HEMISPHERX BIOPHARMA INC
Form 10-K
March 29, 2011

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, 2010
OR
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission File No. 1-13441

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

Delaware	52-0845822
(State or other jurisdiction of 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 ¨ No x

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

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

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 ¨ 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. ¨

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 ¨ Non-accelerated filer ¨ Smaller Reporting Company ¨

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

The aggregate market value of Common Stock held by non-affiliates at June 30, 2010, the last business day of the registrant's most recently completed second fiscal quarter was $61,726,769.

The number of shares of the registrant's Common Stock outstanding as of March 1, 2011 was 135,241,609.

DOCUMENTS INCORPORATED BY REFERENCE: None.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K (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 (the "Exchange Act"), 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 there other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. All statements other than statements of historical fact included in this Form 10-K regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note that statements regarding potential drugs, their potential therapeutic effect, the possibility of obtaining regulatory approval, our ability to manufacture and sell any products, market acceptance or our ability to earn a profit from sales or licenses of any drugs or our ability to discover new drugs in the future are all forward-looking in nature.

Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Hemispherx Biopharma, Inc. and its subsidiaries (collectively, "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 minimal 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®. As of December 31, 2010, construction in progress on this project was $485,000 as compared to $135,000 at December 31, 2009. 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. Please see "Manufacturing" below 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 ir@hemispherx.

OUR PRODUCTS

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

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®, is an experimental, unapproved drug, that would be administered intravenously. Ampligen® has been assigned the generic name rintatolimod by the United States Adopted Names Council (USAN) and has the chemical designation poly(I) poly(C12,U).

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® is also the first ever accepted for review by the FDA for systemic use of a toll-like receptor therapy to treat any condition. In November 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 have carefully reviewed 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. In designing and implementing these additional trials, we believe that it would be very valuable to first have the capability of utilizing a reliable diagnostic test to better identify potential participants. We are therefore pursuing efforts to identify and validate such a test (see "Progress In Search For CFS Test" below). In the Non-Clinical area, the FDA recommended among other things that we complete rodent carcinogenicity studies in two species. While as part of the NDA submission we had requested that these studies be waived, this waiver had not been granted by the FDA in their CRL.

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 current Good Manufacturing Practice ("cGMP") guidelines and our manufacturing enhancement program. 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. We do not anticipate receiving feedback until we submit our complete response to the CLR. The preclinical studies discussed in these reports were the combined work-product of the staffs at Hemispherx and Lovelace Respiratory Research Institute in Albuquerque, New Mexico, and included 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.

The FDA also commented on Ampligen® manufacturing noting the need to resolve outstanding inspection issues at the facilities producing Ampligen®. These include our New Brunswick facility and one of our third-party subcontractor manufacturing facilities, Hollister-Stier Laboratories of Spokane, Washington ("Hollister-Stier"). As discussed in "Manufacturing" below, we believe that these issues have been resolved.

We estimate that it could take approximately 18 months to three years to complete an Ampligen® clinical study for resubmission to the FDA under the industry norm of three to six months to initiate the study, one to two years to accrue and test patients, three to six months to close-out the study and file the necessary documents with the FDA. The actual duration to complete the clinical study may be different based on the final design of an accepted FDA clinical Phase III study, availability of participants, clinical sites, when the study commences and any other factors that could impact the implementation of the study, analysis of results, or requirements of the FDA and other governmental organizations.

Additionally, we estimate that the approximate cost to undertake the Ampligen® Phase III clinical study could range from $12,000 to $18,500 per each of the 600 participating patients, for an estimated range of total incremental costs of $7,200,000 to $11,100,000. Our estimate is based on the belief that our experience from the prior Phase III study and established teams (e.g., Medical, Data Processing, Clinical Monitors, Statisticians, Medical Reporting) along with existing inventory and investigational protocol, could produce financial efficiencies. We believe that these efficiencies could permit our costs of undertaking a Phase III CFS study to be discounted as compared to a potential $28,500 per patient cost approximated as an industry average for running a Phase III study from scratch, as estimated and adjusted for inflation, utilizing data from the business intelligence firm Cutting Edge Information. The actual costs of a Phase III investigation study for CFS may differ based on final design of an accepted FDA Phase III clinical study, prevailing costs to undertake clinical studies, qualification and access to CFS patients, insurance and government requirements along with other potential costs or reimbursements unknown at this time.

Aside from the foregoing, we cannot estimate what additional studies and/or additional testing or information that the FDA may require. Accordingly, as of this time, we are unable to estimate the nature, timing, costs and necessary efforts to obtain FDA clearance, the anticipated completion dates or whether we will obtain FDA clearance.

Notwithstanding the foregoing, we believe that it is important to find a reliable diagnostic test for CFS before committing greater resources to Phase III study (see "Progress In Search For CFS Test" below) since the identification of suitable participants is critical in the undertaking of a Phase III study. In addition, a reliable test would allow for an enhanced means to evaluate the effectiveness of Ampligen® on CFS.

In December 2010, the FDA granted us a one year extension to file a response to the CRL. While the Company remains committed to undertaking the Ampligen® Phase III clinical study, it is diligently working to address the diagnostic challenges related to CFS before commencing the requisite study.

Progress In Search For CFS Test

As stated on the CDC website, diagnosing CFS can be complicated by a number of factors:

1. There is no diagnostic laboratory test or biomarker for CFS;
2. Fatigue and other symptoms of CFS are common to many illnesses;
3. CFS is an invisible illness and many patients don't look sick;
4. The illness has a pattern of remission and relapse;
5. Symptoms vary from person to person in type, number and severity.

These factors have contributed to a very low diagnosis rate in which of the up to four million Americans estimated to have CFS, less than 20 percent of those stricken are being properly diagnosed. Because currently there is no FDA approved blood test, brain scan or other lab test to diagnose CFS, it's a diagnosis of exclusion. If a patient has had six or more consecutive months of severe fatigue that is reported to be unrelieved by sufficient bed rest and that is accompanied by nonspecific symptoms, including flu-like symptoms, generalized pain and memory problems, the patient may have CFS.

In the October 8, 2009 issue of Science Express, a consortium of researchers from the Whittemore Peterson Institute ("WPI"), the National Cancer Institute and the Cleveland Clinic reported a new retrovirus, xenotropic murine leukemia related virus ("XMRV") 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. Retrospective analyses of patient samples from the completed Phase III trial of Ampligen® in potential treatment of CFS continues in collaboration with WPI. While an updated agreement is being finalized with WPI, we continue to collaborate with WPI under the terms of an "Evaluation Agreement" that expired on July 23, 2010, to evaluate Hemispherx' patient samples for XMRV using WPI's flow cytometry assay. We believe that these studies may provide a new perspective on the design of an additional confirmatory Phase III study in this disorder.

In addition, on March 2, 2011, we jointly filed a provisional United States patent application on a blood test for CFS with Chronix Biomedical ("Chronix"). This experimental approach analyzes fragments of DNA often released into the bloodstream during the process of apoptosis or programmed cell death to measure alterations in specific regions of the chromosome, which can be detected as distinctive "signatures" in cell-free blood-borne DNA. The patient-unique signatures captured by Chronix' technology may prove useful as a companion diagnostic and to provide information about the disease process to help pharmaceutical companies select the most efficacious drug candidates. The use of this diagnostic technology for CFS diagnosis will be evaluated in a study being planned by Chronix and Hemispherx.

Alferon N Injection®

Alferon N Injection® is the registered trademark for our injectable formulation of natural alpha interferon, which is approved by the FDA in 1989 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. 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.

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 formulations have been 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 papilloma viruses (“HPV”) cause genital warts, a sexually transmitted disease (“STD”). The Centers for Disease Control and Prevention (“CDC”) estimates that approximately twenty million Americans are currently infected with HPV with another six million becoming newly infected each year. The CDC states that HPV is so common, that at least 50% of sexually active men and women get it at some point in their lives.

Commercial sales of Alferon N Injection® were halted in March 2008 when our finished goods inventory expired. We are in the process of upgrading our manufacturing capability for Alferon N Injection® at our New Brunswick facility. As a result, we expect to be in a position to resume manufacture of Alferon N Injection® [Please see “Alferon® Low Dose Oral (LDO)” and “Manufacturing” below 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 influenza and other emerging viruses. 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.

In October 2009, we submitted a protocol to the FDA proposing to conduct a Phase II, double-blind, adaptive-design, randomized, placebo-controlled, dose-ranging study of 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 be 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 an 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 "Product License" and "Establishment License" for the Alferon N Injection® product. 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. Upon their review, the FDA has been responsive to these new findings and requested additional stability data on the lots proposed for use in this clinical study utilizing the new test methods. The proposed clinical lots were manufactured on June 24, 2010 and placed on stability on June 28, 2010. The FDA had requested three months of stability data on the proposed clinical lots which was compiled, analyzed and submitted to the FDA on November 12, 2010. On December 22, 2010, the FDA informed us that the Agency had completed its review of our complete response to the Clinical Hold and lifted the Clinical Hold, allowing our Phase II Study to proceed.

HISTORICAL COSTS RELATED TO OUR PRODUCTS

The following table sets forth the costs related to our major products for each of the prior three years. Our aggregate expenses from the time that we first started developing nucleic acid pharmaceutical technology in the mid 1980's through March 2003 were substantially related to the development of Ampligen®, and from that date through the current period were substantially related to Ampligen® and Alferon.

Costs and Expenses	(dollars in thousands) Year Ended December 31, 2010				
	Ampligen® NDA	Alferon N Injection®	Alferon® LDO	Other	Total
Production/cost of goods sold	$-	$1,341	$-	$-	$1,341
Research and development	2,787	-	4,658	168	7,613
General and administrative	2,356	1,133	3,937	142	7,568
Total	$5,143	$2,474	$8,595	$310	$16,522

Costs and Expenses	(dollars in thousands) Year Ended December 31, 2009				
	Ampligen® NDA	Alferon N Injection®	Alferon® LDO	Other	Total
Production/cost of goods sold	$-	$584	$-	$-	$584
Research and development	5,026	-	1,784	185	6,995
General and administrative	3,844	447	1,364	141	5,796
Total	$8,870	$1,031	$3,148	$326	$13,375

Costs and Expenses	(dollars in thousands) Year Ended December 31, 2008				
	Ampligen® NDA	Alferon N Injection®	Alferon® LDO	Other	Total
Production/cost of goods sold	$-	$798	$-	$-	$798
Research and development	5,491	-	-	309	5,800
General and administrative	5,392	783	-	303	6,478
Total	$10,883	$1,581	$-	$612	$13,076

PATENTS AND NON-PATENT EXCLUSIVITY RIGHTS

At March 1, 2011, we had 20 patents worldwide with 78 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

5: 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).

Oragens®

In 1999, we acquired a series of patents on Oragens®, potentially a set of oral broad spectrum antivirals and immunological enhancers, through a licensing agreement with Temple University ("Temple") 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. 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 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.

RESEARCH AND DEVELOPMENT ("R&D")

Our general focus is on developing drugs for use in treating viral and immune based chronic disorders and diseases such as ME/CFS, HIV, HPV and West Nile Virus, Cancer and Influenza. 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 influenza.

Our primary focus during the past three fiscal years has been on our Ampligen® New Drug Application for the treatment of CFS. In 2009, we also began to develop Alferon® Low Dose Oral for treatment of viral diseases including influenza.

The following table summarizes our research and development costs for the years 2008, 2009 and 2010 by project:

	(in thousands)		
	2008	2009	2010
Ampligen® New Drug Application for the treatment of Chronic Fatigue Syndrome	$ 5,491	$ 5,026	$ 2,787
Alferon® LDO for influenza	-	1,784	4,658
Alferon N Injection® for influenza	-	-	168
Other projects	309	185	-
Total research and development	$ 5,800	$ 6,995	$ 7,613

On December 22, 2010, the FDA lifted a clinical hold on our Phase II Study for Alferon® LDO, which is the initial stages of development. See “Our Products” above. Due to the inherent uncertainty involved in the design and conduct of clinical trials and the applicable regulatory requirements, including the factors discussed above in “Our Products; Ampligen®”, we cannot predict what additional studies and/or additional testing or information may be required by the FDA. Accordingly, we are unable to estimate the nature, timing, costs and necessary efforts to complete these projects nor the anticipated completion dates. In addition, we have no basis for estimating when material net cash inflows may commence. We have yet to generate any revenues from the sale of these developmental products. As of December 31, 2010, we had approximately $44.4 million in Cash, Cash Equivalents and Marketable Securities. Based upon our current anticipated financial needs, absent unexpected circumstances or new opportunities, we anticipate, but cannot assure, that we will be able to fund operations for at least the next four years. However, if we are unable to timely commercialize and sell Ampligen® for the treatment of CFS or Alferon® LDO and/or recommence material sales of Alferon N Injection®, our operations, financial position and liquidity will be adversely affected (see Item 1A. Risk Factors; “We may require additional financing which may not be available” below).

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 in which CFS is described as a debilitating and complex disorder characterized by profound fatigue that is not improved by bed rest and that may be worsened by physical or mental activity. Persons with CFS most often function at a substantially lower level of activity than they were capable of before the onset of illness. 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 sources for patients, their families and health care professionals including a "CFS Toolkit" that offers a quick and easy-to-use resource for patients and healthcare providers regarding best practices for diagnosing, treating, and managing CFS.

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.

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, chronic Lyme disease 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 "Our Products; Ampligen®; Progress In Search For CFS Test" above concerning experimental approaches to possible CFS diagnostic tests).

Other Viral Diseases

We are engaged in ongoing, experimental studies assessing the efficacy of Ampligen®, Alferon N Injection® and Alferon® LDO against influenza viruses.

A Phase II Trial for intramuscular administration of Ampligen® for seasonal influenza was conducted in Australia through St. Vincent's Hospital with the final patient completing the study in September 2008. This open-label study (Phase IIa Trial) utilized Ampligen® as a potential immune-enhancer in Australia with thirty-eight subjects age 60 or greater with the standard trivalent seasonal influenza vaccines. We continue in good faith to work towards obtaining the clinical data and retrieve the study samples from St. Vincent's recently restructured Clinical Trials Centre and related Clinical Network Services. As a prerequisite of payment, we had requested the confirmation that samples were properly maintained utilizing cGCP and Good Laboratory Practice ("cGLP") for the controlled environment as per our agreement. On February 5, 2010, our Counsel advised representatives of St. Vincent's business units 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 study agreement and that it was our intention to terminate the relationship between the parties. Since February 18, 2010, various offers and counteroffers have been made between us and Clinical Trials Centre and Clinical Network Services, to permit us to retrieve the data by making certain payments to each organization with funds equal to the disputed amount placed in escrow. We would then be granted access to review the data during a two day visit to their sites in Australia. Following our satisfaction that the clinical study was conducted utilizing cGCP along with samples properly maintained utilizing cGLP, the escrow funds would be released to Clinical Trials Centre and Clinical Network Services so that pathology samples could be collected by us. The proposals for data collection and the dollar value of the disputed fees are currently being reviewed by the respective parties.

Ampligen® as a mucosal adjuvant with vaccine has been 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). 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, 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 continued in 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. In July 2010, we released a report prepared by Dr. Hasegawa summarizing the results of the three year Japanese government funded program through the Japanese Minister of Health Labor and Welfare ("MHLW") to develop and test on non-human primates a nasally delivered H5N1 (Avian Flu) vaccine which, when coupled with Ampligen®, produced positive results in a preclinical testing environment showing that the combination provided a more robust and longer lasting immune response as compared to the vaccine used alone. The researchers concluded that their results could be applied to develop intranasally delivered vaccines for influenza virus prophylaxis focused on protection of the mucosal immune system against virus mutations. We had expected that the clinical testing phase of Ampligen®, used in conjunction with a H5N1 (Avian Flu) vaccine, in Japan would begin in 2011. However, the occurrence and timing of clinical testing is dependent upon the successful conclusion of our negotiations with Biken along with their timely filing and approval of an Investigatory New Drug ("IND") application for Ampligen® in Japan. A Material Evaluation Agreement ("MEA") regarding Ampligen® with Biken that was initiated on August 19, 2009, effectively expired on September 1, 2010. Pursuant to the agreement, we supplied Biken with proprietary information related to Ampligen® and Biken purchased Ampligen® from us for use solely in connection with evaluating Ampligen® as a candidate for adjuvant incorporated into potential influenza virus vaccines in the form of intranasal mucosal administration, including conducting further animal studies of intranasal prototype vaccines containing antigens from various influenza sub-types, including H5N1, H1N1, H3N2 and B. Hemispherx and Biken are in correspondence concerning both the possibility of extending or replacing the expired agreement and reconciling the interpretation of experimental results. However until such time that a new agreement can be established, no collaboration is being undertaken between the respective companies.

