HEMISPHERX BIOPHARMA INC
Form 10-K
March 14, 2012

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, 2011

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 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 x No ¨

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

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): ¨ 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, 2011, the last business day of the registrant's most recently completed second fiscal quarter was $51,514,392.

The number of shares of the registrant's Common Stock outstanding as of March 1, 2012 was 135,831,977.

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

Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Hemispherx Biopharma, Inc. and its subsidiaries (collectively, "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 produces Alferon® and Ampligen®. In December 2011, our Board of Directors (the "Board") reevaluated its facility enhancement project to focus on converting the facility to provide for a high volume, more cost effective manufacturing process for Alferon N Injection®, Alferon® LDO and Ampligen®. In this regard, the Board increased the funding allocated to this project from $4.4 million to $6.5 million. The project is in an active construction phase with approximately $1,695,000 spent to date and financed through a Margin Account with an effective interest rate of 2.75%. As of December 31, 2011, construction in progress on this project was $1,484,000 as compared to $485,000 at December 31, 2010. While facility enhancements are being undertaken, this project has not impacted our capability to manufacture Ampligen®. The production of new Alferon® inventory product will not commence until the capital improvement phase is completed, which is projected for mid-2012. While the facility had been granted approval of its Biological License Application ("BLA") by the FDA for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements. Provided we receive a Release Approval from the FDA as to quality and consistency of our existing inventory and final product, we believe that our current lots of Active Pharmaceutical Ingredient ("API") will be sufficient to meet the short-term patient demand for Alferon N Injection® until production of an FDA approved product can recommence. 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.

Our principal executive office is 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 Exchange Act 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 under the Investor Relations tab or by contacting the Investor Relations Department by calling (518) 398-6222 or sending an e-mail message to ir@hemispherx.net.

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 (USANC) and has the chemical designation poly(I) poly(C_{12},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.

In July 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 intend to take the appropriate steps to seek approval and commercialization of Ampligen®. Most notably, the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen® and recommended at least one additional clinical study which shows convincing effect and confirms safety in the target population. The FDA indicated that the additional study should be of sufficient size and sufficient duration (six months) and include appropriate monitoring to rule out the generation of autoimmune

disease. In addition, patients in the study should be on more than one dose regimen, including at least 300 patients on dose regimens intended for marketing. We are examining those two major studies for further insight into efficacy and safety. 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 believed to 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 CRL. 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, Jubilant HollisterStier LLC of Spokane, Washington ("Hollister-Stier"). We believe that these issues have been resolved.

It would take approximately 18 months to three years to complete new well-controlled Ampligen® clinical studies 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 suitable 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.

In 2009, we had estimated 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.

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In December 2010, the FDA granted us a one year extension to file a response to the CRL based on the submission of new data concerning the potential viral etiology of CFS. In January 2012, the FDA granted an additional extension to file a response to the CRL. Unless communicated otherwise by the FDA, our extension will remain open while we continue to amend the NDA. We are currently conducting an open-label treatment protocol in the U.S. and evaluating new diagnostic modalities to provide additional insights into the CFS disorder. It is our plan that the new analyses and other insights will supplement the original study findings. We believe that continued efforts to understand existing data and to advance the development of new data and information, will ultimately support a re-filing of the NDA. Thus, the Company is pursuing the filing of an amended NDA in response to FDA comments in the CRL.

In our original request to the FDA for an extension of time to respond to the CRL, we submitted a protocol to prospectively analyze samples from our Phase III study, AMP-516, for markers of the retrovirus commonly called XMRV (xenotropic murine leukemia related virus). During the course of this past year, the results of a number of studies by experts in this area have been unable to duplicate the original findings published in *Sciencexpress* on XMRV. Our current understanding of the science is that there may be the detection of some type of gamma retrovirus, however, some of the labs found a contamination that may have marred their contribution, therefore it is a route we are no longer pursuing. As with many in the CFS community, it was a disappointing turn of events, however, it does not change the positive effects of Ampligen® in many CFS patients.

We have dedicated our efforts to pursuing a CFS testing program in association with Chronix Biomedical (“Chronix”). On March 2, 2011, we jointly filed a provisional United States patent application on a potential blood test for CFS with Chronix reported at the IACFS/ME Biennial Conference held on September 22-25, 2011, in Ottawa, Ontario, Canada. This experimental approach utilized in the Chronix test analyzes fragments of DNA 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 as a function of disease process. Hemispherx and Chronix continue to collaborate in the utilization of this process towards the development of a diagnostic tool for CFS and to extend the technology to more powerful Massively Parallel Sequencing Platforms in order to increase the statistical power per sample analyzed and to explore whether the technology can be used to identify how different persons with CFS will respond to Ampligen® as compared to placebo. While we believe that finding an accurate diagnostic for CFS is useful, it is not essential for an FDA approval of any CFS treatment including Ampligen®.

In May 1997, the FDA approved an open-label treatment protocol, (“AMP 511”), allowing patient access to Ampligen® for treatment in an open-label safety study under which severely debilitated CFS patients have the opportunity to be on Ampligen® to treat this very serious and chronic condition. The data collected from the AMP 511 protocol through a consortium group with active clinical sites in New York City, NY, Charlotte, NC, Miami, FL, Incline Village, Nevada, and Salt Lake City, UT, provides safety data on the use of Ampligen® in patients to identify adverse events that occur in a patient to determine if it is related to the drug being tested or other health problems identified in trial participants. We are currently enlisting new sites and continue to enroll patients for this study. As of December 31, 2011, we had thirty patients participating in this open label treatment protocol with twenty-six taking treatment and four on drug holiday. We are establishing an enlarged data base on clinical safety profiles, including the absence of data of any evidence of autoimmune disease.

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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. Certain types of human papilloma viruses ("HPV") cause genital warts, a sexually transmitted disease ("STD"). The 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. According to a World Health Organization report on HPV, "Genital warts are very common and are highly infectious, and between 90% and 100% are caused by HPV genotypes 6 and 11. Although they do not usually result in death, genital warts cause significant morbidity and entail substantial health care costs. Recurrence is common."

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 world-wide 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®.

In January 2012, the Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica (“ANMAT”), the agency responsible for the national regulation of drugs, foods and medical technology in Argentina approved the sale and distribution of Alferon N Injection® (under the brand name “Naturaferon”) in Argentina. In June 2010, Hemispherx agreed to provide GP Pharm an option to market Alferon N Injection®, its FDA-approved natural interferon, in Argentina and other Latin America countries. The receipt of the ANMAT approval is the first step of a regulatory process towards the commercial sales of Naturaferon.

Commercial sales of Alferon N Injection® were halted in March 2008 when our finished goods inventory expired. The production of Alferon N Injection® from the Work-In-Process Inventory was restarted in May 2010, continued into January 2011 with its conversion into Active Pharmaceutical Ingredient ("API") and is completed for the related Final Lot Release Test. To formulate, fill, finish and package ("fill and finish") Alferon N Injection® Drug Product, we require a FDA approved third party Contract Manufacturing Organization ("CMO"). The Work-In-Process Inventory has expiration dates of September 30, 2012 through March 10, 2013. Upon the expected mid-2012 completion of the fill and finish process, it is projected that the Alferon N Injection® will then have an expected shelf life of 42 months. In January 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea Technologies, Inc. ("Althea") regarding the fill and finish process for Alferon N Injection®. Provided we receive a Release Approval from the FDA as to quality and consistency of our current inventory and final product as well as Althea is successful in the fill and finish process, we estimate that commercial sales of Alferon N Injection® could commence in the later part of 2012. [Please see "MANUFACTURING" below for more information].

