	$(2,554)	$(1,879)	$(1,868)	$(12,298)
Basic and diluted loss per share	$(.28)	$(.10)	$(.07)	$(.07)	$(.47)

	2000				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Revenues	$ 210	$ 215	$ 225	$ 138	$ 788
Costs and expenses	2,334	2,409	2,413	2,675	9,831
Net loss	(1,972)	(2,059)	(2,066)	(2,455)	(8,552)
Basic and diluted loss per share	$(.07)	$(.07)	$(.07)	$(.08)	$(.29)

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