HEMISPHERX BIOPHARMA INC
Form 10-K
March 12, 2010

FORM 10-K
SECURITIES AND EXCHANGE COMMISSION
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2009
OR
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission File No. 1-13441

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

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

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

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

Common Stock, $.001 par value

Securities registered pursuant to Section 12(g) of the Act:
(Title of Each Class)
NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No x

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one): o Large accelerated filer x Accelerated filer o Non-accelerated filer o Smaller Reporting Company o

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

The aggregate market value of Common Stock held by non-affiliates at June 30, 2009, the last business day of the registrant's most recently completed second fiscal quarter was $299,465,873.

The number of shares of the registrant's Common Stock outstanding as of March 1, 2010 was 132,840,970.

DOCUMENTS INCORPORATED BY REFERENCE: Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2010 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K (the "Form 10-K"), including statements under "Item 1. Business," "Item 1A. Risk Factors," "Item 3. Legal Proceedings" and "Item 6. Management's Discussion and Analysis of Financial Condition and Result of Operations," constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995 (collectively, the "Reform Act"). Certain, but not necessarily all, of such forward-looking statements can be identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should," or "anticipates" or the negative thereof or other varia thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. All statements other than statements of historical fact included in this Form 10-K regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note that statements regarding potential drugs, their potential therapeutic effect, the possibility of obtaining regulatory approval, our ability to manufacture and sell any products, market acceptance or our ability to earn a profit from sales or licenses of any drugs or our ability to discover new drugs in the future are all forward-looking in nature.

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

PART I

ITEM 1. Business.

GENERAL

We are a specialty pharmaceutical company based in Philadelphia, Pennsylvania and engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. We were founded in the early 1970s doing contract research for the National Institutes of Health. Since that time, we have established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of natural interferon and nucleic acids to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of certain chronic diseases. We have three domestic subsidiaries BioPro Corp., BioAegean Corp., and Core BioTech Corp., all of which are incorporated in Delaware and are dormant. Our foreign subsidiary is Hemispherx Biopharma Europe N.V./S.A. established in Belgium in 1998, which has no activity. All significant intercompany balances and transactions have been eliminated in consolidation.

Our current strategic focus is derived from four applications of our two core pharmaceutical technology platforms Ampligen® and Alferon N Injection®. The commercial focus for Ampligen® includes application as a treatment for Chronic Fatigue Syndrome ("CFS") and as an influenza vaccine enhancer (adjuvant) for both therapeutic and preventative vaccine development. Alferon N Injection® is a Food and Drug Administration ("FDA") approved product with an indication for refractory or recurring genital warts. Alferon® LDO (Low Dose Oral) is a formulation currently under development targeting influenza.

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ that was primarily designed to produce Alferon®. On September 16, 2009, our Board of Directors approved up to $4.4 million for full engineering studies, capital improvements, system upgrades and introduction of building management systems to enhance production of three products: Alferon N Injection®, Alferon® LDO and Ampligen®. (Please see "Manufacturing" in Item 1. Business for more information.)

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

AVAILABLE INFORMATION

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

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

OUR PRODUCTS

Our primary pharmaceutical product platform consists of our experimental compound, Ampligen®, our FDA approved natural interferon product, Alferon N Injection® and Alferon® LDO (low dose oral), our experimental liquid natural interferon for oral administration.

Ampligen®

Ampligen® is an experimental drug currently undergoing clinical development for the treatment of Myalgic Encephalomyelitis / Chronic Fatigue Syndrome ("ME/CFS"). Over its developmental history, Ampligen® has received various designations, including Orphan Drug Product Designation (FDA), Treatment IND (e.g., treatment investigational new drugs, or "Emergency" or "Compassionate" use authorization) with Cost Recovery Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports ("AHRQ" or Agency for Healthcare Research and Quality). Ampligen® represents the first drug in the class of large (macromolecular) RNA (nucleic acid) molecules to apply for New Drug Application ("NDA") review. Based on the results of published, peer reviewed pre-clinical studies and clinical trials, we believe that Ampligen® may have broad-spectrum anti-viral and anti-cancer properties. Over 1,000 patients have participated in the Ampligen® clinical trials representing the administration of more than 90,000 doses of this drug.

Nucleic acid compounds represent a potential new class of pharmaceutical products that are designed to act at the molecular level for treatment of human diseases. There are two forms of nucleic acids, DNA and RNA. DNA is a group of naturally occurring molecules found in chromosomes, the cell's genetic machinery. RNA is a group of naturally occurring informational molecules which orchestrate a cell's behavior which, in turn, regulates the action of groups of cells, including the cells which compromise 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

viruses and tumors. Our drug technology utilizes specifically-configured RNA. Our double-stranded RNA drug product, trademarked Ampligen®, an experimental, unapproved drug, is administered intravenously.

Clinical trials of Ampligen® already conducted by us include studies of the potential treatment of ME/CFS, Hepatitis B, HIV and cancer patients with renal cell carcinoma and malignant melanoma. All of these potential uses will require additional clinical trials to generate the safety and effectiveness data necessary to support regulatory approval.

On July 7, 2008, the FDA accepted for review our NDA for Ampligen® to treat CFS, originally submitted in October 2007. We are seeking marketing approval for the first-ever treatment for CFS. At present, only supportive, symptom-based care is available for CFS patients. The NDA for Ampligen®, whose chemical designation is Poly I: Poly C12U, is also the first ever accepted for review by the FDA for systemic use of a toll-like receptor therapy to treat any condition. On February 11, 2009, we were notified by the FDA that the originally scheduled Prescription Drug User Fee Act ("PDUFA") date of February 25, 2009 has been extended to May 25, 2009. On May 22, 2009, we were notified by the FDA that it may require additional time to take action beyond the scheduled PDUFA action date of May 25, 2009. Between March 9, 2009 and September 15, 2009, we issued six new reports to the FDA spanning various subjects including clinical safety assessments, specialized pre-clinical toxicology reports and abbreviated chemistry and manufacturing control reports.

On November 25, 2009, we received a Complete Response Letter ("CRL") from the FDA which described specific additional recommendations related to the Ampligen® NDA. In accordance with its 2008 Complete Response procedure, the FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues.

We are carefully reviewing the CRL and will seek a meeting with the FDA to discuss its recommendations upon the compilation of necessary data to be used in our response. We intend to take the appropriate steps to seek approval and commercialization of Ampligen®. Most notably, the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen® and recommended at least one additional clinical study which shows convincing effect and confirms safety in the target population. The FDA indicated that the additional study should be of sufficient size and sufficient duration (six months) and include appropriate monitoring to rule out the generation of autoimmune disease. In addition, patients in the study should be on more than one dose regimen, including at least 300 patients on dose regimens intended for marketing. We are presently planning a confirmatory clinical study which will utilize the same primary endpoints as our earlier studies but with an enlarged number of subjects to potentially achieve a more representative statistical model. Lastly, additional data including a well-controlled QT interval study (i.e., a measurement of time between the start of the Q wave and the end of the T wave in the heart's electrical cycle) and pharmacokinetic evaluations of dual dosage regiments were requested. Other items required by the FDA include certain aspects of Non-Clinical safety assessment and Product Quality. In the Non-Clinical area, the FDA recommended among other things that we complete rodent carcinogenicity studies in two species. As part of the NDA submission, we had requested that these studies be waived, but the waiver has not been granted as of March 1, 2010.

On January 14, 2010, we submitted reports of new preclinical data regarding Ampligen® to the FDA that we believe should be sufficient to address certain preclinical issues in the FDA's CRL. The preclinical studies discussed in these reports were the combined work-product of the staffs at Hemispherx and our subcontractor, Lovelace Respiratory Research Institute ("LRRI"), Albuquerque, New Mexico, regarding pharmacokinetic analyses in two lower animal species (primate and rodent). The new preclinical data showed no evidence of antibodies against Ampligen® in primates nor evidence of an increase in certain undesirable cytokines (specific modulators of the immune system) at clinically used doses of Ampligen® for CFS. Although most other experimental immunomodulators have been associated with one or more features of aberrant immune activity, including toll-like receptor activators (of which Ampligen® is one), this was specifically not seen with Ampligen® in primates.

Under the Product Quality section of the CRL, the FDA recommended that we submit additional data and complete various analytical procedures. The collection of these data and the completion of these procedures is already part of our ongoing Quality Control, Quality Assurance program for Ampligen® manufacturing under cGMP ("current Good Manufacturing Practice") guidelines and our manufacturing enhancement program.

The FDA also commented on Ampligen® manufacturing noting the need to resolve outstanding inspection issues at the facilities producing Ampligen®. These include our facility located in New Brunswick, NJ and one of our third-party subcontractor manufacturing facilities, Hollister-Stier Laboratories of Spokane, Washington ("Hollister-Stier"). On December 11, 2009 via Hollister-Stier, we submitted comprehensive new data, from the combined work-product of both staffs, to the District Office ("DO") of the FDA in Seattle, WA which we believed demonstrated that certain manufacturing issues noted in the pre-approval inspections at the facility had been fully addressed. On February 2, 2010, Hollister-Stier received a favorable response from the FDA's Seattle DO in which they noted that certain manufacturing issues noted in the pre-approval inspection at this facility had been fully addressed and made a recommendation to the FDA's Center for Drug Evaluation and Research ("CDER") for approval of our subcontractor as a manufacturing site under the Ampligen® NDA. The DO recommendations are not binding on the FDA and pertain only to the specific manufacturing issues cited in the Ampligen® manufacturing response and to the subcontractor site.

We are also engaged in ongoing, experimental studies assessing the efficacy of Ampligen® against influenza viruses. The status of our initiative for Ampligen® as an adjuvant for preventative vaccine development includes the pre-clinical studies in seasonal and pandemic influenza for intranasal administration being conducted by Japan's National Institute for Infectious Diseases ("NIID"). A three year program targeting regulatory approval for pandemic flu and seasonal flu in Japan has been funded by the Japanese Ministry of Health with the NIID and Biken (operational arm of the non-profit Foundation for Microbial Disease of Osaka University) in which Ampligen® is used as a mucosal adjuvant with vaccine. Our arrangement with Biken is part of a process to develop an effective nasal administered vaccine for Japan utilizing the resources of the NIID, varied vaccines and Hemispherx supplied Ampligen®.

A phase II study for intramuscular administration of Ampligen® for seasonal flu was conducted in Australia through St. Vincent's Hospital. We have attempted in good faith to obtain the clinical data and retrieve the study samples from St. Vincent's recently restructured Clinical Trials Centre. As a prerequisite of payment, we requested the confirmation that samples were properly maintained utilizing current Good Clinical Practice ("cGCP") and Good Laboratory Practice ("cGLP") for the controlled environment as per our agreement. On February 5, 2010, our Counsel advised them in correspondence that, due to the failure to meet the condition precedent to payment, we had no choice but to declare them in breach of the agreement and our intention to terminate the relationship between parties. Due to the termination of this agreement, we are not able to test the samples taken for this study for efficacy (i.e., the capacity for beneficial change or therapeutic effect from a given treatment).

4

A study was published in the December 20, 2009 issue of "Virology" by a consortium of researchers at Utah State University and the University of North Carolina, regarding a newly developed animal model of Severe Acute Respiratory Disease Syndrome ("SARS") which, according to the authors, "…largely mimicked human disease". SARS emerged in 2002 in the Guangdong province of Southern China as a new infectious respiratory disease characterized by influenza-like symptoms with a very high mortality rate. The researchers characterized and adapted a new strain of the SARS virus (SARS-CoV) to mice that was 100% lethal and was associated with the overproduction of cytokines and severe lung pathology (Day CW, et al. Virology, 395:210-222, 2009). Multiple agents with purported antiviral activity were evaluated for activity in this unique mouse model of the human disease, including Ampligen®. The researchers found that, unique among the agents tested, Ampligen®, "…protected against death and gross damage to the lungs in the presence of lethal SARS-CoV" and was associated with a reduction in IL-6 concentration in which high levels of the cytokine correlated with the mortality of SARS-CoV infection. Mortality was high, under the conditions tested, for all the other antiviral agents examined that have previously been used extensively in humans with SARS without definitive evidence of efficacy (Stockman LJ, et al. PLoS Med 3 (9),e 343). To date, there are no approved agents for treating SARS. Animal experiments do not necessarily predict safety or efficacy in man. Encouraged by these results, we are now in preliminary discussions with Chinese clinical research organizations in an attempt to initiate clinical antiviral programs in China.

Alferon N Injection®

Alferon N Injection® is the registered trademark for our injectable formulation of natural alpha interferon, which is approved by the FDA for the treatment of certain categories of genital warts. Alferon® is the only natural-source, multi-species alpha interferon currently approved for sale in the U.S.

Interferons are a group of proteins produced and secreted by cells to combat diseases. Researchers have identified four major classes of human interferon: alpha, beta, gamma and omega. Alferon N Injection® contains a multi-species form of alpha interferon. The worldwide market for injectable alpha interferon-based products has experienced rapid growth and various alpha interferon injectable products are approved for many major medical uses worldwide. Alpha interferons are manufactured commercially in three ways: by genetic engineering, by cell culture, and from human white blood cells. All three of these types of alpha interferon are or were approved for commercial sale in the U.S. Our natural alpha interferon is produced from human white blood cells.

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

Alferon N Injection® [Interferon alfa-n3 (human leukocyte derived)] is a highly purified, natural-source, glycosylated, multi-species alpha interferon product. There are essentially no antibodies observed against natural interferon to date and the product has a relatively low side-effect profile.

The recombinant DNA derived alpha interferon are now reported to have decreased effectiveness after one year, probably due to antibody formation and other severe toxicities. These detrimental effects have not been reported with the use of Alferon N Injection®.

The FDA approved Alferon N Injection® in 1989 for the intralesional (within lesions) treatment of refractory (resistant to other treatment) or recurring external genital warts in patients 18 years of age or older. Certain types of human papillomaviruses ("HPV") cause genital warts, a sexually transmitted disease ("STD"). A published report estimates that approximately eight million new and recurrent cases of genital warts occur annually in the United States alone.

Commercial sales of Alferon N Injection® were halted in March 2008 as the current expiration date of our finished goods inventory expired. We are undertaking a major capital improvement program to upgrade our manufacturing capability for Alferon N Injection® at our New Brunswick facility that will continue throughout 2010. As a result, Alferon N Injection® could be available for commercial sales in mid to late 2011. (Please see "Alferon® Low Dose Oral (LDO)" and "Manufacturing" below in Item 1. Business for more information.)

It is our belief that the use of Alferon® N in combination with Ampligen® has the potential to increase the positive therapeutic responses in chronic life threatening viral diseases. While Alferon N Injection® remains in clinical development for treating West Nile Virus, the ability to continue this study has been hampered by the significant reduction in confirmed cases. We also are planning trials of Alferon N Injection® for seriously ill, hospitalized influenza patients in Argentina and potentially other countries. (Please see "Alferon® Low Dose Oral (LDO)" below in Item 1. Business for more information.)

Alferon® Low Dose Oral (LDO)

Alferon® LDO [Low Dose Oral Interferon Alfa-n3 (Human Leukocyte Derived)] is an experimental low-dose, oral liquid formulation of Natural Alpha Interferon and like Alferon N Injection® should not cause antibody formation, which is a problem with recombinant interferon. It is an experimental immunotherapeutic believed to work by stimulating an immune cascade response in the cells of the mouth and throat, enabling it to bolster systemic immune response through the entire body by absorption through the oral mucosa. Oral interferon could be economically feasible for patients and logistically manageable in development programs in third-world countries primarily affected by HIV and other emerging viruses (e.g., SARS, Ebola, bird and swine flu). Oral administration of Alferon® LDO, with its anticipated affordability, low toxicity, no production of antibodies, and broad range of potential bioactivity, could be a breakthrough treatment or prevention for viral diseases.

We have conducted early stage clinical trials as part of an evaluation of the experimental bio-therapeutic Alferon® LDO as a potential new experimental therapy against influenza viruses and other lethal viral diseases, which have high acute death rates. Clinical trials in human volunteers were designed to determine whether Alferon®, delivered in this new, experimental oral drug delivery format, can resuscitate the broad-spectrum antiviral and immunostimulatory genes. While adequate samples were retrieved from the clinical trials sites, the next phase of the study was delayed due to funding considerations and has recently been reinitiated. Potential facilities to undertake the gene expression analysis phase of the study are currently being identified with the intention to complete the clinical trial.

Alferon® LDO is undergoing pre-clinical testing for possible prophylaxis against influenza. Subject to FDA authorization and/or authorization of regulatory authorities in other countries, the finished goods inventory of Alferon N Injection® 5ml vials could be used to produce approximately 11,000,000 sachets of Alferon® Low Dose Oral ("LDO") for clinical trials. However, no assurance can be given that this inventory will be permitted to be used in future clinical trials or for any other clinical use. While the studies to date have been encouraging, preliminary testing in the laboratory and animals is not necessarily predictive of successful results in clinical testing or human treatment. No assurance can be given that similar results will be observed in clinical trials. Use of Alferon® as a possible treatment of any flu or other viral infection requires prior regulatory approval and there can be no assurance that such approval can be obtained either for clinical trial use or commercial sale.

In October 2009, we submitted a protocol to the FDA proposing to conduct a Phase 2, well-controlled, clinical study using Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. Following a teleconference with the FDA in November 2009, the FDA placed the proposed study on "Clinical Hold" because the protocol was deemed by the FDA to deficient in design, and because of the need for additional information to be submitted in the area of chemistry, manufacturing and controls ("CMC"). Thereafter in December 2009, we submitted additional information by Amendment with respect to both the clinical protocol design issues and the CMC items. In January 2010, the FDA acknowledged that our responses to the clinical study design issues were acceptable; however, removal of the Clinical Hold was not warranted because the FDA believed that certain CMC issues had not been satisfactorily resolved. In this regard, the FDA communicated concern regarding the extended storage of Alferon® LDO drug product clinical lots which had been manufactured from an active pharmaceutical ingredient ("API") of Alferon N Injection® manufactured in year 2001. While the biological (antiviral) potency of the product had remained intact, we learned through newly conducted physico-chemical tests (the "new tests" of temperature, pH, oxidation and light on the chemical stability of the active API), that certain changes in the drug over approximately nine storage years (combined storage of Alferon N Injection® plus storage of certain LDO sachets) had introduced changes in the drug which might adversely influence the human safety profile. These "new tests" are part of recent FDA requirements for biological products, such as interferon, which did not exist at the time of the original FDA approval of Alferon N Injection® for commercialization and at the time of FDA approval of the "Establishment License" for Hemispherx' manufacturing facility. Based on the recent FDA request, we have now established and implemented the "new test" procedures. As a result, we have found that certain Alferon N Injection® lots with extended storage (i.e., approximately eight to nine years) do appear to demonstrate some altered physico-chemical properties. However we have also observed that more recent lots, including those manufactured beginning in the year 2006, are superior with respect to the enhanced scrutiny of these tests and, in our view, could be considered appropriate for clinical trials in the Alferon® LDO sachet format. We expect to submit these new data to the FDA in the Spring of 2010 and believe that the full Clinical Hold could be thereafter lifted if the FDA concurs that these data address the outstanding CMC issues cited in the January 2010 FDA recommendations.

Oragens®

In 1999, we acquired a series of patents on Oragens®, potentially a set of oral broad spectrum antivirals and immunological enhancers, through a 10 year licensing agreement with Temple University in Philadelphia, PA. For a $30,000 annual minimum royalty payment and costs to maintain the patents, we were granted an exclusive worldwide license from Temple for the Oragens® products. These compounds had been evaluated in various academic laboratories for application to chronic viral and immunological disorders.

In the 2009 review of our patent rights to determine whether they have continuing value, we undertook an analysis of the Oragen® patents prior to renewing the licensing agreement with Temple University. This review included a cost/benefit analysis of the patents' ultimate revenue and profitability potential in consideration of their remaining life. In addition, management studied the rights as to whether each patent continues to fit into our strategic business plans for Ampligen®, Alferon N Injection® and Alferon® LDO. As a result of this process, we proposed a patent renewal agreement that significantly discounted the prior agreement's annual minimum royalty payment. In February 2010, it was formally communicated by Temple University that they had elected not to pursue our proposal to renew the series of patents on Oragens®. Accordingly as of December 2009, we wrote-off the remaining value of these patents from Patent and Trademark Rights resulting in a net expense for Patents Abandoned of $114,000.

PATENTS AND NON-PATENT EXCLUSIVITY RIGHTS

We have 38 patents worldwide with 46 additional pending patent applications pending comprising our intellectual property. In 2006, we obtained the global patent rights for a compound that enhances DNA vaccination by the efficient intracellular delivery of immunogenic DNA (i.e., DNA that can produce antigenic proteins that simulate an acute viral infection with a resultant humoral and cell-mediated immune response). Please see "Note 4: Patents, Trademark Rights and Other Intangibles" under Notes To Consolidated Financial Statements for more information on these patents.

We continually review our patents rights to determine whether they have continuing value. Such review includes an analysis of the patent's ultimate revenue and profitability potential. In addition, management's review addresses whether each patent continues to fit into our strategic business plans for Ampligen®, Alferon N Injection® and Alferon® LDO.