In September 2011, we entered into an agreement with Armada Health Care, LLC ("Armada") for the sales, marketing and education of Alferon N Injection®. Under this agreement, we will manufacture and supply Alferon N Injection® to Bio Ridge Pharma, LLC ("Bio Ridge"), an Armada authorized distributor that distributes specialty pharmaceuticals and which will warehouse and ship Alferon N Injection® on an exclusive basis for U.S. sales. Additionally, Armada will provide start up and ongoing sales and marketing support.

The production of new Alferon® inventory product will not commence until the capital improvement phase is completed, at our New Brunsick, NJ facility which is projected for mid-2012. While the facility had been granted approval of its BLA by the FDA for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements. Provided we receive a Release Approval from the FDA as to quality and consistency of our existing inventory and final product, we believe that our current lots of API will be sufficient to meet the short-term patient demand for Alferon N Injection® until production of an FDA approved product can recommence.

Alferon® LDO (Low Dose Oral)

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.

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In October 2009, we originally 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. In December 2010, the FDA authorized this Phase II. Our Phase II study has been delayed as we are undertaking a confirmatory study using gene expression measures to identify the systemic gene activation effects in peripheral blood leukocytes following treatment with Alferon® LDO. The outcome of this confirmatory study will allow us to evaluate better the potential effectiveness of this product and to proceed with this study of seasonal and pandemic influenza.

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®.

(dollars in thousands)
Year Ended December 31, 2011

Costs and Expenses	Ampligen® NDA	Alferon N Injection®	Alferon® LDO	Other	Total
Production/cost of goods sold	$0	$ 1,043	$ 0	$0	$1,043
Research and development	2,310	0	4,080	332	6,722
General and administrative	1,990	899	3,516	286	6,691
Total	$4,300	$ 1,942	$ 7,596	$618	$14,456

(dollars in thousands)
Year Ended December 31, 2010

Costs and Expenses	Ampligen® NDA	Alferon N Injection®	Alferon® LDO	Other	Total
Production/cost of goods sold	$0	$ 1,341	$ 0	$0	$1,341
Research and development	2,787	0	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

(dollars in thousands)

Costs and Expenses	Year Ended December 31, 2009				
	Ampligen® NDA	Alferon N Injection®	Alferon® LDO	Other	Total
Production/cost of goods sold	$0	$ 584	$ 0	$0	$584
Research and development	5,026	0	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

PATENTS AND NON-PATENT EXCLUSIVITY RIGHTS

On March 1, 2012, we had 16 patents worldwide with 85 additional pending patent applications comprising our intellectual property. Please see “Note 7: Patents, Trademark Rights and Other Intangibles (FASB ASC 350 General Intangibles Other than Goodwill)” 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. 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). In December 2011, the Company was granted two new United States Patents for the use of Alferon® LDO for the treatment in a number of different human diseases. We believe that oral administration of Alferon® LDO, with its anticipated affordability, low toxicity, expected non-production of antibodies, and broad range of potential bioactivity, could be a breakthrough treatment for prevention for viral diseases including influenza. New therapeutic use patent applications are pending.

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. New therapeutic use patent applications are pending including new patent applications for composition of alternative matter.

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.)

In July 2011, a new United States Patent was granted for the use of Ampligen® as a vaccine adjuvant for use with seasonal influenza vaccine to induce an enhanced immune response against H5N1 avian influenza. The patent describes a method using intranasal administration of Ampligen® along with a seasonal influenza vaccine to enhance an immune response against a H5N1 avian influenza infection compared to the administration of seasonal influenza vaccine alone.

RESEARCH AND DEVELOPMENT ("R&D")

Our general focus during the past three fiscal years has been 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 targeting treatment therapies for ME/CFS, various cancers (as adjunctive therapy) and other viral diseases such as prevention and treatment of seasonal and pandemic H1N1 or influenza.

The following table summarizes our research and development costs for the years 2011, 2010 and 2009 by project:

	2011	2010	2009
Ampligen® New Drug Application for the treatment of Chronic Fatigue Syndrome	$2,310	$2,787	$5,026
Alferon® LDO for influenza	4,080	4,658	1,784
Alferon N Injection® for influenza	0	168	0
Other projects	332	0	185
Total research and development	$6,722	$7,613	$6,995

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”, 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 significant revenues from the sale of these developmental products. As of December 31, 2011, we had approximately $34.4 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 three 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 may 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 states on its website at http://www.cdc.gov/cfs/index.html that “Chronic fatigue syndrome, or CFS, is a devastating and complex disorder characterized by overwhelming fatigue that is not improved by bed rest and that may be worsened by physical or mental activity. People with CFS most often function at a significantly lower level of activity than they were capable of before the onset of illness.”

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.

For their Case Definition, the CDC states that the cause or causes of CFS have not been identified and no specific diagnostic tests are available. Therefore, in order to be diagnosed with chronic fatigue syndrome, a patient must satisfy two criteria:

1. Have severe chronic fatigue for at least six months or longer that is not relieved by rest and not due to medical or psychiatric conditions associated with fatigue as excluded by clinical diagnosis; and

2. Concurrently have four or more of the following symptoms:

- self-reported impairment in short-term memory or concentration severe enough to cause substantial reduction in previous levels of occupational, educational, social, or personal activities;
- sore throat that is frequent or recurring;
- tender cervical or axillary lymph nodes;
- muscle pain;
- multi-joint pain without swelling or redness;
- headaches of a new type, pattern, or severity;
- unrefreshing sleep; and
- post-exertional malaise (extreme, prolonged exhaustion and sickness following physical or mental activity) lasting more than 24 hours.

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.

Dr. Julie Gerberding, former director of the CDC and current president at Merck Vaccines, had 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.

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.

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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/or Clinical Network Services, to permit us to retrieve the data by making certain payments to each organization or a third party escrow account with funds equal to the disputed amount placed in escrow. Upon agreement of the payment terms, we would then be granted access to review some or all of the data. Following our satisfaction that the clinical study was conducted utilizing cGCP along with samples properly maintained utilizing cGLP, the escrow funds could 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 continue to be reviewed by the respective parties.

Ampligen® as a mucosal adjuvant with vaccine had 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 had conducted studies in animals that suggested that Ampligen® could 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®.

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 MEA, 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.

In April 2011, we received correspondence from Biken confirming that the MEA had expired without completion of the Evaluation Program along with their intention not to extend or replace the expired MEA with another agreement. Biken noted in that correspondence that it previously had concluded that "it was possible that Ampligen® would not satisfy the requirements for safety as an adjuvant for influenza vaccines" in Japan and that, after rechecking Hemispherx' basis for disagreement with that finding, it concluded that it could not reconcile the differences between Hemispherx' and its interpretation of experimental results regarding the evaluation of Ampligen® as a candidate adjuvant in influenza vaccines. Biken's primary concern was related to a single intravenous high dose study in rats that resulted in an apparent toxicity when doses of Ampligen® were combined with a whole viron influenza vaccine and Carboxyl Vinyl Polymer ("CVP") or CVP alone. Additionally in both cases of Ampligen® being combined with other product(s), the dosage utilized was several hundred times higher than the intended dosage for humans by body weight and delivered intravenously, rather than the prescribed mucosal (nasal) method. More specifically, we communicated the following points to refute Biken's interpretation of Ampligen® safety data:

- The safety of Ampligen® has been demonstrated by the large body of safety data in humans and in relevant pre-clinical models that were generated to support Hemispherx' NDA for CFS, which was filed with the FDA;
- The single unfavorable rat toxicity study contained in the Biken report must be considered in the context of the rest of safety and efficacy data generated with Ampligen® and we believe that evidence indicates that the results were generated due to flaws in material handling and compounding;
- Hemispherx demonstrated by photographs and other evidences that the toxicity observed at Biken was due to aggregation caused by the CVP additive deployed by Biken to increase attachment of the vaccine/Ampligen® mixture to the nasal mucosa. Numerous experiments performed by the NIID indicated that in both rodents and primates that the additive was unnecessary to achieve the desired antiviral/vaccine enhancement effects of Ampligen®; and
- There are large anomalies between the efficacy data presented in the internal Biken report as compared to the results obtained by Dr. Hasegawa, and thereafter published in peer reviewed articles.