In April 2010, we began the process to undertake a clinical study with Max Neeman International, a leading and large clinical research organization in India. This collaborative clinical research effort is intended to utilize Alferon N Injection® for treatment of seriously ill patients hospitalized with either seasonal influenza or pandemic influenza. The Indian site selection process was initiated and we obtained approval to begin the study from the Indian Drugs Controller General on July 13, 2010. We began enrolling subjects in September 2010 and will continue to enroll subjects through the winter's flu season and the spring's rainy season. As of March 1, 2011, we have five operational Clinical Investigative Sites, with the potential to add additional sites. Our Study has progressed at a rate slower than originally projected with difficulties encountered in the process of screening for subjects who were strickened only with influenza. In an attempt to expedite the process to qualify study subjects, we have added a second "point of care" screening test which we believe will broaden our range of detection for of influenza viruses. Our objective is to qualify and enroll sixty patients for the study.

Collaboration studies in non-human primates conducted by ViroClinics in the Netherlands suggested 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 influenza along with a similar drug (Tamiflu®). In October 2009, we submitted a protocol to the FDA proposing to conduct a Phase II, well-controlled, clinical study using Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects.

MANUFACTURING

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ that was originally designed to produce Alferon N Injection®. 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. Construction in progress on this project was $485,000 and $135,000 at December 31, 2010 and 2009, respectively. The major capital

improvement program is to enhance our manufacturing capability for Alferon N Injection® along with the possibility to produce Alferon® LDO and Ampligen®. The planned capital improvements include an upgrade to the air handling system, building new changing rooms and the purchase of necessary equipment to manufacture Alferon N Injection®. As a result of these manufacturing enhancements, provided we can either promptly renew our prior agreement with a third-party vendor or find another vendor that can provide the needed cGMP formulation, packaging and labeling services, we expect to be able to complete the manufacture of Alferon N Injection® for potential commercial sales by 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 those on the Form FDA 483 discussed above. At our expected meeting with the FDA to review the CRL, we intend to communicate that it is our understanding that these manufacturing issues have been addressed. The FDA also 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 cGMP requirements. We continue to plan to complete the remaining tests needed 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 had a Supply Agreement through March 1, 2011 with Hollister-Stier Laboratories LLC of Spokane, Washington ("Hollister-Stier"), pursuant to which Hollister-Stier would formulate and package Ampligen® from the key raw materials that we would supply to Hollister-Stier. We currently are negotiating with Hollister-Stier to renew the agreement for two years under terms similar to those in the expired Supply Agreement. Pursuant to the expired agreement, at least 90 days prior to our first order, we would be required to provide a written 12 month rolling forecast of our initial requirements for the product and, every 90 days thereafter, provide an extended 12 month forecast of the number of batches we anticipate will be needed and the requested delivery dates. Our baseline cost would be set in the agreement and increases annually based on any percentage increase in the Producer Price Index - Pharmaceutical Preparations. Payment would be due 30 days after our acceptance of the Product. Hollister-Stier would have the right of first refusal to manufacture certain Ampligen® related products. The agreement was terminable by either party upon a material breach by the other party of the agreement that is not cured within 60 days or upon the other party's insolvency or certain filings under the U.S. Bankruptcy Code. If we are unable to renew our agreement with Hollister-Stier on acceptable terms, we will need to find another vendor.

The FDA, in its CRL, also noted the need to resolve outstanding inspection issues at the Hollister-Stier facility. 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.

The production of Alferon N Injection® from our existing Work-In-Progress Inventory, which has an approximate expiration date of 2012, had 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 conversion of existing Alferon N Injection® Work-In-Progress inventory was started up in May 2010 towards the manufacture of new Finished Goods. Provided we can either promptly renew our prior agreement with a third-party vendor or find another vendor that can provide the needed cGMP formulation, packaging and labeling services, we expect to be able to complete the manufacture of Alferon N Injection® for potential commercial sales by mid to late 2011.

We have manufactured purified drug concentrate utilized in the formulation of Alferon N Injection® in our New Brunswick, New Jersey facility. With the initial manufacturing stages of new Alferon® Work-In-Progress underway, we are seeking new vendors that can provide the needed cGMP formulation, packaging and labeling services for this product. It is our intension to utilize this new Alferon® Work-In Progress Inventory for clinical studies and commercial sales.

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.

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On July 15, 2010, we entered into an amended adviser's agreement (the "Sage Agreement") with The Sage Group, Inc. ("Sage") that amends and supersedes all other agreements and arrangements between the parties. Sage was instrumental in securing our relationship with Biken. Pursuant to the Sage Agreement, we have retained Sage to assist us in finding and consummating licensing, partnering, distribution, alliance or other similar transactions pertaining to and promoting the sale of our products and technologies ("Transactions"). Transactions do not include agreements that are non-revenue producing such as research arrangements or feasibility studies. The Sage Agreement runs for 18 months and automatically renews for an additional 18 months unless terminated on 180 days notice prior to the expiration of the term. For its services, Sage is entitled to a monthly fee of $15,000. Should we enter into a Transaction during the term of the Sage Agreement or within 18 months thereafter, Sage is entitled to a success fee equal to five percent of all Consideration (as defined in the Sage Agreement) received by us and our affiliates as a result of the Transaction. The Success Fee is capped at $5,000,000 per year. At the sole discretion of our Board, Sage may receive an additional bonus for extraordinary performance or special projects up to $250,000 per year. Upon execution of the Sage Agreement, we issued an aggregate of 545,000 10 year options to Sage personnel.

In January 2010, we engaged an Argentinean regulatory and business design entity to explore the possibility of initiating clinical trials of Alferon N Injection®, Ampligen® and Alferon® LDO during the influenza season in Argentina. On June 14, 2010, we executed an exclusive Sales, Marketing, Distribution and Supply Agreement for Argentina with GP Pharm Latinoamerica (“GP Pharm”), an affiliate company of Spanish GP Pharm SA. Under this Agreement, GP Pharm will be responsible for gaining regulatory approval in Argentina for Ampligen® to treat CFS in Argentina and for commercializing Ampligen® for this indication in Argentina. We granted GP Pharm the right to expand rights to sell this experimental therapeutic into other Latin America countries based upon GP Pharm achieving certain performance milestones. We also granted GP Pharm an option to market Alferon N Injection®, in Argentina and other Latin America countries as well. Under this Agreement, we will manufacture and supply Ampligen® to GP Pharm. On November 15, 2010, we amended our June 15, 2010 agreement with GP Pharm to include Mexico in the Territory under the Sales, Marketing, Distribution and Supply Agreement. Under this Agreement, GP Pharm Mexico will be responsible for gaining regulatory approval in Mexico for Ampligen®, an experimental therapeutic, to treat CFS in Mexico and for commercializing Ampligen® for this indication in Mexico. The Company has granted GP Pharm the right to expand rights to sell this experimental therapeutic into other Latin America countries based upon GP Pharm achieving certain performance milestones.

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.

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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.

HUMAN RESOURCES

As of March 1, 2011, we had 56 personnel consisting of 29 full-time employees or consultants and 27 regulatory/research medical personnel on a part-time basis. Part-time personnel are paid on a per diem or monthly basis. 37 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 2010 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.

In May 2010, we formed a Data Safety Monitoring Board ("DSMB") that consists of two independent regulatory and medical experts along with a Biostatistics expert. The function of the DSMB is to perform independent safety and efficacy analyses on our clinical trials with Alferon® LDO. However with Alferon® LDO study Phase II, double-blind, randomized, placebo controlled, dose-ranging study only released us from Clinical Hold on December 22, 2010, the DSMD has yet to take action.

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.

In July 2008, the FDA accepted for review our New Drug Application ("NDA") for Ampligen® to treat CFS, originally submitted in October 2007. In November 2009, we received a Complete Response Letter ("CRL") from the FDA which described specific additional recommendations related to the Ampligen® NDA. Please see "Our Products; Ampligen®" in "Item 1. Business" above for more detailed information on the current status of the NDA and CRL.

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 influenza requires prior regulatory approval. In October 2009, we submitted a protocol to the FDA proposing to conduct a Phase II study for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. As discussed in "Our Products; Alferon® Low Dose Oral (LDO)", in November 2009, the FDA placed the proposed study on clinical hold. On December 22, 2010, the FDA informed us that the Agency had completed its review of our complete response to the Clinical Hold and lifted the Clinical Hold, allowing our Phase II Study to proceed.

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.

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, 2010, our accumulated deficit was approximately $(217,725,000). 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, 2010, we had approximately $44,387,000 in Cash, Cash Equivalents and Marketable Securities. 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. We were unable to gather the requisite votes at our annual stockholders' meeting held on June 24, 2009 to amend our Certificate of Incorporation to increase the number of authorized shares of Common Stock from 200,000,000 to 350,000,000. Since we have not been able to obtain approval to increase the number of authorized shares of Common Stock, the amount of proceeds we may receive from the sale of our remaining 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 when our finished goods inventory expired. As a result, we have no finished good product to sell at this time. We have undertaken a major capital improvement program that continues in 2011 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, we anticipate that new lots of Alferon N Injection® could potentially be available 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 to either promptly renew our prior agreement with a third-party vendor or find another vendor that can provide the needed FDA approved services to be

able to complete the manufacture of Alferon N Injection® (see “Manufacturing” in Item 1. Business). Also, certain of the plant and equipment improvements being implemented for production of Alferon N Injection® may require FDA review prior to sale of resulting product, and 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® has been 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). With the collaboration agreements expired, it is unknown if or when the clinical testing phase of Ampligen® will be undertaken in Japan (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 influenza 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.

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 all employees and certain 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®. 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 organizations in the United States available to provide the final steps in the in manufacturing Alferon N Injection®. At present, we currently do not have an agreement with a third-party vendor to provide needed cGMP formulation, packaging and labeling services related to the final steps to manufacture of Alferon N Injection®. We are currently in negotiations with potential third-party vendors to provide such services necessary to complete the manufacture of Alferon N Injection® as to allow for potential commercial sales by mid to late 2011.

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 in the quantities necessary for clinical testing.

If we are unable to obtain or manufacture the required raw materials, as well as procure services needed in the final steps in the manufacturing process, 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.

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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 effect 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 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 limited 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.

We maintain Products Liability and Clinical Trial insurance coverage for Ampligen® and Alferon®. However even with retaining products liability and clinical trial insurance 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.

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.

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, 2015. 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 have sought 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.

While most of the class action lawsuits have, or are in the process of being settled, the existence of these proceedings or any additional such proceedings that may be filed in the future could have a material adverse effect on our ability to access the capital markets to raise additional funds. 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;

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- 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;
- restatement of financial results; 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, 2010, the closing price of our common stock has ranged from $0.44 to $0.87 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, 2010. Depending upon market conditions, we anticipate selling 9,813,687 shares pursuant to the conversion of remaining warrants.

Additionally, 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. We have allocated 32,000,000 shares under this registration statement to an At-The-Market equity offering and, as of December 31, 2010, we have sold 520,000 shares pursuant to this offering.

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 additional sale of securities pursuant to the universal shelf registration statement or upon exercise of outstanding options, 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 5.65% 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 2010, we issued shares of common stock consisting of: 1) 498,867 shares in payment to vendors and consultants for services rendered; 2) 520,000 shares sold at the market; and 3) 1,435,295 shares to our employees for final distribution of shares from the stock for pay program started in 2009.

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 Time Period:	High	Low
January 1, 2010 through March 31, 2010	0.84	0.56
April 1, 2010 through June 30, 2010	0.87	0.44
July 1, 2010 through September 30, 2010	0.62	0.44
October 1, 2010 through December 31, 2010	0.57	0.46
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

As of March 1, 2011, there were approximately 221 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, 2011, the last sale price for our common stock on the NYSE Amex was $0.46 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, 2010:

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average Exercise price of Outstanding options, warrants and rights (b)	Number of securities Remaining available for future issuance under equity compensation plans (excluding securities reflected in column) (a) (c)
Equity compensation plans approved by security holders:	10,332,912	$ 2.28	3,411,560
Equity compensation plans not approved by security holders:	10,983,246	$ 1.61	-
Total	21,316,158	$ 1.93	3,411,560

PERFORMANCE GRAPH

Total Return To Shareholders
(Includes reinvestment of dividends)
ANNUAL RETURN PERCENTAGE

	Years Ending				
Company Name / Index	Dec06	Dec07	Dec08	Dec09	Dec10
Hemispherx Biopharma, Inc.	1.38	-65.45	-52.63	55.56	-11.88
S&P SmallCap 600 Index	15.12	-0.30	-31.07	25.57	26.31
Peer Group	22.33	-20.65	-70.17	67.87	-44.07

INDEXED RETURNS

	Base Period	Years Ending				
Company Name / Index	Dec05	Dec06	Dec07	Dec08	Dec09	Dec10
Hemispherx Biopharma, Inc.	100	101.38	35.02	16.59	25.81	22.74
S&P SmallCap 600 Index	100	115.12	114.78	79.11	99.34	125.47
Peer Group	100	122.33	97.08	28.95	48.60	27.18

Peer Group Companies
CARDIUM THERAPEUTICS INC
CYTRX CORP

GENVEC INC
OXIGENE INC
REGENERX
BIOPHARMACEUTICALS

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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, 2010 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	2006	2007	2008	2009	2010
Statement of Operations Data:					
Revenues and License fee Income	$933	$1,059	$265	$111	$135
Total Costs and Expenses(1)	19,627	20,348	13,076	13,375	16,522
Interest Expense and Financing Costs(2)	1,259	396	-	241	11
Redeemable warrants valuation adjustment	-	-	-	(6,258)	(879)
Net loss	(19,399)	(18,139)	(12,219)	(7,180)	(13,136)
Deemed Dividend	-	-	-	-	-
Net loss applicable to common stockholders	(19,399)	(18,139)	(12,219)	(7,180)	(13,136)
Basic and diluted net loss per share	$(0.31)	$(0.25)	$(0.16)	$(0.07)	$(0.10)
Shares used in computing basic and diluted net loss per share	61,815,358	71,839,782	75,142,075	109,514,401	134,018,243
Balance Sheet Data:					
Working Capital	$16,559	$14,412	$5,646	$55,789	$33,842
Total Assets	31,431	23,142	13,211	64,994	51,680
Debt, net of discount	3,871	-	-	-	-
Stockholders' Equity	24,751	20,955	11,544	58,695	45,947
Cash Flow Data:					
Cash used in operating activities	(13,747)	(15,112)	(9,358)	(9,297)	(11,886)
Capital expenditures	$(1,351)	$(212)	$(73)	$(332)	$(729)

(1) General and Administrative expenses include stock compensation expense of $2,483, $2,291, $573, $826 and $740 for the years ended December 31, 2006, 2007, 2008, 2009 and 2010, respectively.

(2) For information concerning our financing see Note 7 to our consolidated financial statements for the year ended December 31, 2010 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, 2010. 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 20 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.

Fair Value

In connection with equity financings on May 11 and 19, 2009, we issued warrants (the “Warrants”) that are single compound derivatives containing both an embedded right to obtain stock upon exercise (a “Call”) and a series of embedded rights to settle the Warrants for cash upon the occurrence of certain events (each, a “Put”). Generally, the Put provisions allow the Warrant Holders liquidity protection; the right to receive cash in certain situations where the Holders would not have a means of readily selling the shares issuable upon exercise of the Warrants (e.g., where there would no longer be a significant public market for our common stock). However because the contractual formula used to determine the cash settlement value of the embedded Put requires use of certain assumptions, the cash settlement value of the embedded Put can differ from the fair value of the unexercised embedded Call option at the time the embedded Put option is exercised. Specifically, the Put rights would be triggered upon the happening of a “Fundamental Transaction” (as defined below) that also is (1) an all cash transaction; (2) a “Rule 13e-3 transaction” under the Exchange Act (where the Company would be taken private); or (3) a transaction involving a person or entity not traded on a national securities exchange. “Fundamental Transactions” include (i) a merger or consolidation of the Company with or into another person or entity; (ii) a sale, lease, license, transfer or other disposition of all or substantially all of the Company’s assets; (iii) any purchase offer, tender offer or exchange offer in which holders of Company Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property, which offer has been accepted by the holders of 50% or more of the Company’s outstanding Common Stock; (iv) a reclassification, reorganization or recapitalization of the Common Stock pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property; or (v) a stock purchase or other business combination with another person or entity is effected pursuant to which such other person or entity acquires more than 50% of the outstanding shares of Common Stock. Pursuant to the Warrants, the Put rights enable the Warrant Holders to receive cash in the amount of the Black-Scholes value is obtained from the “OV” function on Bloomberg, L.P. (“Bloomberg”) determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Warrant expiration date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg as of the Trading Day immediately following the public announcement of the applicable Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (D) a remaining option time equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Warrant expiration date.

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The Company recomputes the fair value of the Warrants at the end of each quarterly reporting period. Such value computation includes subjective input assumptions that are consistently applied each period. If the Company were to alter its assumptions or the numbers input based on such assumptions, the resulting fair value could be materially different.