With respect to Ampligen®, the main U.S. ME/CFS treatment patent (#6130206) expires October 10, 2017. Our main patents covering HIV treatment (#4820696, #5063209, and #5091374) expired on April 11, 2006, November 5, 2008, and February 25, 2009, respectively; Hepatitis treatment coverage is conveyed by U.S. patent #5593973 which expires on January 14, 2014. Our U.S. Ampligen® Trademark (#73/617,687) has been renewed through December 6, 2018.

In addition to our patent rights relating to Ampligen®, the FDA has granted "orphan drug status" to the drug for ME/CFS, HIV/AIDS, and renal cell carcinoma and malignant melanoma. Orphan drug status grants us protection against the potential approval of other sponsors' versions of the drug for these uses for a period of seven years following FDA approval of Ampligen® for each of these designated uses. The first NDA approval for Ampligen® as a new chemical entity will also qualify for four or five years of non-patent exclusivity during which abbreviated new drug applications seeking approval to market generic versions of the drug cannot be submitted to the FDA. See "Government Regulation" below.

The U.S. patents relating to our Alferon® products expire April 2, 2013 (5,503,828) October 14, 2014 (5,676,942) and December 22, 2017 (5,989,441).

RESEARCH AND DEVELOPMENT ("R&D")

Our focus is on developing drugs for use in treating viral and immune based chronic disorders and diseases such as ME/CFS, HIV, HPV, SARS and West Nile Virus. Our current R&D projects are only targeting treatment therapies for ME/CFS and other viral diseases such as prevention and treatment of seasonal and pandemic H1N1 or Avian influenza.

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

Chronic Fatigue Syndrome (“CFS”), also known as Chronic Immune Dysfunction Syndrome (“CFIDS”) and, Myalgic Encephalomyelitis (“ME”) is a serious and debilitating chronic illness and a major public health problem. ME/CFS is recognized by both the government and private sector as a major health problem, including the National Institutes of Health, FDA and the U.S. Centers for Disease Control and Prevention (“CDC”). The CDC listed ME/CFS as a priority disease, causing severe health and financial problems for patients, their family, and the community. ME/CFS is endemic in the population, but occasionally seen in clusters suggesting an infectious basis. A variety of immunological, endocrine, autonomic nervous system, and metabolic abnormalities have been documented.

Dr. Julie Gerberding, former director of the CDC and current president of Merck & Company’s vaccine division, has stated that "The CDC considers Chronic Fatigue Syndrome to be a significant public health concern and we are committed to research that will lead to earlier diagnosis and better treatment of the illness." A variety of studies by the CDC and others have shown that between 1 and 4 million Americans suffer from CFS. While those with the disease are seriously impaired and at least a quarter are unemployed or on disability because of CFS, only about half have consulted a physician for their illness. Equally important, about 40% of people in the general population who report symptoms of ME/CFS have a serious, treatable, previously unrecognized medical or psychiatric condition (such as diabetes, thyroid disease, substance abuse). ME/CFS is a serious illness and poses a dilemma for patients, their families and health care providers.

The CDC has launched a national public education and awareness campaign on CFS. The campaign, called "Get Informed. Get Diagnosed. Get Help." is designed to increase awareness among clinicians and the public because 80 percent of Americans afflicted with CFS illness may not know they have it. The campaign provides information regarding the diagnosis and treatment of CFS, and is designed to raise awareness of the disease among patients and clinicians. A CDC sponsored website at www.cdc.gov/cfs provides easy to understand, downloadable educational tools for patients, their families and health care professionals.

While ME/CFS strikes people of all age, racial, ethnic, and socioeconomic groups, it is most prevalent amongst women. Research has shown that ME/CFS is about three times as common in women as men, a rate similar to that of many autoimmune diseases, such as multiple sclerosis and lupus. To put this into perspective, ME/CFS is over four times more common than HIV infection in women, and the rate of ME/CFS in women is considerably higher than a woman's lifetime risk of getting lung cancer as published by the CFIDS Association of America.

Many severe ME/CFS patients become completely disabled or totally bedridden and are afflicted with severe pain and mental confusion even at rest. ME/CFS is characterized by incapacitating fatigue with profound exhaustion and extremely poor stamina, sleep difficulties and problems with concentration and short-term memory. It is also accompanied by flu-like symptoms, pain in the joints and muscles, tender lymph nodes, sore throat and new headaches. A distinctive characteristic of the illness is a worsening of symptoms following physical or mental exertion which do not subside with rest.

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

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

9

Because no cause for ME/CFS has been identified, current treatment programs are directed at relieving symptoms, with the goal of the patient regaining some level of function and well-being. Diagnosis of ME/CFS is a time-consuming and challenging process for which there is no FDA approved diagnostic test or biomarker to clearly identify the disorder. Diagnosis is primarily arrived at by taking a patient's medical history, completing a physical exam and lab tests to rule out other conditions excluding other illnesses with similar symptoms and comparing a patient's symptoms with the case definition. Overlapping symptoms can occur with several diseases, such as fibromyalgia, Gulf War Illnesses and multiple chemical sensitivities. Many diseases have similar symptoms including Lupus and Lyme disease which may closely mimic ME/CFS that they need to be considered when making a diagnosis to rule them out. If there are no abnormal test results or other physical ailments identified, clinicians can use standardized tests to quantify the level of fatigue and evaluate symptoms. Diagnosis can be complicated by the fact that the symptoms and severity of CFS vary considerably from patient to patient. New diagnostic approaches to possibly accelerate the identification of ME/CFS are being developed (see below in this section regarding the Whittemore Peterson Institute).

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

In the October 8, 2009 issue of Science Express, a consortium of researchers from the Whittemore Peterson Institute, the National Cancer Institute and the Cleveland Clinic report a new retrovirus in the blood cells of 67% of CFS patients and 3.7% in healthy control subjects. The infectious virus was also greater than 99% identical to that previously detected in prostate cancer. Patients with CFS are known to display various abnormalities in immune system functions and experience both higher cancer rates and neurological pathology, which have been associated with the human retroviruses HIV and HTLV-1. While an updated agreement is being finalized, we continue to collaborate with the Whittemore Peterson Institute under the terms of a “Material Transfer And Research Agreement” that had expired on September 1, 2009, to evaluate the potential role of Ampligen®, in the clinical treatment of CFS patients who have a specific deficiency in Natural Killer (“NK”) cell activity. Immunosuppression is often seen in CFS patients and may be a feature of many retroviruses in animal and man. We are presently also collaborating with the Institute with respect to the potential roles of the novel retrovirus more generally found in CFS. These studies are taking the form of both retrospective analysis from stored samples of CFS patients, with and without Ampligen® treatment, along with prospective clinical studies.

Other Viral Diseases

We are engaged in ongoing, experimental studies assessing the efficacy of Ampligen®, Alferon N Injection® and Alferon® LDO against influenza viruses. Ampligen® as a mucosal adjuvant with vaccine is being studied at Japan’s National Institute of Infectious Disease (“NIID”) and at Biken (the for profit operational arm of the Foundation for Microbial Diseases of Osaka University). We have been focusing our resources on the studies being undertaken in Japan and the United States along with the design of new Alferon® LDO studies for both prevention and treatment of seasonal or pandemic influenza.

Pursuant to the current Biken material evaluation agreement which concludes in August 2010 or when the evaluation program is completed, which ever is earlier, Biken purchases Ampligen® for use in conducting further animal studies of intranasal prototype vaccines containing antigens from influenza sub-types H1N1, H3N2 and B. This collaboration may progress to human studies and is supported by the Japanese Health Ministry.

Investigators from Japan's NIID have conducted studies in animals that suggest that Ampligen® can stimulate a sufficiently broad immune response to provide cross-protection against a range of virus genetic types, including H5N1 and derivative clades. Japan's Council for Science & Technology Policy ("CSTP"), a cabinet level position, has awarded funds from Japan's CSTP to advance research with influenza vaccines utilizing Ampligen. The Principal Investigator, Dr. Hideki Hasegawa, M.D., Ph.D., Chief of Laboratory of Mucosal Vaccine Development Virus Research Center, undertook studies in 2009 and plans to continue these studies throughout 2010 that focus on mucosal immunity and the inherent advantages of a vigorous immune response to respiratory pathogens. Dr. Hasegawa has published data that the formulation of pandemic vaccine mixed with Ampligen® increases immuno-genicity and may demonstrate cross protection against mutated strains. Initial data from findings in mice exposed to the most virulent forms of pandemic influenza (H5N1) suggest that standard human seasonal influenza vaccines given alone, and having no benefit on H5N1 influenza virus pathology and clinical status, were nonetheless effective against pandemic virus when combined with Ampligen® when applied intranasally in very small doses in a prophylactic treatment setting. Clinical trials emanating from successful primate (monkey) studies are anticipated to begin in 2010.

Dr. Hasegawa expanded the data on Ampligen® in an October 23, 2009, issue of "Vaccine" (Vol. 27, issue 45, pp 6276-6279) to include the conveyance of cross-protective immunity against various variants of the pandemic influenza virus. In this article, jointly published by researchers at NIID and Yale University, it was communicated that Ampligen® may convey two additional biological properties, in addition to the above referenced cross-protection, when co-administered intranasally with pandemic flu vaccines: 1) the enhancement of immunity with higher IgA and IgG levels, which may convey a survival/therapeutic advantage in animal model systems, and 2) the potential to widen the therapeutic (preventative) profile ("heterosubtypic immunity") by protecting against a phenomenon known as "antigenic drift" in which the pandemic virus may escape the preventative effect of the vaccine; this phenomenon is well-established with avian H5N1 virus and mitigated the potential effectiveness of various influenza vaccines manufactured several years ago in the U.S.A. Animal model experiments do not necessarily predict biological behavior in man.

We received notice of an Annual Report (April 2008-March 2009) prepared by a Director of the NIID to the governing organization of the Japanese Ministry of Health ("MHLW") reporting a series of successful preclinical studies in new pandemic vaccines which rely on Ampligen® (Poly I: Poly C12U). Efficacy in these studies was shown both within the airways themselves as well as systemically. As a result, the program is expected to be accelerated from animal studies into human volunteers promptly under supervision of NIID staff. The project is officially titled "Clinical Application of the Influenza Virus Vaccine in the Intranasal Dosage Form for Mucosal Administration". To date, only very few pharmaceutical companies world-wide have achieved regulatory authorizations to sell intranasally administered influenza vaccines versus many companies receiving approval for intramuscular vaccine delivery routes.

Concurrently, Biken successfully completed in co-operation with NIID a series of animal/preclinical tests on new pandemic vaccines with Ampligen® as a mucosal adjuvant. Biken is expected to undertake studies for regulatory requirements such as safety, stability and formulation to be shared with NIID. Successful studies in animal models, including the monkey studies conducted to date under auspices of the NIID, do not necessarily predict human safety and efficacy of any investigational product including Ampligen®. To support preclinical studies, Ampligen® especially formulated for intranasal use had been manufactured and on August 17, 2009 we shipped Ampligen® to Biken for use in the preclinical studies they are conducting prior to initiating human clinical trials.

The emergence of a new H1N1 Swine Flu strain provides additional significance to the Japanese studies. The original studies by Dr. Hasegawa and his colleagues provided the basis for the expanded preclinical trials that demonstrated cross-clade protection against H5N1 isolates following vaccination with a seasonal influenza vaccine (J Infect Dis.196:1313-1320, 2007). With this in mind, Biken is concentrating its efforts to proceed on a regulatory path for the registration of H5N1 intranasal vaccine combined with Ampligen® in Japan.

On January 1, 2010, we entered into an Advisory Agreement with Bio-Starting Latam, an Argentinean regulatory and business design entity, with the goal to explore the possibility of initiating clinical trials of Alferon N Infection®, Ampligen® and Alferon® LDO during the 2010 influenza season in Argentina.

The clinical trial in Australia utilized Ampligen® administered intramuscularly ("IM") in combination with seasonal flu vaccine. This open-label study (Phase IIa) utilized Ampligen® (Poly I: Poly C12U) as a potential immune-enhancer in Australia with thirty-eight subjects age 60 or greater with the standard trivalent seasonal influenza vaccines. We have attempted in good faith to obtain the clinical data and retrieve the study's samples from St. Vincent's recently restructured Clinical Trials Centre. As a prerequisite of payment, we requested the confirmation that samples were properly maintained utilizing current Good Clinical Practice ("cGCP") and Good Laboratory Practice ("cGLP") for the controlled environment as required by our agreement. In February 2010, our General Counsel advised them in correspondence that due to the failure to meet the condition precedent for payment, we had no choice but to declare them in breach of the agreement and our intention to terminate the relationship between parties. Due to the termination of this agreement, we are not able to test the samples collected in this study for efficacy (i.e., the capacity for beneficial change or therapeutic effect from a given treatment).

A peer-reviewed article providing study data on Ampligen® was published in a recent issue of the "American Journal of Obstetrics and Gynecology" (January 15, 2010, vol. 202). The report, whose lead author is Dr. Jonathan S. Berek, Professor and Chair, Obstetrics and Gynecology, Stanford University School of Medicine, discussed the value of stimulating a periodic "danger signal" with a TLR3 agonist such as poly(I)•poly(C12U) as part of immunotherapeutic cancer treatment regimens, and suggested such regimens may have broad potential application to boost the effects of many immunotherapies of cancer. The authors concluded that poly(I)•poly(C12U) "shows promise as a potential agent for selective enhancement of effect with currently available and future cancer immunotherapies". According to the authors, "immunotherapy of cancer holds the promise of disease-specific intervention without the toxicity that is associated with traditional therapeutic modalities". This reported study was supported by an Ovarian Cancer Research Fund COGI Grant, Advanced Immune Therapeutics, Hemispherx Biopharma, and grants from the National Institute of Health (Grants CA 33399, CA 34233), the Ruth Kirschstein Award (Grant 5 T32 AI07290, and the Ruth L. Kirschstein Award (Grant F32 DKO78416).

Collaboration studies in non-human primates conducted by ViroClinics in the Netherlands suggest a potential role for Alferon® LDO as another novel therapeutic approach to viral pandemics. In these studies, Alferon® LDO treatment appeared to be more effective than published results for a neuraminidase inhibitor (Relenza®), which is a current standard for care of seasonal flu along with a similar drug (Tamiflu®). The opportunity for Alferon® LDO is reinforced by new reports of severe side effects secondary to Tamiflu®, by both the FDA and Japanese health authorities. Also, Tamiflu® resistant strains of flu virus are now raising serious concerns on a world-wide basis. We are planning to expand this Alferon® LDO effort into H1N1 Swine Flu preclinical models in the United States and preclinical laboratory studies are initially underway.

MANUFACTURING

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ that was primarily designed to produce Alferon®. On September 16, 2009, our Board of Directors approved up to $4.4 million for engineering studies, capital improvements, system upgrades and building management systems. In 2008, production of Alferon N Injection® from our Work-In-Progress Inventory had been put on hold due to the resources needed to prepare our New Brunswick facility for the FDA preapproval inspection with respect to our Ampligen® NDA.

We are currently undertaking a major capital improvement program to enhance our manufacturing capability for Alferon N Injection®, Alferon® LDO and Ampligen®. The planned capital improvements include upgrade to the ventilation and electrical distribution systems; upgrade of the high pressure boiler to support process equipment and battery management system; building a utility mezzanine to support the installation of a new water and waste treatment process. In addition, we have increased our manufacturing staff with the addition of Directors for Quality Assurance and Quality Control. As a result, Alferon N Injection® could be available for commercial sales in mid to late 2011.

The New Jersey District Office of the FDA conducted an inspection of the New Brunswick, New Jersey facility in late January and early February 2009 in connection with review of the Ampligen® NDA. A one-page Form FDA 483 was issued citing a need to re-perform four method validations to generate data in the New Brunswick Laboratories. These validations had been performed at another site also owned and operated by us prior to transferring the equipment to New Brunswick. The validations have been completed and the reports were forward to the FDA in April 2009 for review. As a result, the New Jersey office of the FDA has indicated that there are no more preapproval review issues at that time. In addition to having addressed all known FDA Form 483 issues, we reported to the regional office of the FDA that the New Brunswick facility is in progress of validating certain manufacturing steps and compiling data that will be sent to the FDA after NDA approval or as required.

The FDA, in its November 25, 2009 CRL, noted that its field investigators had conveyed deficiencies to us at our New Jersey facility that needed to be resolved before the NDA could be approved. We believe these issues to be the same as communicated by the New Jersey District Office of the FDA in a one-page Form FDA 483 issued in early 2009 that cited a need to reperform four method validations to generate data in the New Brunswick Laboratories. These validations had been completed and the reports forward to the FDA on April 28, 2009 for their review. As a result, the New Jersey office of the FDA indicated that there are no more preapproval review issues at that time. At our expected meeting with the FDA to review the CRL, we intend to communicate that it is our understanding that these manufacturing issues had been previously addressed.

The FDA described specific recommendations related to the Ampligen® NDA in the "Product Quality" section of the CRL which identified additional analytic procedures to be submitted to the FDA. We believe that these procedures are already part of our ongoing Quality Control, Quality Assurance program for Ampligen® manufacturing under current Good Manufacturing Practice ("cGMP") requirements. We are currently undertaking the majority of the tests needed for the validation phase to address the issues identified in the CRL as part of our originally scheduled post-approval testing prior to any commercial sales of Ampligen®.

We outsource certain components of our research and development, manufacturing, marketing and distribution while maintaining control over the entire process through our quality assurance group and our clinical monitoring group. We have a Supply Agreement through March 1, 2011 with Hollister-Stier Laboratories LLC ("Hollister-Stier") of Spokane, Washington related to the manufacture of Ampligen. Pursuant to the agreement, we supply the key raw materials and Hollister-Stier formulates and bottles Ampligen®. On November 25, 2009, we received a Complete Response Letter ("CRL") from the FDA which commented on Ampligen® manufacturing noting the need to resolve outstanding inspection issues at the facilities producing Ampligen®. These include our facility located in New Brunswick, NJ and Hollister-Stier. On December 11, 2009 via Hollister-Stier, we submitted comprehensive new data to the District Office ("DO") of the FDA in Seattle, WA, which we believed demonstrated that certain manufacturing issues noted in the pre-approval inspections at the facility had been fully addressed. On February 2, 2010, Hollister-Stier received a favorable response from the FDA's Seattle DO in which they noted that certain manufacturing issues noted in the pre-approval inspection at this facility had been fully addressed and that they had forwarded a recommendation to the FDA's CDER for approval of Hollister-Stier as a manufacturing site under the Ampligen® NDA. The DO recommendations are not binding on the FDA and pertain only to the specific manufacturing issues cited in the Ampligen® manufacturing response and to the subcontractor site.

We have manufactured purified drug concentrate utilized in the formulation of Alferon N Injection® in our New Brunswick, New Jersey facility. On February 8, 2006, we executed a Manufacturing and Safety Agreement with Hyaluron, Inc. of Burlington, Massachusetts, for the formulation, packaging and labeling of Alferon N Injection®. This agreement has been permitted to expire primarily as a result of our decision to suspend Alferon N Injection® production in 2008. With manufacturing of Alferon® expected to take place in 2011, we are seeking new vendors that can provide the needed cGMP formulation, packaging and labeling services for this product.

MARKETING/DISTRIBUTION

Our marketing strategy for Ampligen® reflects the differing health care systems around the world along with the different marketing and distribution systems that are used to supply pharmaceutical products to those systems. In the U.S., we expect that, subject to receipt of regulatory approval, Ampligen® may be utilized in four medical arenas: physicians' offices, clinics, hospitals and the home treatment setting. We remain in the process of developing pre-launch and launch driven marketing plans focusing on those audience development, medical support and payor reimbursement initiatives which will facilitate product acceptance and utilization at the time of regulatory approval. Similarly, we continue to develop distribution scenarios for the Specialty Pharmacy/Infusion channel which will insure market access, offer 3PL (third party logistics) capabilities and provide the requisite risk management control mechanisms. It is our intent to utilize third party service providers to execute elements of both the marketing/sales and distribution plans. We currently plan to utilize a small group of Managed Market account managers to introduce the product to payor, employer and government account audiences. We believe that this approach will establish a market presence and facilitate the generation of revenue without incurring the substantial costs associated with a traditional sales force. Furthermore, Management believes that the approach will enable us to retain many options for future marketing strategies.

For example, our commercialization strategy for Ampligen®-CFS may include licensing/co-marketing agreements utilizing the resources and capacities of a strategic partner(s). We are seeking world-wide marketing partner(s), with the goal of having a relationship in place before approval is obtained. In parallel to partnering discussions, appropriate pre-marketing activities will be undertaken. We intend to control manufacturing of Ampligen on a world-wide basis.

In 1998, we entered into a strategic alliance with Accredo to develop certain marketing and distribution capacities for Ampligen® in the United States. Accredo, a division of MEDCO, is one of the nation's largest Specialty Pharmacy providers. Pursuant to the agreement, Accredo assumed certain responsibilities for distribution of Ampligen® for which they received a fee. Through this arrangement, we may mitigate the necessity of incurring certain up-front costs. Accredo has also worked with us in connection with the Amp 511 ME/CFS cost recovery treatment program, Amp 516 ME/CFS Phase III clinical trial and the Amp 719 (combining Ampligen® with other antiviral drugs in HIV-salvage therapy and Amp 720 HIV Phase IIb clinical trials now under way). There can be no assurances that this alliance will develop a significant commercial position in any of its targeted chronic disease markets. The agreement had an initial one year term from February 9, 1998 with successive additional one year terms unless either party notifies the other not less than 180 days prior to the anniversary date of its intent to terminate the agreement. Also, the agreement may be terminated for uncured defaults, or bankruptcy, or insolvency of either party and will automatically terminate upon our receiving an NDA for Ampligen® from the FDA, at which time, a new agreement will need to be negotiated with Accredo or another major drug distributor. This agreement offers the potential to provide some marketing and distribution capacity in the United States. There has been no communication or activity under this agreement for the past few years.