As a result of Biken's intension not to extend or replace the MEA or complete the related Evaluation Program, we have concluded that our association with Biken has come to a conclusion with no expected future association.

Dr. Hideki Hasegawa, M.D., Ph.D., Chief of Laboratory of Infectious Disease Pathology for the Department of Pathology for the NIID, undertook studies in 2009 and 2010 that focused 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. Dr. Hasegawa has expressed a desire to continue preclinical development of this concept, and as such, he continues to organize and participate in meetings with other qualified corporate vaccine partners in Japan who have intranasal vaccines under development along with necessary facilities to test, develop and commercialize the vaccine enhancement utilizing Ampligen® in an attempt to achieve cross-protection against pandemic strains in a commercial environment.

In July 2011, we received FDA authorization to proceed with the initiation of a new clinical trial of intranasal Ampligen® to be used in conjunction with commercially approved seasonal influenza vaccine. This study is similar to the initial studies of influenza application conducted at Japan's NIID noted above. The primary objective of this study is to evaluate the safety of three cycles of intranasal Ampligen® administered three days following each intranasal dose of seasonal influenza vaccine. Secondary objectives of this study include evaluation of various immune responses to the trivalent seasonal influenza vaccine administered intranasally with and without Ampligen®. We have selected a clinical site that has the resources to support the implementation of this study and are proceeding with obtaining the documentation necessary to be able to initiate the clinical trial.

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 continue to enroll subjects with expectation of greater patient participation in the upcoming flu season. As of December 31, 2011, we have eight operational Clinical Investigative Sites, with the intention of adding additional sites. Twenty-five patients have completed the study. Our study has progressed at a rate slower than originally projected due to difficulties encountered in the process of screening for subjects with influenza, rather than other illnesses with symptoms similar to influenza, along with India currently experiencing an unusually mild flu season. In an attempt to expedite the process to qualify study subjects, we added a second "point of care" screening test which has been implemented at the sites as we attempt to qualify subjects for the upcoming flu season. It is our objective to qualify and enroll sixty patients for the study.

In June 2011, we entered into a Material Transfer and Research Agreement with the University of Pennsylvania's School of Medicine to provide Ampligen® for testing as a vaccine adjuvant in a human clinical study in ovarian cancer. This study is a Phase I/II randomized clinical trial for subjects with recurring ovarian, fallopian tube or primary peritoneal cancer to determine the feasibility and safety as well as immunogenicity of a vaccine comprised of autologous oxidized tumor cell lysate ("OC-L") administered by intradermal/subcutaneous injection in combination with intravenous Ampligen®. The OC-L vaccine is an experimental cancer immunotherapy under development by the University of Pennsylvania. This study represents the first use of Ampligen® as a cancer vaccine adjuvant in a randomized clinical study with and without Ampligen®. As of December 31, 2011, three patients have participated in this study.

In August 2011, a study utilizing Ampligen® was initiated by investigators from the Tumor Vaccine Group ("TVG") at the University of Washington in Seattle, WA. As of December 31, 2011, twenty-four patients have enrolled in this eighty-eight patient Phase I-II Study of HER2 Vaccination with Ampligen® as an adjuvant in optimally treated Breast Cancer patients. The goal of this study is to see how well the combination works in treating patients with Stage II-IV human epidermal growth factor receptor 2 ("HER2")-positive breast cancer. Vaccines made from synthetic HER2/neu peptides may help the body build an effective immune response to kill tumor cells that express HER-2/neu. The TVG has developed vaccines against several cancer proteins, and in this study, they are researching a new approach in an attempt to make the immune response to the vaccine even better. Compounds that specifically stimulate TLR receptors are promising immune stimulators, and Ampligen® has the potential to provide a profile of immune stimulation that could be clinically beneficial. As a result of medical staff limitations at the site, this study is not currently enrolling additional patients.

MANUFACTURING

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ that produces Alferon® and Ampligen®. In December 2011, our Board of Directors (the "Board") reevaluated its facility enhancement project to focus on converting the facility to provide for a high volume, more cost effective manufacturing process for Alferon N Injection®, Alferon® LDO and Ampligen®. In this regard, the Board increased the funding allocated to this project from $4.4 million to $6.5 million. The project is in an active construction phase with approximately $1,695,000 spent to date and financed through a Margin Account with an effective interest rate of 2.75%. As of December 31, 2011, construction in progress on this project was $1,484,000 as compared to $485,000 at December 31, 2010. As expected in any construction project, we had experienced some delay due to permit issues, demolition concerns and design revisions. Accordingly, we had used this time to pursue cost savings where possible, including locating and acquiring equipment from major U.S. pharmaceutical manufacturers that have recently curtailed or eliminated certain manufacturing activities or plants. As a result, we have estimated a cost savings of approximately $827,000 to date for the project as compared to acquiring the equipment directly from the original manufacturer. While facility enhancements are being undertaken, this project has not impacted our capability to manufacture Ampligen®.

The production of new Alferon® inventory product will not commence until the capital improvement phase is completed, which is projected for mid-2012. While the facility had been granted approval of its BLA by the FDA for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements. Provided we receive a Release Approval from the FDA as to quality and consistency of our existing inventory and final product, we believe that our current lots of Active Pharmaceutical Ingredient ("API") will be sufficient to meet the short-term patient demand for Alferon N Injection® until production of an FDA approved product can recommence.

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.

In September 2011 and similar to our prior agreements, we executed an amendment to the Supply Agreement that will extend through March 11, 2014 with Jubilant Hollister-Stier Laboratories LLC of Spokane, Washington ("Hollister-Stier"). Pursuant to this agreement, Hollister-Stier will formulate, fill, finish and package ("fill and finish") Ampligen® from the key raw materials that we would supply. Hollister-Stier would have the right of first refusal to manufacture certain Ampligen® related products.

Commercial sales of Alferon N Injection® were halted in March 2008 when our finished goods inventory expired. The production of Alferon N Injection® from the Work-In-Process Inventory was restarted in May 2010, continued into January 2011 with its conversion into API and is completed for the related Final Lot Release Test. We have manufactured purified drug concentrate utilized in the formulation of Alferon N Injection® in our New Brunswick, New Jersey facility. To formulate, fill, finish and package ("fill and finish") Alferon N Injection® API that we have already produced, we require an FDA approved third-party CMO. In June 2011, our designated CMO reported to us

that they had received an FDA 483 form that identified production issues that needed to be addressed prior to resumption of production. As a result, we evaluated alternative CMOs to undertake the fill and finish process. On January 26, 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea regarding the fill and finish process for Alferon N Injection®. Althea shall commence production of Alferon N Injection® and Hemispherx shall provide a twelve-month forecast of the quantities of the product in each month beginning with the date scheduled for commencement of Production. Althea shall ship all Alferon N Injection® finished product to Hemispherx or designated consignee (i.e., Bio Ridge Pharma, LLC). As of March 1, 2012, we are diligently working with Althea in the Technology Transfer phase of the process that includes evaluation of manufacturing and technology transfer feasibility, equipment and/or equipment modification requirements, engineering runs, process definition along with development and approval of the Master Batch Record. Provided we receive a Release Approval from the FDA as to quality and consistency of our current inventory and final product, as well as Althea is successful in the fill and finish process, we estimate that commercial sales of Alferon N Injection® could commence in the later part of 2012.