Fair value at measurement dates during the period from Warrants' issuances at May 10, 2009, May 18, 2009 and May 21, 2009 to December 31, 2009 and 2010, were estimated using the following assumptions:

	2009	2010
Underlying price per share	$0.56 - $2.54	$0.47-$0.74
Exercise price per share	$1.10 – $1.65	$1.31-$1.65
Risk-free interest rate	0.19% - 2.67%	0.83%-2.36%
Expected holding period	0.122-5.50 years	3.38-4.63 years
Expected volatility	94.99%–226.46%	112.16%-122.02%
Expected dividend yield	None	None

The significant assumptions using the Monte Carlo Simulation approach for valuation of the Warrants are:

(i) Risk-Free Interest Rate. The risk-free interest rates for the Warrants are based on U.S Treasury constant maturities for periods commensurate with the remaining expected holding periods of the warrants.
(ii) Expected Holding Period. The expected holding period represents the period of time that the Warrants are expected to be outstanding until they are exercised. The Company utilizes the remaining contractual term of the Warrants at each valuation date as the expected holding period.
(iii) Expected Volatility. Expected stock volatility is based on daily observations of the Company's historical stock values for a period commensurate with the remaining expected holding period on the last day of the period for which the computation is made.
(iv) Expected Dividend Yield. Expected dividend yield is based on the Company's anticipated dividend payments over the remaining expected holding period. As the Company has never issued dividends, the expected dividend yield is $-0- and this assumption will be continued in future calculations unless the Company changes its dividend policy.
(v) Expected Probability of a Fundamental Transaction. The possibility of the occurrence of a Fundamental Transaction triggering a Put right is extremely remote. As discussed above, a Put right would only arise if a Fundamental Transaction 1) is an all cash transaction; (2) results in the Company going private; or (3) is a transaction involving a person or entity not traded on a national securities exchange. The Company believes such an occurrence is highly unlikely because:

a. The Company only has one product that is FDA approved;
b. The Company will have to perform additional clinical trials for FDA approval of its flagship product;
c. Industry and market conditions continue to include a global market recession, adding risk to any transaction;
d. Available capital for a potential buyer in a cash transaction continues to be limited;
e. The nature of a life sciences company is heavily dependent on future funding and high fixed costs, including Research & Development;

f. According to Forbes.com, of approximately 17,000 public companies, fewer than 30 went private in 2008 and less than 100 were completed in 2007, representing 0.18% and 0.6%, respectively. This would be further reduced based on the nature of a life sciences company and the potential lack of revenues, cash flows and the Company's funding needs; and

g. The Company's Rights Agreement makes it less attractive to a potential buyer.

With the above factors utilized in analysis of the likelihood of the Put's potential Liability, the Company estimated the range of probabilities related to a Put right being triggered as:

Range of Probability	Probability
Low	0.5%
Medium	1.0%
High	5.0%

The Monte Carlo Simulation incorporated a 5.0% probability of a Fundamental Transaction.

(vi) Expected Timing of Announcement of a Fundamental Transaction. As the Company has no specific expectation of a Fundamental Transaction, for reasons elucidated above, the Company utilized a discrete uniform probability distribution over the Expected Holding Period to model in the potential announcement of a Fundamental Transaction occurring during the Expected Holding Period.

(vii) Expected 100 Day Volatility at Announcement of a Fundamental Transaction. An estimate of future volatility is necessary as there is no mechanism for directly measuring future stock price movements. Daily observations of the Company's historical stock values for the 100 days immediately prior to the Warrants' grant dates, with a floor of 100%, were utilized as a proxy for the future volatility.

(viii) Expected Risk-Free Interest Rate at Announcement of a Fundamental Transaction. The Company utilized a risk-free interest rate corresponding to the forward U.S. Treasury rate for the period equal to the time between the date forecast for the public announcement of a Fundamental Transaction and the Warrant expiration date for each simulation.

(ix) Expected Time Between Announcement and Consummation of a Fundamental Transaction. The expected time between the announcement and the consummation of a Fundamental Transaction is based on the Company's experience with the due diligence process performed by acquirers, and is estimated to be six months. The Monte Carlo Simulation approach incorporates this additional period to reflect the delay Warrant Holders would experience in receiving the proceeds of the Put.

RESULTS OF OPERATIONS

Year ended December 31, 2010 versus December 31, 2009

Net Loss

Our net loss of approximately $13,136,000 for the year ended December 31, 2010 was 83% higher when compared to the same period in 2009. This $5,956,000 increase in loss was primarily due to:

1) increased Research and Development costs in 2010 of approximately $618,000 or 9% as compared to the same period in 2009;

2) increased Production/Cost of Goods Sold in 2010 of approximately $757,000 or 130%; and

3) increased General and Administrative expenses of approximately $1,772,000 or 31% as compared to the same period in 2009; which increases were offset by

4) an increase in interest and other income in 2010 of approximately $2,316,000 or 3,457% as compared to the same period in 2009;

5) a decrease in non-cash financing costs of $241,000 in 2010 as compared to the same period in 2009 primarily due to the issuance of Common Stock Purchase Warrants in 2009 as part of the February 2009 Standby Financing Agreement; and

6) an adjustment at December 31, 2009 to record the change in fair value for a Liability related to certain redeemable warrants issued in May 2009. This Liability was recorded in May 2009, adjusted and revalued to $3,684,000 at December 31, 2009, resulting in a related non-cash gain of $6,258,000 in 2009. The value of this Liability at December 31, 2010 was $2,805,000. The adjustment needed at December 31, 2010 to revalue the liability resulted in a related non-cash gain of $879,000 at December 31, 2010.

Net loss per share for the year ended 2010 was approximately $(0.10) versus approximately $(0.07) as restated for the same period in 2009.

Revenues

Revenues from our Ampligen® cost recovery treatment program for the year ended December 31, 2010 were approximately $135,000 compared to revenues of $111,000 for the same period in 2009, an increase of $24,000 or 22% for approximately 18 patients in 2009 and 21 patients in 2010 participating in the program. Commercial sales of Alferon N Injection® were halted in March 2008 when our Finished Goods Inventory expired. As a result, we had no Alferon N Injection® product to commercially sell in 2009 or 2010 and all sales revenue in 2009 and 2010 has been generated from Ampligen® cost recovery clinical treatment programs.

In 2010 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 have been undertaken throughout 2010 and continue in 2011 (see “Manufacturing” in Item 1. Business).

Production/Cost of Goods Sold

Production/Cost of Goods Sold was approximately $1,341,000 and $584,000, respectively, for the twelve months ended December 31, 2010 and 2009. This represents an increase of $757,000 or 130% as compared to the same period in 2009. The main cause for the increase in costs was the shrinkage of work in process due to restarting the manufacturing process and the resulting necessary additional testing of equipment, work in process and finished goods inventory for quality control. The additional costs related to addressing manufacturing issues were approximately $451,000. The other expenses primarily represent additional costs to maintain Alferon N Injection® and Ampligen® inventories including storage, stability testing, transport and reporting costs including Ampligen® NDA work undertaken in 2008.

Research and Development Costs

Overall Research and Development costs for the year ended December 31, 2010 were approximately $7,613,000 as compared to $6,995,000 for the same period a year ago, reflecting an increase of $618,000 or 9%. The Ampligen® NDA and related expenses were approximately $2,239,000 lower in 2010 primarily due to the scientific effort spent in 2009 on getting the NDA prepared and filed. Research and Development expenses related to Alferon® LDO had increased approximately $2,874,000 in 2010 due to our efforts in responding to the FDA's clinical hold issues as well as implementing the influenza clinical trials in India.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the year ended December 31, 2010 and 2009 were approximately $7,568,000 and $5,796,000, respectively, reflecting an increase of $1,772,000 or 31%. The primary reasons for this increase in expense were an additional $1,364,000 in legal fees and services associated with our successful Judgment against Johannesburg Consolidated Investments along with our defense efforts in other legal proceedings (See "Part I; ITEM 3. Legal Proceedings"), an additional $388,000 in stock compensation to consultants and net increases in various other administrative expenses of $247,000 that were offset by a decrease in fees of $227,000 paid to the Sage Group.

Interest and Other Income

Interest and other income for the year ended December 31, 2010 and 2009 was approximately $2,383,000 and $67,000, respectively, representing an increase of $2,316,000 or 3,457%. The primary cause for the increase of interest income in 2010 was the purchase of a diverse portfolio of short and long-term investments that included the PIMCO mutual fund. The interest income from these investments is recognized as the investments mature.

Interest Expense and Financing Costs

In 2010, we financed through capital leases some office equipment vital to the overall operations of the Company as well as manufacturing equipment utilized in the production of Alferon®. Accordingly in 2010, we had interest expense of approximately $11,000 as compared to $-0- for 2009. 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 was undertaken in 2010. For detailed information on this agreement, please see "Standby Financing Agreement" below.

Redeemable Warrants Valuation Adjustment

As a result of the adjustment to the valuation of the liability of the redeemable warrants issued in May 2009 for years ended December 31, 2009 and 2010, a net gain of $879,000 was recorded in 2010 as compared to $6,258,000 recorded in 2009.

RESULTS OF OPERATIONS

Year ended December 31, 2009 versus December 31, 2008

Net Loss

Our net loss of approximately $7,180,000 for the year ended December 31, 2009 was 41% lower when compared to the same period in 2008. This $5,039,000 decrease 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 issued 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.

6) An adjustment at December 31, 2009 to record the change in fair value for a Liability related to the Warrants issued in May 2009. This Liability was recorded in May 2009, adjusted and revalued to $3,684,000 at December 31, 2009, resulting in a related non-cash gain of $6,258,000.

Net loss per share for the year ended 2009 was $(0.07) compared to $(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 when our Finished Goods Inventory expired. As a result, we had 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.

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 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.

In September 2008, we engaged Lovelace Respiratory Research Institute 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.

Redeemable Warrants Valuation Adjustment

As a result of the correction to the valuation of a Liability related to Warrants issued in May 2009, a net gain of 6,258,000 was recorded in 2009. The Monte Carlo Simulation approach was used to determine the fair value of this Liability with regard to these Warrants of $17,359,000 at their inception in May 2009, increased by the losses from the exercised Warrants in May and June 2009 of $3,675,000 and reduced by $7,417,000 for the exercised Warrants. At December 31, 2009 the fair value of this Liability related to the unexercised Warrants had decreased to $3,684,000. The net effect to reflect the change in the fair value of this Liability during 2009 resulted in a gain of $9,933,000. The approximate combined losses of $3,675,000 from the exercised Warrants and the gain of $9,933,000 from the fair value adjustment resulted in a net total non-cash gain of $6,258,000.

Liquidity and Capital Resources

Cash used in operating activities for the year ended December 31, 2010 was $11,886,000 compared to $9,297,000 for the same period in 2009, an increase of $2,589,000. We had proceeds from financing activities of approximately $250,000 compared to $61,824,000 during the twelve months ended December 31, 2010 and 2009, respectively. As of December 31, 2010, we had approximately $44,387,000 in Cash, Cash Equivalents and Marketable Securities or a decrease of approximately $13,685,000 from December 31, 2009.

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 decrease in wages, none elected this alternative. 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” receive their distribution of stock from the Program in June and July 2010.

In addition, certain vendors and service providers have agreed to accept shares of our Common Stock as partial payment of their bills. We issued 498,867 and 1,925,408 shares of common stock for services rendered in 2010 and 2009, respectively.

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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®. During 2009, we raised in the aggregate approximately $33,712,000 in equity financing pursuant to the two Rodman financings in May 2009 and an aggregate of approximately $28,112,000 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.

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. We were unable to gather the requisite votes at our annual stockholders' meeting held on June 24, 2009 to amend our Certificate of Incorporation to increase the number of authorized shares of Common Stock from 200,000,000 to 350,000,000. Since we have not been able to obtain approval to increase the number of authorized shares of Common Stock, the amount of proceeds we may receive from the sale of our remaining Common Stock is limited.

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.

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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 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. The outstanding warrants include a cash settlement feature if certain conditions are met. As of December 31, 2010, 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, received 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. The warrants include a cash settlement feature if certain conditions are met. Rodman also was entitled to a fee equal to 5.5% of the Series II Warrants that were exercised. In 2009, Rodman received $165,000 in fees with regard to the exercise of the Series II Warrants. The outstanding warrants include a cash settlement feature if certain conditions are met. As of December 31, 2010, none of the Series I Warrants have been exercised.

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. The outstanding warrants include a cash settlement feature if certain conditions are met. As of December 31, 2010, 1,895,000 of these Warrants have 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 outstanding warrants include a cash settlement feature if certain conditions are met. As of December 31, 2010, none of the Warrants have been exercised.

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. Consistent with Section 11(k)(iv), we formally terminated the Purchase Agreement on April 7, 2010.

Pursuant to our May 28, 2010 Equity Distribution Agreement (the “Agreement”) with Maxim Group LLC (“Maxim”) we established an At-The-Market (“ATM”) Equity Program pursuant to which we may sell up to 32,000,000 shares of our Common Stock from time to time through Maxim as our sales agent (the “Agent”). Under the Agreement, the Agent is entitled to a commission at a fixed commission rate of 4.0% of the gross sales price per Share sold, up to aggregate gross proceeds of $10,000,000, and, thereafter, at a fixed commission rate of 3.0% of the gross sales price per Share sold. We have no obligation to sell any shares under this program, and may at any time terminate the Agreement. During the fiscal quarters ended September 30, 2010 and December 31, 2010, we sold no shares through this program and received no net cash proceeds. As of December 30, 2010, we sold 520,000 shares through the ATM that resulted in net cash proceeds of $292,785 and commissions paid to Maxim of $12,199.

Because of our long-term capital requirements, we may seek to access the public equity market through the above ATM equity program or otherwise 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® and new utilization of Alferon® products. Our ability to raise funds from the sale of equity is limited due to the limited number of shares of common stock authorized but not issued or reserved (please see "Part I; Item 1A. Risk Factors; We may require additional financing which may not be available; The limited number of shares of common stock available for financing or other purposes may hinder our ability to raise additional funding or utilize equity securities for other corporate purposes").

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

There can be no assurances that, if needed, 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.

	(dollars in thousands) Obligations Expiring by Period			
Contractual Cash Obligations	Total	2011	2012	2013
Operating Leases	$ 265	$ 198	67	$ -0-
Total	$ 265	$ 198	$ 67	$ -0-

New Accounting Pronouncements

Refer to "Note 2(h) – 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.

Redeemable Warrants

We utilize the guidance contained ASC 480 (formerly SFAS 150) in the determination of whether to record warrants and options as Equity and/or Liability. If the guidance of ASC 480 is deemed inconclusive, we continue our analysis utilizing ASC 815 (formerly EITF 00-19).

Our method of recording the related value attempts to be consistent with the standards as defined by the Financial Accounting Standards Board utilizing the concept of "Fair Value" from ASC 820-10-55-1 that states that any fair value measurement requires that the reporting entity to determine the valuation technique(s) appropriate for the measurement, considering the availability of data with which to develop inputs that represent the assumptions that market participants would use in pricing the asset or liability and the level in the fair value hierarchy within which the inputs fall.

We recomputed the value of the redeemable warrants at the end of each quarterly period. We use the Monte Carlo Simulation approach which includes subjective input assumptions that are consistently applied each quarter. If we were to alter our assumptions or the numbers input based on such assumptions, the resulting fair value could be materially different. As discussed in greater detail in “Fair Value” at the beginning of this ITEM 7, the significant assumptions using this model are: (i) Risk-Free Interest Rate; (ii) Expected Holding Period; (iii) Expected Volatility; (iv) Expected Dividend Yield; (v) Expected Probability of a Fundamental Transaction; (vi) Expected Timing of Announcement of a Fundamental Transaction; (vii) Expected 100 Day Volatility at Announcement of a Fundamental Transaction; (viii) Expected Risk-Free Interest Rate at Announcement of a Fundamental Transaction; and (ix) Expected Time Between Announcement and Consummation of a Fundamental Transaction.

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 both December 31, 2010 and 2009 there were no receivables.

There were no sales for years ended December 31, 2010 and 2009.

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

We had approximately $44,387,000 in cash, cash equivalents and Marketable Securities at December 31, 2010. 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, 2009 and 2010, 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, 2010, 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, 2010, 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, 2010 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, 2010. 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, 2010. 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, 2010, 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, 2010 has been audited by McGladrey and Pullen, LLP, an independent registered public accounting firm, as stated in their report which appears herein.

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, 2010, 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, 2010 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, 2010 consolidated financial statements of Hemispherx Biopharma, Inc. and our report dated March 28, 2011 expressed an unqualified opinion.

/s/ McGladrey & Pullen, LLP
Blue Bell, Pennsylvania
March 28, 2011

ITEM 9B. Other Information.

None.

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.	73	Chairman of the Board, Chief Executive Officer and Chief Science Officer
Thomas K. Equels	58	Executive Vice Chairman of the Board (effective June 1, 2010), Secretary and General Counsel
Richard C. Piani	84	Lead Director
William M. Mitchell, M.D., Ph.D.	76	Director
Iraj Eqhbal Kiani, N.D., Ph.D.	65	Director
Charles T. Bernhardt, CPA	49	Chief Financial Officer and Chief Accounting Officer
David R. Strayer, M.D.	65	Chief Medical Officer and Medical Director, Regulatory Affairs
Robert Dickey IV	55	Senior Vice President
Wayne Springate	40	Vice President of Operations
Russel Lander, Ph.D.	61	Vice President of Process and Quality Assurance
Ralph C. Cavalli, Ph.D.	53	Vice President of Quality Control (effective April 15, 2010)

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.