In 2007, we had executed a marketing strategy for Alferon N Injection® by relaunching the product via a collaborative marketing initiative between Hemispherx and Armada Healthcare, a Specialty Pharmacy network encompassing specialty pharmacists, pharmacies, distributors and targeted physician specialists. This effort was intended to direct our efforts in the most appropriate and productive market fully exposing our product in the indicated market. This initiative had a positive impact on Alferon® revenues in 2007 by focusing on direct, non-personal selling efforts to targeted physician audiences. It was our intent to promote Alferon® to those dermatologists, OB GYNs and Family practice/IMs who are involved in the treatment of patients with refractory or recurring external genital warts and who currently utilize both injectable interferons as well as topical therapeutic agents. While this marketing initiative has been put on hold due to lack of commercially marketable product, the agreement remains in place and we expect to reactivate Alferon® N production along with its marketing program in 2011.

COMPETITION

RNA based products and toll-like receptors (TLRs) have demonstrated great promise in preclinical and limited clinical applications resulting in active research and development by large pharmaceutical companies and emerging Biotech firms. As such, our potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have.

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

The major pharmaceutical competitors with biotech capabilities/vaccine franchises include Pfizer, GSK, Wyeth (now part of Pfizer), Merck, Novartis, Gilead Pharmaceutical, and Schering-Plough Corp (now part of Merck). Biotech competitors include Baxter, Fletcher/CSI, AVANT Immunotherapeutics, AVI Biopharma and GENTA. When we recommence sales of Alferon N Injection®, it will again compete with products produced by Schering-Plough Corp. and others for treating genital warts. 3M Pharmaceutical also markets its immune response modifier product, Aldera®, for the treatment of genital and perianal warts. We believe the approval and marketing of this product is the main reason that past sales of Alferon N Injection® have not met our expectations since acquisition. In November 2006, the botanical drug, Veregen® (marketed by Bradley Pharmaceuticals) was also approved for the topical treatment of genital and perianal warts. In addition, because certain competitive products are not dependent on a source of human blood cells, such products may be able to be produced in greater volume and at a lower cost than Alferon N Injection®. Our wholesale price on a per unit basis of Alferon N Injection® is higher than that of the competitive recombinant alpha and beta interferon products.

GOVERNMENT REGULATION

Regulation by governmental authorities in the U.S. and foreign countries is and will be a significant factor in the manufacture and marketing of Alferon® N products and our ongoing research and product development activities. Ampligen® and other products developed from the ongoing research and product development activities will require regulatory clearances prior to commercialization. In particular, new drug products for humans are subject to rigorous preclinical and clinical testing as a condition for clearance by the FDA and by similar authorities in foreign countries. The lengthy process of seeking these approvals, and the ongoing process of compliance with applicable statutes and regulations, has, and will continue to require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect the marketing of any products developed by us and our ability to receive product or royalty revenue. We have received Orphan Drug designation for certain therapeutic indications, which might, under certain conditions, help to accelerate the process of drug development and commercialization. Alferon N Injection® is only approved for use in intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection® for other applications requires regulatory approval.

We are subject to various federal, state and local laws, regulations and recommendations relating to such matters as safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use of and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. Our laboratory and production facility in New Brunswick, New Jersey is approved for the manufacture of Alferon N Injection® and we believe it is in substantial compliance with all material regulations. However, there can be no assurance that this facility, or facilities owned and operated by third parties that are utilized in the manufacture of our products, will be considered by the FDA to be in substantial compliance at the present time or in the future.

16

RESEARCH, CONSULTING, LICENSING AND SUPPLY AGREEMENTS

Please see “Note 9: Research, Consulting and Supply Agreements” under Notes to Consolidated Financial Statements.

HUMAN RESOURCES

As of March 1, 2010, we had 44 personnel consisting of 32 full-time employees or consultants and 12 regulatory/research medical personnel on a part-time basis. Part-time personnel are paid on a per diem or monthly basis. 25 personnel are engaged in our research, development, clinical, and manufacturing effort. 19 of our personnel perform regulatory, general administration, data processing, including bio-statistics, financial and investor relations functions. We have no union employees and we believe our relationship with our employees is good.

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

SCIENTIFIC ADVISORY BOARD AND DATA SAFETY MONITORING BOARD

Our Scientific Advisory Board presently consists of two individuals who we believe have particular scientific and medical expertise in Virology, Cancer, Immunology, Biochemistry and related fields. Dr. James Rahal, Director of the Infectious Disease Section of New York Hospital Queens, is one of the nation's foremost experts on the West Nile Virus. Professor Luc Montagnier of the Institut Pasteur in Paris has devoted his career to the study of viruses and is perhaps best known for the 2008 receipt of the Nobel Prize in Medicine related to his discovery of the Human Immunodeficiency Virus (HIV). It is the role of this Board to advise us about current and long-term scientific planning including research and development. The Scientific Advisory Board conducts periodic meetings as needed. No Scientific Advisory Board meetings were held in 2008 or 2009 primarily due to fewer active scientific projects. However, individual Scientific Advisory Board Members sometime consult with and meet informally with our employees or Board Members. Members of the Scientific Advisory Board are employed by others and may have commitments to and/or consulting agreements with other entities, including our potential competitors.

We are in the process of forming a Data Safety Monitoring Board (“DSMB”) that is projected to consist of independent regulatory and medical experts and a Biostatistics expert. The expected function of the DSMB would be to perform independent safety and efficacy analyses on our clinical trials, including those with Alferon® LDO.

ITEM 1A. Risk Factors.

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 Form 10-K. Among the key factors that have a direct bearing on our results of operations are:

Risks Associated With Our Business

No assurance of successful product development.

Ampligen® and related products. The development of Ampligen® and our other related 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 right of third parties. Our investigational products are in various stages of clinical and pre-clinical development and require further clinical studies and appropriate regulatory approval processes before any such products can be marketed. We do not know when, if ever, Ampligen® or our other products will be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale. Please see the next risk factor.

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

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

All of our drugs and associated technologies, other than Alferon N Injection®, are investigational and must receive prior regulatory approval by appropriate regulatory authorities for commercial distribution and sale and are currently legally available only through clinical trials with specified disorders. At present, Alferon N Injection® is only approved for the intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection® for other indications will require regulatory approval.

Our products, including Ampligen®, are subject to extensive regulation by numerous governmental authorities in the United States (“U.S.”) and other countries, including, but not limited to, the FDA in the U.S., the Health Protection Branch (“HPB”) of Canada, and the Agency for the Evaluation of Medicinal Products (“EMEA”) in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen® or any other proposed product and receive product revenues or royalties. 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 U.S. and Europe, 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. In addition, although Ampligen® has been authorized by the FDA for treatment use under certain conditions, including provision for cost recovery, there can be no assurance that such authorization will continue in effect.

On July 7, 2008, the FDA accepted for review our New Drug Application (“NDA”) for Ampligen® to treat CFS, originally submitted in October 2007.

On November 25, 2009, we received a Complete Response Letter (“CRL”) from the FDA which described specific additional recommendations related to the Ampligen® NDA. In accordance with its 2008 Complete Response procedure, the FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues. We are carefully reviewing the CRL and will seek a

meeting with the FDA to discuss its recommendations. We intend to take the appropriate steps to seek approval and commercialization of Ampligen®. Most notably, the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen® and recommended at least one additional clinical study which shows convincing effect and confirms safety in the target population. The FDA indicated that the additional study should be of sufficient size and sufficient duration (6 months) and include appropriate monitoring to rule out the generation of autoimmune disease. In addition, patients in the study should be on more than one dose regimen, including at least 300 patients on dose regimens intended for marketing. Finally, additional data including a well-controlled QT interval study of the heart's electrical cycle and pharmacokinetic evaluations of dual dosage regiments was requested. Other items required by the FDA include certain aspects of Non-Clinical safety assessment and product Quality. In the Non-Clinical area, the FDA recommended among other things that we complete rodent carcinogenicity studies in two species. As part of the NDA submission, we had requested that these studies be waived, but the waiver has not been granted.

If we are unable to generate the additional data required by the FDA or if, for that or any other reason, Ampligen® or one of our other products does not receive regulatory approval in the U.S. or elsewhere, our operations most likely will be materially adversely affected.

Alferon® LDO is undergoing pre-clinical testing for possible prophylaxis against influenza. While the studies to date have been encouraging, preliminary testing in the laboratory and in animal models is not necessarily predictive of successful results in clinical testing or human treatment. No assurance can be given that similar results will be observed in clinical trials. Use of Alferon® as a possible treatment of any flu requires prior regulatory approval. In October 2009, we submitted a protocol to the FDA proposing to conduct a Phase 2, well-controlled, clinical study for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. Following a teleconference with the FDA in November 2009, the FDA placed the proposed study on "Clinical Hold" because the protocol was deemed by the FDA to be deficient in design and because additional information was required to be submitted in the area of chemistry, manufacturing and controls ("CMC"). Thereafter in December 2009, we submitted additional information by Amendment with respect to both the clinical protocol design issues and the CMC items. In January 2010, the FDA acknowledged that our responses to the clinical issues were acceptable; however, the Clinical Hold was maintained in effect because the FDA believed that certain CMC issues had not yet been satisfactorily resolved. In this regard, the FDA communicated continuing questions regarding the extended storage of Alferon® LDO drug product clinical lots which had been manufactured from an active pharmaceutical ingredient ("API") of Alferon N Injection® manufactured in year 2001. Only the FDA can determine whether a drug is safe, effective or appropriate for clinical testing or treating a specific application. Therefore, no assurance can be given that the use of our existing inventory will be permitted for use in future clinical trials.

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

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses, as we pursued our clinical trial effort to get our experimental drug, Ampligen®, approved. As of December 31, 2009, our accumulated deficit was approximately $(210,847,000). We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

We may require additional financing which may not be available.

The development of our products will require the commitment of substantial resources to conduct the time consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of December 31, 2009, we had approximately $58,072,000 in Cash and Cash Equivalents. Given the harsh economic conditions, we continue to review every aspect of our operations for cost and spending reductions to assure our long-term financial stability while maintaining the resources necessary to achieve our primary objectives of obtaining NDA approval of Ampligen® and securing a strategic partner.

If we are unable to commercialize and sell Ampligen® or Alferon® LDO and/or recommence and increase sales of Alferon N Injection® or our other products, we eventually may need to secure other sources of funding through additional equity or debt financing or other sources in order to satisfy our working capital needs and/or complete the necessary clinical trials and the regulatory approval processes on which the commercialization of our products depends.

Our ability to raise additional funds from the sale of equity securities is limited. In this regard, we only have approximately 32,200,000 shares authorized but unissued and unreserved. At our annual stockholders' meeting held on June 24, 2009, we sought approval of an amendment to our Certificate of Incorporation to increase the number of authorized shares of Common Stock from 200,000,000 to 350,000,000. At this meeting, there was an insufficient number of votes in favor of the proposal and voting on this proposal had been left open until September 3, 2009. We announced on September 2, 2009 that insufficient votes were obtained for passage of Proposal No. 3 contained in the proxy for the 2009 Annual Meeting of Stockholders. With voting on this proposal as the sole purpose of the adjourned Stockholders' Meeting scheduled for September, 4, 2009, this meeting was cancelled. Since the approval was not obtained to increase the number of authorized shares of Common Stock, the amount of proceeds we may receive from the sale of our Common Stock is limited.

There can be no assurances that we will raise adequate funds which may have a material adverse effect on our ability to develop our products or continue our operations.

Our Alferon N Injection® Commercial Sales were halted due to lack of finished goods inventory.

Commercial sales of Alferon N Injection® were halted in March 2008 as the current expiration date of our finished goods inventory expired in March 2008. As a result, we have no product to sell at this time. We are undertaking a major capital improvement program, that will continue throughout 2010, to enhance our manufacturing capability to produce the purified drug concentrate used in the formulation of Alferon N Injection® at our New Brunswick facility. As a result, Alferon N Injection® could be available for commercial sales in mid to late 2011. However our agreement with a third party to formulate, package and label Alferon N Injection® has expired and we are seeking new vendors to supply this service. Also, each production lot of Alferon N Injection® is subject to FDA review and approval prior to releasing the lots to be sold. In light of these contingencies, there can be no assurances that the approved Alferon N Injection® product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

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

Ampligen® is currently being tested as a vaccine adjuvant for H5N1, a pathogenic avian influenza virus ("HPAIV") in Japan, where the preclinical data has shown activity in preventing lethal challenge with the original virus used for vaccination as well as the other related, but not identical, isolates of H5N1 virus (i.e., cross-reactivity). The clinical testing phase of Ampligen® in Japan is expected to begin in 2010 (see "Item 2: Management's Discussion and Analysis of Financial Condition and Results of Operations; Overview; General" in Part I above). No assurance can be given that similar results will be observed in clinical trials. Use of Ampligen® in the treatment of flu requires prior regulatory approval. Only the FDA or other corresponding regulatory agencies world-wide can determine whether a drug is safe, effective and appropriate for treating a specific application. As discussed above, obtaining regulatory approvals is a rigorous and lengthy process (see "Our drugs and related technologies are investigational and subject to regulatory approval. If we are unable to obtain regulatory approval, our operations will be significantly adversely affected" above).

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

We need to preserve and acquire enforceable patents covering the use of Ampligen® for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen® for such disease. We obtained all rights to Alferon N Injection®, and we plan to preserve and acquire enforceable patents covering its use for existing and potentially new diseases. Our success depends, in large part, on our ability to preserve and obtain patent protection for our products and to obtain and preserve our trade secrets and expertise. Certain of our know-how and technology is not patentable, particularly the procedures for the manufacture of our experimental drug, Ampligen®. We also have 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 yet 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. With regard to Alferon N Injection®, we have acquired from ISI its patents for natural alpha interferon produced from human peripheral blood leukocytes and its production process and we have filed a patent application for the use of Alferon® LDO in treating viral diseases including avian influenza. We cannot assure that our competitors will not seek and obtain patents regarding the use of similar products in combination with various other agents, for a particular target indication prior to our doing so. If we cannot protect our patents covering the use of our products for a particular disease, or obtain additional patents, we may not be able to successfully market our products.

The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves complex legal and factual questions.

To date, no consistent policy has emerged regarding the breadth of protection afforded by pharmaceutical and biotechnology patents. There can be no assurance that new patent applications relating to our products or technology will result in patents being issued or that, if issued, such patents will afford meaningful protection against competitors with similar technology. It is generally anticipated that there may be significant litigation in the industry regarding patent and intellectual property rights. Such litigation could require substantial resources from us and we may not have the financial resources necessary to enforce the patent rights that we hold. No assurance can be made that our patents will provide competitive advantages for our products or will not be successfully challenged by competitors. No assurance can be given that patents do not exist or could not be filed which would have a materially adverse effect on our ability to develop or market our products or to obtain or maintain any competitive position that we may achieve with respect to our products. Our patents also may not prevent others from developing competitive products using related technology.

21

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

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

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

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

We have limited marketing and sales capability. If we are unable to obtain additional distributors and our current and future distributors do not market our products successfully, we may not generate significant revenues or become profitable.

We have limited marketing and sales capability. We are dependent upon existing and, possibly future, marketing agreements and third party distribution agreements for our products in order to generate significant revenues and become profitable. As a result, any revenues received by us will be dependent in large part on the efforts of third parties, and there is no assurance that these efforts will be successful.

Our commercialization strategy for Ampligen® for ME/CFS may include licensing/co-marketing agreements utilizing the resources and capacities of a strategic partner(s). We continue to seek world-wide marketing partner(s), with the goal of having a relationship in place before approval is obtained. In parallel to partnering discussions, appropriate premarketing activities will be undertaken. We intend to control manufacturing of Ampligen® on a world-wide basis.

We cannot assure that our U.S. or foreign marketing strategy will be successful 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. Our inability to establish viable marketing and sales capabilities would most likely have a materially adverse effect on us.

There are no long-term agreements with suppliers of required materials and services. If we are unable to obtain the required raw materials and/or services, we may not be able to manufacture Alferon N Injection® and/or Ampligen®.

A number of essential materials are used in the production of Alferon N Injection®, including human white blood cells. We do not have, but are working towards having long-term agreements for the supply of such materials. There can be no assurance we can enter into long-term supply agreements covering essential materials on commercially reasonable terms, if at all.

There are a limited number of manufacturers in the United States available to provide the polymers for use in manufacturing Ampligen®. At present, we do not have any agreements with third parties for the supply of any of these polymers. We have established relevant manufacturing operations within our New Brunswick, New Jersey facility for the production of Ampligen® polymers from raw materials in order to obtain polymers on a more consistent manufacturing basis.

If we are unable to obtain or manufacture the required raw materials, we may be unable to manufacture Alferon N Injection® and/or Ampligen®. The costs and availability of products and materials we need for the production of Ampligen® and the commercial production of Alferon N Injection® and other products which we may commercially produce are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, and FDA and other governmental regulations and there can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all.

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

Changes in methods of manufacturing, including commercial scale-up, may affect the chemical structure of Ampligen® and other RNA drugs, as well as their safety and efficacy. The transition from limited production of pre-clinical and clinical research quantities to production of commercial quantities of our products will involve distinct management and technical challenges and will require additional management and technical personnel and capital to the extent such manufacturing is not handled by third parties. There can be no assurance that our manufacturing will be successful or that any given product will be determined to be safe and effective, or capable of being manufactured under applicable quality standards, economically, and in commercial quantities, or successfully marketed.

We have limited manufacturing experience.

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

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

We have never produced Ampligen® or any other products in large commercial quantities. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen® or enter into third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Also, each production lot of Alferon N Injection® is subject to FDA review and approval prior to releasing the lots to be sold. This review and approval process could take considerable

time, which would delay our having product in inventory to sell.

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

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

Our products may be subject to substantial competition.

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

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

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

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

Ampligen®. 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 15-20% of patients treated in our various studies. This reaction is occasionally accompanied by a rapid heart beat, a tightness of the chest, urticaria (swelling of the skin), anxiety, shortness of breath, subjective reports of “feeling hot”, sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by reducing the rate of infusion. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, transient visual disturbances, slow or irregular heart rate, decreases in platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills, fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months. One or more of the potential side effects might deter usage of Ampligen® in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

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

We may be subject to product liability claims from the use of Ampligen®, Alferon N Injection®, or other of our products which could negatively affect our future operations. We have discontinued product liability insurance.

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 affected from the litigation costs, settlement expenses and lost product sales inherent to these claims. While we will continue to attempt to take appropriate precautions, we cannot assure that we will avoid significant product liability exposure.

On November 28, 2008, we suspended product liability insurance for Alferon N Injection® and Ampligen®. We now require third parties to indemnify us in conjunction with all overseas emergency sales of Ampligen® and Alferon® LDO. We concluded that years of successfully addressing the limited number of product liability claims filed against Ampligen® and Alferon® LDO, combined with the informed consent and other patient waivers completed as an element of clinical trials, and the lack of any commercial sales since April 2008, that temporarily discontinuing the liability insurance was an acceptable risk until we receive regulatory clearance for Ampligen® or Alferon® LDO or until Alferon N Injection® again becomes available.

Currently, without product liability coverage for Ampligen®, Alferon N Injection® and Alferon® LDO, a claim against the products could have a materially adverse effect on our business and financial condition.

The loss of services of key personnel including Dr. William A. Carter could hurt our chances for success.

Our success is dependent on the continued efforts of our staff, especially certain doctors and researchers along with the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen®, and his knowledge of our overall activities, including patents and clinical trials. The loss of the services of Dr. Carter or other personnel key to our operations, could have a material adverse effect on our operations and chances for success. As a cash conservation measure, we have elected to discontinue the Key Man life insurance on the life of Dr. Carter. An employment agreement continues to exist with Dr. Carter that, as amended, runs until December 31, 2010. However, Dr. Carter has the right to terminate his employment upon not less than 30 days prior written notice. The loss of Dr. Carter or other key personnel or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

Uncertainty of health care reimbursement for our products.

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

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

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

A Number of Purported Class Action Lawsuits Have Been Filed Against Us and We May Be Subject to Civil Liabilities.

A number of purported class action lawsuits have been filed against us alleging securities fraud. The complaints seek monetary damages, costs, attorneys' fees, and other equitable and injunctive relief. Securities class action suits and derivative suits are often brought against companies following periods of volatility in the market price of their

securities. Defending against these suits, even if meritless, can result in substantial costs to us and could divert the attention of our management.

The existence of these proceedings could have a material adverse effect on our ability to access the capital markets to raise additional funds. While management believes that the lawsuits are without merit, we cannot predict or determine the timing or final outcomes of the lawsuits and are unable to estimate the amount or range of loss that could result from unfavorable outcomes. Adverse results in some or all of these legal proceedings could be material to our results of operations, financial condition or cash flows.