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 audience development, medical support and payor reimbursement initiatives which will facilitate product acceptance and utilization at the time of regulatory approval. Similarly, we continue to develop distribution scenarios for the Specialty Pharmacy/Infusion channel which will insure market access, offer 3PL (third party logistics) capabilities and provide the requisite risk management control mechanisms. It is our intent to utilize third party service providers to execute elements of both the marketing/sales and distribution plans. We currently plan to utilize a small group of Managed Market account managers to introduce the product to payor, employer and government account audiences. We believe that this approach will establish a market presence and facilitate the generation of revenue without incurring the substantial costs associated with a traditional sales force. Furthermore, Management believes that the approach will enable us to retain many options for future marketing strategies.

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

In December 2011, we entered into a Second Amended Adviser's Agreement for twenty-four months with The Sage Group, Inc. ("Sage"), effective June 15, 2011, that amends and supersedes all other agreements and arrangements between the parties. Pursuant to this agreement, Sage is to assist us to identify, qualify, negotiate and close one or more licensing, partnering, alliance or similar transactions pertaining to our products and technology including, but not limited to, any and all uses of Ampligen®, Alferon® and related intellectual property as well as acquisition of companies in whole or in part and the sale or the merger of our Company ("Transactions"). In consideration for services performed or attributed to Sage resulting in Transactions, Sage is entitled to a monthly "Adviser's Fee" of $20,000, a one-time distribution of 200,000 Options that vest proportionately over 18 months with an exercise price of 110% of the closing price of the Company Stock on the NYSE Amex on the closing price of the day preceding the execution date of the agreement plus preapproved expenses along with the potential for a "Success Fee" of five percent (5%) of all consideration that is capped at $5,000,000 per annum for Transactions introduced to us by Sage. A Transaction can occur during the term of the agreement or 18 months thereafter. This Agreement may be terminated by us for cause after we deliver written notice to Sage of a failure to perform and such failure is not cured within 15 days.

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. Under these agreements, we will manufacture and supply Ampligen® and Alferon N Injection® 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. We have 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. In December 2010, GP Pharm exercised this right and in July 2011 GP Pharm submitted an application for approval to ANMAT, the agency responsible for the national regulation of drugs, foods and medical technology in Argentina. As a result of the efforts of GP Pharm, in January 2012, ANMAT approved the sale and distribution of Alferon N Injection® (under the brand name "Naturaferon") in Argentina. The receipt of the ANMAT approval is the first step of a regulatory process towards the commercial sales of Naturaferon.

On September 6, 2011 we executed an amended agreement with Armada Healthcare, LLC ("Armada"), effective August 15, 2011 through August 14, 2012, to undertake the marketing, education and sales of Alferon N Injection® throughout the United States. Armada will also provide us with start-up and ongoing sales and marketing support.

Also on September 6, 2011, we executed a new agreement with licensed specialty distributor, BioRidge Pharma, LLC ("BioRidge") to warehouse, ship and distribute Alferon N Injection® on an exclusive basis in support of U.S. sales. The term of this Agreement shall begin on the Effective Date and shall expire one (1) year thereafter unless earlier terminated in accordance with this Agreement.

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), European Medicines Agency (“EMA”) and Health Protection Branch ("HPB") (in Canada), and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, EMEA and HPB product approvals more rapidly than us. If any of our products receive regulatory approvals and we commence commercial sales of our products, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have no experience. Our competitors may possess or obtain patent protection or other intellectual property rights that prevent, limit or otherwise adversely affect our ability to develop or exploit our products.

The major pharmaceutical competitors with biotech capabilities/vaccine franchises include Pfizer, GlaxoSmithKline, Merck, Novartis and AstraZeneca. Biotech competitors include Baxter International, Fletcher/CSI, AVANT Immunotherapeutics, AVI BioPharma and Genta. When we recommence sales of Alferon N Injection®, it will compete with Intron® A, an injectable from Merck that attempts to kill virus and prevent reproduction along with topical treatments that are normally applied by a doctor that have a risk of damaging the skin around the wart, such as:

- Aldara®, also known as Imiquimod®, is a cream which is marketed to boost the immune systems in an attempt to rid itself of genital warts;
- Veregen®, which utilizes Sinecatechins that is a natural substance found in certain green tea leaves, is a self-administered ointment used to treat the symptoms or infection of the warts;
- Condylox® (podoflox) and Podofin® (podophyllin resin) attempt to destroy the genital warts by halting cell growth; and
- Trichloroacetic acid (TCA) or Bichloroacetic acid (BCA) are chemical treatments which attempt to burn off genital warts.

GOVERNMENT REGULATION

Regulation by governmental authorities in the U.S. and foreign countries is and will be a significant factor in the manufacture and marketing of Alferon® 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. Prior to our construction phase, our laboratory and production facility in New Brunswick, New Jersey was approved for the manufacture of Alferon N Injection®. While our facility had been granted approval of its BLA by the FDA for the manufacture of Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements. Upon completion of our enhanced manufacturing process, we believe it will again be able to obtain FDA approval. 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 obtain and/or continue to maintain FDA approval.

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HUMAN RESOURCES

As of March 1, 2012, we had 59 personnel consisting of 47 full-time employees or consultants and 12 regulatory/research medical personnel on a part-time basis. Part-time personnel are paid on a per diem or monthly basis. 41 personnel are engaged in our research, development, clinical, and manufacturing effort. 18 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 MONITORING COMMITTEE

With the unfortunate June 2011 passing of Dr. James Rahal, formally Director of the Infectious Disease Section of New York Hospital Queens and one of the nation's foremost experts on the West Nile Virus, our Scientific Advisory Board is presently being reorganized. 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 the last three years, primarily due to fewer active scientific projects. Individual Scientific Advisory Board Members may informally consult with and/or meet with our employees or Board Members. Members of the Scientific Advisory Board could be 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 Monitoring Committee (“DMC”) that consists of two independent regulatory and medical experts along with a Biostatistics expert. The function of the DMC is to perform independent safety and efficacy analyses on our clinical trials.

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 European Medicines Agency ("EMA") 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 NDA for Ampligen® to treat CFS, originally submitted in October 2007. On November 25, 2009, we received a Complete Response Letter ("CRL") from the FDA which described specific additional recommendations related to the Ampligen® NDA. In accordance with its 2008 Complete Response procedure, the FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues. In December 2010, the FDA granted us a one year extension to file a response to the CRL based on the submission of new data. In January 2012, the FDA granted an additional extension to file a response to the CRL. Unless communicated otherwise by the FDA, this extension will remain open while Hemispherx continues to amend the NDA. We are currently conducting an open-label treatment protocol in the U.S. and evaluating new diagnostic modalities to provide additional insights into the CFS disorder. It is our plan that the new analyses and other insights will supplement the original study findings. We believe that continued efforts to understand existing data and to advance the development of new data and information, will ultimately support a re-filing of the NDA. Thus, the Company is pursuing the filing of an amended NDA in response to FDA comments in the CRL.

The production of Alferon N Injection® from the Work-In-Process Inventory continued into January 2011 with its conversion into API and is completed for the related Final Lot Release Test. To formulate, fill and finish Alferon N Injection® Drug Product, we require a FDA approved third party Contract Manufacturing Organization ("CMO").