We believe our Board Members represent a desirable diversity of backgrounds, skills, education and experiences, and they all share the personal attributes of dedication to be effective directors. In recommending Board candidates, Corporate Governance and Nomination Committee considers a candidate's: (1) general understanding of elements relevant to the success of a publicly traded company in the current business environment; (2) understanding of our business; and (3) diversity in educational and professional background. The Committee also gives consideration to a candidate's judgment, competence, dedication and anticipated participation in Board activities along with experience, geographic location and special talents or personal attributes. The following are qualifications, experience and skills for Board members which are important to Hemispherx's business and its future:

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Leadership Experience: We seek directors who have demonstrated strong leadership qualities. Such leaders bring diverse perspectives and broad business insight to our Company. The relevant leadership experience that we seek includes a past or current leadership role in a large or entrepreneurial company, a senior faculty position at a prominent educational institution or a past elected or appointed senior government position.

Industry or Academic Experience: We seek directors who have relevant industry experience, both with respect to the disease areas where we are developing new therapies as well as with the economic and competitive dynamics of pharmaceutical markets, including those in which our drugs will be prescribed.

Scientific, Legal or Regulatory Experience: Given the highly technical and specialized nature of biotechnology, we desire that certain of our directors have advanced degrees, as well as drug development experience. Since we are subject to substantial regulatory oversight, both here and abroad by the FDA and other agencies, we also desire directors who have legal or regulatory experience.

Finance Experience: We believe that our directors should possess an understanding of finance and related reporting processes, particularly given the complex budgets and long timelines associated with drug development programs.

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 from April 1995 to November 2006; 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 Professor and Director of Clinical Research for Hahnemann Medical University's Institute for Cancer and Blood Diseases, and as a member of the faculty 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.

WILLIAM A. CARTER, M.D. - Director Qualifications:

- Leadership Experience – Chairman and CEO of Hemispherx;
- Industry Experience - Knowledge of new and existing technologies, particularly as they relate to anti-viral and immune therapies;
- Scientific, Legal or Regulatory Experience - M.D., co-inventor of Ampligen®, leading innovator in the development of interferon-based drugs and expertise in patent development; and
- Finance Experience – Extensive knowledge of financial markets and successfully completed numerous financing efforts on behalf of Hemispherx.

THOMAS K. EQUELS has been a director since 2008 and presently serves as our Executive Vice Chairman, Secretary and 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 and the American Bar Association.

THOMAS K. EQUELS - Director Qualifications:

- Leadership Experience – President, Managing Director of Equels Law Firm;
- Industry Experience –legal counsel to Hemispherx; and
- Scientific, Legal or Regulatory Experience - Law degree with over 25 years as a practicing attorney specializing in litigation.

RICHARD C. PIANI has been a director since 1995 and our Lead director since April, 2005. 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.

RICHARD C. PIANI - Director Qualifications:

- Leadership Experience – Chairman of Industrielle du Batiment-Morin, Chairman and CEO of Societe "La Cellophane";
- Industry Experience - Rhone-Poulenc (now Sanofi Aventis);
- Scientific, Legal or Regulatory Experience – Law degree, delegate for Industry to the City of Science and Industry; and
- Finance Experience – over 40 years of diverse international business experience.

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 and is a board certified physician. Dr. Mitchell earned a M.D. from Vanderbilt and a Ph.D. from Johns Hopkins University, where he served as House Officer in Internal Medicine, followed by a Fellowship at its School of Medicine. Dr. Mitchell has published over 200 papers, reviews and abstracts that relate to viruses, anti-viral drugs, immune responses to HIV infection, and other biomedical topics. Dr. Mitchell has worked for and with many professional societies, that have included the American Society of Investigative Pathology, the International Society for Antiviral Research, the American Society of Biochemistry and Molecular Biology, the American Society of Microbiology. Dr. Mitchell is a member of the American Medical Association. He has served on numerous 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.

WILLIAM M. MITCHELL, M.D., Ph.D. - Director Qualifications:

- Leadership Experience – Professor at Vanderbilt University School of Medicine. He is a member of the Board of Directors for Chronix Biomedical and is Chairman of its Medical Advisory Board. Additionally, he has served on multiple governmental review committees of the National Institutes of Health, Centers for Disease Control and Prevention and for the European Union, including key roles as Chairman;
- Academic and Industry Experience – Well published medical researcher with extensive investigative experience on virus and immunology issues relevant to the scientific business of Hemispherx along with being a Director of an entrepreneurial diagnostic company (Chronix Biomedical) that is involved in next generation DNA sequencing for medical diagnostics; and
- Scientific, Legal or Regulatory Experience - M.D., Ph.D. and professor at a top ranked school of medicine, and inventor of record on numerous U.S. and international patents who is experienced in regulatory affairs through filings with the FDA.

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 and resides in Newport Beach, California. Dr. Kiani served in various local government positions including the Mayor and Governor of Yasoi, Capital of Boyerahmand, Iran. In early 1980, Dr. Kiani moved to England, where he established and managed several trading companies over a period of some 20 years. Dr. Kiani is a planning and logistic specialist who is now applying his knowledge and experience to build a worldwide immunology network, which will use our proprietary technology. Dr. Kiani received his Ph.D. degree from the University of Ferdosi in Iran, ND from American University.

IRAJ EQHBAL KIANI, N.D., Ph.D. - Director Qualifications:

- Leadership Experience – former Mayor and Governor of Yasoi in Iran;
- Industry Experience – Broad international network and contacts within the field of immunology;
- Scientific, Legal or Regulatory Experience – N.D. and Ph.D. with trading company management experience; and
- Finance Experience – over 30 years of international business experience.

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 formerly 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.

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 capital improvement budget to enhance our Alferon® facility in accordance with 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 assists the CEO in details of operations on a daily basis and is involved in all aspects of manufacturing, warehouse management, distribution and logistics.

RUSSEL J. LANDER, Ph.D. is Vice President Process and Quality Assurance. Dr. Lander joined Hemispherx in 2005, assuming responsibility for Chemistry, Manufacturing and Control writing for the NDA filing of Ampligen®. He subsequently served 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.

RALPH CHRISTOPHER CAVALLI, Ph.D. was named Vice President of Quality Control effective April 15, 2010. Dr. Cavalli most recently served as Director of Quality Control at the Company's New Brunswick, NJ manufacturing facility. He is currently responsible for manufacturing Alferon® Purified Drug Concentrate and active pharmaceutical ingredients for Ampligen® along with overseeing our Quality Control ("QC") Department to continue our Good Laboratory Practices and Good Manufacturing Practices. Prior to joining Hemispherx, Dr. Cavalli served as Senior Director of Manufacturing Operations at Cytogen Corporation from 2006 until 2009, where he was responsible for the manufacture of Cytogen's three commercial products. From 1999 until 2006, he initially worked at Discovery Laboratories as Associate Director of Analytical Services and then ultimately as Senior Director of Analytical and Technical Services, for which he was responsible for Quality Control and Process Development. Dr Cavalli received a Ph.D. in Chemistry from Temple University in Philadelphia, PA.

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, 2010, 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 2010. Specifically, Dr. Carter filed two Forms 4 late concerning his receipt of Options and one Form 4 late related to a donation of stock; Mr. Equels and Mr. Bernhardt each filed one Form 4 late concerning their receipt of Options; and Mr. Lander filed late an initial Form 3 and one Form 4 concerning five 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., Ph.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 because we believe that Richard Piani, an existing director, has sufficient experience. Mr. Piani has 40 years of 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.

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.

COMPENSATION DISCUSSION AND ANALYSIS

This discussion and analysis describes our executive compensation philosophy, process, plans and practices as they relate to our "Named Executive Officers" ("NEO") listed below and gives the context for understanding and evaluating the more specific compensation information contained in the narratives, tables and related disclosures that follow:

- Dr. William A. Carter, Chief Executive Officer ("CEO") and Chief Science Officer ("CSO");
- Charles T. Bernhardt, Chief Financial Officer ("CFO") & Chief Accounting Officer ("CAO");
- Thomas K. Equels, General Counsel and Litigation Counsel (effective June 1, 2010);
- Dr. David Strayer, Chief Medical Officer ("CMO") and Medical Director;
- Robert Dickey, IV, Senior Vice President ("S.V.P.");
- Russel J. Lander, Vice President ("V.P.") of Process and Quality Assurance; and
- Wayne S. Springate, Vice President ("V.P.") of Operations.

Overview of Our Business Environment

Hemispherx is 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.

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 FDA approved product for refractory or recurring genital warts. Alferon® LDO (Low Dose Oral) is a formulation currently under development targeting influenza.

Governance

The Compensation Committee consists of the following three directors, each of whom is "independent" under applicable NYSE Amex rules, a "Non-Employee Director" as defined in Rule 16b-3 under the Securities Exchange Act of 1934, as amended, and an "Outside Director" as defined under the treasury regulations promulgated under Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"): Dr. William Mitchell, M.D., Richard C. Piani, and Dr. Iraj E. Kiani, N.D. The Compensation Committee makes recommendations concerning salaries and compensation for senior management and other highly paid professionals or consultants to Hemispherx. The full text of the Compensation Committee Charter, as approved by the Board, is available on our website: www.hemispherx.net in the "Investor Relations" tab under "Corporate Governance". This Committee met one time in 2010 and all committee members were in attendance. Our Chief Financial Officer and the Director of Human Resources support the Compensation Committee in its work.

Process

Our Compensation Committee is responsible for determining the compensation of our NEO included in the “Summary Compensation Table” below. For purposes of determining compensation for our NEO, our Compensation Committee takes into account the recommendation of our Chief Executive Officer. The Compensation Committee is also responsible for overseeing our incentive compensation plans and equity-based plans, under which stock option grants have been made to employees, including the NEO, as well as non-employee Directors and strategic consultants.

The following table summarizes the roles of each of the key participants in the executive compensation decision-making process:

Compensation Committee	• Fulfills the Board of Directors' responsibilities relating to compensation of Hemispherx’ NEO, other non-officer Executives and non-Executives. • Oversees implementation and administration of Hemispherx’ compensation and employee benefits programs, including incentive compensation and equity compensation plans. • Reviews and approves Hemispherx’ goals and objectives and, in light of these, evaluates each NEO's performance and sets his annual base salary, annual incentive opportunity, long-term incentive opportunity and any special/supplemental benefits or payments. • Reviews and approves compensation for all other non-officer Executives of Hemispherx including annual base salary, annual incentive opportunity, long-term incentive opportunity and any special/supplemental benefits or payments. • In consultation with the CEO and CFO, reviews the talent development process within Hemispherx to ensure it is effectively managed and sufficient to undertake successful succession planning. • Reviews and approves employment agreements, severance arrangements, issuances of equity compensation and change in control agreements.
Chairman and CEO	• Presents to the Compensation Committee the overall performance evaluation of, and compensation recommendations for, each of the NEO and other non-officer Executives.

CFO and Director of Human Resources	• Reports directly or indirectly to the Chief Executive Officer. • Assists the Compensation Committee with the data for competitive pay and benchmarking purposes. • Reviews relevant market data and advises the Compensation Committee on interpretation of information, including cost of living statistics, within the framework of Hemispherx. • Informs the Compensation Committee of regulatory developments and how these may affect Hemispherx' compensation program.

Objectives and Philosophy of Executive Compensation

The primary objectives of the Compensation Committee of our Board of Directors with respect to Executive compensation are to attract and retain the most talented and dedicated Executives possible, to tie annual and long-term cash and stock incentives to achievement of measurable performance objectives, and to align Executives' incentives with stockholder value creation. To achieve these objectives, the Compensation Committee expects to implement and maintain compensation plans that tie a substantial portion of Executives' overall compensation to key strategic financial and operational goals such as the establishment and maintenance of key strategic relationships, the development of our products, the identification and advancement of additional products and the performance of our common stock price. The Compensation Committee evaluates individual Executive performance with the goal of setting compensation at levels the Committee believes are comparable with Executives in other companies of similar size and stage of development operating in the biotechnology industry while taking into account our relative performance and our own strategic goals.

Use of Compensation Data

Our compensation plans are developed by utilizing publicly available compensation data for national and regional companies in the biopharmaceutical industry as well as web sites that specialize in compensation and/or employment data. We believe that the practices of this group of companies and/or data obtained from employment industry organizations, provide us with appropriate compensation benchmarks necessary to review the compensation recommendations by the CEO, CFO and/or Human Resources Department. While not utilized in 2009 or 2008 due to our maintaining Base Salary at existing levels with the exception of cost of living adjustments, in 2010 we utilized web based organizations and data bases to help us analyze compensation data and compare our programs with the practices of the similar national and/or regional companies represented in the biopharmaceutical industry.

Elements of Executive Compensation

The Compensation Committee has adopted a mix among the compensation elements in order to further our compensation goals. The elements include:

- Base salary (impacted by cost of living adjustments);

- Variable compensation consisting of a cash bonus based upon individual and corporate performance;

- Long-term bonus incentive programs consisting of the Goal Achievement Program and Employee Bonus Pool Program; and

- Stock option grants with exercise prices set at the fair market value at the time of grant.

Executive compensation consists of the following elements:

Base Salary

Base salaries for our Executives are established based on the scope of their responsibilities, taking into account competitive market compensation paid by other companies for similar positions. Generally, we believe that Executive base salaries should be targeted near the median of the range of salaries for executives in similar positions with similar responsibilities at comparable companies, in line with our compensation philosophy. For those NEO with employment agreements, base salary is determined and set forth in the agreement and the Compensation Committee reviews the base salary prior to renewal of such agreement. Base salaries for the other NEO are normally reviewed annually, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. While this review process would normally occur in the fourth quarter of each year, it was not undertaken as a formal process regarding 2008, 2009, 2010 or 2011 base salaries. However after analysis of overall Company compensation, the Committee authorized a non-discriminatory and universally applied cost of living increase to the base salaries of all full-time employees of record effective July 1, 2009, January 1, 2010 and December 31, 2010. Therefore, with the exception of these cost of living adjustments, no other modifications were made to the base salary rate of our NEO during 2008 or 2009. However in 2010, modifications were made to the Base Salary of NEO for which employment agreements were modified or renewed. Additional changes to our NEO's base salaries could be undertaken in a future determination by the Compensation Committee at its discretion. In this regard, in June 2010, we entered into amended and restated agreements with Dr. Carter, and an employment agreement with Mr. Equels, pursuant to which, Mr. Equels acts as our General Counsel, Secretary and Executive Vice Chairman of the Board of Directors. These employment agreements were further amended in July 2010. Additionally, Mr. Dickey's employment agreement was amended in February 2010 and renewed in September 2010, and Mr. Bernhardt entered into an employment agreement in December 2010 as our Chief Financial Officer and Chief Accounting Officer.

Annual Bonus

Our compensation program includes eligibility for an annual performance-based cash bonus in the case of all NEO and certain senior, non-officer Executives. The amount of the cash bonus depends on the level of achievement of the stated corporate, department, and individual performance goals, with a target bonus generally set as a percentage of base salary. As provided in their respective employment agreement, during the year ended December 31, 2010, the following NEO were eligible for an annual performance bonus based of their salaries, the amount of which, if any, is determined by the Board of Directors in its sole discretion based on the recommendation of the Compensation Committee:

- Dr. William Carter, Chairman & CEO (bonus opportunity up to 25%);
- Thomas Equels, General Counsel, Litigation Counsel, Secretary and Executive Vice Chairman of the Board (bonus opportunity up to 25%);
- Charles Bernhardt, Chief Financial Officer and Chief Accounting Officer (bonus opportunity up to 25%); and

- Wayne Springate, V.P. of Operations (bonus opportunity up to 20%).

The Compensation Committee utilizes annual incentive bonuses to compensate NEO and certain senior, non-officer executives (the "Executive Team") for attainment or success towards overall corporate financial and/or operational goals along with achieving individual annual performance objectives. These objectives will vary depending on the individual Executive, but generally relate to strategic factors such as establishment and/or maintenance of key strategic relationships, development of our products, identification, research and/or development of additional products, enhancing financial factors such as raising capital, cost containment and/or improving the results of operations. The Compensation Committee, in light of established individual and Company-wide goals and objectives, evaluated the performance of each NEO, key executive and consultant in order to determine each respective annual incentive opportunity included an analysis by the Compensation Committee that provides the following information:

1. The Company-wide goals & objectives along with individual performance goals for each NEO used to determine annual bonuses for the fiscal year;
2. How each goal individually or in totality was weighted, if applicable, to the extent that any of the performance goals were quantitative and/or quantitative measurable;
3. The threshold, target, and maximum levels of achievement of each performance goal, if applicable;
4. The intended relationship between the level of achievement of Company-wide performance goals and the amount of bonus to be awarded;
5. The intended relationship between the level of achievement of each NEO's individual performance goals and the amount of bonus to be awarded;
6. The evaluation by the Committee of the level of achievement by each NEO of the Company-wide and individual performance goals applicable to him individually;
7. If applicable, whether the Committee reviewed any report(s) from compensation consultant(s);
8. How this level of achievement translated into the actual bonuses awarded for the 2010 fiscal year;
9. The adequate disclosure of the percentage of base salary awarded in the form of an incentive bonus to each NEO as a result of their or the Company's performance; and
10. If applicable, how the Company's compensation policies and practices relate to the Company's risk management.