Risks Associated With an Investment in Our Common Stock

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

The market price of our common stock has been and is likely to be volatile. This is especially true given the current significant instability in the financial markets. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

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

Our common stock is listed for quotation on the NYSE Amex. For the 12 month period ended December 31, 2009, the closing price of our common stock has ranged from $0.32 to $3.75 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. In this regard, please see “A Number of Purported Class Action Lawsuits Have Been Filed Against Us and We May Be Subject to Civil Liabilities” above.

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

In May 2009 we issued an aggregate of 25,543,339 shares and warrants to purchase an additional 14,708,687 shares under a universal shelf registration statement. 4,895,000 of these warrants have been exercised as of December 31, 2009. Depending upon market conditions, we anticipate selling 9,813,687 shares pursuant to the conversion of remaining warrants.

In addition to the foregoing, we registered with the SEC on September 29, 2009, 1,038,527 shares issuable upon exercise of certain other warrants. To the extent the exercise price of our outstanding warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the exercise price of certain of these warrants are adjusted pursuant to anti-dilution protection, the warrants could be exercisable or convertible for even more shares of common stock. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. In this regard we have registered $150,000,000 of securities for public sale pursuant to a universal shelf registration, none of which has been designated or issued. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock.

Sales of substantial amounts of our common stock in the public market, including our sale of securities pursuant to the universal shelf registration statement, could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in Management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November 2002, we adopted a Stockholder Rights Plan (“Rights Plan”) and, under the Rights Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one-hundredth unit of preferred stock for $30.00. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Dr. Carter, our Chief Executive Officer, who already beneficially owns 5.4% of our common stock, the Rights Plan’s threshold will be 20%, instead of 15%. The Rights Plan will expire on November 19, 2012, and may be redeemed prior thereto at $.01 per Right under certain circumstances.

Special Note Regarding Forward Looking Statements

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

ITEM 1B. Unresolved Staff Comments.

None.

ITEM 2. Properties.

We currently lease our headquarters located in Philadelphia, Pennsylvania consisting of a suite of offices of approximately 9,000 square feet. We also currently own, occupy and use our New Brunswick, New Jersey laboratory and production facility that we acquired from ISI. These facilities consist of two buildings located on 2.8 acres. One building is a two story facility consisting of a total of 31,300 square feet. This facility contains offices, laboratories, production space and shipping and receiving areas. It also contains space designated for research and development, our pharmacy, packaging, quality assurance and quality control laboratories. Building Two has 11,670 square feet consisting of offices, laboratories and warehouse space. The property has parking space for approximately 100 vehicles.

ITEM 3. Legal Proceedings.

Please see “Note 14 – Contingencies” under Notes to Consolidated Financial Statements.

ITEM 4. Removed and Reserved

PART II

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

In 2009, we issued shares of common stock consisting of 1) 1,514,272 shares in payment to vendors and consultants for services rendered; 2) 11,862,866 shares issued pursuant to the 2008 Purchase Agreement with Fusion; and 3) 426,136 shares to our Directors pursuant to our Directors’ Compensation Program. In addition, in February 2009, we issued an aggregate of 980,392 warrants with an expiration period of ten years and exercise price of $0.51 per share to Dr. Carter and Mr. Equels, pursuant to the terms of the Standby Financing Agreement.

The foregoing issuances of securities were private transactions and exempt from registration under section 4(2) of the Securities Act and/or regulation D rule 506 promulgated under the Securities Act.

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

COMMON STOCK	High	Low
Time Period:		
January 1, 2009 through March 31, 2009	0.84	0.26
April 1, 2009 through June 30, 2009	4.54	0.44
July 1, 2009 through September 30, 2009	3.58	1.86
October 1, 2009 through December 31, 2009	2.16	0.54
January 1, 2008 through March 31, 2008	0.89	0.59
April 1, 2008 through June 30, 2008	1.00	0.62
July 1, 2008 through September 30, 2008	1.20	0.25
October 1, 2008 through December 31, 2008	0.70	0.25

As of March 1, 2010, there were approximately 220 holders of record of our Common Stock. This number was determined from records maintained by our transfer agent and does not include beneficial owners of our securities whose securities are held in the names of various dealers and/or clearing agencies.

On March 1, 2010, the last sale price for our common stock on the NYSE Amex was $0.69 per share.

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

The following table gives information about our Common Stock that may be issued upon the exercise of options, warrants and rights under all of our equity compensation plans as of December 31, 2009:

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average Exercise price of Outstanding options, warrants and rights	Number of securities Remaining available for future issuance under equity compensation plans(excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders:	8,797,912	$ 2.60	13,755,325
Equity compensation plans not approved by security holders:	11,008,246	$ 1.44	-
Total	19,806,158	$ 1.96	13,755,325

Performance Graph

Total Return To Shareholders
(Includes reinvestment of dividends)

ANNUAL RETURN PERCENTAGE
Years Ending

Company Name / Index	Dec 05	Dec 06	Dec 07	Dec 08	Dec 09
Hemispherx Biopharma, Inc.	14.21	1.38	-65.45	-52.63	55.56
S&P SmallCap 600 Index	7.68	15.12	-0.30	-31.07	25.57
Peer Group	-7.61	12.86	-28.20	-67.93	78.77

INDEXED RETURNS
Years Ending

Company Name / Index	Base Period Dec 04	Dec 05	Dec 06	Dec 07	Dec 08	Dec 09
Hemispherx Biopharma, Inc.	100	114.21	115.79	40.00	18.95	29.47
S&P SmallCap 600 Index	100	107.68	123.96	123.59	85.19	106.97
Peer Group	100	92.39	104.27	74.87	24.01	42.92

Peer Group Companies
AVI BIOPHARMA INC.
CARDIUM THERAPEUTICS INC.
CYTRX CORP.
GENVEC INC.
OXIGENE INC.
REGENERX BIOPHARMACEUTICALS INC.

31

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

The selected consolidated financial data set forth below should be read in conjunction with our consolidated financial statements, and the related notes thereto, and "Management's Discussion and Analysis of Financial Condition and Results of Operations", included in this Annual Report. The statement of operations and balance sheet data presented below for, and as of the end of, each of the years in the five year period ended December 31, 2009 are derived from our audited consolidated financial statements. Historical results are not necessarily indicative of the results to be expected in the future.

Year Ended December 31	2005	2006	2007	2008	2009
Statement of Operations Data:					
Revenues and License fee Income	$ 1,083	$ 933	$ 1,059	$ 265	$ 111
Total Costs and Expenses(1)	10,998	19,627	20,348	13,076	13,375
Interest Expense and Financing Costs(2)	3,121	1,259	396	-	241
Net loss	(12,446)	(19,399)	(18,139)	(12,219)	(13,438)
Deemed Dividend	-	-	-	-	-
Net loss applicable to common stockholders	(12,446)	(19,399)	(18,139)	(12,219)	(13,438)
Basic and diluted net loss per share	$ (0.24)	$ (0.31)	$ (0.25)	$ (0.16)	$ (0.12)
Shares used in computing basic and diluted net loss per share	51,475,192	61,815,358	71,839,782	75,142,075	109,514,401
Balance Sheet Data:					
Working Capital	$ 16,353	$ 16,559	$ 14,412	$ 5,646	$ 55,789
Total Assets	24,654	31,431	23,142	13,211	64,994
Debt, net of discount	4,171	3,871	-	-	-
Stockholders' Equity	18,627	24,751	20,955	11,544	62,379
Cash Flow Data:					
Cash used in operating activities	(7,231)	(13,747)	(15,112)	(9,358)	(9,297)
Capital expenditures	$ (1,002)	$ (1,351)	$ (212)	$ (73)	$ (332)

(1) General and Administrative expenses include stock compensation expense of $391, $2,483, $2,291, $573 and $826 for the years ended December 31, 2005, 2006, 2007, 2008 and 2009, respectively.

(2) For information concerning our financing see Note 6 to our consolidated financial statements for the year ended December 31, 2009 contained herein.

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, 2009. This information should be read in conjunction with Item 5 – “Selected Financial Data” and our consolidated financial statements and related notes thereto beginning on F-1 of this Form 10-K.

Statement of Forward-Looking Information

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

Background

We are a specialty pharmaceutical company based in Philadelphia, Pennsylvania and engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. Our flagship products include Alferon N Injection® and the experimental therapeutics Ampligen®. Alferon N Injection® is approved for a category of STD infection, and Ampligen® represents an experimental RNA nucleic acids being developed for globally important viral diseases and disorders of the immune system. Hemispherx' platform technology includes large and small agent components for potential treatment of various severely debilitating and life threatening diseases. We have 38 patents comprising our core intellectual property estate, a product (Alferon N Injection®) and cGMP certified manufacturing facilities for our novel pharmaceutical products.

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

RESULTS OF OPERATIONS

Year ended December 31, 2009 versus December 31, 2008

Net Loss

Our net loss of approximately $13,438,000 for the year ended December 31, 2009 was 10.0% higher when compared to the same period in 2008. This $1,219,000 increase in loss was primarily due to:

1) Increased Research and Development costs in 2009 of approximately $1,195,000 or 21% as compared to the same period in 2008.

2) Sales of Alferon N Injection® for 2008 of approximately $173,000 compared to no sales recorded in 2009.

3) Decreased interest and other income in 2009 of approximately $525,000 or 89% as compared to the same period in 2008.

4) Increased non-cash financing costs of $241,000 in 2009 in the form of Common Stock Commitment Warrants incurred as a result of the February 2009 implementation of the Standby Financing Agreement. No agreement of this type was in effect during 2008.

5) Decreased Production/Cost of Goods Sold in 2009 of approximately $214,000 or 27% and decreased General and Administrative expenses of approximately $682,000 or 11% as compared to the same period in 2008.

Net loss per share for the year ended 2009 was $(0.12) versus $(0.16) for the same period in 2008.

Revenues

There were no revenues related to the sale of Alferon N Injection® for the twelve month period ended 2009 while there were approximately $173,000 of sales for the same period of 2008. Revenues from our Ampligen® cost recovery treatment program for the year ended December 31, 2009 were approximately $111,000 compared to revenues of $92,000 for the same period in 2008, an increase of $19,000 or 21% for approximately the same number of patients participating in the program. Commercial sales of Alferon N Injection® were halted in March 2008 as the expiration date of our Finished Goods Inventory expired in March 2008. As a result, we have no Alferon N Injection® product to commercially sell in 2009 and all revenue in 2009 has been generated from Ampligen® cost recovery clinical treatment programs.

In 2008 and 2009 production of Alferon N Injection® had been put on hold due to the resources needed to prepare our New Brunswick facility for the FDA preapproval inspection with respect to our Ampligen® NDA. We now have the financial resources to commence manufacturing upgrades that will be undertaken throughout 2010. As a result, Alferon N Injection® could be available for commercial sales in mid to late 2011.

Production/Cost of Goods Sold

Production/Cost of Goods Sold was approximately $584,000 and $798,000, respectively, for the twelve months ended December 31, 2009 and 2008. This represents a decrease of $214,000 or 27% as compared to the same period in

2008. These expenses primarily represent the costs to maintain Alferon N Injection® and Ampligen® inventories including storage, stability testing, transport and reporting costs including Ampligen® NDA work undertaken in 2008. Additionally, there was a reduction in Cost of Goods Sold for 2009 due to the lack of Alferon N Injection® sales.

Research and Development Costs

Overall Research and Development costs for the year ended December 31, 2009 were approximately $6,995,000 as compared to $5,800,000 for the same period a year ago reflecting an increase of $1,195,000 or 21%. 2009's Research and Development costs include the write-off of approximately $214,000 for patents that Management either has not renewed the rights to or deemed no longer of value and/or material to future operations. Additionally, Research and Development costs increased approximately $254,000 due to Research and Clinical employees participating in the Employee Wage Or Hour Reduction Program (see "Liquidity and Capital Resources" below for details), approximately $386,000 to evaluate and begin to ready the New Brunswick Plant for production and a net increase of $341,000 in comparing 2009 to 2008 expenses related to the efforts of employees in responding to the FDA and 2009 issued bonus awards.

During 2008 and 2009, we spent considerable time and effort preparing for the preapproval inspection by the FDA of manufacturing of Ampligen® product and its raw materials, polynucleotides Poly I and Poly C12U. A satisfactory recommendation from the FDA Office of Compliance based upon an acceptable preapproval inspection is required prior to approval of the product. The preapproval inspection determines compliance with current Good Manufacturing Practices ("cGMP") as well as a product specific evaluation concerning the manufacturing process of product. The inspection includes many aspects of the cGMP requirements, such as manufacturing process validation, equipment qualification, analytical method validation, facility cleaning, quality systems, documentation system and part 11 compliance. In its November 25, 2009 CRL, the FDA described specific additional recommendations related to the Ampligen® NDA. The FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues.

On September 19, 2008, we executed an agreement with Lovelace Respiratory Research Institute ("Lovelace") in Albuquerque, New Mexico to perform certain animal toxicity studies in support of our Ampligen® NDA. These studies were requested by the FDA and have been done in collaboration with the resources of the New Brunswick facility. On January 14, 2010, we submitted reports of new preclinical data regarding Ampligen® for potential treatment of CFS to the FDA which we believe to be sufficient to address certain preclinical issues referenced in the CRL. The new preclinical data showed no evidence of antibodies against Ampligen® in primates and no evidence of an increase in certain undesirable cytokines (specific modulators of the immune system) at clinically used doses of Ampligen® for CFS. Although most other experimental immunomodulators have been associated with one or more features of aberrant immune activity, including toll-like receptor activators (of which Ampligen® is one), this was specifically not seen with Ampligen® in primates.

We are engaged in ongoing, experimental studies assessing the efficacy of Ampligen®, Alferon N Injection® and Alferon® LDO against influenza viruses. As a result, we have been focusing our resources on the studies being undertaken in Japan and United States as well as the design of new Alferon® LDO studies for both prevention and treatment of seasonal or pandemic influenza.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the year ended December 31, 2009 and 2008 were approximately $5,796,000 and $6,478,000, respectively, reflecting a decrease of $682,000 or 11%. This decrease relates primarily to the effect of the cash conservation and cost reduction program implemented in January 2009. Accordingly, areas of expenses were reduced including legal fees of approximately $440,000, stock compensation of approximately $220,000, accounting and related fees of approximately $214,000, a reduction in personnel costs of approximately $259,000 along with reduced expenses of approximately $433,000 related to discontinuation of sales of Alferon®. These cost savings were somewhat offset by an increase of approximately $130,000 of incremental non-cash labor expenses resulting from G&A employees participating in the Employee Wage Or Hour Reduction Program along with an increase of approximately $328,000 in financial consulting, security filings and transfer fees, approximately $44,000 in costs related to the second round of stockholder voting and approximately $387,000 in professional advisor fees.

Interest and Other Income

Interest and other income decreased approximately $525,000 or 89% during the twelve months ended December 30, 2009 as compared to the same period in 2008 due to reduction of Cash available to invest during the first five months of 2009 at lower interest rates. While we received an infusion of cash from the two Rodman deals in May 2009, along with the receipt of additional cash from Fusion Capital in the third quarter of 2009, historically low interest rates existed for conservative investments throughout 2009.

Interest Expense and Financing Costs

We had no interest expense for 2009 or 2008. In February 2009, we entered into a Standby Financing Agreement that produced finance costs of $241,000 in Common Stock Commitment Warrants for the twelve months ended December 31, 2009 for which no agreement of this type existed during the prior period in 2008. For detailed information on this agreement, please see "Standby Financing Agreement" below.

Year ended December 31, 2007 versus December 31, 2008

Net loss

Our net loss of approximately $12,219,000 for the year ended December 31, 2008 was 33% lower when compared to the same period in 2007. This $5,920,000 reduction in loss was primarily due to:

1) Decreased research and development expenses in 2008 of approximately $4,644,000 as compared to the same period in 2007.

2) Alferon N Injection® had no sales of Alferon N Injection® for the last nine months of 2008. Sales of Alferon N Injection® for the twelve months ended December 31, 2008 and 2007 amounted to approximately $173,000 and $925,000, respectively for a reduction of $752,000 or 81%.

3) Decreased general and administrative expenses of approximately $2,496,000 during the twelve months ended December 31, 2008 versus the same period a year.

4) Decreased interest and other income of $608,000 or 51% for the twelve months ended December 31, 2008 as compared to the same period in 2007.

5) Decreased Production/Cost of Goods Sold in 2008 of $132,000 being applied to Inventory due to the halting of Alferon® N production.

6) In September 2007, an increase of $346,000 in other income occurred due to the reversal of accrued liquidated damages in 2006 with respect to our debentures.

Net loss per share was $(0.16) for the 12 month period 2008 versus $(0.25) for the same period in 2007.

Revenues

Revenues for the year ended December 31, 2008 were $265,000 as compared to revenues of $1,059,000 for the same period in 2007. Ampligen® sold under the cost recovery clinical program was down $42,000 and Alferon N Injection® sales were down $752,000 or 81% as compared to the prior period.

Ampligen® sold under the cost recovery clinical program is a product of physicians and ME/CFS patients applying to us to enroll in the program. This program has been in effect for several years and is offered as a treatment option to patients severely affected by CFS. As the name "cost recovery" implies, we have no gain or profit on these sales. The benefits to us include 1) physicians and patients becoming familiar with Ampligen®; and 2) collection of clinical data relating to the patients' treatment and results. Revenues from our Ampligen® cost recovery program were down 32% as fewer patients are participating in the program. Our clinical staff has not encouraged cost recovery clinical enrollments in order that our internal resources could address the Ampligen® NDA and related documents preparatory to filing for a full commercial license.

The primary reason for the 81% drop in the sales Alferon® for the twelve months ended December 31, 2008 is that commercial sales of Alferon N Injection® were halted in March 2008 as the expiration date of our finished good inventory expired in March 2008. As a result, we had no product to sell for the last nine months of 2008.

Production costs/cost of goods sold

Production/cost of goods sold was approximately $930,000 and $798,000, respectively, for the twelve months ended December 31, 2007 and 2008. This represented a decrease of approximately $132,000 or 14% as compared to the same period in 2007. These costs primarily represent: 1) costs of goods sold of approximately $381,000 and $-0-, respectively, for the twelve months ended December 31, 2007 and 2008; and 2) Costs to maintain Alferon N Injection® Inventory including storage, stability testing and reporting costs incurred in our attempt to have the FDA extend the commercial sales life of our Alferon N Injection® Finished Goods. The primary reason for the decrease in cost of goods sold can be attributed to the lack of Alferon N Injection® sales since April 1, 2008 and its impact on costs of goods sold.

Research and Development Costs

Overall research and development costs for the twelve months ended December 31, 2008 were $5,800,000 as compared to $10,444,000 for the same period a year ago reflecting a decrease of $4,644,000 or 44%. This decrease was primarily due to reduced outside consulting fees and other costs related to the preparation and filing of our NDA for Ampligen®.

In 2008, we spent considerable time and effort preparing for the preapproval inspection by the FDA for manufacturing of Ampligen® product and its raw materials, polynucleotides Poly I and Poly C12U. A satisfactory recommendation from the FDA Office of Compliance based upon an acceptable preapproval inspection is required prior to approval of the product. The preapproval inspection determines compliance with current Good Manufacturing Practices ("cGMP") as well as a product specific evaluation concerning the manufacturing process of product. The inspection includes many aspects of the cGMP requirements, such as manufacturing process validation, equipment qualification, analytical method validation, facility cleaning, quality systems, documentation system and part 11 compliance.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the twelve months ended December 31, 2007 and 2008 were approximately $8,974,000 and $6,478,000, respectively, reflecting a decrease of $2,496,000 or 28% primarily due to reductions in the cost of non-cash stock compensation of $1,718,000, director fees for $137,000, impairment charges of $526,000, accounting fees of $34,000 and various other general administrative expenses that were partially offset by an increase of legal fees for $635,000 resulting from litigation to settle existing suits.

In 2007, we incurred impairment charges amounting to $526,000 as compared to no such charges in the current year. The primary reason for these charges stemmed from the $228,000 write-down of a water purification system that was determined to be unnecessary at our New Jersey facility due to a change in manufacturing plans. Additionally in 2007, we wrote down the value of our intangible asset associated with the repurchase of a 6% Royalty on Alferon N Injection® sales by $298,000. We determined in 2007 that we did not have sufficient inventory on hand to realize the full economic benefit of this asset; therefore, it was written down to its net realizable value.

Reversal of Previously Accrued Interest Expense

In September 2007, an increase of $346,000 in other income occurred due to the reversal of accrued liquidated damages in 2006 with respect to our debentures holders. These damages related to certain debenture covenants were settled without charge in the maturation and pay down of the debenture holder's outstanding loan balance in 2007.

Interest and Other Income

Interest and other income for the year ended December 31, 2007 and 2008 was $1,200,000 and $592,000, respectively, representing a decrease of $608,000 or 51%. The decrease in interest and other income during the current period was mainly due to a reduction in funds available for Short-Term Investments compounded by the lower interest rates.

Interest Expense and Financing Costs

We had no interest expense or non-cash financing costs for the twelve months ended December 31, 2008 as compared to $396,000 for the same period a year prior. The expenses reflected for the year ended 2007 reflect financing costs and interest charges related to our convertible debentures which matured in June 2007 when all outstanding loan balances were paid.

Liquidity and Capital Resources

Cash used in operating activities for the year ended December 31, 2009 was $9,297,000 compared to $9,358,000 for the same period in 2008, a reduction of $61,000. The cash used in operating activities was essentially flat and did not change significantly. We had proceeds from financing activities of approximately $61,824,000 compared to $270,000 during the twelve months ended December 31, 2009 and 2008, respectively. As of December 31, 2009, we had approximately $58,072,000 in Cash and Cash Equivalents or an increase of approximately $51,953,000 from December 31, 2008.