On January 26, 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea regarding the fill and finish process for Alferon N Injection®. We are diligently working with Althea in the Technology Transfer phase of the process that includes evaluation of manufacturing and technology transfer feasibility, equipment and/or equipment modification requirements, engineering runs, process definition along with development and approval of the Master Batch Record. When the Technology Transfer process is complete, it will be necessary to conduct production tests with the resulting data to be submitted to the FDA. Only upon the finished product lots obtaining approval from the FDA will we be able to commercially sell Alferon N Injection®. Provided we receive a Release Approval from the FDA as to quality and consistency of our current inventory and final product, as well as Althea is successful in the fill and finish process, we estimate that commercial sales of Alferon N Injection® could commence in the later part of 2012. Please see Part 1, ITEM 1. "Business; MANUFACTURING above for more detailed information. We are unable to provide any assurances that the FDA will approve the final inventory lots produced by the CMO. If this finish goods inventory is not granted approval by the FDA for clinical sales, our operations most likely will be materially adversely affected.

Alferon® LDO is undergoing pre-clinical testing for possible use as 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 influenza requires prior regulatory approval. In October 2009, we originally 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. In December 2010, the FDA authorized this 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. Our Phase II study has been delayed as we are undertaking a confirmatory study using gene expression measures to identify the systemic gene activation effects in peripheral blood leukocytes following treatment with Alferon® LDO. The outcome of this confirmatory study will allow us to evaluate better the potential effectiveness of this product and to proceed with this study of seasonal and pandemic influenza. We are unable to provide any assurances that Phase II Alferon® LDO study for the prophylaxis and treatment of seasonal and pandemic influenza will be undertaken. Please see Part 1, ITEM 1. "Business; MANUFACTURING above for more detailed information.

If we are unable to generate the additional data, successfully complete inspections or obtain approvals as required by the FDA, determine that any of our clinical studies are not cost/justified to undertake or if, for that or any other reason, Ampligen®, Alferon® or one of our other products or production processes do not receive necessary regulatory approval in the U.S. or elsewhere, our operations may 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, with a major emphasis on new drug diagnostic and development, we have incurred substantial operating losses, as we pursued our clinical trial effort to get our experimental drug, Ampligen®, approved. As of December 31, 2011, our accumulated deficit was approximately $(226,740,000). 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 limited number of shares of common stock available for financing without prior stockholder approval may hinder our ability to raise additional funding.

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, 2011, we had approximately $34,391,000 in Cash, Cash Equivalents and Marketable Securities (inclusive of $3,101,000 in Marketable Securities collateralizing certain debts). Given the challenging 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 31,800,000 shares authorized but unissued and unreserved. While we recently increased the number of authorized shares of Common Stock from 200,000,000 to 350,000,000, the additional 150,000,000 shares cannot be issued for fundraising purposes without prior stockholder approval.

There can be no assurances that we can obtain the requisite stockholder approval to use any of the newly authorized shares of Common Stock for funding purposes or raise adequate funds from other sources. If we are unable to obtain

additional funding, if necessary, our ability to develop our products or continue our operations may be materially adversely affected.

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. The production of Alferon N Injection® from the Work-In-Process Inventory was restarted in May 2010, continued into January 2011 with its conversion into API and is completed for the related Final Lot Release Test. To fill and finish Alferon N Injection® Drug Product, we require a FDA approved third party CMO. In January 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea regarding the fill and finish process for Alferon N Injection®. Our Work-In-Process Inventory has expiration dates of September 30, 2012 through March 10, 2013. Upon the expected mid-2012 completion of the fill and finish process, it is projected that Alferon N Injection® will have an expected shelf life of 42 months. Provided we receive a Release Approval from the FDA as to quality and consistency of our current inventory and final product, as well as Althea is successful in the fill and finish process, we estimate that commercial sales of Alferon N Injection® could commence in the later part of 2012. We are unable to provide any assurances that the Work-In-Process Inventory will be converted into Finished Goods prior to the product's expiration nor that the FDA will approve the final inventory lots manufactured by us or produced by Althea. If this Finished Goods inventory does not complete the fill and finish steps prior to their expiration or the inventory is not granted approval by the FDA for clinical sales, our operations most likely will be materially adversely affected. (see "MANUFACTURING" in ITEM 1. Business).

We continue to undertake at our New Brunswick, NJ facility a major capital improvement program to enhance our manufacturing capability to produce bulk quantities of Alferon N Injection® API. The production of new Alferon® inventory product will not commence until the capital improvement phase is completed, which is projected for mid-2012. While the facility had been granted approval of its BLA by the FDA for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements. Provided we receive a Release Approval from the FDA as to quality and consistency of our existing inventory and final product, we believe that our current lots of API will be sufficient to meet the short-term patient demand for Alferon N Injection® until production of an FDA approved product can recommence. 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. Certain of the plant and equipment improvements being implemented for production of Alferon N Injection® may require FDA review prior to commercial sale of the resulting new product, and each production lot of Alferon N Injection® using this new process 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, in the laboratories of Dr. Hasegawa at the National Institute of Infectious Diseases in Japan, where the preclinical data has shown activity in preventing lethal challenge with the original N5N1 viral strain used for vaccination as well as the other related, but not identical, isolates of H5N1 virus (i.e., cross-reactivity). We had an agreement regarding Ampligen® with Biken pursuant to which 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. Biken concluded that it was possible that Ampligen® would not satisfy the requirements for safety as an adjuvant for influenza vaccines in Japan. Biken's primary concern was related to a single intravenous high dose study in rats that resulted in an apparent toxicity when doses of Ampligen® were combined with a whole viron influenza vaccine and Carboxyl Vinyl Polymer ("CVP") or CVP alone. Additionally in both cases of Ampligen® being combined with other product(s), the dosage utilized was several hundred times higher than the intended dosage for humans by body weight and delivered intravenously, rather than the prescribed mucosal (nasal) method. While we have disputed Biken's findings, the relationship has effectively ended with no further resolution to the dispute expected. See Part 1, ITEM 1. "Business; RESEARCH AND DEVELOPMENT ("R&D"); Other Viral Diseases" above.

No assurance can be given that positive results will be observed in clinical trials. Use of Ampligen® or Alferon® 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). If we are unable to obtain the necessary regulatory approval in the U.S. or elsewhere, generate the data of successfully completed clinical studies, or determine that a clinical study is not cost/justified to undertake, or if for that or any other reason, our operations most likely will be materially and/or adversely impacted.

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 AmpligenÒ 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 Interferon Sciences, Inc. ("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, process 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, process and technology 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 or process 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.

Our commercialization strategy for Alferon N Injection® may include the utilization of internal functions and/or licensing/co-marketing agreements that would utilize the resources and capacities of one or more strategic partners. Accordingly, we have engaged Armada Healthcare to undertake the marketing, education and sales of Alferon N Injection® throughout the United States along with GP Pharm for Argentina, Mexico and other Latin America countries.

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 can be no assurances that the approved Alferon N Injection® product will be returned to prior sales levels.

There are no long-term agreements with suppliers of required materials and services for Ampligen® and there are a limited number of raw material suppliers. If we are unable to obtain the required raw materials and/or services, we may not be able to manufacture Ampligen®.