The Compensation Committee also undertook the initial steps to establish goals and objectives for the Executive Team regarding possible bonuses for the year ending December 31, 2010. On an overall basis, all bonus eligible member of the Executive Team would share the following Company-wide goals:

A. Continued productive interaction with the FDA concerning issues necessary for approval of Ampligen® for CFS;
B. FDA approval of Ampligen® for CFS and/or confirmatory clinical study;
C. Continued productive interaction with the FDA concerning issues necessary for approval of Ampligen® for CFS and/or confirmatory clinical;
D. The start of confirmatory clinical trial for CFS as necessary towards obtaining FDA approval;
E. A country by country strategic plan for Ampligen® to be submitted and approved by the Board;

F. An overall strategic plan for marketing and partners for Ampligen® and Alferon® to be submitted to the Board;
G. An overall strategic plans for the marketing and partners for Alferon® to be submitted to the Board;
H. Continued development of microbiological enhancement of vaccines requiring Ampligen®;
I. Success in the protection of Company Intellectual Property;
J. Continued development of Alferon® LDO;
K. Continued development of Ampligen® for flu;
L. Maintaining the overall financial strength of the Company and operations consistent with the budget; and
M. Implementation of research & development partnerships.

On a specific employee basis, each bonus eligible member of the Executive Team would be judged on his/her success as to meeting or exceeding elements of his/her specific job duties. This would be accomplished by a year-end process, and at the sole discretion of the Compensation Committee and with input from the Chief Executive Officer or the Executive's direct supervisor, the Committee would evaluate the individual performance of each member of the Executive Team as to his/her achievement and/or contribution towards meeting the overall Company-wide goals along with his/her accomplishments specific to his/her job description. The outcome of the Committee's analysis would be utilized to determine if a bonus was warranted, and if so, the dollar amount or percentage of the Executive Team member's year-end base pay rate to be awarded.

Prior to year-end or during the first fiscal quarter of the subsequent year, the Compensation Committee would complete their analysis utilizing any internal and external documentation desired, including but not limited to reports from independent analysts and/or corporate benchmarking organizations. Upon analysis completion, the Compensation Committee made formal recommendations to the Board based on their findings with regard to bonuses for the respective year ended. Due to the subjective nature of the Company-wide goals regarding the success and analysis of an Executive in meeting or exceeding elements of his/her specific job duties, the goals were not designed to be weighted in value or quantitative in nature. The bonuses were designed to be awarded based on a subjective cumulate nature of the goals deemed attainable, employee performance and progress towards achievement. The bonus threshold was designed to range from zero percent to twenty-five percent, with a target bonus of approximately twenty or twenty-five percent, calculated from the individual's year-end base pay rate.

In December 2010, the Compensation Committee reviewed the Executive Team's Company-wide goals as detailed in the Committee's Meeting Minutes of March and May 2010 and specific goals documented in each individual's job description. The Committee believed that the Executive Team had excelled in meeting their goals and responsibilities as documented in each individual's job description as well as made significant progress in meeting corporate goals with outstanding success.

Specifically, with regards to the NEO, the Compensation Committee determined that these Executives had demonstrated sufficient progress or exceeded expectations related to the following established goals described above and designated by the letters "A" through "M":

(i) Dr. William Carter, Chairman & CEO: Goals “A”, “C”, “E”, “F”, “G”, “H”, “I”, “J”, “K”, “L” and “M
(ii) Thomas Equels, General Counsel and Litigation Counsel : Goals “E”, “F”, “G”, “I”, “L” and “M”;
(iii) Charles Bernhardt, CFO & CAO: Goals “E”, “F”, “G”, “I”, “J”, “L” and “M”;
(iv) Dr. David Strayer, Medical Director: Goals “A”, “C”, “E”, “F”, “G”, “H”, “I”, “J”, and “K”;
(v) Russel Lander, V.P of Process and Quality Assurance: “A”, “C”, “G”, “I”, “J”, and “K”; and
(vi) Wayne Springate, V.P. of Operations: Goals “E”, “F”, “G”, “H”, “I”, “J”, “K”, and “L”.

For their achievements identified above, on December 22, 2010 the Compensation Committee awarded each of the identified NEO with a performance bonus of twenty percent of their respective base salary rate at year-end 2010.

For what the Compensation Committee designated as unusual meritorious service during the year, they awarded the following NEO with an extra five percent performance bonus of their respective base salary rate at year-end 2010:

1. Dr. William Carter, related to his development of strategic plans for the Company, obtaining product testing, marketing and sales partnership agreements, issuance of new U.S. Patents for Ampligen® and spearheading the successful raising of new capital through the At The Market stock program;
2. Charles Bernhardt, related to his outstanding service as Chief Financial Officer in completing SEC filings, controlling the Company’s cash burn rate and enforcing budgetary requirements; and
3. Thomas Equels, related to his work and efforts towards settling the various class action suits and judgment against Johannesburg Consolidated Investments (“JCI”) and former JCI officers R.B. Kebble and H.C. Buitendag.

Employee Appraisal And Merit Bonus Program

For the year ending 2010, the Compensation Committee initiated an Employee Appraisal and Merit Bonus Program for those employees not eligible for the key employee Annual Bonus. This Program incorporates a team concept by conducting appraisals for eligible employees in each department throughout the calendar year and then averaging the total scores per department in order to determine a year-end, department-wide merit bonuses. Like with all Company bonus programs, the Program is annually renewed and at the ultimate discretion of the Compensation Committee based on various factors, including the Company’s overall accomplishment of milestones and access to Working Capital. For the year-ended December 31, 2010, the average employee bonus from this Program was 3.4% of the respective employee’s year-end Base Salary.

Long-Term Bonus Incentive Programs

The Compensation Committee believes that team oriented performance by our NEO, non-officer Executive officers and all employees, consistent with our short and long-term goals, can be achieved through the use of goal or result oriented bonus programs. Accordingly, two programs have been established to provide our employees, including our NEO and certain senior, non-officer Executives, with incentives to help align their financial interests with that of Hemispherx and its stockholders. One program terminated in March 2010 and the other is ongoing.

Goal Achievement Incentive Program

On November 17, 2008 the Board of Directors authorized the Goal Achievement Incentive Program. This program is designed to intensify the efforts of the parties involved in securing strategic partnering agreements with third parties. We will pay the parties participating in the Program an incentive bonus for each timely agreement (as defined below) entered into by us with any and all third parties in which we receive cash (as defined below) from such third parties as a result of the execution of such agreements ("Strategic Partnering Agreements"), provided, however, Strategic Partnering Agreements shall not include agreements whereby we receive cash as a result of (i) only the sale of Ampligen® or other Hemispherx products, (ii) our only being reimbursed for expenses, not including expenses for prior research conducted by us, incurred by us, (iii) an agreement in which the only economic benefit to us is one or more loans, and (iv) an agreement, other than an agreement which results in a change of control of Hemispherx, in which the only economic benefit to us is the sale of our equity or other securities. The incentive bonus shall be in an amount equal to one percent (1%) of the amount of all cash received by us pursuant to each such Strategic Partnering Agreement between the dates of the execution of each such Strategic Partnering Agreement and the first commercial sale of Ampligen® following the full commercial approval of the sale of Ampligen® in each jurisdiction. All incentive bonus payments shall be payable in readily available funds within ten (10) days following receipt by us of readily available funds as a result of our receipt of such first cash. For purposes hereof "timely agreements" means all agreements entered into by us with any and all third parties (a) on or before June 30, 2009 and (b) on or before March 31, 2010 with third parties with which we had been in active negotiations on or before June 30, 2009. For purposes hereof "cash" means any asset which is either (a) readily available funds or (b) capable of being converted into readily available funds in value equal to the value ascribed to such asset in the Strategic Partnering Agreement within six months of the receipt of such asset by Hemispherx. This program presently includes Dr. William Carter, CEO, Dr. Chaunce Bogard, strategic consultant, The Sage Group (strategic advisor firm), Anthony Bonelli, our former President and Chief Operating Officer, Dr. David R. Strayer, Medical Director and all of our active full-time employees as of January 1, 2009.

From the inception through its March 31, 2010 expiration, Hemispherx paid no compensation related to the Goal Achievement Incentive Program.

Employee Bonus Pool Program

An element of the Employee Wage Or Hours Reduction Program was the establishment of a Bonus Pool (the "Pool") in the case of FDA Approval ("Approval") of Ampligen®. This bonus is to award to each employee of record at January 1, 2009 a pretax sum of 30% in wages, calculated on their base salary per annum compensation at the time of the Approval, and awarded within three months of Approval. Participants who terminate their employment prior to the Approval will not qualify for this bonus.

For the year ending 2010, Hemispherx paid no compensation related to the Employee Bonus Pool Program.

Stock Options

The Compensation Committee believes that long-term performance is achieved through an ownership culture that encourages such performance by our NEO, non-officer Executives and all employees through the use of stock and stock-based awards. Our stock plans have been established to provide our employees, including our NEO and senior non-officer Executives, with incentives to help align their interests with the interests of stockholders. Accordingly, the Compensation Committee believes that the use of stock and stock-based awards offers the best approach to achieving long-term performance goals because:

- Stock options align the interests of Executives and employees with those of the stockholders, support a pay-for-performance culture, foster employee stock ownership, and focus the management team on increasing

value for the stockholders;

- Stock options are performance based. All the value received by the recipient of a stock option is based on the growth of the stock price; and
- Stock options help to provide a balance to the overall executive compensation program as base salary and our discretionary annual bonus program focus on short-term compensation.

We have historically elected to use stock options as the primary long-term equity incentive vehicle and expect to continue to use stock options as a long-term incentive vehicle. We have adopted stock ownership guidelines and our stock compensation plans have provided the principal method, other than through direct investment for our executive Officers to acquire equity in our Company. The Compensation Committee believes that the annual aggregate value of these awards should be set near competitive median levels for comparable companies. However, in the early stage of our business, we provided a greater portion of total compensation to our Executives through our stock compensation plans than through cash-based compensation.

In determining the number of stock options to be granted to NEO, non-officer Executives and employees, we take into account the individual's position, scope of responsibility, ability to affect profits and stockholder value and the individual's historic and recent performance and the value of stock options in relation to other elements of the individual's total compensation.

Our stock plans authorize us to grant options to purchase shares of common stock to our NEO, employees, Directors and consultants. Our Compensation Committee oversees the administration of our stock option plan. The Compensation Committee reviews and recommends approval by our Board of Directors of stock option awards to NEO based upon a review of competitive compensation data, its assessment of individual performance, a review of each Executive's existing long-term incentives and retention considerations. Periodic stock option grants are made at the discretion of the Board of Directors upon recommendation of the Compensation Committee to eligible NEO and employees and, in appropriate circumstances, the Compensation Committee considers the recommendations of the CEO.

In 2009, Robert Dickey IV was the only employee granted stock options as an element of his acceptance of the Senior Vice President position on June 11, 2009. He was granted the option to purchase 150,000 shares of our common stock at an exercise price of $2.81 per share, or 110% of the $2.55 closing price of the stock on the NYSE Amex. These options are designed to vest proportionately over each month for four years beginning July 1, 2009.

On June 11, 2010, we granted options to purchase shares of our common stock at an exercise price of $0.66 per share, or 110% of the $0.60 closing price of the stock on the NYSE Amex as of June 10, 2010, to the following NEO consistent with their respective employment agreements:

- William A. Carter, CEO and CSO for 500,000 shares with immediate vesting; and
- Thomas K. Equels, General Counsel and Litigation Counsel for 300,000 shares with immediate vesting.

On December 6, 2010, we granted options to purchase 100,000 shares of our common stock at an exercise price of $0.55 per share, or 110% of the $0.50 closing price of the stock on the NYSE Amex as of December 3, 2010, to Charles T. Bernhardt, Chief Financial Officer and Chief Accounting Officer consistent with his employment agreement.

On December 22, 2010, we granted ten year options to purchase 73,728 shares of our common stock at an exercise price of $2.71 per share, to replace options for the same number of shares and at the same exercise price that had been issued on August 8, 1991 and had expired to William A. Carter, CEO and CSO, consistent with approval of the Compensation Committee and the Board.

Other Compensation

We provide the following benefits to our NEO generally on the same bases as benefits provided to all full-time employees:

- Health, vision and dental insurance;
- Life insurance;
- Short and long-term disability insurance; and
- 401(k) with company match of up to 6% of employee's contribution.

The Compensation Committee believes that these benefits are consistent with those offered by other companies, specifically those provided by our peers.

Occasionally, certain Executives separately negotiate other benefits in addition to the benefits described above. The following additional benefits were provided in 2010 NEO as an element of their respective employment:

Dr. William Carter, CEO and CSO, as an element of his employment:

- Automobile allowance;
- Reimbursement of home office and phone expenses; and
- Supplementary life and disability insurance policies.

Thomas Equels, General Counsel and Litigation Counsel, as an element of his employment (effective June 1, 2010):

- Reimbursement of home office and phone expenses; and
- Supplementary life and disability insurance policies.

Commencing as of June 2010, as provided in their respective employment agreement, the following NEO were eligible for incentive bonuses related to: (i) product sales, joint ventures or corporate partnering arrangements ("Sales or Arrangements"), and (ii) any sale of our Company or substantially all of our assets not in the ordinary course of our business ("Asset Sale"): Dr. William Carter, Chairman, CEO & CSO (2.5% of Sales or Arrangements and 5% of any Asset Sale); and Thomas Equels, General Counsel, Litigation Counsel , Secretary and Executive Vice Chairman of the Board (5% of Sales or Arrangements and 5% of any Asset Sale). These incentive bonuses, if earned, are not to exceed in the aggregate an annual maximum of $5,000,000 per Executive. During 2010, there were no bonus payments related to this incentive.

401(k) Plan

In December 1995, we established a defined contribution plan, effective January 1, 1995, entitled the Hemispherx Biopharma employees 401(k) Plan and Trust Agreement. All of our full-time employees are eligible to participate in the 401(k) plan following one year of employment. Subject to certain limitations imposed by Federal Tax laws, participants are eligible to contribute up to 15% of their salary (including bonuses and/or commissions) per annum. Through March 14, 2008, Participants' contributions to the 401(k) plan were matched by Hemispherx at a rate determined annually by the Board of Directors. Each participant immediately vests in his or her deferred salary contributions, while our contributions will vest over one year.

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Effective March 15, 2008 and continuing through December 31, 2009, we halted our matching of 401(k) contributions provided to the account for each eligible participant. Effective January 1, 2010, our Compensation Committee reestablished Hemispherx' 100% matching of up to 6% of the 401(k) contributions provided to the account for each eligible participant, including without exception each eligible Named Executive Officer.

Key Employee Retention

On December 31, 2008, we entered into a severance/consulting agreement with the former Chief Financial Officer, Robert E. Peterson. This agreement provides a monthly fee of $4,000 plus travel expenses and Options to purchase 20,000 shares of the our common stock at the end of each calendar quarter through December 31, 2011 in return for consulting services. The exercise price of the Options is to be equal to 120% of the closing price of the our stock on the NYSE Amex on the last trading day of the calendar quarter for which the Options are being issued. Additionally, the severance/consulting agreement allows for the possibility of a one percent fee to be paid to Mr. Peterson in the event of financial transactions to raise capital for a maximum potential pay-out value of $518,328 (two times the amount of compensation paid to Mr. Peterson by us for calendar year 2008). Mr. Peterson may terminate the Advisory Services at any time upon giving us sixty (60) days notice in writing of the intention to terminate his Advisory Services.

Severance

In determining whether to approve and setting the terms of severance arrangements, the Compensation Committee recognizes that Executives, especially highly ranked Executives, often face challenges securing new employment following termination. Upon termination of employment, the following NEO currently are entitled to receive severance payments under their employment and/or engagement agreements:

- William A. Carter, Chairman of the Board & Chief Executive Officer;
- Thomas K. Equels, Executive Vice Chairman of the Board, Secretary and General (effective June 1, 2010);
- Charles T. Bernhardt, Chief Financial Officer and Chief Accounting Officer (effective December 3, 2010); and
- Wayne Springate, Vice President of Operations.

The Compensation Committee believes that severance agreements provided these individuals are generally in line with severance packages offered to executive officers of the companies of similar size. Mr. Dickey, Dr. Strayer and Dr. Lander are currently not covered under a severance agreement and any severance benefits payable to them under similar circumstances would be determined by the Compensation Committee in its discretion. See "Estimated Payments Following Severance — Named Executive Officers.

Conclusion

Our compensation policies are designed to retain and motivate our Executive Officers, other non-officer Executives and non-Executives and to ultimately reward them for outstanding individual and corporate performance.

COMPENSATION COMMITTEE REPORT

The Compensation Committee of our Board of Directors oversees our compensation program on behalf of the Board. In fulfilling its oversight responsibilities, the Committee reviewed and discussed with Management the Executive Compensation Discussion and Analysis set forth in this Form 10-K for the fiscal year ended December 31, 2010.

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In reliance on the review and discussions referred to above, the Committee recommended to the Board that the Compensation Discussion and Analysis be included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and Hemispherx' Proxy Statement to be filed in connection with Hemispherx' 2011 Annual Meeting of Stockholders.