In an effort to conserve our cash, the Employee Wage Or Hours Reduction Program (the "Program") was ratified by our Board effective January 1, 2009. In a mandatory program that was estimated to be in effect for up to six months, compensation of all active full-time employees as of January 1, 2009 ("Participants") were reduced through a reduction in their wages for which they would be eligible to receive shares of our common stock ("Stock") six months after the shares were earned. While all employees were also offered the option to reduce their work hours with a proportional

decease in wages, of which none elected this alternative.

On a semi-monthly basis, Participants received rights to Stock ("Incentive Rights") that could not be traded. Six months after the date the Incentive Rights were awarded, we established a process to have Incentive Rights converted into Stock and issued to each Participant on a monthly basis. We established and maintain a record for the number of Incentive Rights awarded to each Participant. At the end of each semi-monthly period, we determined the number of Incentive Rights by converting the proportionate incentive award to the value of the Stock by utilizing the closing price of the Stock on the NYSE Amex based on the average daily closing price for the period.

The Plan was administered for full-time employees as follows:

- Employees earning $90,000 or less per year elected a wage reduction of 10% per annum and received an incentive of two times the value in Stock;
- Employees earning $90,001 to $200,000 per year elected a wage reduction of 25% per annum received an incentive of two times the value in Stock;
- Employees earning over $200,000 per year elected a wage reduction of 50% per annum and received an incentive of three times the value in Stock;
- Any employee could have elected a 50% per annum wage reduction which would allow them to be eligible for an incentive award of three times the value of Stock.

We worked with Wachovia Securities, LLC to establish a trading account for each Participant. Incentive Rights constitute income to the Participants and be subject to payroll taxes upon Stock issuance. We will bear all expenses related to selling the Stock at Wachovia Securities (i.e.; broker fees, transaction costs, commissions, etc.) for payroll withholding tax purposes. Thereafter, for each Participant that remains an active employee during the period, we will continue to bear such costs from their Wachovia Securities' accounts for the maintenance of these account and all expenses related to selling our Stock. Participants leaving us or voluntarily separating from the Plan will receive the Stock earned upon the six month conversion of their Incentive Rights. The Plan benefits for individuals that are no longer Participants will become fixed and we will not continue to bear such costs from the designated brokerage firm for the maintenance of an account nor any expenses related to selling our stock except for the initial costs associated to the selling of stock for payroll withholding tax purposes.

The Program was suspended as of May 31, 2009 with employees returning back to their rate of pay from January 1, 2009. At the passage of six months for each of their months of participation, non-affiliate employees have been issued shares for the months ended July 31, August 31, September 30, October 30 and November 30, 2009. Individuals defined by Rule 144 in the Securities Act of 1933 as an "affiliate" have yet to receive their distribution of stock from the Program.

In addition, certain vendors and service providers have agreed to accept shares of our Common Stock as partial payment of their bills. We issued 1,514,272 and 3,017,276 shares of common stock for services rendered in 2009 and 2008, respectively.

We have been using the proceeds from our financings with the assistance of Rodman & Renshaw, LLC ("Rodman") as placement agent and from Fusion Capital Fund II, LLC ("Fusion Capital") equity financing to fund operating expense and infrastructure growth including preparation for manufacturing, regulatory compliance and market development costs related to the FDA approval process for Ampligen®. We were able to raise in the aggregate of approximately $33,712,000 in equity financing pursuant to the two Rodman financings in May 2009 and an aggregate of approximately $28,111,700 in equity financing pursuant to the Fusion Capital Agreement. For more details on the Rodman and Fusion Capital financings, please see "Equity Financing" below.

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. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. 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 processes, including the commercializing of Ampligen® products.

Notwithstanding our cost and spending reduction activities, we may need to raise additional funds through additional equity or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes including the commercializing of Ampligen® products. There can be no assurances that we will raise adequate funds from these or other sources, especially considering current adverse market conditions, which may have a material adverse effect on our ability to develop our products. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. We may also need additional funding earlier than anticipated, and our cash requirements, in general, may vary materially from those now planned, for reasons including, but not limited to, changes in our research and development programs, clinical trials, competitive and technological advances, the regulatory process, and higher than anticipated expenses and lower than anticipated revenues from certain of our clinical trials for which cost recovery from participants has been approved.

Standby Financing Agreement

In February 2009, we entered into a Standby Financing Agreement pursuant to which certain individuals ("Individuals"), consisting of Dr. William Carter and Thomas Equels, agreed to loan us up to an aggregate of $1,000,000 in funds should we be unable to obtain additional financing, if needed. Under the Standby Financing Agreement, we would use our best efforts in 2009 to obtain one or more additional financing agreements on such terms as our Board deems to be reasonable and appropriate in order to maintain our operations. If at any time after December 1, 2009 and prior to June 30, 2010 a majority of our independent Directors deems that in the event a financing of at least $2.5 Million has not been obtained and additional funds are needed to maintain our operations, we would send written notice to each of the Individuals informing them of the total amount of additional funds required and the specific amount that would be required from each Individual. Such funding as prescribed by the agreement was obtained in May 2009.

For agreeing to be obligated to loan us money, each Individual received 10 year warrants (the "Commitment Warrants") to purchase our common stock at the rate of $50,000 worth in warrants per $100,000 committed. The exercise price of these warrants is $0.51 (125% of the market closing price of our Common Stock on the date that Agreement was executed). These warrants vested immediately.

Equity Financing

On May 8, 2009, we entered into a letter agreement (the "Engagement Letter") with Rodman & Renshaw, LLC ("Rodman") as placement agent, relating to a proposed offering of our securities. The proceeds from the May 10 and 18, 2009 equity transactions are net of all related offering costs, including the fair value of warrants issued.

On May 10, 2009, we entered into Securities Purchase Agreements with two institutional investors. Pursuant to the Securities Purchase Agreements, we issued to these investors in the aggregate: (a) 13,636,363 shares of our common stock; (b) Series I warrants to purchase an additional 6,136,363 shares of common stock at an exercise price of $1.65 per share ("Series I Warrants"); and (c) Series II warrants to purchase up to 3,000,000 shares of common stock at an exercise price of $1.10 per share ("Series II Warrants", and together with the Series I Warrants, the "Warrants"). The Series I Warrants could be exercised at any time on or after the six month anniversary of the May 18, 2009 closing date of the offering and for a five year period thereafter. The Series II Warrants could be exercised at any time on or after the May 18, 2009 date of delivery of the Series II Warrants and for a period of 45 days thereafter. As of December 31, 2009, all Series II Warrants were exercised and none of the Series I Warrants have been exercised.

Rodman, as placement agent for the May 10, 2009 Securities Purchase Agreements, acted on a best efforts basis for the offering and received a placement fee equal to $825,000 as well as Series I Warrants to purchase 750,000 shares of our common stock equal at an exercise price of $1.38 per share. The Series I Warrants can be exercised at any time on or after the six month anniversary of the May 18, 2009 closing date of the offering and for a five year period thereafter. Rodman also was entitled to a fee equal to 5.5% of the Series II Warrants that were exercised. As of December 31, 2009, Rodman received $165,000 in fees with regard to the exercise of the Series II Warrants.

On May 18, 2009, we entered into Securities Purchase Agreements with two institutional investors. Pursuant to the Securities Purchase Agreements, we issued to these investors in the aggregate: (a) 11,906,976 shares of common stock; and (b) warrants to purchase an additional 4,167,440 shares of common stock at an exercise price $1.31 per share ("Warrants"). The Warrants could be exercised at any time on or after their May 21, 2009 date of issuance and for a five year period thereafter. As of December 31, 2009, 1,895,000 of these Warrants had been exercised.

Rodman, as placement agent for the May 18, 2009 Securities Purchase Agreements, acted on a best efforts basis for the offering and received a placement fee equal to $797,500 as well as Warrants to purchase 654,884 shares of common stock at an exercise price of $1.34375 per share. The Warrants could be exercised at any time on or after the six month anniversary of the May 21, 2009 closing date of the offering and for a five year period thereafter.

Refer to Note 17 -"Fair Value" under Notes to Consolidated Financial Statements for further explanation of the warrants in these agreements. The warrants include a cash settlement feature if certain conditions are met.

On July 2, 2008, we entered into a $30 million Common Stock Purchase Agreement (the "Purchase Agreement") with Fusion Capital Fund II, LLC (“Fusion Capital”), an Illinois limited liability company. Concurrently with entering into the Purchase Agreement, we entered into a registration rights agreement with Fusion Capital. Under the registration rights agreement, we filed a registration statement related to the transaction with the U.S. Securities & Exchange Commission (“SEC”) covering the shares that have been issued or may be issued to Fusion Capital under the common stock purchase agreement. That registration statement was declared effective by the SEC on August 12, 2008. As reported in the registration statement related to the transaction, we had the right over a 25 month period from August 2008 to sell our shares of common stock to Fusion Capital from time to time in amounts between $120,000 and $1 million depending on certain conditions as set forth in the agreement, up to a maximum of $30 million. The purchase price of the shares related to the $30.0 million of future funding was based on the prevailing market prices of our shares at the time of sales as computed under the Purchase Agreement without any fixed discount, and we had control of the timing and amount of any sales of shares to Fusion Capital. However, Fusion Capital could not purchase any shares of our common stock pursuant to the Purchase Agreement if the price of our common stock had three trading days with an average value below $0.40 over the prior twelve trading days. There were no negative covenants, restrictions on future funding, penalties or liquidated damages in the agreement. In consideration for entering into the Purchase Agreement, we issued to Fusion Capital 650,000 shares as a commitment fee. Also, we were to issue to Fusion Capital up to an additional 650,000 shares as a commitment fee pro rata as we receive up to the $30.0 million of future funding. As of September 1, 2009, Fusion Capital had purchased the maximum number of shares that were registered under the Registration Statement, an aggregate of 20,000,000 shares for $28,111,695 and received 1,259,086 commitment shares, thereby in effect exhausting the Purchasing Agreement.

Under the rules of the NYSE Amex, we could issue no more than 14,823,651 shares (19.99% of our outstanding shares as of July 2, 2008, the date of the purchase agreement) without first obtaining the approval of stockholders. That approval was obtained on November 11, 2008. As of December 31, 2008, we had executed transactions pursuant the Fusion Capital Stock Purchase Agreement valued at $270,000 and 1,211,122 shares, which included 650,000 shares as the initial fee for the financing.

In April 2006 we entered into a prior common stock purchase agreement with Fusion Capital, pursuant to which we sold an aggregate of 10,682,032 shares for total gross proceeds of approximately $19,739,000 through November, 2007. No purchases were made by Fusion Capital in 2008 or 2009 under this agreement, which expired on July 31, 2008.

The proceeds from our financing has been used to fund infrastructure growth including manufacturing, regulatory compliance and market development.

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. In this regard we also have previously registered $150,000,000 worth of our securities in a universal shelf registration statement, none of which has been designated or issued. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. 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 processes, including the commercializing of Ampligen® products.

There can be no assurances that we will raise adequate funds from these or other sources, which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

42

Contractual Cash Obligations	(dollars in thousands) Obligations Expiring by Period			
	Total	2010	2011	2012
Operating Leases	$ 58	$ 58	$ -0-	$ -0-
Total	$ 58	$ 58	$ -0-	$ -0-

New Accounting Pronouncements

Refer to “Note 2(i) – Recent Accounting Standards and Pronouncements” under Notes to Consolidated Financial Statements.

Disclosure About Off-Balance Sheet Arrangements

None.

Critical Accounting Policies

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

Revenue

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

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

Inventories

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

Patents and Trademarks

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

Stock Based Compensation

Under FASB ASC 718-Compensation-Stock Compensation ("ASC 718") share-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the requisite service period. We adopted the provisions of ASC-718, using a modified prospective application. Under this method, compensation cost is recognized for all share-based payments granted, modified or settled after the date of adoption, as well as for any unvested awards that were granted prior to the date of adoption.

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model. Expected volatility is based on the historical volatility of the price of our common stock. The risk-free interest rate is based on U.S. Treasury issues with a term equal to the expected life of the option. We use uses historical data to estimate expected dividend yield, expected life and forfeiture rates.

Concentration of Credit Risk

Our policy is to limit the amount of credit exposure to any one financial institution and place investments with financial institutions evaluated as being credit worthy, or in short-term money markets, which are exposed to minimal interest rate and credit risks. At and since December 31, 2009, we have had bank deposits and overnight repurchase agreements that exceed federally insured limits.

Concentration of credit risk, with respect to receivables, is limited through our credit evaluation process. We do not require collateral on our receivables. Our receivables historically consisted principally of amounts due from wholesale drug companies. At December 31, 2009 there were no receivables and those at December 31, 2008 were fully reserved as doubtful accounts.

Sales to three large wholesalers represented approximately 77% of our total sales for the year ended December 31, 2008. There were no sales for year ended December 31,2009.

Item 7A. Quantitative And Qualitative Disclosures About Market Risk.

We had approximately $58,072,000 in cash and cash equivalents at December 31, 2009. To the extent that our cash and cash equivalents exceed our near term funding needs, we intend to invest the excess cash in money market accounts or three to eighteen month financial instruments. We employ established conservative policies and procedures to manage any risks with respect to investment exposure.

ITEM 8. Financial Statements and Supplementary Data.

The consolidated balance sheets as of December 31, 2008 and 2009, and our consolidated statements of operations, changes in stockholders' equity and comprehensive loss and cash flows for each of the years in the three year period ended December 31, 2009, together with the report of McGladrey & Pullen, LLP, independent registered public accountants, is included at the end of this report. Reference is made to the "Index to Financial Statements and Financial Statement Schedule" on page F-1.

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

None.

ITEM 9A. Controls and Procedures.

Effectiveness of Control Procedures

As of December 31, 2009, the end of the period covered by this report, we carried out an evaluation under the supervision and with the participation of our Management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Act of 1934, as amended, as of December 31, 2008. Our disclosure controls and procedures are intended to ensure that the information we are required to disclose in the reports that we file or submit under the Securities Exchange Act of 1934 is (i) recorded, processed, summarized and reported within the time periods specified in the Securities Exchange Commission’s rules and forms and (ii) accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as the principal executive and financial officers, respectively, to allow final decisions regarding required disclosures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the controls and procedures were effective as of December 31, 2009 to ensure that material information was accumulated

and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Our management has concluded that the financial statements included in this Form 10-K present fairly, in all material respects our financial position, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States of America.

Changes in Internal Control over Financial Reporting

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

Management's Report on Internal Control Over Financial Reporting

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

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

Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2009. In making this assessment, management used the criteria set forth in the framework established by the Committee of Sponsoring Organizations of the Treadway Commission Internal Control—Integrated Framework, (COSO). Based on this assessment, management has not identified any material weaknesses as of December 31, 2009. A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

Management has concluded that we did maintain effective internal control over financial reporting as of December 31, 2009, based on the criteria set forth in "Internal Control—Integrated Framework" issued by the COSO.

Our internal control over financial reporting as of December 31, 2009 has been audited by McGladrey and Pullen, LLP, an independent registered public accounting firm, as stated in their report which appears herein.

ITEM 9B. Other Information.

None.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Hemispherx Biopharma, Inc.

We have audited Hemispherx Biopharma, Inc.'s internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Hemispherx Biopharma, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Hemispherx Biopharma, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009 based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the December 31, 2009 consolidated financial statements of Hemispherx Biopharma, Inc. and our report dated March 12, 2010 expressed an unqualified opinion.

/s/ McGladrey & Pullen, LLP
Blue Bell, Pennsylvania
March 12, 2010

PART III

Item 10. Directors and Executive Officers and Corporate Governance.

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

Name	Age	Position
William A. Carter, M.D.	72	Chairman, Chief Executive Officer
Charles T. Bernhardt, CPA	48	Chief Financial Officer
David R. Strayer, M.D.	64	Medical Director, Regulatory Affairs
Robert Dickey IV	54	Senior Vice President
Carol A. Smith, Ph.D.	58	Vice President of Manufacturing Quality and Process Development
Richard C. Piani	81	Director
Thomas K. Equels	57	Director, Secretary and General Counsel
Katalin Ferencz-Biro, Ph.D.	63	Senior Vice President of Regulatory Affairs
William M. Mitchell, M.D.	75	Director
Iraj Eqhbal Kiani, N.D.	64	Director
Wayne Springate	39	Vice President of Operations
Russel Lander, Ph.D.	59	Vice President of Quality Assurance

Each director has been elected to serve until the next annual meeting of stockholders, or until his earlier resignation, removal from office, death or incapacity. Each executive officer serves at the discretion of the Board of Directors, subject to rights, if any, under contracts of employment.

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

State University of New York at Buffalo. Dr. Carter is a Board certified physician and author of more than 200 scientific articles, including the editing of various textbooks on anti-viral and immune therapy.

CHARLES T. BERNHARDT is a Certified Public Accountant who has served as our Chief Financial Officer and Chief Accounting Officer since January 1, 2009. He attained an undergraduate in Accountancy from Villanova University and received a Masters' Degree in Business Administration from West Chester University of Pennsylvania. Mr. Bernhardt was formally the Director of Accounting for Healthcare Division of Thomson Reuters, where he was responsible for their accounting operations including the Physicians' Desk Reference business and shared financial services for the Healthcare and Scientific Divisions from 2006 to 2008. He was also the Regional Controller for Comcast Cable during 1999 to 2002, Director of Finance for TelAmerica Media for 2003 to 2006 and earlier in his career a member of the Internal Audit management teams American Stores Corporation and ICI Americas/Zeneca (currently AstraZeneca Pharmaceuticals). In 1986, he became a C.P.A. licensed in Pennsylvania and New Jersey while with public accounting's "Big Four" firm of KPMG.

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

ROBERT DICKEY IV has served as Senior Vice President since June 2009. He has approximately 15 years of previous experience in biotech management as a CFO, COO and CEO following a career as an investment banker. His experience spans startups to revenue stage companies involved in cancer and CNS drug development, transplantation and computational drug design. Mr. Dickey has specific expertise in fund raising, business development, project management, restructuring and international operations. Previously he spent 18 years as an investment banker, 14 of those at Lehman Brothers, with his background evenly split between M&A and capital markets transactions across a variety of industries. He has an undergraduate degree from Princeton University and an MBA from The Wharton School, University of Pennsylvania.

CAROL A. SMITH, Ph.D. is Vice President of Manufacturing Quality and Process Development who has served as our Director of Manufacturing and Process Development from 1995 to 2003, as Director of Operations from 1993 to 1995 and as the Manager of Quality Control from 1991 to 1993, with responsibility for the manufacture, quality control, process development, technology transfer to contract manufacturers and the chemistry of Ampligen®. Dr. Smith was Scientist/Quality Assurance Officer for Virotech International, Inc. from 1989 to 1991 and Director of the Reverse Transcriptase and Interferon Laboratories and a Clinical Monitor for Life Sciences, Inc. from 1983 to 1989. She received her Ph.D. in Medical Sciences with a concentration on Virology from the University of South Florida, College of Medicine in 1980 and was an NIH post-doctoral fellow in the Department of Microbiology and Virology at the Pennsylvania State University College of Medicine from 1980 to 1983.

RICHARD C. PIANI has been a director since 1995. Mr. Piani has been employed as a principal delegate for Industry to the City of Science and Industry, Paris, France, a billion dollar scientific and educational complex. Mr. Piani provided consulting to us in 1993, with respect to general business strategies for our European operations and markets. Mr. Piani served as Chairman of Industrielle du Batiment-Morin, a building materials corporation, from 1986 to 1993. Previously Mr. Piani was a Professor of International Strategy at Paris Dauphine University from 1984 to 1993. From 1979 to 1985, Mr. Piani served as Group Director in Charge of International and Commercial Affairs for Rhone-Poulenc and from 1973 to 1979 he was Chairman and Chief Executive Officer of Societe "La Cellophane", the French company which invented cellophane and several other worldwide products. Mr. Piani has a Law degree from Faculte de Droit, Paris Sorbonne and a Business Administration degree from Ecole des Hautes Etudes Commerciales, Paris.

49

THOMAS K. EQUELS has been a director since 2008 and presently serves as our secretary, general counsel and litigation counsel. Mr. Equels is the President and Managing Director of the Equels Law Firm based in Miami Florida that focuses on litigation. For over a quarter century, Mr. Equels has represented national and state governments as well as companies in the banking, insurance, aviation, pharmaceutical and construction industries. Mr. Equels received his Juris Doctor degree with high honors from Florida State University. He is a summa cum laude graduate of Troy University and also obtained his Masters Degree from Troy. He is a member of the Florida Bar Association, the American Bar Association and the Academy of Florida Trial Lawyers.

WILLIAM M. MITCHELL, M.D., Ph.D. has been a director since July 1998. Dr. Mitchell is a Professor of Pathology at Vanderbilt University School of Medicine. Dr. Mitchell earned a M.D. from Vanderbilt and a Ph.D. from Johns Hopkins University, where he served as an Intern in Internal Medicine, followed by a Fellowship at its School of Medicine. Dr. Mitchell has published over 200 papers, reviews and abstracts dealing with viruses, anti-viral drugs and immune responses to HIV infection. Dr. Mitchell has worked for and with many professional societies, including the International Society for Antiviral Research, the American Society of Biochemistry and Molecular Biology, the American Society of Microbiology and government review committees, among them the National Institutes of Health, AIDS and Related Research Review Group. Dr. Mitchell previously served as one of our directors from 1987 to 1989.