A number of essential raw materials are used in the production of Ampligen®. We do not have, but continue to work towards having long-term agreements for the supply of such materials, when possible. 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 suppliers in the United States available to provide the raw materials for use in manufacturing Ampligen®. At present, we do not have any agreements with third parties for the supply of any of these raw materials. 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 a more consistent manufacturing basis in the quantities necessary for clinical testing. In September 2011 and similar to our prior agreements, Hollister-Stier has agreed to undertake the manufacturing sets to formulate, fill, finish and package Ampligen® from the key polymers that we would supply. Hollister-Stier would have the right of first refusal to manufacture certain Ampligen® related products.

If we are unable to obtain or manufacture the required raw materials, and/or procure services needed in the final steps in the manufacturing process, we may be unable to manufacture Ampligen®. The costs and availability of products and raw materials we need for the production of Ampligen® 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.

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There is no assurance that our existing Alferon N Injection® inventory will receive Release Approval from the FDA or that our manufacturing facility will again be granted a BLA certification by the FDA upon completion of the manufacturing enhancements or return to commercial, large-scale production.

The production of Alferon N Injection® from the Work-In-Process Inventory was restarted in May 2010, continued into January 2011 with its conversion into API and is completed for the related Final Lot Release Test. To formulate, fill and finish Alferon N Injection® drug product, we require a FDA approved third-party CMO. In January 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea regarding the formulation, fill, finish and packaging process for Alferon N Injection®. The Work-In-Process Inventory has expiration dates of September 30, 2012 through March 10, 2013. Upon the expected mid-2012 completion of the fill and finish process, it is projected that the Alferon N Injection® will have an expected shelf life of 42 months. Provided we receive a Release Approval from the FDA as to quality and consistency of our current inventory and final product, as well as Althea is successful in the fill and finish process, we estimate that commercial sales of Alferon N Injection® could commence in the later part of 2012. There can be no assurance that some or all of our existing Alferon® API will be successfully converted into finished product prior to their expiration, that our inventory will obtain FDA approval from their Final Lot Release Test, nor that the final drug product will obtain FDA approval upon completion of the fill and finish stage. Without FDA approval, our existing Alferon N Injection® will not be considered suitable for commercial sales. Additionally, there can be no assurance that the final manufacturing steps will be timely or successful, that any given product will be determined to be safe and effective, or capable of being manufactured under applicable quality standards.

The production of new Alferon® inventory product will not commence until the capital improvement phase is completed, which is projected for mid-2012. Upon completion of the capital improvements, our manufacturing facility will need to be recertified by the FDA prior to the production of commercially sellable Alferon®. While our manufacturing facility had been previously granted approval of its BLA status for Alferon® by the FDA, there can be no assurance the BLA status will be recertified by the FDA upon the completion of the enhancement process or that the manufacturing facility will return to commercial, large-scale production for Alferon®. Additionally, there can be no assurance that the capital improvements will be timely or successful, that any given product will be determined to be safe and effective, or capable of being manufactured under applicable quality standards.

Provided that we receive a Release Approval from the FDA as to quality and consistency of our existing inventory and final product, we believe that our current lots of API will be sufficient to meet the short-term patient demand for Alferon N Injection® until production of an FDA approved product can recommence. There can be no assurance that the FDA will determine that our existing inventory and final product to be safe and effective, will meet the short-term patient demand for Alferon N Injection® or will be permitted to be sold as commercial product.

In light of these contingencies, there can be no assurances that the approved Alferon N Injection® product will be returned to commercial production or sale 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.

There are a limited number of organizations in the United States available to provide the final manufacturing steps of formulation, fill, finish and packing sets for Alferon N Injection® and Ampligen®.

There are a limited number of organizations in the United States available to provide the final steps in the manufacturing for Alferon N Injection® and Ampligen®. To formulate, fill, finish and package our products ("fill and finish"), we require a FDA approved third party CMO. Please see Part 1, ITEM 1. "Business; MANUFACTURING" above for more detailed information.

On January 26, 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea regarding the fill and finish process for Alferon N Injection® (see Part 1, ITEM 1. “Business; MANUFACTURING” above). However, because we must first receive a Release Approval from the FDA as to quality and consistency of our current inventory and final product and there are a number of steps that Althea is required to successfully complete with regard to the fill and finish process, we estimate that commercial sales of Alferon N Injection® will not commence until at least the later part of 2012. We are unable to provide any assurances that the FDA will approve the final inventory lots manufactured by us or produced by Althea. If this finished goods inventory is not granted approval by the FDA for clinical sales, our operations most likely will be materially adversely affected. In light of this contingency, there can be no assurances that the approved Alferon N Injection® product will be returned to commercial sales 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.

In September 2011, we executed an amendment to the Supply Agreement that will extend through March 11, 2014. Pursuant to this agreement, Hollister-Stier will formulate, fill, finish and package Ampligen® from the key raw materials that we would supply. We are unable to provide any assurances that the FDA will approve the inventory manufactured by us or produced by Hollister-Stier. If this finish goods inventory is not granted approval by the FDA, our operations may be materially adversely affected.

If we are unable to 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 may require additional management, technical personnel and capital to the extent such manufacturing is not handled by third parties. While we believe that the Company could successfully convert unutilized production capability at our New Brunswick, NJ facility in a commercial scale-up of Ampligen®, there can be no assurance that our manufacturing will be successful or that any given product will be determined to be safe and effective, or capable of being manufactured under applicable quality standards, economically, and in commercial quantities, or successfully marketed.

We have limited manufacturing experience for Ampligen®.

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, filling, finish 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. While we believe them to be adequate for our future needs, our current facilities may not be adequate for the production of our proposed products for large-scale commercialization. We intend to ramp up our existing facility and/or 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 or maintaining our BLA status. 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 the production of our proposed products for large-scale commercialization or 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 continue to maintain third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Should the NDA be approved, we may need to find an additional vendor to manufacture the product for commercial sales. 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, nor can we provide any assurance as to the receipt of FDA approval of our finished inventory product. There can be no assurances that the Ampligen® can be commercially produced at costs acceptable to us.

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 Pfizer, GlaxoSmithKline, Merck, Novartis and AstraZeneca. Biotech competitors include Baxter International, Fletcher/CSI, AVANT Immunotherapeutics, AVI BioPharma and Genta. 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 Merck's injectable recombinant alpha interferon product (INTRON® A) for the treatment of genital warts. In addition, other pharmaceutical firms offer self-administered topical cream, for the treatment of external genital and perianal warts such as Graceway Pharmaceuticals (Aldara®), Watson Pharma (Condylox®) and MediGene (Veregen®). 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.

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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 maintain Products Liability and Clinical Trial insurance coverage world-wide 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®, Alferon N Injection® 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, 2016. 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.

Risks Associated With an Investment in Our Common Stock:

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

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

- announcements of the results of clinical trials by us or our competitors;
- announcement of legal actions against us and/or settlements or verdicts adverse to us;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency comments regarding the safety or effectiveness of our products, or the adequacy of the procedures, facilities or controls employed in the manufacture of our products;

- changes in U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards;

- overall investment market fluctuation;
- restatement of prior financial results;
- notice of NYSE Amex non-compliance with requirements; 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, 2011, the closing price of our common stock has ranged from $0.18 to $0.55 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.

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, 2011. 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, we have sold a total of 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.

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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 $0.01 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 through April 2013, our headquarters located in Philadelphia, Pennsylvania consisting of a suite of offices of approximately 9,000 square feet. We also 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 and production space. It also contains space designated for research and development, packaging, quality assurance and quality control laboratories. Building Two has 11,670 square feet consisting of offices, laboratories, warehouse space, shipping, receiving and packaging areas. The property has parking space for approximately 100 vehicles.

Our subsidiary, Hemispherx Biopharma Europe N.V./S.A. subleases on an informal basis a 2,000 sq. ft., fully furnished and equipped office at 97 Rue Jean Jaures, Levallois, Perret, France.