COMPENSATION COMMITTEE
Dr. Iraj Eqhbal Kiani, Committee Chairman
Dr. William M/ Mitchell
Richard C. Piani

The foregoing Compensation Committee report shall not be deemed incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, and shall not otherwise be deemed filed under these acts, except to the extent we incorporate by reference into such filings.

Compliance With Internal Revenue Code Section 162(m) and 409A & 409(b).

One of the factors the Compensation Committee considers in connection with compensation matters is the anticipated tax treatment to Hemispherx and to the Executives of the compensation arrangements. The deductibility of certain types of compensation depends upon the timing of an executive's vesting in, or exercise of, previously granted rights. Moreover, interpretation of, and changes in, the tax laws and other factors beyond the Compensation Committee's control also affect the deductibility of compensation. Accordingly, the Compensation Committee will not necessarily limit executive compensation to that deductible under Section 162(m) or 409A & 409(b) of the Code. The Compensation Committee will consider various alternatives to preserving the deductibility of compensation payments and benefits to the extent consistent with its other compensation objectives.

COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

Our Compensation Committee of the Board of Directors, consisting of Dr. Iraj Eqhbal Kiani, the Committee Chair, Dr. William M. Mitchell and Richard C. Piani are all independent directors. There are no interlocking relationships.

EXECUTIVE COMPENSATION

The following table provides information on the compensation during the fiscal years ended December 31, 2008, 2009 and 2010 of our Chief Executive Officer, Chief Financial Officers and three other most highly compensated Executive officers, constituting the NEO, in 2009 for each fiscal year.

Summary Compensation Table

Name & Principal Position	Year	Salary / Fees	Bonus	Stock Awards (5)	Option Awards (5)	Non-Equity Incentive Plan Compensation	Change in Pension Value and NQDC Earnings	All Other Compensation	Total
William A. Carter	2010	$951,837	$200,000 (9)	$405,083 (17)	$253,721 (1)	$-0-	—$100,699 (10)		$1,911,340
Chief Executive	2009	$554,105	$482,072 (6)(7)	$188,311 (17)	$-0-	$-0-	—$76,896 (10)		$1,301,384
Officer (1)	2008	$664,624	$-0-	$-0-	$316,571 (18)	$-0-	—$106,094 (10)		$1,087,289
Thomas K. Equels	2010	$398,333	$250,000 (8)(9)	$-0-	$140,528 (2)	$-0-	—$39,973 (11)		$828,834
General Counsel (2)	2009	$-0-	$-0-	$-0-	$-0-	$-0-	—$-0-		$-0-
	2008	$-0-	$-0-	$-0-	$-0-	$-0-	—$-0-		$-0-
Charles T. Bernhardt	2010	$194,133	$50,000 (9)	$117,296 (17)	$37,301 (3)	$-0-	—$24,273 (12)		$423,003
Chief Financial Officer (3)	2009	$134,662	$44,000 (7)	$45,334 (17)	$-0-	$-0-	—$9,380 (12)		$233,376
	2008	$-0-	$-0-	$-0-	$-0-	$-0-	—$26,000 (12)		$26,000
Robert Dickey (4)	2010	$302,500	$-0-	$-0-	$-0-	$-0-	—$8,232 (13)		$310,732
Sr. Vice President	2009	$152,131	$-0-	$-0-	$252,312 (4)	$-0-	—$4,824 (13)		$409,267
	2008	$-0-	$-0-	$-0-	$-0-	$-0-	—$-0-		$-0-
David Strayer	2010	$243,685	$48,737 (9)	$132,587 (17)	$-0-	$-0-	—$13,227 (14)		$438,236
Medical Director	2009	$167,484	$194,306 (6)(7)	$53,054 (17)	$-0-	$-0-	—$3,229 (14)		$418,073
	2008	$201,389	$-0-	$-0-	$16,168 (18)	$-0-	—$-0-		$217,557
Russel Lander	2010	$215,380	$43,076 (9)	$-0-	$-0-	$-0-	—$18,632 (15)		$277,088
Vice President	2009	$171,596	$39,160 (7)	$118,912 (17)	$-0-	$-0-	—$9,648 (15)		$339,316
	2008	$178,000	$-0-	$-0-	$-0-	$-0-	—$8,929 (15)		$186,929
Wayne Springate	2010	$181,580	$36,300 (9)	$109,777 (17)	$-0-	$-0-	—$16,507 (16)		$344,114
V.P., Operations	2009	$126,250	$33,000 (7)	$42,500 (17)	$-0-	$-0-	—$3,229 (16)		$204,979
	2008	$150,000	$-0-	$-0-	$-0-	$-0-	—$7,354 (16)		$157,354

Notes:

(1) Dr. Carter renewed his Employment Agreements on June 11, 2010, which was amended on July 15, 2010, that granted him the Options to purchase 500,000 shares of Hemispherx common stock as an element of his Employment Agreement.

(2) Mr. Equels transitioned from the role of external to internal General Counsel and Litigation Counsel effective June 1, 2010 with an Employment Agreement of June 11, 2010, which was amended on July 15, 2010, that granted him the Options to purchase 300,000 shares of Hemispherx common stock as an element of his Employment Agreement.

(3) Mr. Bernhardt transitioned from the role of a contract consultant in 4th Quarter 2008 to Chief Financial Officer effective January 1, 2009. He entered into an Employment Agreement on December 6, 2010 and was granted the Option to purchase 100,000 shares of Hemispherx common stock as an element of his Employment Agreement.

(4) Mr. Dickey joined Hemispherx effective June 11, 2009 and was granted the Options to purchase 150,000 shares of Hemispherx common stock as an element of his Employment Agreement.

(5) The value was obtained using the Black-Scholes pricing model for stock based compensation in accordance with FASB ASC 718 (formerly SFAS 123R). See Note 2(j) Equity based compensation in the financial statements.

(6) On May 20, 2009, our Board of Directors awarded bonuses of $300,000 to Dr. William Carter, and $150,000 to Dr. David Strayer in recognition for their accomplishment of 2008 corporate goals and objectives.

(7) On February 8, 2009, our Board of Directors awarded bonuses to certain NEO and senior, non-officer Executives in recognition for their achievement towards of 2009 Company-wide and individual goals.

(8) On December 6, 2010, our Board of Directors awarded an extraordinary bonus of $150,000 to Mr. Equels related to his service as external legal counsel from 2008 through May 2010.

(9) On December 22, 2010, our Board of Directors awarded bonuses to certain NEO and senior, non-officer Executives in recognition for their achievement towards of 2009 Company-wide and individual goals.

(10) Dr. Carter's All Other Compensation Consists of:

	2008	2009	2010
Life and Disability Insurance	$ 66,411	$ 38,679	$ 64,707
Healthcare Insurance	28,586	28,586	24,139
Company Car Expenses	11,097	9,631	11,853
401(k) matching funds	-0-	-0-	-0-
	$ 106,094	$ 76,896	$ 100,699

(11) Mr. Equels' All Other Compensation consists of:

	2008	2009	2010
Life and Disability Insurance	$ -0-	$ -0-	$ 34,140
Healthcare Insurance	-0-	-0-	5,833
401(k) matching funds	-0-	-0-	-0-
	$ -0-	$ -0-	$ 39,973

(12) Mr. Bernhardt's All Other Compensation consists of:

	2008	2009	2010
Life and Disability Insurance	$ -0-	$ -0-	$ -0-
Healthcare Insurance	-0-	9,380	9,985
Company Common Stock	26,000	-0-	-0-
401(k) matching funds	-0-	-0-	14,288
	$ 26,000	$ 9,380	$ 24,273

(13) Mr. Dickey's All Other Compensation consists of:

	2008	2009	2010
Life and Disability Insurance	$ -0-	$ -0-	$ -0-
Healthcare Insurance	-0-	4,824	8,232
401(k) matching funds	-0-	-0-	-0-
	$ -0-	$ 4,824	$ 8,232

(14) Dr. Strayer's All Other Compensation consists of:

	2008	2009	2010
Life and Disability Insurance	$ -0-	$ -0-	$ -0-
Healthcare Insurance	-0-	3,229	3,727
401(k) matching funds	-0-	-0-	9,500
	$ -0-	$ 3,229	$ 13,227

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(15) Dr. Lander's All Other Compensation consists of:

	2008	2009	2010
Life and Disability Insurance	$ -0-	$ -0-	$ -0-
Healthcare Insurance	8,929	9,648	3,360
401(k) matching funds	-0-	-0-	15,272
	$ 8,929	$ 9,648	$ 18,632

(16) Mr. Springate's All Other Compensation consists of:

	2008	2009	2010
Life and Disability Insurance	$ -0-	$ -0-	$ -0-
Healthcare Insurance	3,229	3,229	3,637
401(k) matching funds	4,125	-0-	12,870
	$ 7,354	$ 3,229	$ 16,507

(17) Hemispherx' "Employee Wage Or Hours Reduction Program" allowed an individual to elected a 50% reduction in salary/fees which would them to be eligible for an incentive award of three times the value of Stock based on the average NYSE Amex closing value of the stock during the respective months of January through May, 2009. The value was obtained using the Black-Scholes pricing model for stock based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

(18) Issue of options for options previously granted that expired unexercised.

Grants Of Plan Based Awards

Name	Grant Date (3)(5)	Estimated Future Payouts Under Non-Equity Incentive Plan Awards(1) Threshold ($)	Target ($)	Maximum ($)	Estimated Future Payouts Under Equity Incentive Plan Awards Threshold ($)	Target ($)(4)	Maximum ($)	All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Securities of Underlying Options (#)(3)	Exercise or Base Price of Option Awards ($/Sh)	Grant Date Fair Value of Stock and Option Awards ($)
William A. Carter, Chief Executive Officer		—	164,803	206,004	—	—	—	—	—	$ —	—
	06/11/10					186,505			500,000	0.66	253,721
Thomas K. Equels, General Counsel		—	82,402	103,002	—	—	—	—	—	$ —	—
	06/11/10					111,903			300,000	0.66	140,528
Charles T. Bernhardt, Chief Financial Officer		—	41,203	51,504	—	—	—	—	—	$ —	—
	12/06/10		25,000 (2)	25,000 (2)					100,000	0.55	37,301
	N/A	—	60,500	75,625	—	—	—	—	—	$ —	—

Robert Dickey, Senior Vice President											$	
David Strayer, Medical Director	N/A	—	50,199	62,749	—	—	—	—	—	$ —	—	
Russel Lander, Vice President	N/A	—	44,371	55,464	—	—	—	—	—	$ —	—	
Wayne Springate, Vice President	N/A	—	37,392	46,740	—	—	—	—	—	$ —	—	

Notes:

(1) For 2010 or 2011, the Compensation Committee did not establish or estimate possible future payouts to the NEO under a Cash Bonus Plan. All Bonuses are at the discretion of the Compensation Committee. Utilizing existing Employment Agreements as a benchmark and the respective employees' Base Salary at December 31, 2010, the "Target" was estimated at 20% of the Base Salary and "Maximum" estimated at 25% of Base Salary. Details regarding all of which reported as Non-Equity Incentive Plan Compensation in the 2010 is reported in the Summary Compensation Table above.

(2) Consists of an extraordinary bonus granted Mr. Bernhardt on March 3, 2011.

(3) Consists of stock options granted during 2010 under our 2009 Equity Incentive Plan. The stock options have a ten-year term and an exercise price equal to 110% of the closing market price of the our common stock on the date of grant. The value was obtained using the Black-Scholes pricing model for stock based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

(4) Consists of stock options contractually required per the employee's respective Employment Agreement to be granted during 2011 under our 2009 Equity Incentive Plan. The stock options have a ten-year term and an exercise price equal to 110% of the closing market price of the our common stock on the date of grant. For the purpose of this schedule, a NYSE Amex closing price at December 31, 2010 of $0.49 was assumed with an estimated exercise price of $0.54. The value was obtained using the Black-Scholes pricing model for stock based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

(5) N/A represents Not Applicable.

Outstanding Equity Awards At Fiscal Year End

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights that Have Not Vested (#)
William A. Carter	1,450,000	0	0	2.20					
Chief	1,000,000	0	0	2.00	09/9/17				
Executive	190,000	0	0	4.00	02/18/18				
Officer	73,728	0	0	2.71	12/12/20				
	10,000	0	0	4.03	01/3/11				
	167,000	0	0	2.60	09/7/14				
	153,000	0	0	2.60	012/7/14				
	100,000	0	0	1.75	04/26/15				
	465,000	0	0	1.86	06/30/15				
	70,000	0	0	2.87	12/9/15				
	300,000	0	0	2.38	01/1/16				
	10,000	0	0	2.61	12/8/15				
	376,650	0	0	3.78	02/22/16				
	1,400,000	0	0	3.50	09/30/17				
	500,000	0	0	0.66	06/11/20				
Thomas K. Equels General Counsel	300,000	0	0	0.660	06/11/20				
Charles Bernhardt Chief Financial Officer	100,000	0	0	0.55	12/06/19				
Robert Dickey,	56,250	93,750	0	2.55	06/11/19				

Sr. Vice President					
David Strayer, Medical Director	50,000	0	0	2.00	09/09/17
	50,000	0	0	4.00	02/28/18
	10,000	0	0	4.03	01/03/11
	20,000	0	0	2.37	01/23/17
	10,000	0	0	1.90	12/07/14
	10,000	0	0	2.61	12/08/15
	15,000	0	0	2.20	11/20/16
	25,000	0	0	1.30	12/06/17
Russel Lander Vice President	150,000	0	0	1.30	12/06/14
Wayne Springate, Vice President	1,812	0	0	1.90	12/07/14
	2,088	0	0	2.61	12/08/15
	5,000	0	0	2.20	11/20/16
	20,000	0	0	1.78	04/30/17
	20,000	0	0	1.30	12/06/17

Option Exercises And Stock Vested

	Option Awards		Stock Awards	
Name and Principal Position	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting ($)
William A. Carter, Chief Executive Officer	—	—	—	—
Thomas K. Equels, , General Counsel	—	—	—	—
Charles T. Bernhardt, Chief Financial Officer	—	—	—	—
Robert Dickey, Senior Vice President	—	—	—	—
David Strayer, Medical Director	—	—	—	—
Russel Lander, Vice President	—	—	—	—
Wayne Springate, VP, Operations	—	—	—	—

Payments on Disability

Each current NEO has the same short and long-term disability coverage which is available to all eligible employees. The coverage for short-term disability provides up to six months of full salary continuation up to 60% of weekly pay, less other income, with a $1,500 weekly maximum limit. The coverage for group long-term disability provides coverage at the exhaustion of short-term disability benefits of full salary continuation up to 60% of monthly pay, less other income, with a $10,000 monthly maximum limit. The maximum benefit period for the group long-term disability coverage is 60 months for those age 60 and younger at the time of the claim with the coverage period proportionately reduced with the advanced age of the eligible employee to a minimum coverage period of 12 months for those of 69 years old and elder as of the date of the claim. Additionally in 2009 and through May 2010, Dr. Carter received additional coverage of $200,000 per annum payable under the terms of a disability insurance policy paid for by us. In June 2010, pursuant to their new employment agreements and payable by us, Dr. Carter is entitled to receive total disability coverage of $500,000 and Mr. Equels is entitled to receive total disability coverage of $400,000.

Payments on Death

Each NEO has coverage of group life insurance, along with accidental death and dismemberment benefits, consistent to the dollar value available to all eligible employees. The benefit is equal to two times current salary or wage with a maximum limit of $300,000, plus any supplemental life insurance elected and paid for by the NEO. Additionally, in 2009 through May 2010, William A. Carter, Chief Executive Officer's beneficiaries received a benefit of $4,850,000 payable under the terms of a term life insurance policies paid for by us. In June 2010, pursuant to their new employment agreements and payable by us, Dr. Carter is entitled to receive total death benefit coverage of $6,000,000 and Mr. Equels is entitled to receive total death benefit coverage of $3,000,000.

Estimated Payments Following Severance — Named Executive Officers

At December 31, 2010, we had employment agreements with Dr. Carter, Mr. Equels, Mr. Bernhardt, Mr. Dickey and Mr. Springate, of which some of the agreements entitled employees to severance benefits on certain types of employment terminations not related to a change in control. Dr. Strayer and Dr. Lander were not covered under a general severance plan and any severance benefits payable to them under similar circumstances would be determined by the Compensation Committee in its discretion. The dollar amounts below assume that the termination occurred on December 31, 2010. The actual dollar amounts to be paid can only be determined at the time of the NEO's separation from Hemispherx based on their prevailing compensation and employment agreements along with any determination by the Compensation Committee in its discretion.