IRAJ EQHBAL KIANI, N.D., Ph.D., was appointed to the Board of Directors on May 1, 2002. Dr. Kiani is a citizen of the United States and England that resides in Newport, California. Dr. Kiani served in various local government positions including the Mayor and Governor of Yasoi, Capital of Boyerahmand, Iran. In 1970, Dr. Kiani moved to England, where he established and managed several trading companies over a period of some 20 years. Dr. Kiani is a planning and logistic specialist who is now applying his knowledge and experience to build a worldwide immunology network, which will use our proprietary technology. Dr. Kiani received his Ph.D. degree from the University of Ferdosi in Iran, ND from American University.

WAYNE S. SPRINGATE is Vice President of Operations and joined Hemispherx in 2002 as Vice President of Business Development. Mr. Springate came on board when Hemispherx acquired Alferon N Injection® and its New Brunswick, NJ manufacturing facilities. He led the consolidation of our Rockville facility to our New Brunswick location as well as coordinated the relocation of manufacturing polymers from South Africa to our production facility in New Brunswick. He was also responsible for preparing and having a successful Preapproval Inspection by the FDA for our New Brunswick manufacturing plant in connection with the filing of our Ampligen® NDA. Currently he is managing a $4.4 million capital improvement budget to enhance our Alferon® facility in accordance with current Good Manufacturing Practice (“cGMP”). Previously, Mr. Springate served as President for World Fashion Concepts in New York and oversaw operations at several locations throughout the United States and overseas. Mr. Springate assisted the CEO in details of operations on a daily basis and was involved in all aspects of manufacturing, warehouse management, distribution and logistics.

KATALIN FERENCZ-BIRO, Ph.D. has served as Senior Vice President of Regulatory Affairs and Quality Assurance Departments since January 2007. She served as the Director of Regulatory Affairs and Quality Assurance from 2006 to 2007. Previously from 1987 to 2003, she served Interferon Sciences Inc, in various positions including Senior Director of Regulatory Affairs, Quality Control and Quality Assurance Departments, and official FDA contact for our FDA approved product, Alferon N Injection®. Dr. Ferencz-Biro received her Ph.D. in Chemistry/ Biochemistry in 1972 from the University of Eötvös Lóránd, Budapest, Hungary, and her M.S., in Chemistry and Biology in 1971 from University of Eötvös Lóránd, Budapest, Hungary. She was a postdoctoral fellow from 1981-1984 in Rutgers University, Center for Alcohol Studies, Piscataway, New Jersey. She is an author and co-author of several scientific publications, patents and presentations on the field of biochemistry. Currently she is a member of Regulatory Affairs Professionals Society.

50

RUSSEL J. LANDER, Ph.D. is Vice President Quality Assurance. Dr. Lander joined Hemispherx in 2005, assuming responsibility for CMC writing for the NDA filing of Ampligen®. He subsequently served at the New Brunswick site as Director of Quality Control and provided guidance to the efforts to improve and validate the manufacturing process for the synthesis of Ampligen® polynucleotide raw materials, Poly I and Poly C12U. He is currently directing research and development activities in New Brunswick. Dr. Lander was formerly employed at Merck and Co., Inc. in the process development groups for drug development (1977-1991) and vaccines (1991-2005). Dr. Lander received his Ph.D. in Chemical/Biochemical Engineering from the University of Pennsylvania. He has authored numerous scientific publications and invention disclosures.

Ransom W. Etheridge, who has been associated with us for nearly 20 years, left our employment when his agreement expired on December 31, 2009. Mr. Etheridge first contributed to the Company in 1980 when he provided consulting services and participated in negotiations with respect to our initial private placement. Over time, his roles included service as our Secretary and General Counsel as well as being on our Board of Directors from October 1997 through November 2008.

Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Exchange Act requires our officers and directors, and persons who own more than ten percent of a registered class of equity securities, to file reports with the Securities and Exchange Commission reflecting their initial position of ownership on Form 3 and changes in ownership on Form 4 or Form 5. Based solely on a review of the copies of such Forms received by us, we found that, during the fiscal year ended December 31, 2008, certain of our officers and directors had not complied with all applicable Section 16(a) filing requirements on a timely basis with regard to transactions occurring in 2009. Specifically, Dr. Carter, Dr. Strayer and Mr. Bernhardt each filed four form 4 late concerning their receipt of five sets of Incentive Rights through the “Employee Wage Or Hours Reduction Program” and Mr. Springate filed a form 4 late related to his receipt of five sets of Incentive Rights through the “Employee Wage Or Hours Reduction Program”; Mr. Bernhardt, Mr. Dickey and Mr. Springate each filed late an initial Form 3; Mr. Equels filed three form 4 late concerning five transactions; Dr. Kiani, Dr. Mitchell and Mr. Piani each have two form 4 filed late regarding two transactions.

Audit Committee and Audit Committee Expert

The Audit Committee of our Board of Directors consists of Richard Piani, Committee Chairman, William Mitchell, M.D. and Iraj Eqbal Kiani, N.D. Mr. Piani, Dr. Mitchell, and Mr. Kiani are all determined by the Board of Directors to be independent directors as required under Section 121B(2)(a) of the NYSE Amex Company Guide. We do not have a financial expert as defined in the SEC rules on the committee in the true sense of the description. However, Mr. Piani has 40 years experience in business and has served in senior level and leadership positions for international businesses. His working experience includes reviewing and analyzing financial statements and dealing with financial institutions. We believe Mr. Piani, Dr. Mitchell, and Dr. Kiani to be independent of management and free of any relationship that would interfere with their exercise of independent judgment as members of this committee. The principal functions of the Audit Committee are to (i) assist the Board in fulfilling its oversight responsibility relating to the annual independent audit of our consolidated financial statements and internal control over financial reporting, the engagement of the independent registered public accounting firm and the evaluation of the independent registered public accounting firm’s qualifications, independence and performance, (ii) prepare the reports or statements as may be required by NYSE Amex or the securities laws, (iii) assist the Board in fulfilling its oversight responsibility relating to the integrity of our financial statements and financial reporting process and our system of internal accounting and financial controls, (iv) discuss the financial statements and reports with management, including any significant adjustments, management judgments and estimates, new accounting policies and disagreements with management, and (v) review disclosures by our independent registered public accounting firm concerning relationships with us and the performance of our independent accountants.

51

Code of Ethics

Our Board of Directors adopted a revision to the Code of Ethics and business conduct for officers, directors, employees, agents and consultants on October 15, 2009. The principal amendments included broadening the Code's application to our agents and consultants, adoption of a regulatory compliance policy and adoption of a policy for protection and use of Company computer technology for business purposes only. This Code has been presented, reviewed and signed by each officer, director and employee and strategic consultants with none of the amendments constituting a waiver of provision of the Code of Ethics on behalf of the our Chief Executive Officer, Chief Financial Officer, Controller, or persons performing similar functions.

You may obtain a copy of this code by visiting our web site at www.hemispherx.net (Investor Relations / Corporate Governance) or by written request to our office at 1617 JFK Boulevard, Suite 660, Philadelphia, PA 19103.

Item 11. Executive Compensation.

Information concerning the compensation of directors and executive officers will be provided under the headings "Directors' Compensation", "Compensation Discussion and Analysis" and "Executive Compensation" in the Proxy Statement for our 2010 annual meeting of stockholders. This document will be filed with the Securities and Exchange Commission no later than 120 days after the end of our fiscal year and the information under those headings is hereby incorporated by reference.

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

The following table sets forth as of March 1, 2010, the number and percentage of outstanding shares of common stock beneficially owned by:

- Each person, individually or as a group, known to us to be deemed the beneficial owners of five percent or more of our issued and outstanding common stock;
- each of our directors and the Named Executives; and
- all of our officers and directors as a group.

As of March 1, 2010, there were no other persons, individually or as a group, known to us to be deemed the beneficial owners of five percent or more of our issued and outstanding common stock. "Incentive Rights" are rights to receive common stock issuable upon exercise under our "Employee Wage Or Hours Reduction Program" that was in effect from January 1, 2009 to May 31, 2009 (see "Liquidity and Capital Resources" in Part II, Item 6. Management's Discussion and Analysis of Financial Condition and Results of Operations).

Name and Address of Beneficial Owner	Shares Beneficially Owned	% Of Shares Beneficially Owned
William A. Carter, M.D.	7,565,360(1)(2)	5.4%
Richard C. Piani 97 Rue Jeans-Jaures Levaillois-Perret France 92300	757,420(3)	*
Charles T. Bernhardt CPA	265,214(4)	*
Thomas K. Equels	1,428,622(5)	1.1%
William M. Mitchell, M.D. Vanderbilt University Department of Pathology Medical Center North 21st and Garland Nashville, TN 37232	616,025(6)	*
Iraj Eqhbal Kiani, N.D., Ph.D. Orange County Immune Institute 18800 Delaware Street Huntingdon Beach, CA 92648	323,271(7)	*
David R. Strayer, M.D.	471,832(8)	*
Wayne Springate	235,525(9)	*
Robert Dickey, IV	152,500(10)	*
Russel Lander, Ph.D.	168,073(11)	*
Katalin Ferencz-Biro, Ph.D.	15,000(12)	*
Carol A. Smith, Ph.D.	87,999(13)	*
All directors and executive officers as a group (12 persons)	12,086,841	9.1%

* Ownership of less than 1%

(1) Dr. Carter is our Chairman and Chief Executive Officer. He owns 487,960 shares of common stock and beneficially owns 7,075,256 shares issuable or issued upon exercise of:

	Plan	Date Issued		Exercise Price	Number Of Shares	Expiration Date
Options						
	1990	08/08/91	$	2.71	73,728	12/31/10
	1990	12/03/01	$	4.03	10,000	01/03/11
	2004	09/08/04	$	2.60	167,000	09/07/14
	2004	12/07/04	$	2.60	153,000	12/07/14
	2004	04/26/05	$	1.75	100,000	04/26/15
	2004	07/01/05	$	1.86	465,000	06/30/15
	2004	12/09/05	$	2.61	10,000	12/08/15
	2004	12/09/05	$	2.87	70,000	12/09/15
	2004	01/01/06	$	2.38	300,000	01/01/16
	2004	02/22/06	$	3.78	376,650	02/22/16
	2004	09/10/07	$	2.00	1,000,000	09/09/17
	2004	10/01/07	$	3.50	1,400,000	09/30/17
	2004	02/18/08	$	4.00	190,000	02/18/18
	2007	09/17/08	$	2.20	1,450,000	09/17/18
Total Options					5,765,378	

Warrants					
Total Warrants	2009	02/1/09	$ 0.51	491,196	02/01/19

Incentive Rights

Plan	Date Issued	Number Of Shares
2007	01/31/09	206,646
2007	02/28/09	199,263
2007	03/31/09	192,870
2007	04/30/09	154,527
2007	05/31/09	65,376
Total Incentive Rights		818,682

(2) Dr. Kovari is the spouse of Dr. Carter and accordingly all shares owned by each are deemed to be beneficially owned by the other. She beneficially owns 2,144 shares issuable upon exercise of:

Incentive Rights	Plan	Date Issued	Number Of Shares
	2007	01/31/09	536
	2007	02/28/09	494
	2007	03/31/09	510
	2007	04/30/09	408
	2007	05/31/09	196
Total Incentive Rights			2,144

(3) Mr. Piani is a member of our Board of Directors who owns 432,812 shares of common stock and beneficially owns 324,608 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	2004	09/08/04	$ 2.60	54,608	09/07/14
	2004	04/26/05	$ 1.75	100,000	04/26/15
	2004	02/24/06	$ 3.86	50,000	02/24/16
	2004	09/10/07	$ 2.00	100,000	09/09/17
	2004	02/18/08	$ 4.00	20,000	02/18/18
Total Options				324,608	

(4) Charles T. Bernhardt is our Chief Financial Officer and owns 67,079 shares of common stock along with the following rights to received 198,135 shares issuable upon exercise of:

Incentive Rights	Plan	Date Issued	Number Of Shares
	2007	01/31/09	49,569
	2007	02/28/09	45,642
	2007	03/31/09	47,118
	2007	04/30/09	37,791
	2007	05/31/09	18,015
Total Incentive Rights			198,135

(5) Mr. Equels is a member of our Board of Directors, Secretary and General Counsel who owns 937,426 shares of common stock and beneficially owns 491,196 shares issuable or issued upon exercise of:

Warrants	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
Total Warrants	2009	02/1/09	$ 0.51	491,196	02/01/19

(6) Dr. Mitchell is a member of our Board of Directors that owns 304,025 shares of common stock and beneficially owns 312,000 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	2004	09/08/04	$ 2.60	50,000	09/07/14

	2004	04/26/05	$ 1.75	100,000	04/26/15
	2004	02/24/06	$ 3.86	50,000	02/24/16
	2004	09/10/07	$ 2.00	100,000	09/09/17
	2004	09/17/08	$ 6.00	12,000	09/17/18
Total Options				312,000	

(7) Dr. Kiani is a member of our Board of Directors who owns 246,271 shares of common stock and beneficially owns 77,000 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	2004	04/26/05	$ 1.75	15,000	04/26/15
	2004	06/02/05	$ 1.63	12,000	06/30/15
	2004	02/24/06	$ 3.86	50,000	02/24/16
Total Options				77,000	

(8) Dr. Strayer is our Medical Director that has ownership of 51,246 shares of common stock and beneficially owns 420,586 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	1990	12/03/01	$ 4.03	10,000	01/03/11
	2004	12/07/04	$ 1.90	10,000	12/07/14
	2004	12/09/05	$ 2.61	10,000	12/08/15
	2004	11/20/06	$ 2.20	15,000	11/20/16
	2004	01/23/07	$ 2.37	20,000	01/23/17
	2004	09/10/07	$ 2.00	50,000	09/09/17
	2004	12/06/07	$ 1.30	25,000	12/06/17
	2004	02/18/08	$ 4.00	50,000	09/18/18
Total Options				190,000	
Incentive Rights					
	2007	01/31/09		58,089	
	2007	02/28/09		54,453	
	2007	03/31/09		54,015	
	2007	04/30/09		43,962	
	2007	05/31/09		20,067	
Total Incentive Rights				230,586	

(9) Mr. Springate is our Vice President of Operations who owns 877 shares of common stock and beneficially owns 234,648 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	2004	12/07/04	$ 1.90	1,812	12/07/14
	2004	12/09/05	$ 2.61	2,088	12/08/15
	2004	11/20/06	$ 2.20	5,000	11/20/16
	2004	05/01/07	$ 1.78	20,000	09/09/17
	2004	12/06/07	$ 1.30	20,000	12/06/17
Total Options				48,900	
Incentive Rights					
	2007	01/31/09		46,473	

2007	02/28/09	42,789
2007	03/31/09	44,172
2007	04/30/09	35,427
2007	05/31/09	16,887
Total Incentive Rights		185,748

(10) Mr. Dickey is our Senior Vice President and owns 2,500 shares of common stock and beneficially owns 150,000 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
Total Options	2009	07/01/09	$ 2.81	150,000	07/01/19

(11) Dr. Lander is our Vice President of Quality Assurance who owns 153,073 shares of common stock and beneficially owns 15,000 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
Total Options	2004	12/06/07	$ 1.30	15,000	12/06/17

(12) Dr. Ferencz-Biro is our Senior Vice President of Regulatory Affairs who beneficially owns 15,000 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
Total Options	2004	12/06/07	$ 1.30	15,000	12/06/17

(13) Dr. Smith is our Vice President of Manufacturing Quality and Process Development who owns 23,708 shares of common stock and beneficially owns 64,291 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	1990	11/20/96	$ 2.20	7,500	11/20/16
	2004	01/22/97	$ 2.37	6,791	01/22/17
	2004	01/03/01	$ 4.03	10,000	01/03/11
	2004	12/07/04	$ 1.90	10,000	12/07/14
	2004	12/08/05	$ 2.61	10,000	12/08/15
	2004	09/10/07	$ 2.00	20,000	09/09/17
Total Options				64,291	

Item 13. Certain Relationships and Related Transactions, and Director Independence.

We have employment agreements with certain of our executive officers and have granted such officers and directors options and warrants to purchase our common stock, as discussed under the headings, “Item 10. Executive Compensation,” and “Item 11. Security Ownership of Certain Beneficial Owners and Management,” as noted above.

Ransom W. Etheridge was our General Counsel through December 31, 2009. Currently he is an attorney in private practice who renders corporate legal services to us from time to time. As General Counsel, he received fees totaling approximately $144,469 and $105,400 in 2009 and 2008, respectively. In addition, Mr. Etheridge served on the Board of Directors until November 2008 for which he received Director's Fees of cash and stock valued at $150,000 for the time served in 2008.

We used the property acquired in late 2004 by Retreat House, LLC an entity in which the children of William A. Carter have a beneficial interest. We paid Retreat House, LLC $82,400 and $41,200 in 2009 and 2008, respectively, for the use of the property at various times.

Tom Equels was elected to the Board of Directors at the Annual Stockholders Meeting on November 17, 2008. Mr. Equels has provided legal services to us for several years. In 2009 and 2008, we paid Mr. Equels' law firm $386,809 and $395,000, respectfully, for services rendered. Mr. Equels received $150,000 and $37,500 in cash and stock for his Board fees in each 2009 and 2008, respectively.

For her part-time services to us as Assistant Medical Director Kati Kovari, M.D. was paid $13,000 and $13,000 in 2009 and 2008, respectively. Dr. Kovari is the spouse of W. A. Carter, our CEO. From January 1 through May 31, 2009, Dr. Kovari's compensation as an employee was changed pursuant to our "Employee Wage Or Hours Reduction Program" pursuant to which she elected to receive 50% of her wages in Incentive Rights on a three-to-one conversion basis.

ITEM 14. Principal Accountant Fees and Services.

All audit and professional services are approved in advance by the Audit Committee to assure such services do not impair the auditor's independence from us. The total fees by McGladrey & Pullen, LLP ("McGladrey") for 2009 and 2008 were $322,000 and $315,000, respectively. The following table shows the aggregate fees for professional services rendered during the year ended December 31, 2009 and 2008.

	Amount ($)	
Description of Fees	2009	2008
Audit Fees	$ 322,000	$ 315,000
Audit-Related Fees	-0-	-0-
Tax Fees	-0-	-0-
All Other Fees	-0-	-0-
Total	$ 322,000	$ 315,000

Audit Fees

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

Audit-Related Fees

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

The Audit Committee has determined that McGladrey's rendering of these audit-related services was compatible with maintaining auditor's independence. The Board of Directors considered McGladrey to be well qualified to serve as our independent public accountants. The committee also pre-approved the charges for services performed in 2009 and 2008.

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

PART IV

ITEM 15. Exhibits and Financial Statement Schedules.

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

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

(b) Exhibits - See exhibit index below.