ITEM 3. Legal Proceedings.

Please see “Note 16 – Contingencies” under Notes to Consolidated Financial Statements.

ITEM 4. Mine Safety Disclosures.

Not Applicable.

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. In 2011, we issued 145,440 shares of common stock in payment to vendors and consultants for services rendered and 255,254 shares to Ronald Ritz, Sr. Director of Manufacturing in payment of 50% of his compensation.

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

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

COMMON STOCK	High	Low
Time Period:		
January 1, 2011 through March 31, 2011	$0.55	$0.45
April 1, 2011 through June 30, 2011	$0.53	$0.37

July 1, 2011 through September 30, 2011	$0.40	$0.27
October 1, 2011 through December 31, 2011	$0.30	$0.18
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

As of March 1, 2012 there were approximately 220 holders of record of our Common Stock. This number was determined from records maintained by our transfer agent and does not include beneficial owners of our securities whose securities are held in the names of various dealers and/or clearing agencies.

On March 1, 2012, the last sale price for our common stock on the NYSE Amex was $0.31 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, 2011:

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average Exercise price of Outstanding options, warrants and rights	Number of securities Remaining available for future issuance under equity compensation plans (excluding securities reflected in column) (a)
	(a)	(b)	(c)
Equity compensation plans approved by security holders:	11,642,912	$ 2.07	9,795,492
Equity compensation plans not approved by security holders:	10,978,246	$ 1.55	0
Total	22,621,158	$ 1.82	9,795,492

PERFORMANCE GRAPH

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

Company Name / Index	Dec07	Dec08	Dec09	Dec10	Dec11
Hemispherx Biopharma, Inc.	-65.45	-52.63	55.56	-11.88	-60.47
S&P SmallCap 600 Index	-0.30	-31.07	25.57	26.31	1.02
Peer Group	-20.65	-70.17	67.87	-44.07	-60.97

INDEXED RETURNS
Base Period
Years Ending

Company Name / Index	Dec06	Dec07	Dec08	Dec09	Dec10	Dec11
Hemispherx Biopharma, Inc.	100	34.55	16.36	25.45	22.43	8.87
S&P SmallCap 600 Index	100	99.70	68.72	86.29	109.00	110.10
Peer Group	100	79.35	23.67	39.73	22.22	8.67

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, 2011 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	2007	2008	2009	2010	2011
Statement of Operations Data:	$1,059	$265	$111	$135	$161
Revenues and License fee Income					
Total Costs and Expenses[1]	20,348	13,076	13,375	16,522	14,456
Interest Expense and Financing Costs[2]	396	0	241	11	41
Redeemable warrants valuation adjustment	0	0	(6,258)	(879)	(2,425)
Net loss	(18,139)	(12,219)	(7,180)	(13,136)	(9,015)
Deemed Dividend	0	0	0	0	0
Net loss applicable to common stockholders	(18,139)	(12,219)	(7,180)	(13,136)	(9,015)
Basic and diluted net loss per share	$(0.25)	$(0.16)	$(0.07)	$(0.10)	$(0.07)
Shares used in computing basic and diluted net loss per share	71,839,782	75,142,075	109,514,401	134,018,243	135,432,395
Balance Sheet Data:					
Working Capital	$14,412	$5,646	$55,789	$33,842	$26,717
Total Assets	23,142	13,211	64,994	51,680	43,513

Debt, net of discount	0	0	0	0	1,695
Stockholders' Equity	20,955	11,544	58,695	45,947	37,965
Cash Flow Data:					
Cash used in operating activities	(15,112)	(9,358)	(9,297)	(11,886)	(10,096)
Capital expenditures	$(212)	$(73)	$(332)	$(729)	$(1,802)

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(1) General and Administrative expenses include stock compensation expense of $2,291, $573, $826, $740 and $377 for the years ended December 31, 2007, 2008, 2009, 2010 and 2011, respectively.

(2) For information concerning our financing see Note 21 “Margin Account Loan” to our consolidated financial statements for the year ended December 31, 2011 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, 2011. This information should be read in conjunction with ITEM 6 – “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 therapeutic Ampligen®. Alferon N Injection® is approved for a category of STD infection, and Ampligen® represents an experimental RNA nucleic acid 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 16 patents comprising our core intellectual property estate and a FDA approved product (Alferon N Injection®).

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.

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.

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Fair value at measurement dates during the period from Warrants' issued May 10, 2009, May 18, 2009 and May 21, 2009 to December 31, 2011, 2010 and 2009, were estimated using the following assumptions:

	2011	2010	2009
Underlying price per share	$0.20-$0.46	$0.47-$0.74	$0.56 - $2.54
Exercise price per share	$1.31-$1.65	$1.31-$1.65	$1.10 – $1.65
Risk-free interest rate	0.29%-1.58%	0.83%-2.36%	0.19% - 2.67%
Expected holding period	2.38-3.63 years	3.38-4.63 years	0.122-5.50 years
Expected volatility	74.55%-120.55%	112.16%-122.02%	94.99%–226.46%
Expected dividend yield	None	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 for sale, but such product will not be available for commercial sales until at least the second half of 2012;

b. The Company will have to perform additional clinical trials for FDA approval of its flagship product as well as to diversify the applications of its FDA approved 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. The Company has minimal revenue streams which are insufficient to meet the funding needs for the cost of operations or construction at their manufacturing facility; and

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g. The Company's Rights Plan and Executive Employment Agreements make 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 has incorporated a 5.0% probability of a Fundamental Transaction for the life to date for these securities.

(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, 2011 versus December 31, 2010

Net Loss

Our net loss of approximately $9,015,000 for the year ended December 31, 2011 was 31% lower when compared to the same period in 2010. This $4,121,000 decrease in loss was primarily due to:

1) decreased Research and Development costs in 2011 of approximately $891,000 or 12% as compared to the same period in 2010;

2) decreased Production/Cost of Goods Sold in 2011 of approximately $298,000 or 22%;

3) decreased General and Administrative expenses of approximately $877,000 or 12% as compared to the same period in 2010;

4) an adjustment at December 31, 2011 to record the change in fair value for a Liability related to certain redeemable warrants originally issued in May 2009. This Liability was recorded in May 2009, adjusted and revalued to $2,805,000 at December 31, 2010, resulting in a related non-cash gain of $879,000 in 2010. The value of this Liability at December 31, 2011 was $380,000. The cumulative quarterly adjustments needed during 2011 to revalue the liability resulted in a related non-cash gain of $2,425,000 for year ended December 31, 2011. This resulted in a decrease in loss of $1,545,000 in 2011 compared to 2010.

5) the 2011 receipt of funds from the sale of State New Jersey tax net operating losses for years 2003 to 2008 for $2,272,000; which were offset by

6) a decrease in interest and other income in 2011 of approximately $1,759,000 or 74% as compared to the same period in 2010;

Net loss per share for the year ended 2011 was approximately $(0.07) versus approximately $(0.10) for the same period in 2010.

Revenues

Revenues from our Ampligen® cost recovery treatment program for the year ended December 31, 2011 were approximately $161,000 compared to revenues of $135,000 for the same period in 2010, an increase of $26,000 or 19% for approximately 36 patients in 2011 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 2011 or 2010 and all sales revenue in 2011 and 2010 has been generated from Ampligen® cost recovery clinical treatment programs. We currently have the financial resources to undertake manufacturing upgrades that have been undertaken throughout 2011 and 2010 (see “MANUFACTURING” in ITEM 1. Business).