Name	Event	Cash Severance ($)	Value of Stock Awards That Will Become Vested (1) ($)	Continuation of Medical Benefits (2) ($)	Additional Life Insurance (3) ($)	Total ($)
William A. Carter	Involuntary (no cause)	4,120,080	932,525	106,301	337,928	5,496,832
Chief Executive Officer	Termination (for cause)	—	—	—	—	—
	Death or disability	824,016	186,505	21,260	67,586	1,099,367
	Termination by employee or retirement	824,016	186,505	21,260	67,586	1,099,367
Thomas K. Equels	Involuntary (no cause)	2,060,040	559,515	29,163	170,700	2,819,418
General Counsel	Termination (for cause)	—	—	—	—	—
	Death or disability	412,008	111,903	5,833	34,140	563,884
	Termination by employee or retirement	412,008	111,903	5,833	34,140	563,844
Charles T. Bernhardt	Involuntary (no cause)	206,015	—	6,662	3,323	216,000
		—	—	—	—	—

Chief Financial Officer	Termination (for cause)					
	Death or disability	206,015	—	6,662	3,323	216,000
	Termination by employee or retirement	206,015	—	6,662	3,323	216,000
Robert Dickey Senior Vice President	Involuntary (no cause)	25,208	—	567	119	25,894
	Termination (for cause)	25,208	—	567	119	25,894
	Death or disability	—	—	—	—	—
	Termination by employee or retirement	25,208	—	567	119	25,894
David Strayer Medical Director	Involuntary (no cause)	—	—	—	—	—
	Termination (for cause)	—	—	—	—	—
	Death or disability	—	—	—	—	—
	Termination by employee or retirement	—	—	—	—	—
Russel Lander Vice President	Involuntary (no cause)	—	—	—	—	—
	Termination (for cause)	—	—	—	—	—
	Death or disability	—	—	—	—	—
	Termination by employee or retirement	—	—	—	—	
Wayne Springate Vice President	Involuntary (no cause)	67,820	—	124	1,088	69,032
	Termination (for cause)	—	—	—	—	—
	Death or disability	—	—	—	—	—
	Termination by employee or retirement	—	—	—	—	—

Notes:

(1) Consists of stock options contractually required per the employee's respective Employment Agreement to be granted during each calendar year of the term under our 2009 Equity Incentive Plan. The stock options have a ten-year term and an exercise price equal to 110% of the closing market price of the our common stock on the date of grant. For the purpose of this schedule, a NYSE Amex closing price of $0.49 was assumed with an estimated exercise price of $0.54. The value was obtained using the Black-Scholes pricing model for stock based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

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(2) This amount reflects the current premium incremental cost to us for continuation of elected benefits to the extent required under an applicable agreement.

(3) The life insurance benefit represents life insurance paid for by us including the standard coverage.

Payments On Termination in Connection With a Change in Control - Named Executive Officers

At December 31, 2010, we had employment agreements with Dr. Carter, Mr. Equels and Mr. Bernhardt that entitled them to severance benefits on certain types of employment terminations related to a change in control. Based on their employment agreements, Mr. Dickey and Mr. Springate would receive the same severance benefits as if an Involuntary Termination took place. Dr. Strayer and Dr. Lander are not covered under any employment agreement nor any severance plan specific to a change in control. Any specific benefits for these four NEO would be determined by the Compensation Committee in its discretion. The dollar amounts below assume that the termination occurred on December 31, 2010. The actual dollar amounts to be paid can only be determined at the time of the NEO's separation from Hemispherx based on their prevailing compensation and employment agreements along with any determination by the Compensation Committee in its discretion.

The dollar amounts in the chart below assume that change in control termination occurred on December 31, 2010, based on the employment agreements that existed at that time. The actual dollar amounts to be paid can only be determined at the time of the NEO's separation from Hemispherx based on their prevailing compensation and employment agreements along with any determination by the Compensation Committee in its discretion.

Estimated Benefits on Termination Following a Change in Control — December 31, 2010

The following table shows potential payments to the NEO if their employment terminates following a change in control under contracts, agreements, plans or arrangements at December 31, 2010. The amounts assume a December 31, 2010 termination date regarding base pay and use the closing price of $0.49 on the NYSE Amex for our common stock at that date.

Name	Aggregate Severance Pay ($)	PVSU Acceleration (4) ($)	Early Vesting of Restricted Stock (5) ($)	Early Vesting of Stock Options and SARs (5) ($)	Acceleration and Vesting of Supplemental Award (6) ($)	Welfare Benefits Continuation (7) ($)	Outplacement Assistance ($)	Parachute Tax Gross-up Payment ($)	Total ($)
William A. Carter	4,120,128 (1)	-0-	-0-	-0-	1,492,040	886,766 (1)(8)	-0-	-0-	6,498,934
Thomas K. Equels	3,296,064 (1)	-0-	-0-	-0-	895,224	495,781 (1)(8)	-0-	-0-	4,687,069
Charles T. Bernhardt	824,064 (1)	-0-	-0-	-0-	-0-	127,940 (1)(8)	-0-	-0-	952,004
Robert Dickey	25,208 (2)	-0-	-0-	-0- (5)	-0-	47 (2)	-0-	-0-	60,225
David Strayer	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-
Russel Lander	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-
Wayne Springate	67,820 (3)	-0-	-0-	-0-	-0-	41 (3)	-0-	-0-	67,861

Notes:

(1)This amount represents the base salary or benefits for remaining term of the NEO's employment agreement plus a three year extension in the occurrence of termination from a change in control.

(2)This amount represents the one-twelfth of base salary or benefits for the NEO.

(3)This amount represents the four-twelfth of base salary or benefits for the NEO.

(4)This amount represents the payout of all outstanding performance-vesting share units ("PVSU") awards on a change in control at the target payout level with each award then pro-rated based on the time elapsed for the applicable three-year performance period.

(5)This amount is the intrinsic value [fair market value on December 31, 2010 ($0.49 per share) minus the per share exercise price] of all unvested stock options for each NEO, including Stock Appreciation Rights ("SAR"). Any option with an exercise price of greater than fair market value was assumed to be cancelled for no consideration and, therefore, had no intrinsic value.

(6)This amount represents the options to be issued annually for remaining term of the NEO's employment agreement plus a three year extension in the occurrence of termination from a change in control. The calculation was based on a NYSE Amex closing price for December 31, 2010 of $0.49 with an estimated exercise price of $0.54. The value was obtained using the Black-Scholes pricing model for stock based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

(7)This amount represents the employer-paid portion of the premiums for medical, dental and life insurance coverage.

(8)This amount also includes the estimated cost of Company matching 401(k) contributions of $22,000 per year.

Definition of "Change in Control". For each agreement, a "Change in Control" is defined generally as any such event that requires a report to the SEC, but includes any of the following:

- Any person or entity other than Hemispherx, any of our current directors or officers or a trustee or fiduciary holding our securities, becomes the beneficial owner of more than 50% of the combined voting power of our outstanding securities;
- An acquisition, sale, merger or other transaction that results in a change in ownership of more than 50% of the combined voting power of our stock or the sale/transfer of more than 75% of our assets;
- A change in the majority of our Board of Directors over a two-year period that is not approved by at least two-thirds of the directors then in office who were directors at the beginning of the period; or
- Execution of an agreement with Hemispherx, which if consummated, would result in any of the above events.

Definition of "Constructive Termination". A "Constructive Termination" generally includes any of the following actions taken by Hemispherx without the executive's written consent following a change in control:

- Significantly reducing or diminishing the nature or scope of the executive's authority or duties;
- Materially reducing the executive's annual salary or incentive compensation opportunities;
- Changing the executive's office location so that he must commute more than 50 miles, as compared to his commute as of the date of the agreement;
- Failing to provide substantially similar fringe benefits, or substitute benefits that were substantially similar taken as a whole, to the benefits provided as of the date of the agreement; or

- Failing to obtain a satisfactory agreement from any successor to Hemispherx to assume and agree to perform the obligations under the agreement.

However, no constructive termination occurs if the executive:

- Fails to give us written notice of his intention to claim constructive termination and the basis for that claim at least 10 days in advance of the effective date of the executive's resignation; or
- We cure the circumstances giving rise to the constructive termination before the effective date of the executive's resignation.

Available Information

Our Internet website is www.hemispherx.net and you may find our SEC filings in the "Investor Relations" under "SEC Filings". We provide access to our filings with the SEC, free of charge through www.sec.gov, as soon as reasonably practicable after filing with the SEC. Our Internet website and the information contained on that website, or accessible from our website, is not intended to be incorporated into this Annual Report on Form 10-K or any other filings we make with the SEC.

The provision for change in control within the employment agreements for Thomas K. Equels and Charles T. Bernhardt did not become effective until June 1, 2010 and December 6, respectively, while the amended employment agreement with Robert Dickey IV, effective February 1, 2010, no longer included a change in control provision.

Post-Employment Compensation

We have agreements with the following NEO who have benefits upon termination: an employment and an engagement agreement with Dr. William Carter, our Chairman and Chief Executive Officer; an employment agreement with Thomas K. Equels (effective June 1, 2010), our Executive Vice Chairman, Secretary and General Counsel; Charles T. Bernhardt (effective December 6, 2010) our Chief Financial Officer and Chief Accounting Officer; and Wayne Springate, our Vice President of Operations.

The following is a description of post-employment compensation payable to the NEO. If a NEO does not have a specific benefit, he is not mentioned in the subsection. In such event, the NEO does not have any such benefits upon termination unless otherwise required by law.

Termination For Cause

All of our NEO can be terminated for cause. For Dr. Carter, Mr. Equels and Mr. Bernhardt, "Cause" means the willful engaging by a NEO in illegal conduct or gross misconduct or gross violation of the Company's Code of Ethics And Business Conduct for Officers which is demonstrably and materially injurious to the Company. For purposes of their respective agreements, no act, or failure to act, on a NEO's part shall be deemed "willful" unless done intentionally by a NEO and not in good faith and without reasonable belief that a NEO 's action or omission was in the best interest of the Company. Notwithstanding the foregoing, a NEO shall not be deemed to have been terminated for Cause unless and until the Company delivers to a NEO a copy of a resolution duly adopted by the affirmative vote of not less than three-quarters of the directors of the Board at a meeting of the Board called and held for such purpose (after reasonable notice to a NEO and an opportunity for a NEO, together with counsel, to be heard before the Board) finding that, in the good faith opinion of the Board, a NEO was guilty of conduct set forth above and specifying the particulars thereof in detail. In the event that their employment is terminated for Cause, the Company shall pay them, at the time of such termination, only the compensation and benefits otherwise due and payable to him through the last day of his actual employment by the Company.

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Mr. Springate can be terminated for cause. “Cause” means his failure, other than by reason of disability, to perform his services under his employment agreement or his willful engaging in illegal conduct or gross misconduct which is injurious to the Company. If he is terminated for cause, he is entitled to only the fees due and payable to him through the date of the termination of his employment agreement.

Termination Without Cause

Dr. Carter, Mr. Equels, Mr. Bernhardt and Mr. Springate are each entitled to the compensation and benefits otherwise due and payable to him through the last day of the then current term of his agreements. In the event that he is terminated at any time without "Cause" the Company shall pay to him, at the time of such termination, the compensation and benefits otherwise due and payable to him through the last day of the then current term of his Agreement. However, benefit distributions that are made due to a “separation from service” occurring while he is a Named Executive Officer shall not be made during the first six months following “separation from service”. Rather, any distribution which would otherwise be paid to him during such period shall be accumulated and paid to him in a lump sum on the first day of the seventh month following the “separation from service”. All subsequent distributions shall be paid in the manner specified.

Death or Disability

Dr. Carter, Mr. Equels and Mr. Bernhardt can be terminated for death or disability. For each, “Disability” means his inability to effectively carry out substantially all of his duties under his agreement by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted for a continuous period of not less than 12 months. In the event his employment is terminated due to his death or disability, the Company will pay to him (or his estate as the case may be), at the time of such termination, the Base Salary and applicable benefits otherwise due and payable through the last day of the month in which such termination occurs and for an additional 12 month period.

Mr. Springate can be terminated for death or disability which lasts for a continuous period of not less than three months. If he is terminated due to his death or disability, he (or his estate as the case may be) are entitled to the fees due him through the last day of the month in which such termination occurs.

Termination by Officer and Employee

All executive Officers, other non-officer Executives and non-Executives have the right to terminate their respective agreement upon not less than thirty (30) days of prior written notice of termination. In such event, Dr. Carter, Mr. Equels and Mr. Bernhardt are entitled to fees due to them through the last day of the month in which such termination occurs and for 12 months thereafter. All others are entitled to the fees due to them through the last day of the month in which such termination occurs.

Change in Control

Dr. Carter, Mr. Equels and Mr. Bernhardt are entitled to benefits upon a Change of Control or Constructive Termination. Dr. Carter has a Change of Control agreement that currently runs through December 31, 2012 and as of each December 31st automatically renews through the third anniversary thereof, unless we notify him by written notice of refusal to renew at least 180 days prior to the initial termination date or the expiration date of any renewal period. Dr. Carter's, Mr. Equels' and Mr. Bernhardt's employment agreements also provide that, upon the happening of a Change of Control or Constructive Termination, the terms of such agreements automatically extend for an additional three years.

Compensation of Directors

Our Compensation, Audit and Corporate Governance and Nomination Committees, consist of Dr. Iraj Eqhbal Kiani, Compensation Committee Chair, Dr. William M. Mitchell, Corporate Governance and Nomination Committee Chair, and Richard C. Piani, Audit Committee Chair, all of whom are independent Board of Director members.

In 2009, Non-employee Board member compensation consisted of an annual retainer ("Directors' fees") of $150,000. In 2010, all Board members received Directors' fees of $165,000.

On November 28, 2008, Thomas K. Equels joined our Board of Directors as a non-employee Board member in which his compensation of $150,000 for all director fees were agreed to be paid in the form of our common stock. The number of shares paid were determined by the closing price of our common stock on the NYSE Amex on the last day of the calendar quarter. Effective April 1, 2009, Mr. Equels began receiving payment in cash for his proportionate portion of annual retainer.

Hemispherx reimburses Directors for travel expenses incurred in connection with attending board, committee, stockholder and special meetings along with other Company business-related expenses. Hemispherx does not provide retirement benefits or other perquisites to non-employee Directors under any current program.

All Directors have been granted options to purchase common stock under our Stock Option Plans and/or Warrants to purchase common stock. We believe such compensation and payments are necessary in order for us to attract and retain qualified outside directors. To the extent that share compensation would exceed 1,000,000 shares in the aggregate for the ten year period commencing January 1, 2003, as previously approved by Resolution of the Board of September 9, 2003, shares for share compensation shall be issued under the our 2007 and 2009 Equity Incentive Plans.

Commencing as of January 1, 2011, Board member Directors' fee compensation was increased to an annual retainer of $169,950. Director's fees will continue to be paid in cash quarterly at the end of each calendar quarter.

Director Compensation - 2010

Name and Title	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compen-sation ($)	Change in pension Value and Nonqualified Deferred Compensation Earnings ($)	All Other Compen-sation ($)	Total ($)
W. Carter, Chairman & Chief Executive Officer	165,000	0	253,721 (1)	0	0	1,492,619 (2)	1,911,340
T. Equels, Executive Vice Chairman, Secretary & General Counsel	165,000	0	140,528 (3)	0	0	523,306 (4)	828,837
W. Mitchell, Director	165,000	0	0	0	0	0	165,000
R. Piani, Director	165,000	0	0	0	0	0	165,000
I. Kiani, Director	165,000	0	0	0	0	0	165,000

Notes:

(1) Ten year Option to purchase 500,000 shares at $0.66 per share awarded consistent with Employment Agreement of June 11, 2010. The value was obtained using the Black-Scholes pricing model for stock based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

(2) Chief Executive Officer salary and Consultant fees paid consistent with Engagement Agreements in effect during 2010 along the year-end performance bonus for 2010.

(3) Ten year Option to purchase 300,000 shares at $0.66 per share awarded consistent with Employment Agreement of June 11, 2010. The value was obtained using the Black-Scholes pricing model for stock based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

(4) General Counsel salary and Consultant fees paid consistent with Engagement Agreements in effect June 1, 2010 along the performance bonus in 2010 of $150,000 for services prior to employment and year-end performance bonus for 2010.

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

The following table sets forth as of March 1, 2011, 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.

Name and Address of Beneficial Owner	Shares Beneficially Owned		% Of Shares Beneficially Owned	
William A. Carter, M.D.	7,637,159	(1)(2)	5.65	%
Thomas K. Equels	1,728,622	(3)	1.28	%
Richard C. Piani 97 Rue Jeans-Jaures Levaillois-Perret, France 92300	757,420	(4)	*	
William M. Mitchell, M.D. Vanderbilt University Department of Pathology Medical Center North 21st and Garland Nashville, TN 37232	616,025	(5)	*	
Iraj Eqhbal Kiani, N.D., Ph.D. Orange County Immune Institute 18800 Delaware Street Huntingdon Beach, CA 92648	323,271	(6)	*	
Charles T. Bernhardt CPA	277,420	(7)	*	
David R. Strayer, M.D.	410,932	(8)	*	
Wayne Springate	152,421	(9)	*	
Robert Dickey, IV	152,500	(10)	*	
Russel Lander, Ph.D.	168,073	(11)	*	
Ralph C. Cavalli, Ph.D.	20,000	(12)	*	
All directors and executive officers as a group (11 persons)	12,243,843		9.06	%

* Ownership of less than 1%

(1) Dr. Carter is our Chairman and Chief Executive Officer. He owns 889,570 shares of common stock and beneficially owns 6,746,574 shares issuable or issued upon exercise of:

	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
Options					
	2009	12/22/10	$ 2.71	73,728	12/22/20
	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
	2009	06/11/10	$ 0.66	500,000	06/11/20
Total Options				6,255,378	
Warrants					
Total Warrants	2009	02/1/09	$ 0.51	491,196	02/01/19

(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 owns 1,015 shares of common stock.