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

Exhibit No.	Description
1.1	Engagement Letter between the Company and Rodman & Renshaw, LLC. (23)
2.1	First Asset Purchase Agreement dated March 11, 2003, by and between the Company and ISI.(1)
2.2	Second Asset Purchase Agreement dated March 11, 2003, by and between the Company and ISI.(1)
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended, along with Certificates of Designations.
3.1.1	Series E Preferred Stock.
3.2	Amended and Restated By-laws of Registrant. (17)
4.1	Specimen certificate representing our Common Stock.
4.2	Rights Agreement, dated as of November 19, 2002, between the Company and Continental Stock Transfer & Trust Company. The Right Agreement includes the Form of Certificate of Designation, Preferences and Rights of the Series A Junior Participating Preferred Stock, the Form of Rights Certificate and the Summary of the Right to Purchase Preferred Stock.(2)
4.3	Form of 6% Convertible Debenture of the Company issued in March 2003.(1)
4.4	Form of Warrant for Common Stock of the Company issued in March 2003.(1)
4.5	Form of Warrant for Common Stock of the Company issued in June 2003.(3)
4.6	Form of 6% Convertible Debenture of the Company issued in July 2003.(4)
4.7	Form of Warrant for Common Stock of the Company issued in July 2003.(4)
4.8	Form of 6% Convertible Debenture of the Company issued in October 2003.(5)
4.9	Form of Warrant for Common Stock of the Company issued in October 2003.(5)
4.10	Form of 6% Convertible Debenture of the Company issued in January 2004.(6)
4.11	Form of Warrant for Common Stock of the Company issued in January 2004.(6)
4.12	Form of Warrant for Common Stock of the Company. (9)

58

4.13	Amendment Agreement, effective October 6, 2005, by and among the Company and debenture holders.(11)
4.14	Form of Series A amended 7% Convertible Debenture of the Company (amending Debenture due October 31, 2005).(11)
4.15	Form of Series B amended 7% Convertible Debenture of the Company (amending Debenture issued on January 26, 2004 and due January 31, 2006).(11)
4.16	Form of Series C amended 7% Convertible Debenture of the Company (amending Debenture issued on July 13, 2004 and due January 31, 2006).(11)
4.17	Form of Warrant issued effective October 6, 2005 for Common Stock of the Company.(11)
4.18	Form of Commitment Warrant issued in February 2009 under the Standby Financing Agreement.*
4.19	Form of Indenture filed with Universal shelf registration statement. (18)
4.20	Form of Series I common stock purchase warrant pursuant to May 10, 2009 Securities Purchase Agreement. (23)
4.21	Form of Series II common stock purchase warrant pursuant to May 10, 2009 Securities Purchase Agreement. (23)
4.22	Form of common stock purchase warrant pursuant to May 18, 2009 Securities Purchase Agreement. (24)
10.1	1990 Stock Option Plan.
10.2	1992 Stock Option Plan.
10.3	1993 Employee Stock Purchase Plan.
10.4	Form of Confidentiality, Invention and Non-Compete Agreement.
10.5	Form of Clinical Research Agreement.
10.6	Form of Collaboration Agreement.
10.7	Amended and Restated Employment Agreement by and between the Company and Dr. William A. Carter, dated as of July 1, 1993. (7)
10.8	Employment Agreement by and between the Registrant and Robert E. Peterson, dated April 1, 2001.
10.9	License Agreement by and between the Company and The Johns Hopkins University, dated December 31, 1980.
10.10	Technology Transfer, Patent License and Supply Agreement by and between the Company, Pharmacia LKB Biotechnology Inc., Pharmacia P-L Biochemicals Inc. and E.I. du Pont de Nemours and Company, dated November 24, 1987.
10.11	Pharmaceutical Use Agreement, by and between the Company and Temple University, dated August 3, 1988.
10.12	Assignment and Research Support Agreement by and between the Company, Hahnemann University and Dr. David Strayer, Dr. lsadore Brodsky and Dr. David Gillespie, dated June 30, 1989.
10.13	Lease Agreement between the Company and Red Gate Limited Partnership, dated November 1, 1989, relating to the Company's Rockville, Maryland facility.
10.14	Agreement between the Company and Bioclones (Proprietary) Limited.
10.15	Amendment, dated August 3, 1995, to Agreement between the Company and Bioclones (Proprietary) Limited (contained in Exhibit 10.14).
10.16	Licensing Agreement with Core BioTech Corp.
10.17	Licensing Agreement with BioPro Corp.
10.18	Licensing Agreement with BioAegean Corp.
10.19	Agreement with Esteve.
10.20	Agreement with Accredo (formerly Gentiva) Health Services.
10.21	Agreement with Biovail Corporation International.
10.22	Forbearance Agreement dated March 11, 2003, by and between ISI, the American National Red Cross and the Company.(1)
10.23	Forbearance Agreement dated March 11, 2003, by and between ISI, GP Strategies Corporation and the Company.(1)
10.24	

	Securities Purchase Agreement, dated March 12, 2003, by and among the Company and the Buyers named therein.(1)
10.25	Registration Rights Agreement, dated March 12, 2003, by and among the Company and the Buyers named therein.(1)
10.26	Securities Purchase Agreement, dated July 10, 2003, by and among the Company and the Buyers named therein.(4)
10.27	Registration Rights Agreement, dated July 10, 2003, by and among the Company and the Buyers named therein.(4)

10.28	Securities Purchase Agreement, dated October 29, 2003, by and among the Company and the Buyers named therein.(5)
10.29	Registration Rights Agreement, dated October 29, 2003, by and among the Company and the Buyers named therein.(5)
10.30	Securities Purchase Agreement, dated January 26, 2004, by and among the Company and the Buyers named therein.(6)
10.31	Registration Rights Agreement, dated January 26, 2004, by and among the Company and the Buyers named therein.(6)
10.32	Memorandum of Understanding with Fujisawa. (8)
10.33	Securities Purchase Agreement, dated July 30, 2004, by and among the Company and the Purchasers named therein.(9)
10.34	Registration Rights Agreement, dated July 30, 2004, by and among the Company and the Purchasers named therein. (9)
10.35	Agreement for services of R. Douglas Hulse, (12)
10.36	Amended and Restated Employment Agreement of Dr. William A. Carter. (10)
10.37	Engagement Agreement with Dr. William A. Carter. (10)
10.38	Amended and restated employment agreement of Dr. William A. Carter (12)
10.39	Amended and restated engagement agreement with Dr. William A. Carter (12)
10.40	Amended and restated engagement agreement with Robert E. Peterson (12)
10.41	Engagement Agreement with Ransom W. Etheridge (12)
10.42	Change in control agreement with Dr. William A. Carter (12)
10.43	Change in control agreement with Dr. William A. Carter (12)
10.44	Change in control agreement with Robert E. Peterson (12)
10.45	Change in control agreement with Ransom Etheridge (12)
10.46	Supply Agreement with Hollister-Stier Laboratories LLC
10.47	Manufacturing and Safety Agreement with Hyaluron, Inc.
10.48	Common Stock Purchase Agreement, dated July 8, 2005, by and among the Company and Fusion Capital Fund II, LLC.(13)
10.49	Registration Rights Agreement, dated July 8, 2005, by and among the Company and Fusion Capital Fund II, LLC.(13)
10.48	Common Stock Purchase Agreement, dated April 12, 2006, by and among the Company and Fusion Capital Fund II, LLC.(14)
10.49	Registration Rights Agreement, dated April 12, 2006, by and among the Company and Fusion Capital Fund II, LLC.(14)
10.50	Supply Agreement with Hollister-Stier Laboratories LLC. (15)
10.51	Manufacturing and Safety Agreement with Hyaluron, Inc. (15)
10.52	April 19, 2006 Amendment to Common Stock Purchase Agreement by and among the Company and Fusion Capital Fund II, LLC.(15)
10.53	July 21, 2006 Letter Amendment to Common Stock Purchase Agreement by and among the Company and Fusion Capital Fund II, LLC.(15)
10.54	Royalty Purchase Agreement with Stem Cell Innovations, Inc. (15)
10.55	Biken Activating Agreement. (16)
10.56	Biken Material Evaluation Agreement. (16)
10.57	Common Stock Purchase Agreement, dated July 2, 2008, by and among the Company and Fusion Capital.(19)
10.58	Registration Rights Agreement, dated July 2, 2008, by and among the Company and Fusion Capital.(19)
10.59	Amendment to Common Stock Purchase Agreement, dated July 23, 2008, by and among the Company and Fusion Capital.(20)
10.60	Employee Wage Or Hours Reduction Program.(22)

10.61	Standby Financing Agreement.(22)
10.62	Engagement Agreement with Charles T. Bernhardt, CPA.(22)
10.63	Goal Achievement Incentive Award Program. (21)
10.64	Form of Securities Purchase Agreement entered into on May 10, 2009. (23)
10.65	Form of Securities Purchase Agreement entered into on May 18, 2009. (24)
10.66	Engagement Agreement with Robert Dickey IV, dated June 11, 2009. *
10.67	Engagement Agreement with Robert Dickey IV, dated February 1, 2010. *
10.68	Amendment to Supply Agreement with Hollister-Stier Laboratories LLC dated February 25, 2010. *
10.69	August 2009 Material Evaluation Agreement with Biken. *
21	Subsidiaries of the Registrant.
23.1	McGladrey & Pullen, LLP consent.*
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer.*

31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer.*
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer.*
32.2	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer.*

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* Filed herewith

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(15) Filed with the Securities and Exchange Commission on July 31, 2006 as an exhibit to the Company's Form S-1 Registration Statement (No. 333-136187) and is hereby incorporated by reference.

(16) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) dated December 13, 2007 and is hereby incorporated by reference.

(17) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) filed October 22, 2008 and is hereby incorporated by reference.

(18) Filed with the Securities and Exchange Commission as an exhibit to the Company's Form S-3 Registration Statement (No. 333-151696) and is hereby incorporated by reference.

(19) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) filed July 8, 2008 and is hereby incorporated by reference.

(20) Filed with the Securities and Exchange Commission as an exhibit to the Company's quarterly report on Form 10-Q (No. 1-13441) for the period ended June 30, 2008 and is hereby incorporated by reference.

(21) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) filed November 28, 2008 and is hereby incorporated by reference.

(22) Filed with the Securities and Exchange Commission as an exhibit to the Company's annual report on Form 10-K (No. 1-13441) for the year ended December 31, 2008 and is hereby incorporated by reference.

(23) Filed with the Securities and Exchange Commission as an exhibit to the Company's quarterly report on Form 10-Q (No. 1-13441) for the period ended March 31, 2009 and is hereby incorporated by reference.

(24) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) dated May 18, 2009 and is hereby incorporated by reference.

SIGNATURES

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

HEMISPHERx BIOPHARMA, INC.

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

March 11, 2010

Pursuant to the requirements of Section 13 or 15(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 William A. Carter, M.D.	Chairman of the Board, Chief Executive Officer and Director	March 11, 2010
/s/ Richard Piani Richard Piani	Director	March 11, 2010
/s/ Charles T. Bernhardt Charles T. Bernhardt CPA	Chief Financial Officer and Chief Accounting Officer	March 11, 2010
/s/ Thomas K. Equels Thomas Equels	Director, Secretary and General Counsel	March 11, 2010
/s/ William Mitchell William Mitchell, M.D., Ph.D.	Director	March 11, 2010
/s/ Iraj E. Kiani Iraj E. Kiani, N.D., Ph.D.	Director	March 11, 2010

HEMISPHERx BIOPHARMA, INC AND SUBSIDIARIES
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To 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, 2008 and 2009 and the related consolidated statements of operations, stockholders' equity and comprehensive loss and cash flows for each of the three years in the period ended December 31, 2009. Our audits also included the financial statement schedule of Hemispherx Biopharma, Inc. listed in Item 14(a). These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Hemispherx Biopharma, Inc. and Subsidiaries as of December 31, 2008 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule for each of the three years in the period ended December 31, 2009, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Hemispherx Biopharma, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 12, 2010, expressed an unqualified opinion on the effectiveness of Hemispherx Biopharma, Inc.'s internal control over financial reporting.

/s/ McGladrey & Pullen, LLP
Blue Bell, Pennsylvania
March 12, 2010

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2008 and 2009

(in thousands, except for share and per share amounts)

	2008	2009
ASSETS		
Current assets:		
Cash and cash equivalents (Notes 2 & 16)	$ 6,119	$ 58,072
Inventories (Note 3)	864	-
Prepaid expenses and other current assets	330	332
Total current assets	7,313	58,404
Property and equipment, net (Note 2)	4,877	4,704
Patent and trademark rights, net (Notes 2 & 4)	969	830
Investment	35	35
Construction in progress (Note 2)	-	135
Other assets(Note 3)	17	886
Total assets	$ 13,211	$ 64,994
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 791	$ 1,294
Accrued expenses (Notes 2 & 5)	876	1,321
Total current liabilities	1,667	2,615
Commitments and contingencies (Notes 10, 12, 13 & 14)		
Stockholders' equity (Note 7):		
Preferred stock, par value $0.01 per share, authorized 5,000,000; issued and outstanding; none	-	-
Common stock, par value $0.001 per share, authorized 200,000,000 shares; issued and outstanding 78,750,995 and 132,787,447, respectively	79	133
Additional paid-in capital	208,874	273,093
Accumulated deficit	(197,409)	(210,847)
Total stockholders' equity	11,544	62,379
Total liabilities and stockholders' equity	$ 13,211	$ 64,994

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Years ended December 31,		
	2007	2008	2009
Revenues:			
Sales of product, net	$ 925	$ 173	$ -
Clinical treatment programs	134	92	111
Total Revenues	1,059	265	111
Costs and Expenses:			
Production/cost of goods sold	930	798	584
Research and development	10,444	5,800	6,995
General and administrative	8,974	6,478	5,796
Total Costs and Expenses:	20,348	13,076	13,375
Operating loss	(19,289)	(12,811)	(13,264)
Reversal of previously accrued interest expense	346	-	-
Interest and other income	1,200	592	67
Interest expense	(116)	-	-
Financing costs (Note 7)	(280)	-	(241)
Net loss	$ (18,139)	$ (12,219)	$ (13,438)
Basic and diluted loss per share	$ (.25)	$ (.16)	$ (.12)
Weighted average shares outstanding Basic and Diluted	71,839,782	75,142,075	109,514,401

See accompanying notes to consolidated financial statements.

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

	Common Stock Shares	Common Stock .001 Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
Balance December 31, 2006	66,816,764	$ 67	$ 191,689	$ 46	$ (167,051)	$ 24,751
Shares issued for:						
Interest on convertible debt	116,745	-	193	-	-	193
Private placement, net of issuance costs	6,651,502	7	11,613	-	-	11,620
Stock issued for settlement of accounts payable	175,435	-	292	-	-	292
Stock based compensation	-	-	2,291	-	-	2,291
Net comprehensive loss	-	-	-	(53)	(18,139)	(18,192)
Balance December 31, 2007	73,760,446	74	206,078	(7)	(185,190)	20,955
Shares issued for:						
Private placement, net of issuance costs	1,211,122	1	269	-	-	270
Settlement of accounts payable	3,779,427	4	1,954	-	-	1,958
Stock based compensation	-	-	573	-	-	573
Net comprehensive loss	-	-	-	7	(12,219)	(12,212)
Balance December 31, 2008	78,750,995	79	208,874	-	(197,409)	11,544
Shares issued for:						
Warrants exercised	5,589,790	6	6,133	-	-	6,139
Options exercised	293,831	-	130	-	-	130
Private placement, net of issuance costs	45,591,304	46	55,524	-	-	55,570
Settlement of accounts payable	1,925,408	2	1,365	-	-	1,367
Stock based compensation	636,119	-	826	-	-	826
Standby Finance- finance costs	-	-	241	-	-	241
Net comprehensive loss	-	-	-	-	(13,438)	(13,438)
Balance December 31, 2009	132,787,447	$ 133	$ 273,093	$ -	$ (210,847)	$ 62,379

See accompanying notes to consolidated financial statements

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

	Years ended December 31		
	2007	2008	2009
Cash flows from operating activities:			
Net loss	$ (18,139)	$ (12,219)	$ (13,438)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of property and equipment	266	342	359
Amortization of patent, trademark rights, and royalty interest	170	374	381
Finance costs amortization and for Standby financing	281	-	241
Stock option and warrant compensation and service expense	2,291	573	826
Gain on disposal of equipment	-	-	(83)
Impairment losses	526	-	-
Inventory reserve	109	(65)	-
Interest on convertible debt	181	-	-
Changes in assets and liabilities:			
Inventory	337	(288)	-
Accounts and other receivables	(148)	77	-
Assets held for sale	(678)	450	-
Prepaid expenses and other current assets	22	(184)	93
Other assets	-	-	(5)
Accounts payable	(138)	1,702	1,884
Accrued expenses	(192)	(120)	45
Net cash used in operating activities	(15,112)	(9,358)	(9,297)
Cash flows from investing activities:			
Purchases of property and equipment and construction in progress,net	(212)	(73)	(332)
Additions to patent and trademark rights	(211)	(142)	(242)
Maturities of short term investments	21,132	3,951	-
Purchase of short term investments	(6,754)	-	-
Net cash (used in) provided by investing activities	$ 3,955	$ 3,736	$ (574)

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

	Years ended December 31,		
	2007	2008	2009
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	$ 11,620	$ 270	$ 55,570
Payment of long-term debt	(4,102)	-	-
Collection of advance receivable	1,464	-	-
Proceeds from exercise of stock Warrants and options	-	-	6,254
Net cash provided by financing activities	8,892	270	61,824
Net (decrease) increase in cash and cash equivalents	7,825	(5,352)	51,953
Cash and cash equivalents at beginning of year	3,646	1,471	6,119
Cash and cash equivalents at end of year	$ 11,471	$ 6,119	$ 58,072
Supplemental disclosures of cash flow information:			
Issuance of common stock for accounts payable and accrued expenses	$ 292	$ 1,958	$ 1,382
Issuance of common stock for debt conversion, interest payments and debt payments	$ 181	-	-
Unrealized gains/(losses) on investments	$ (53)	$ 7	$ -

See accompanying notes to consolidated financial statements.

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

(1) Business

The Company is a specialty pharmaceutical engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. The Company was founded in the early 1970s doing contract research for the National Institutes of Health. Since that time, the Company has established a strong foundation of laboratory, pre-clinical, and clinical data with respect to the development of nucleic acids to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of certain chronic diseases.

The consolidated financial statements include the financial statements of Hemispherx Biopharma, Inc. and its wholly-owned subsidiaries. The Company has three domestic subsidiaries BioPro Corp., BioAegean Corp. and Core BioTech Corp., all of which are incorporated in Delaware and are dormant. The Company's foreign subsidiary of Hemispherx Biopharma Europe N.V./S.A. was established in Belgium in 1998, and has no activity. All significant intercompany balances and transactions have been eliminated in consolidation.

On July 7, 2008, the U.S. Food and Drug Administration (FDA) accepted for review the Company's New Drug Application (NDA) for Ampligen®, an experimental therapeutic to treat Chronic Fatigue Syndrome (CFS), originally submitted in October 2007. The Company is seeking marketing approval for the first-ever treatment for CFS.

On November 25, 2009, the Company was notified in a Complete Response Letter ("CLR") from the FDA that described specific additional recommendations related to the Ampligen® NDA. In accordance with its 2008 "Complete Response" procedure, the FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues. The Company is carefully reviewing the CRL and will seek a meeting with the FDA to discuss its recommendations upon the compilation of necessary data to be used in their response.

(2) Summary of Significant Accounting Policies

(a) Cash and Cash Equivalents

Cash and Cash Equivalents consist of cash and money market with fair value of $6,119,000 and $58,072,000 at December 31, 2008 and 2009, respectively.

(b) Assets held for sale (FASB ASC 360-45-9 Long Lived Assets Classified as Held for Sale)

Assets held for sale consisted of equipment purchases related to the purified water system that was to be installed at the Company's manufacturing facility in New Brunswick, NJ. The Company reevaluated their manufacturing needs to determine the cost/benefit for installing the purified water system as compared to selling this asset. As a result of this process, in 2007 the Company reclassed the Equipment of $678,000 to Assets Held for Sale and then recorded an impairment charge of $228,000 to bring the cost down to its net realizable value of $450,000 as per FASB ASC 360-45-9. In December 2008, the asset was sold for $450,000 without the need to recognize gain or loss on sale.

(c) Property and Equipment

	(in thousands) December 31,	
	2008	2009
Land, buildings and improvements	$ 4,094	$ 4,139

Furniture, fixtures, and equipment		2,495		2,629
Leasehold improvements		85		85
Total property and equipment		6,674		6,853
Less accumulated depreciation and amortization		1,797		2,149
Property and equipment, net	$	4,877	$	4,704

Property and equipment is recorded at cost. Depreciation and amortization is computed using the straight-line method over the estimated useful lives of the respective assets, ranging from five to thirty-nine years.

Construction in progress consists of funds used for the construction and installation of property and equipment within the Company's New Jersey facility. As of December 31, 2009, construction in progress was $135,000 as compared to $-0- for year-end 2008 when all construction was on hold.

(d) Patent and Trademark Rights

Patents and trademarks are stated at cost (primarily legal fees) and are amortized using the straight line method over the established useful life of 17 years. The Company reviews its patents and trademark rights periodically to determine whether they have continuing value. Such review includes an analysis of the patent and trademark's ultimate revenue and profitability potential. Management's review addresses whether each patent continues to fit into the Company's strategic business plans.

(e) Revenue

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

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

Commercial sales of Alferon N Injection® were halted in March 2008 as the current expiration date of our finished goods inventory expired in March 2008. The Company is undertaking a major capital improvement program to enhance their manufacturing capability for Alferon N Injection® at the New Brunswick facility that will continue throughout 2010. As a result, Alferon N Injection® could be available for commercial sales in mid to late 2011.

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Equivalent common shares, consisting of stock options and warrants including the Company's convertible debentures, amounted to 16,686,281, 29,335,536 and 21,241,453 shares, are excluded from the calculation of diluted net loss per share for the years ended December 31, 2007, 2008 and 2009, respectively, since their effect is antidilutive.

(f) Accounting for Income taxes (FASB ASC 740 Income Taxes)

The Company adopted the provisions of FASB ASC 740-10 Uncertainty in Income Taxes. As a result of the implementation, there has been no material change to the Company's tax position as they have not paid any corporate income taxes due to operating losses. All tax benefits will likely not be recognized due to the substantial net operating loss carryforwards which will most likely not be realized prior to expiration. With no tax due for the foreseeable future, the Company has determined that a policy to determine the accounting for interest or penalties related to the payment of tax is not necessary at this time.

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.

(g) Comprehensive loss

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

(h) Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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.

(i) Recent Accounting Standards and Pronouncements:

In June 2009, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 168 ("SFAS 168"), the Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles. SFAS 168 names the FASB Accounting Standards Codification ("ASC") as the source of authoritative accounting and reporting standards in the United States, in addition to guidance issued by the SEC. The ASC is a restructuring of accounting and reporting standards designed to simplify user access to all authoritative U.S. Generally Accepted Accounting Principals ("GAAP") by providing the authoritative literature in a topically organized structure. The ASC reduces the U.S. GAAP hierarchy to two levels, one that is authoritative and one that is not. The ASC is not intended to change U.S. GAAP or any requirements of the SEC. The ASC became authoritative upon its release on July 1, 2009 and is effective for interim and annual periods ending after September 15, 2009.

The Codification supersedes all existing non-SEC accounting and reporting standards. All other nongrandfathered non-SEC accounting literature not included in the Codification are nonauthoritative. Following Statement 168, the FASB will not issue new standards in the form of Statements, FASB Staff Positions, or Emerging Issues Task Force Abstracts. Instead, the FASB will issue Accounting Standards Updates, which will serve only to: (a) update the Codification; (b) provide background information about the guidance; and (c) provide the bases for conclusions on the change(s) in the Codification.

The FASB has published FASB Accounting Standards Update 2009-01 through 2009-17.

The adoption of SFAS 168 and published FASB Accounting Standards Update 2009-01 through 2009-17 have no material effect on the Company's financial statements for the year-ended December 31, 2009.

(j) Equity Based Compensation

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

The Equity Incentive Plan of 2007, effective June 20, 2007, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 8,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan of 2007. Unless sooner terminated, the Equity Incentive Plan of 2007 will continue in effect for a period of 10 years from its effective date.

The Equity Incentive Plan of 2009, effective June 24, 2009, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 15,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan of 2009. Unless sooner terminated, the Equity Incentive Plan of 2007 will continue in effect for a period of 10 years from its effective date.

The Equity Plan of 2004 and the Equity Incentive Plans of 2007 and 2009 are administered by the Board of Directors. The Plans provide for awards to be made to such officers, other key employees, non-employee directors, consultants and advisors of the Company and its subsidiaries as the Board may select.

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

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model. Expected volatility is based on the historical volatility of the price of the Company's stock. The risk-free interest rate is based on U.S. Treasury issues with a term equal to the expected life of the option. The Company uses historical data to estimate expected dividend yield, expected life and forfeiture rates. The fair values of the options granted, were estimated based on the following weighted average assumptions:

	December 31,		
	2007	2008	2009
Risk-free interest rate	3.39 - 4.77%	2.52 – 3.74%	1.76 - 2.69%
Expected dividend yield	-	-	-
Expected lives	5 yrs.	2.5 - 5 yrs.	2 - 5 yrs.
Expected volatility	70.01 – 77.52%	73.84 – 79.2%	86.78 - 137.47%
Weighted average fair value of options and warrants issued in the years 2007, 2008 and 2009 respectively	$2,216,091	$473,954	$536,378

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

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

Stock option activity during the years ended December 31, 2007, 2008 and 2009 is as follows:

Stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2007	2,001,969	2.51	8.01	-
Options granted	2,624,120	2.77	9.05	-
Options forfeited	-	-	-	-
Outstanding December 31, 2007	4,626,089	$ 2.66	8.25	-
Options Granted	1,655,000	2.42	9.69	-
Options Forfeited	(22,481)	2.13	-	-
Outstanding December 31, 2008	6,258,608	$ 2.60	7.92	-
Options granted	-	-	-	-
Options forfeited	(29,856)	2.24	5.75	-
Outstanding December 31,2009	6,228,752	$ 2.60	6.95	-
Exercisable December 31, 2009	6,190,419	$ 2.60	6.96	-

The weighted-average grant-date fair value of employee options granted during the year 2009 was $-0-.

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2007	113,986	2.26	9.05	-
Options granted	130,000	1.34	10.00	-

Options vested	(77,223)	(6.86)	8.29	-
Outstanding December 31, 2007	166,673	$ 1.59	7.18	-
Options granted	-0-	-0-	-0-	-
Options vested	(73,420)	1.68	8.58	-
Options forfeited	(16,399)	2.00	6.18	-
Outstanding December 31, 2008	76,944	$ 1.41	3.89	-
Options granted	-	-	-	-
Options vested	(38,611)	1.28	7.92	-
Options forfeited	-	-	-	-
Outstanding December 31,2009	38,333	$ 1.54	8.00	-

Stock option activity for non-employees during the year:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2007	1,326,732	$ 2.63	8.18	-
Options granted	608,750	1.99	9.94	-
Options forfeited	-0-	-0-	-0-	-
Outstanding December 31, 2007	1,935,482	2.43	8.05	-
Options granted	482,000	2.02	6.72	-
Options forfeited	-0-	-0-	-0-	-
Outstanding December 31, 2008	2,417,482	$ 2.35	6.98	-
Options granted	361,250	2.12	7.00	-
Options exercised	(293,831)	1.56	7.93	-
Options forfeited	(251,469)	2.14	7.43	-
Outstanding December 31,2009	2,233,432	$ 2.44	5.73	-
Exercisable December 31, 2009	2,093,848	$ 2.42	6.05	-

The weighted-average grant-date fair value of non-employee options granted during the year 2009 was $1.27.

Unvested stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2007	37,100	$ 2.28	9.81	-
Options granted	25,000	$ 1.30	10.00	-
Options vested	(22,100)	(2.30)	8.23	-
Outstanding December 31, 2007	40,000	$ 1.50	9.30	-
Options granted	-	-	-	-
Options vested	(13,333)	(1.64)	6.91	-
Outstanding December 31, 2008	26,667	$ 1.43	9.00	-
Options granted	131,250	2.81	3.42	-
Options vested	(18,333)	1.79	7.45	-
Outstanding December 31,2009	139.584	$ 2.68	3.76	-

The impact on the Company's results of operations of recording stock-based compensation for the year ended December 31, 2009 was to increase general and administrative expenses by approximately $353,000 and reduce earnings per share by $.01 per basic and diluted share.

As of December 31, 2009, there was $230,000 of unrecognized stock-based compensation cost related to options granted under the Equity Incentive Plans.

(k) Accounts Receivable

Concentration of credit risk, with respect to accounts receivable, is limited due to the Company's credit evaluation process. The Company does not require collateral on its receivables. The Company did not have any receivables as of December 31, 2008 and 2009.

(3) Inventories and Other assets

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

Inventories consist of the following:

	(in thousands) December 31,	
	2008	2009

Raw materials and work in process	$ 864	$ -
Finished goods, net of reserves of $286,000 and $282,000 at December 31, 2008 and 2009	-	-
	$ 864	$ -

The production of Alferon N Injection® from our Work-In-Progress Inventory, which has an approximate expiration date of 2012, has remained on hold for conversion due to the dedication of resources to prepare the New Brunswick facility for the FDA preapproval inspection with respect to Ampligen® NDA. Since adequate financial resources were obtained to commence upgrades to the Ampligen® and Alferon® manufacturing process, the project has commenced and will be undertaken throughout 2010. As a result, conversion of Alferon N Injection® Work-In-Progress inventory is projected to begin in late 2010 or early 2011 to allow for the creation of new Finished Goods available for commercial sales in mid to late 2011. As a result of delaying the conversion of Work-In-Progress until potentially 2011, in 2009 the Company has reclassed the $864,000 value of inventory to "Other assets".

Other assets consist of the following:

	(in thousands) December 31,	
	2008	2009
Inventory work in process	$ -	$ 864
Security deposit	17	15
Internet Domain Names	-	7
	$ 17	$ 886

Alferon® LDO is undergoing pre-clinical testing for possible prophylaxis against influenza. The Company's testing of the product supports their belief that a significant portion of this product is not impaired and could be safely utilized in clinical trails. Subject to FDA authorization and/or authorization of regulatory authorities in other countries, the finished goods inventory of Alferon N Injection® 5ml vials may be used to produce approximately 11,000,000 sachets of Alferon® Low Dose Oral ("LDO") for clinical trials. However, no assurance can be given that this inventory will be permitted for use in future clinical trials or for any other clinical use. While the studies to date on Alferon ® LDO have been encouraging, preliminary testing in the laboratory and in animals is not necessarily predictive of successful results in clinical testing or human treatment. No assurance can be given that similar results will be observed in clinical trials. Use of Alferon® LDO as a possible prevention or treatment of any flu requires prior regulatory approval. Only the FDA can determine whether a drug is safe, effective or appropriate for use in clinical testing or for treating a specific application.

In October 2009, the Company submitted a protocol to the FDA proposing to conduct a Phase 2, well-controlled, clinical study for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. Following a teleconference with the FDA in November 2009, the FDA placed the proposed study on "Clinical Hold" because the protocol was deemed by the FDA to be deficient in design and because additional information was required to be submitted in the area of chemistry, manufacturing and controls ("CMC"). Thereafter in December 2009, the Company submitted additional information by Amendment with respect to both the clinical protocol design issues and the CMC items. In January 2010, the FDA acknowledged that our responses to the clinical issues were acceptable; however, the Clinical Hold remained in effect because the FDA believed that certain CMC issues had not yet been satisfactorily resolved. In this regard, the FDA communicated concern regarding the extended storage of Alferon® LDO drug product clinical lots which had been manufactured from an active pharmaceutical ingredient ("API") of Alferon N Injection® manufactured in the year 2001. While the biological (antiviral) potency of the product had remained intact, the Company learned through newly conducted physico-chemical tests (the "new tests" of temperature, pH, oxidation and light on the chemical stability of an active API), that certain changes in the drug over approximately nine storage years (combined storage of Alferon N Injection® plus storage of certain LDO sachets) had introduced changes in the drug which might adversely influence the human safety profile. The "new tests" are part of recent FDA requirements for biological products, such as interferon, which did not exist at the time of the original FDA approval of Alferon N Injection® for commercialization and at the time of FDA approval of the "Establishment License" for Hemispherx' manufacturing facility. Based on the recent FDA request, the Company has

now established and implemented the “new test” procedures. As a result, the Company has found that certain Alferon N Injection® lots with extended storage (i.e., approximately eight to nine years) do appear to demonstrate some altered physico-chemical properties. However the Company has also observed in more recent lots, including those manufactured beginning in the year 2006, are superior with respect to the enhanced scrutiny of these tests and, in the Company’s view, may be considered appropriate for clinical trials in the Alferon® LDO sachet format. The Company expects to submit these new data to the FDA in the Spring of 2010 and believes that the Clinical Hold could be thereafter lifted if the FDA agrees that these data address the outstanding CMC issues cited in the January 2010 FDA recommendations.

(4) Patents, Trademark Rights and Other Intangibles (FASB ASC 350-30 General Intangibles Other than Goodwill)

Patents are stated at cost and amortized over the established useful life of 17 years for patents or over the period which the asset is expected to directly or indirectly contribute to the Company's cash flow.

The Company records the acquisition of patents as an intangible asset to be amortized over the remaining life of the patent under guidance set forth in FASB ASC 350-30.

On July 26, 2006, the Company executed an agreement with Stem Cell Innovations, Inc. (formerly Interferon Sciences, Inc.) whereby it acquired the royalty interest previously granted Interferon Sciences with respect to the Company's sale of products containing alpha interferon in exchange for 250,000 shares of common stock. The Company registered these shares on behalf of Stem Cell Innovations for public resale. The Company recorded this transaction on its balance sheet as an intangible asset under guidance provided by FASB ASC 350-30. The total consideration paid to Stem Cell under the agreement amounted to $620. The intangible asset was amortized over the period which the asset is expected to contribute directly or indirectly to the Company's cash flow. In 2007, the Company recorded an impairment charge of $298,000 as the Company determined that sufficient inventory is not on hand to realize the full economic benefit; therefore, the asset was written down to its estimated net realizable value. The balance of this intangible asset, as of December 31, 2008 and 2009, was $-0-. The balance was written-off in 2008 as we had no more Alferon® to sell.

During the years ended December 31, 2007, 2008 and 2009, the Company decided not to pursue certain patents in various countries for strategic reasons and recorded abandonment charges of $7,000, $4,000 and $228,000 respectively, which are included in research and development. Amortization expense was $103,000, $122,000 and $153,000 in 2007, 2008 and 2009, respectively. The total cost of the patents was $2,760,000 and $1,814,000 as of December 31, 2008 and 2009, respectively. The accumulated amortization as of December 31, 2008 and 2009 is $1,791,000 and $984,000, respectively.

As of December 31, 2009, the weighted average remaining life of the patents and trademarks was 5.4 years. Amortization of patents and trademarks for each of the next five years is as follows: 2010 - $153,000, 2011 - $153,000, 2012 - $153,000, 2013 - $153,000 and 2014 – $153,000.

(5) Accrued Expenses

Accrued expenses at December 31, 2008 and 2009 consists of the following:

	(in thousands) December 31,	
	2008	2009
Compensation	$ 192	$ 716
Professional fees	497	421
Other expenses	54	71
Other liability	133	113
	$ 876	$ 1,321

(6) Debenture Financing

In June 2007, the Company retired all remaining debt related to its convertible debentures issued in October 2003, January 2004 and July 2004. Of the outstanding debt of approximately $4,102,000, only $2,638,000 was required to be paid in new funds to retire the debentures, with the balance being covered by the Company's advance receivable held as collateral by one of the debenture holders.

October 2003 Debentures

Interest expense for the years ended December 31, 2007, 2008 and 2009, with regard to the October 2003 Debentures was approximately $72,000, $-0- and $-0-, respectively.

January 2004 Debentures

Interest expense for the years ended December 31, 2007, 2008 and 2009, with regard to the January 2004 Debentures was approximately $9,000, $-0- and $-0-, respectively.

July 2004 Debentures

The Company recorded financing costs for the years ended December 31, 2007, 2008 and 2009, with regard to the July 2004 Debentures of $231,000, $-0- and $-0-, respectively. Interest expense for the year ended December 31, 2007, 2008 and 2009, with regard to the July 2004 Debentures was approximately $35,000, $-0- and $-0-, respectively.

(7) Stockholders' Equity

(a) Preferred Stock

The Company is authorized to issue 5,000,000 shares of $.01 par value preferred stock with such designations, rights and preferences as may be determined by the board of directors. There were no preferred shares issued and outstanding at December 31, 2008 and 2009.

(b) Common Stock

The Company's stockholders approved an amendment to the Company's corporate charter at the Annual Shareholder meeting held in Philadelphia, PA on September 20, 2006. This amendment increased the Company's authorized shares

from 100,000,000 to 200,000,000.

As of December 31, 2008 and 2009, 78,750,995 and 132,787,447 shares, were outstanding, respectively.

(c) Equity Financings

On April 12, 2006, the Company entered into a Common Stock Purchase Agreement ("Purchase Agreement") with Fusion Capital Fund II, LLC ("Fusion Capital") an Illinois limited liability company. Pursuant to the terms of the Purchase Agreement, Fusion Capital had agreed to purchase from the Company up to $50,000,000 of common stock over a period of approximately twenty-five (25) months. Pursuant to the terms of the Registration Rights Agreement, dated as of April 12, 2006, the Company registered 12,386,723 shares issuable to or issued to Fusion under the Purchase Agreement. Once the Registration Statement was declared effective, each trading day during the term of the Purchase Agreement the Company had the right to sell to Fusion Capital up to $100,000 of the Company's common stock on such date or the arithmetic average of the three lowest closing trade prices of the common stock during the immediately proceeding 12 trading day period. At the Company's option under certain conditions, Fusion Capital was required to purchase greater amounts of common stock during a given period. In connection with entering into the Purchase Agreement, the Company issued to Fusion Capital as commitment shares 321,751 shares of common stock and the Company was obligated to issue an additional 321,751 commitment shares. These additional commitment shares were issued in an amount equal to the product of (x) 321,751 and (y) the Purchase Amount Fraction. The "Purchase Amount Fraction" means a fraction, the numerator of which is the purchase price at which the shares were being purchased by Fusion and the denominator of which is $50,000,000.

The purchase price was be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction. Fusion Capital could not purchase shares of the Company's common stock under the common stock purchase agreement if it, together with its affiliates, would beneficially own more than 9.9% of the common stock outstanding at the time of the purchase by Fusion Capital. Fusion Capital had the right at any time to sell any shares purchased under the 2006 Purchase Agreement which would allow it to avoid the 9.9% limitation. Due to NYSE Amex guidelines, without prior stockholder approval, we did not have the right or the obligation under the Agreement to sell shares to Fusion Capital in excess of 12,386,723 shares (i.e. 19.99% of the 61,964,598 outstanding shares of our common stock on April 12, 2006, the date of the 2006 Purchase Agreement) inclusive of commitment shares issued to Fusion Capital under the Agreement. In addition, Fusion Capital could not purchase more than 27,386,723 shares, inclusive of the commitment shares under the Agreement. On September 20, 2006 stockholders voted to allow the sale of up to 27,386,723 shares pursuant to the terms of the Fusion agreement.

As of December 31, 2007, Fusion Capital had purchased from the Company 10,682,032 shares for aggregate gross proceeds of approximately $19,739,000. In addition, the Company issued to Fusion Capital 127,065 shares towards the remaining commitment fee. No purchases were made by Fusion in 2008 or 2009 under this agreement, which expired July 31, 2008.

On July 2, 2008, the Company entered into a $30 million Common Stock Purchase Agreement (the "Purchase Agreement") with Fusion Capital. Concurrently with entering into the Purchase Agreement, we entered into a registration rights agreement with Fusion Capital. Under the registration rights agreement, we filed a registration statement related to the transaction with the U.S. Securities & Exchange Commission ("SEC") covering the shares that have been issued or may be issued to Fusion Capital under the common stock purchase agreement. That registration statement was declared effective by the SEC on August 12, 2008. As reported in the registration statement related to the transaction, we had the right over a 25 month period from August 2008 to sell our shares of common stock to Fusion Capital from time to time in amounts between $120,000 and $1 million depending on certain conditions as set forth in the agreement, up to a maximum of $30 million. The purchase price of the shares related to the $30.0 million of future funding was based on the prevailing market prices of the Company's shares at the time of sales as computed under the Purchase Agreement without any fixed discount, and the Company had control of the timing and amount of any sales of shares to Fusion Capital. However, Fusion Capital could not purchase any shares of our common stock pursuant to the Purchase Agreement if the price of our common stock had three trading days with an average value below $0.40 over the prior twelve trading days. There were no negative covenants, restrictions on future funding,

penalties or liquidated damages in the agreement. In consideration for entering into the Purchase Agreement, we issued to Fusion Capital 650,000 shares as a commitment fee. Also, we were to issue to Fusion Capital up to an additional 650,000 shares as a commitment fee pro rata as we receive up to the $30.0 million of future funding. As of September 1, 2009, Fusion Capital had purchased the maximum number of shares that were registered under the Registration Statement, an aggregate of 20,000,000 shares for $28,111,695 and received 1,259,086 commitment shares.

On May 8, 2009, the Company entered into a letter agreement (the "Engagement Letter") with Rodman & Renshaw, LLC ("Rodman") as placement agent, relating to a proposed offering of the our securities. The proceeds from the May 10 and 18, 2009 equity transactions are net of all related offering costs, including the fair value of warrants issued.

On May 10, 2009, the Company entered into Securities Purchase Agreements with two institutional investors. Pursuant to the Securities Purchase Agreements, the Company issued to these investors in the aggregate: (a) 13,636,363 shares of our common stock; (b) Series I warrants to purchase an additional 6,136,363 shares of common stock at an exercise price of $1.65 per share ("Series I Warrants"); and (c) Series II warrants to purchase up to 3,000,000 shares of common stock at an exercise price of $1.10 per share ("Series II Warrants", and together with the Series I Warrants, the "Warrants"). The warrants include a cash settlement feature if certain conditions are met. The Series I Warrants could be exercised at any time on or after the six month anniversary of the May 18, 2009 closing date of the offering and for a five year period thereafter. The Series II Warrants could be exercised at any time on or after the May 18, 2009 date of delivery of the Series II Warrants and for a period of 45 days thereafter. As of December 31, 2009, all Series II Warrants were exercised and none of the Series I Warrants have been exercised.

Rodman, as placement agent for the May 10, 2009 Securities Purchase Agreements, acted on a best efforts basis for the offering and received a placement fee equal to $825,000 as well as Series I Warrants to purchase 750,000 shares of our common stock equal at an exercise price of $1.38 per share. The Series I Warrants can be exercised at any time on or after the six month anniversary of the May 18, 2009 closing date of the offering and for a five year period thereafter. Rodman also was entitled to a fee equal to 5.5% of the Series II Warrants that were exercised. As of December 31, 2009, Rodman received $165,000 in fees with regard to the exercise of the Series II Warrants.

On May 18, 2009, the Company entered into Securities Purchase Agreements with two institutional investors. Pursuant to the Securities Purchase Agreements, The Company issued to these investors in the aggregate: (a) 11,906,976 shares of common stock; and (b) warrants to purchase an additional 4,167,440 shares of common stock at an exercise price $1.31 per share ("Warrants"). The warrants include a cash settlement feature if certain conditions are met. The Warrants could be exercised at any time on or after their May 21, 2009 date of issuance and for a five year period thereafter. As of December 31, 2009, 1,895,000 of these Warrants had been exercised.

Rodman, as placement agent for the May 18, 2009 Securities Purchase Agreements, acted on a best efforts basis for the offering and received a placement fee equal to $797,500 as well as Warrants to purchase 654,884 shares of common stock at an exercise price of $1.34375 per share. The Warrants could be exercised at any time on or after the six month anniversary of the May 21, 2009 closing date of the offering and for a five year period thereafter.

The proceeds from this financing have been used to fund infrastructure growth including manufacturing, regulatory compliance and market development.

(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. This plan is no longer in effect and no further options will be issued from this plan.

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

	2007			2008			2009		
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price
Outstanding, beginning of year	400,702	$ 2.71-4.03	$ 3.08	345,728	$ 2.71-4.03	$ 3.01	345,728	$ 2.71-4.03	$ 3.01
Granted	-	-	-	-	-	-	-	-	-
Canceled	(54,974)	$ 3.50-4.03	$ 3.53	-	-	-	(10,000)	$ 4.03	$ 4.03
Exercised	-	-	-	-	-	-	-	-	-
Outstanding, end of year	345,728								