(3) Mr. Equels is Executive Vice Chairman of our Board of Directors, Secretary and General Counsel who owns 937,426 shares of common stock and beneficially owns 791,196 shares issuable or issued upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
Total Options	2009	06/11/10	$ 0.66	300,000	06/11/20

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

(4) 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	

(5) 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	

(6) 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	

(7) Charles T. Bernhardt is our Chief Financial Officer and owns 177,420 shares of common stock and beneficially owns 100,000 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
Total Options	2009	12/06/09	$ 0.55	100,000	12/06/19

(8) Dr. Strayer is our Medical Director that has ownership of 230,932 shares of common stock and beneficially owns 180,000 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	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				180,000	

(9) Mr. Springate is our Vice President of Operations who owns 103,521 shares of common stock and beneficially owns 48,900 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	

(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. Ralph C. Cavalli is our Vice President of Quality Control who beneficially owns 20,000 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
Total Options	2009	06/11/10	$ 0.66	20,000	06/11/20

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.

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 $123,200 and $82,400 in 2010 and 2009, respectively, for the use of the property at various times for off-site meetings and lodging.

Tom Equels was elected to the Board of Directors at the Annual Stockholders Meeting on November 17, 2008. Mr. Equels has provided external legal services to us for several years through May 31, 2010 and his firm continues to support the Company. For 2010 and 2009, we paid Mr. Equels’ law firm $729,000 and $387,000 respectfully, for services rendered.

For her part-time services to us as Assistant Medical Director Kati Kovari, M.D. was paid $26,000 and $13,000 in 2010 and 2009, 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 2010 and 2009 were $304,000 and $413,000, respectively. The following table shows the aggregate fees for professional services rendered during the year ended December 31, 2010 and 2009.

	Amount ($)	
Description of Fees:	2010*	2009*
Audit Fees	$ 270,000	$ 413,000
Audit-Related Fees	34,000	-0-
Tax Fees	-0-	-0-
All Other Fees	-0-	-0-
Total	$ 304,000	$ 413,000

* Includes fees related to the restatement of our audited financial statements for the fiscal year ended December 31, 2009 and 2010 quarterly unaudited financial statements.

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 2010 and 2009.

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. (1)
1.2	May 28, 2010 Equity Distribution Agreement with Maxim Group LLC (18)
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended, along with Certificates of Designations.
3.2	Amended and Restated By-laws of Registrant. (2)
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.(3)
4.3	Form of Commitment Warrant issued in February 2009 under the Standby Financing Agreement. (11)
4.4	Form of Indenture filed with Universal shelf registration statement. (4)
4.5	Form of Series I common stock purchase warrant pursuant to May 10, 2009 Securities Purchase Agreement. (1)
4.6	Form of Series II common stock purchase warrant pursuant to May 10, 2009 Securities Purchase Agreement. (1)
4.7	Form of common stock purchase warrant pursuant to May 18, 2009 Securities Purchase Agreement. (5)
10.1	Form of Confidentiality, Invention and Non-Compete Agreement.
10.2	Form of Clinical Research Agreement.
10.5	Change in control agreement with Dr. William A. Carter. (6)
10.6	Change in control agreement with Dr. William A. Carter. (6)
10.7	Supply Agreement with Hollister-Stier Laboratories LLC. (7)
10.8	Biken Activating Agreement. (8)
10.9	Biken Material Evaluation Agreement. (8)
10.10	Common Stock Purchase Agreement, dated July 2, 2008, by and among the Company and Fusion Capital. (9)
10.11	Registration Rights Agreement, dated July 2, 2008, by and among the Company and Fusion Capital. (9)
10.12	Amendment to Common Stock Purchase Agreement, dated July 23, 2008, by and among the Company and Fusion Capital. (10)
10.13	Employee Wage Or Hours Reduction Program. (11)
10.14	Standby Financing Agreement.(11)
10.15	Employment Agreement with Charles T. Bernhardt, CPA. (15)

10.16	Goal Achievement Incentive Award Program. (12)
10.17	Form of Securities Purchase Agreement entered into on May 10, 2009. (1)
10.18	Form of Securities Purchase Agreement entered into on May 18, 2009. (5)
10.19	Amended and Restated Employment Agreement with Robert Dickey IV, dated September 1, 2010. (14)
10.20	Amendment to Supply Agreement with Hollister-Stier Laboratories LLC dated February 25, 2010. (16)
10.21	August 2009 Material Evaluation Agreement with Biken. (16)
10.22	Amended and Restated Employment Agreement of Dr. William A. Carter dated June 11, 2010 (14)
10.23	Amended and Restated Engagement Agreement of Dr. William A. Carter dated July 15, 2010. (13)
10.24	Amended Employment Agreement with Thomas K. Equels dated July 15, 2010. (14)

10.25	Amended Adviser's Agreement with The Sage Group Inc. dated July 15, 2010. (14)
10.26	Employment Agreement with Charles T. Bernhardt dated December 3, 2010. (15)
10.27	Employment Agreement with Wayne Springate dated January 1, 2007. (16)
21	Subsidiaries of the Registrant. (16)
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. *

* Filed herewith.

(1) 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.

(2) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) filed January 11, 2011 and is hereby incorporated by reference.

(3) 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.

(4) 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.

(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 May 18, 2009 and is hereby incorporated by reference.

(6) 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.

(7) 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.

(8) 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.

(9) 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.

(10) 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.

(11) 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.

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(12) 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.

(13) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) filed June 15, 2010 and is hereby incorporated by reference.

(14) 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, 2010 and is hereby incorporated by reference.

(15) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) filed December 8, 2010 and is hereby incorporated by reference.

(16) 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, 2009 and is hereby incorporated by reference.

(17) Filed with the Securities and Exchange Commission as an exhibit to the Company's Annual Report on Form 10-K/A-2 (No. 1-13441) for the year ended December 31, 2009 and is hereby incorporated by reference.

(18) 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 28, 2010 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 28, 2011

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 28, 2011
/s/ Richard Piani Richard Piani	Director	March 28, 2011
/s/ Charles T. Bernhardt Charles T. Bernhardt CPA	Chief Financial Officer and Chief Accounting Officer	March 28, 2011
/s/ Thomas K. Equels Thomas Equels	Director, Secretary and General Counsel	March 28, 2011
/s/ William Mitchell William Mitchell, M.D., Ph.D.	Director	March 28, 2011
/s/ Iraj E. Kiani Iraj E. Kiani, N.D., Ph.D.	Director	March 28, 2011

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, 2009 and 2010 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, 2010. Our audits also included the financial statement schedule of Hemispherx Biopharma, Inc. listed in Item 15(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, 2009 and 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule 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, 2010, 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 28, 2011, 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 28, 2011

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2009 and 2010
(in thousands, except for share and per share amounts)

	2009	2010
ASSETS		
Current assets:		
Cash and cash equivalents (Notes 2 and 16)	$58,072	$2,920
Marketable securities maturing in less than one year(Note 4)	-	32,689
Inventories (Note 3)	-	787
Prepaid expenses and other current assets	332	278
Total current assets	58,404	36,674
Property and equipment, net (Note 2)	4,704	4,876
Patent and trademark rights, net (Notes 2 & 5)	830	794
Investment	35	35
Marketable securities maturing in one year or more(Note 4)	-	8,778
Construction in progress (Note 2)	135	485
Other assets(Note 3)	886	38
Total assets	$64,994	$51,680
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,294	$1,328
Accrued expenses (Note 6)	1,321	1,443
Current portion of capital lease (Note 18)	-	61
Total current liabilities	2,615	2,832
Long-term liabilities:		
Long-term portion of capital lease (Note 18)	-	96
Redeemable warrants (Note 17)	3,684	2,805
Total liabilities	6,299	5,733
Commitments and contingencies (Notes 9,11, 12, 13, 14 & 18)		
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 132,787,447 and 135,241,609, respectively	133	135
Additional paid-in capital	263,151	264,511
Unrealized loss	-	(974)
Accumulated deficit	(204,589)	(217,725)
Total stockholders' equity	58,695	45,947

Total liabilities and stockholders' equity	$64,994	$51,680

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,		
	2008	2009	2010
Revenues:			
Sales of product, net	$173	$-	$-
Clinical treatment programs	92	111	135
Total Revenues	265	111	135
Costs and Expenses:			
Production/cost of goods sold	798	584	1,341
Research and development	5,800	6,995	7,613
General and administrative	6,478	5,796	7,568
Total Costs and Expenses	13,076	13,375	16,522
Operating loss	(12,811)	(13,264)	(16,387)
Interest and other income	592	67	2,383
Interest expense	-	-	(11)
Financing costs from standby financing agreement	-	(241)	-
Redeemable warrants valuation adjustment (Note 17)	-	6,258	879
Net loss	$(12,219)	$(7,180)	$(13,136)
Basic and diluted loss per share	$(.16)	$(.07)	$(.10)
Weighted average shares outstanding Basic and Diluted	75,142,075	109,514,401	134,018,243

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, 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
Redeemable warrants valuation adjustment	-	-	(9,942)	-	-	(9,942)
Net comprehensive loss	-	-	-	-	(7,180)	(7,180)
Balance December 31, 2009	132,787,447	133	263,151	-	(204,589)	58,695
Shares issued for:						
Settlement of accounts payable	498,867	-	329	-	-	329
Shares sold at the market	520,000	-	292	-	-	292
Stock based compensation	1,435,295	2	739	-	-	741
Net comprehensive loss	-	-	-	(974)	(13,136)	(14,110)
Balance December 31, 2010	135,241,609	$135	$264,511	$ (974)	$ (217,725)	$ 45,947

See accompanying notes to consolidated financial statements

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

	Years ended December 31		
	2008	2009	2010
Cash flows from operating activities:			
Net loss	$(12,219)	$(7,180)	$(13,136)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of property and equipment	342	359	407
Amortization of patent, trademark rights, and royalty interest	374	381	373
Finance costs amortization and for Standby financing	-	241	-
Redeemable warrants valuation adjustment	-	(6,258)	(879)
Stock option and warrant compensation and service expense	573	826	740
Gain on disposal of equipment	-	(83)	-
Inventory reserve	(65)	-	-
Changes in assets and liabilities:			
Inventories	(288)	-	77
Accounts and other receivables	77	-	-
Assets held for sale	450	-	-
Prepaid expenses and other current assets	(184)	93	54
Other assets	-	(5)	(7)
Accounts payable	1,702	1,884	362
Accrued expenses	(120)	45	123
Net cash used in operating activities	(9,358)	(9,297)	(11,886)
Cash flows from investing activities:			
Purchases of property and equipment and construction in progress, net	(73)	(332)	(729)
Additions to patent and trademark rights	(142)	(242)	(337)
Capital lease deposit	-	-	(9)
Maturities of short term investments	3,951	-	7,448
Purchase of short term investments	-	-	(49,889)
Net cash (used in) provided by investing activities	$3,736	$(574)	$(43,516)

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

	Years ended December 31,		
	2008	2009	2010
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	$270	$55,570	$293
Payments on capital leases	-	-	(43)
Proceeds from exercise of stock Warrants and options	-	6,254	-
Net cash provided by financing activities	270	61,824	250
Net (decrease) increase in cash and cash equivalents	(5,352)	51,953	(55,152)
Cash and cash equivalents at beginning of year	1,471	6,119	58,072
Cash and cash equivalents at end of year	$6,119	$58,072	$2,920
Supplemental disclosures of cash flow information:			
Issuance of common stock for accounts payable and accrued expenses	$1,958	$1,382	$329
Equipment acquired by capital leases	$-	$-	$200
Unrealized losses on investments	$7	$-	$(974)
Redeemable warrants valuation adjustment	$-	$(6,258)	$(879)

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 minimal 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 continues to review 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. On December 2, 2010, the FDA granted the Company a one year extension to file a response to the CRL. While the Company remains committed to undertaking the Ampligen® Phase III clinical study, it is diligently working to address the diagnostic challenges related to CFS.

(2) Summary of Significant Accounting Policies

(a) Cash, Cash Equivalents and Marketable Securities

Cash, Cash Equivalents and Marketable Securities consist of cash, money market and marketable securities with fair values of $58,072,000 and $44,387,000 at December 31, 2009 and 2010, respectively.

(b) Property and Equipment

	(in thousands) December 31,	
	2009	2010
Land, buildings and improvements	$ 4,139	$ 4,193
Furniture, fixtures, and equipment	2,629	3,154
Leasehold improvements	85	85
Total property and equipment	6,853	7,432
Less accumulated depreciation and amortization	2,149	2,556
Property and equipment, net	$ 4,704	$ 4,876

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, 2010, construction in progress was $485,000 as compared to $135,000 at December 31, 2009.

(c) 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.

(d) 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 when the finished goods inventory expired. 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 in 2011. Along with these manufacturing enhancements, provided the Company can either promptly renew their prior agreement with a third-party vendor or find another vendor that can provide the needed cGMP formulation, packaging and labeling services, Alferon N Injection® could potentially be available for commercial sales in mid to late 2011.

(e) 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.

(f) 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.

(g) 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.

(h) 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 Principles ("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 in 2009 and 2010-01 through 2010-29 in 2010.

The adoption of SFAS 168 and published FASB Accounting Standards Update 2009-01 through 2009-17 and 2010-01 through 2010-29 have no material effect on the Company's financial statements for the year-ended December 31, 2009 and 2010, respectively.

(i) 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 9,000,000 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-Merton 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,		
	2008	2009	2010
Risk-free interest rate	2.52 – 3.74 %	1.76 - 2.69 %	1.02 - 2.06 %
Expected dividend yield	-	-	-
Expected lives	2.5 - 5 yrs.	2 - 5 yrs.	5 yrs.
Expected volatility	73.84 – 79.2%	86.78-137.47 %	106.28%-110.01 %
Weighted average fair value of options and warrants issued in the years 2008, 2008 and 2010 respectively	$ 473,954	$ 536,378	$ 674,281

For stock options or warrants granted to employees and non-employees, the Company measures fair value of the equity instruments utilizing the Black-Scholes-Merton 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 options and warrants granted was equal to or greater than the fair market value of the underlying common stock on the date of the grant.

Stock option activity during the years ended December 31, 2008, 2009 and 2010 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, 2008	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	-
Options granted	993,728	.80	9.42	-
Options forfeited	-	-	-	-
Outstanding December 31, 2010	7,222,480	$2.35	6.21	-
Exercisable December 31, 2010	7,171,928	$2.35	6.23	-

The weighted-average grant-date fair value of employee options granted during the year 2010 was $441,000 for 993,728 options at $0.44 per option.

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2008	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	-
Options granted	20,000	.66	9.50	-
Options vested	(7,778)	.66	9.50	-
Options forfeited	-	-	-	-
Outstanding December 31, 2010	50,555	$1.33	7.60	-

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, 2008	1,935,482	$2.43	8.05	-
Options granted	482,000	2.02	6.72	-
Options forfeited	-	-	-	-
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	-
Options granted	625,000	.55	9.52	-
Options exercised	-	-	-	-
Options forfeited	(10,000)	2.46	-	-
Outstanding December 31, 2010	2,848,432	$2.03	5.80	-
Exercisable December 31, 2010	2,746,348	$2.00	6.05	-

The weighted-average grant-date fair value of non-employee options granted during the year 2010 was $233,000 for 625,000 options at $0.37 per option.

Unvested stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
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	-
Options granted	-	-	-	-
Options vested	(37,500)	2.81	2.5	-
Outstanding December 31, 2010	102,084	$2.63	3.54	-

The impact on the Company's results of operations of recording stock-based compensation for the year ended December 31, 2010 was to increase general and administrative expenses by approximately $741,000 and reduce earnings per share by $.01 per basic and diluted share.

As of December 31, 2010, there was $163,000 of unrecognized stock-based compensation cost related to options granted under the Equity Incentive Plans.

(j) 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, 2009 and 2010.

(k) Common Stock Per Share Calculation

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 amounted to 29,335,536, 21,241,453 and 52,796,158 shares, are excluded from the calculation of diluted net loss per share for the years ended December 31, 2008, 2009 and 2010, respectively, since their effect is antidilutive.

(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,	
	2009	2010
Raw materials and work in process	$ -	$ -
Transfer from Other Assets	-	864
Production	-	373
Spoilage	-	(450)
Finished goods, net of reserves of $250,000 and $250,000 at December 31, 2009 and 2010	-	-
	$ -	$ 787

The production of Alferon N Injection® from the Work-In-Progress Inventory, which has an approximate expiration date of 2012, had 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 conversion of existing Alferon N Injection® Work-In-Progress inventory was started up again in May 2010 towards the manufacture of new Finished Goods.

Other assets consist of the following:

	(in thousands) December 31,	
	2009	2010
Inventory work in process	$864	$-
Office Security Deposit	15	15
Deposits on Capital Leases	-	9
Other Deposit	-	7
Internet Domain Names	7	7
	$886	$