Production/Cost of Goods Sold

Production/Cost of Goods Sold was approximately $1,043,000 and $1,341,000, respectively, for the twelve months ended December 31, 2011 and 2010. This decrease of $298,000 or 22% was primarily due to 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 $259,000 and the lower cost to maintain existing Alferon N Injection® and Ampligen® inventory including storage, stability testing, transport and reporting costs due to our efforts to reduce the production costs of Alferon N Injection® for potential future commercial sales. These savings achieved in 2011 were somewhat offset by comparison to 2010 due to last year’s recognition of insurance proceeds of

$96,000 received for storm damages which occurred at the New Brunswick, NJ facility and September 2011 costs related to the transfer of existing Alferon N Injection® and Ampligen® inventory to a new vendor (BioRidge) in coordination with the sales, marketing and education effort to be undertaken by Armada Healthcare for Alferon N Injection®.

Research and Development Costs

Overall Research and Development costs for the year ended December 31, 2011 were approximately $6,722,000 as compared to $7,613,000 for the same period a year ago, reflecting a decrease of $891,000 or 12%. In 2011 we spent approximately $2,310,000 for the Ampligen® new drug treatment of Chronic Fatigue Syndrome, approximately $4,080,000 for Alferon® LDO for influenza and approximately $332,000 for other projects. The primary factors for the decrease in research and development costs were a suspension of some clinical, research and development costs related to Alferon® LDO as we work to select a vendor to conduct a confirmatory study, which will help us to further evaluate the potential effectiveness of this product and determine the cost/benefit of proceeding with the planned study of seasonal and pandemic influenza.

General and Administrative Expenses

General and Administrative expenses for the year ended December 31, 2011 and 2010 were approximately $6,691,000 and $7,568,000, respectively, reflecting a decrease of $877,000 or 12%. The primary reason for this decrease in expense in 2011 consisted primarily of a decrease in legal fees totaling $941,000 due to settlement in 2010 of various legal proceedings.

Interest and Other Income

Interest and other income for the years ended December 31, 2011 and 2010 was approximately $625,000 and $2,383,000, respectively, representing an decrease of $1,759,000 or 74%. The primary causes for the decrease of interest income in 2011 were (1) the use of some of the proceeds from investments in operations, thereby diminishing the amounts available for investments and proportionately reducing the flow of interest income; and (2) the receipt of capital gain distributions in 2010 of $1,079,000 which did not re-occur in 2011.

Interest Expense and Financing Costs

In 2011 and 2010 prior to the establishment of the Margin Account Loan, 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®. For the year ended December 31, 2011 and 2010, we had interest expense of approximately $41,000 and $11,000, respectively. For detailed information on the Margin Account Loan and capital leases, see “Liquidity and Capital Resources” below.

Sale of New Jersey Tax Net Operating Loss

In February 2011, the Company received $2,272,000 from the sale of the State of New Jersey tax net operating losses for years 2003 to 2008 (see “Note 15**:** Income Taxes (FASB ASC 740 Income Taxes) and Subsequent Event”). No such sale occurred in 2010.

Redeemable Warrants Valuation Adjustment

The December 31, 2011 and 2010 revaluations resulted in non-cash adjustments to the Redeemable Warrants Liability as of December 31, 2011 and 2010 of approximately $2,425,000 and $879,000, respectively, representing an increase of $1,545,000 (see “Note 19: Fair Value”).

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 21 patients in 2010 and 18 patients in 2009 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 2010 or 2009 and all sales revenue in 2010 and 2009 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, NJ facility for the FDA preapproval inspection with respect to our Ampligen® NDA. We now have the financial resources to commence manufacturing upgrades that had been undertaken throughout 2010 and continue in 2011.

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 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, 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 Sage.

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.

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, 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, 2010 and 2009, a net gain of $879,000 was recorded in 2010 as compared to $6,258,000 recorded in 2009.

Liquidity and Capital Resources

Cash used in operating activities for the twelve months ended December 31, 2011 was $10,096,000 compared to $11,886,000 for the same period in 2010, a decrease of $1,790,000 or 15%. This reduction in Cash used was primarily due to lower operating costs and a cash gain from the sale of prior years' New Jersey Net Operating Loss in 2011. As of December 31, 2010, the Company had approximately $44,000,000 of New Jersey state net operating loss carry forwards (expiring in the years 2011 through 2017) available to offset future state taxable income. In February 2011, the Company effectively sold $28,000,000 of its New Jersey state net operating loss carry forwards (for the years 2003 through 2008) for approximately $2,272,000. As of December 31, 2011, the Company had approximately $25,000,000 of New Jersey state net operating loss carry forwards (expiring in the years 2016 through 2018) available to offset future state taxable income or possibly sell though the State of New Jersey's Corporate Business Tax Transfer Program.

Excluding the proceeds from the sale of New Jersey net operating loss carry forwards, Cash used in operating activities for the twelve months ended December 31, 2011 increased by approximately $483,000 over the comparable period in 2010. As of December 31, 2011, we had approximately $34,391,000 in Cash, Cash Equivalents and Marketable Securities (inclusive of $3,101,000 in Marketable Securities collateralizing certain debts), or a decrease of approximately $9,996,000 from December 31, 2010.

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 along with an aggregate of approximately $28,112,000 in equity financing pursuant to the Fusion Capital Agreement during 2008 and 2009.

A Margin Account was established on July 26, 2011, with Wells Fargo Advisors for which the proceeds of this flexible form of indebtedness effectively serves the Company as a line of credit to finance the capital improvement project underway at the New Brunswick, New Jersey Manufacturing facility**.** While this Margin Account has no material establishment or maintenance fees, it currently carries an effective interest rate of approximately 3% per annum applied against the "Margin Debit Balance" (i.e., those funds withdrawn and outstanding), based on the prevailing "Wells Fargo Base Rate" less 2.75%. As of December 31, 2011, the principal loan balance of the Margin Account was approximately $1,695,000 (see "Note 21: Margin Account Loan").

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 twelve months ended December 31, 2011, we sold no shares through this program and received no net cash proceeds. For the approximately seven months ended December 31, 2010 that the ATM was in existence, we sold an aggregate of 520,000 shares that resulted in net cash proceeds of approximately $293,000 and commissions paid to Maxim of approximately $12,000.

There can be no assurances that, if needed, we will be able to raise adequate funds from these or other sources. Our inability to raise such funds, if needed, could 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. 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, acquisitions of intellectual property or assets, enhancements to the manufacturing process, competitive and technological advances, the regulatory processes including the commercializing of Ampligen® products or new utilization of Alferon® products.

Our ability to raise additional funds from the sale of equity securities is limited. In this regard, we only have approximately 31,800,000 shares authorized but unissued and unreserved. While we recently increased the number of authorized shares of Common Stock from 200,000,000 to 350,000,000, the additional 150,000,000 shares cannot be issued for fundraising purposes without prior stockholder approval. 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 without prior stockholder approval may hinder our ability to raise additional funding."

Standby Financing Agreement

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

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

Other 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, 2011 and 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, 2011 and 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, 2011 and 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, 2011, none of the Warrants have been exercised.

Refer to Note 19 - "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.

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 available without first obtaining stockholder approval (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 without prior stockholder approval may hinder our ability to raise additional funding").

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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	2012	2013	2014	2015	2016
Margin Account Loan	$1,695	$1,695	$0	$ 0	$ 0	$ 0
Capital Leases	194	71	60	39	23	1
Operating Leases	262	197	65	0	0	0
Total	$2,151	$1,963	$125	$ 39	$ 23	$ 1

Certain Relationships and Related Transactions

During the quarter ended September 30, 2011, our internal controls identified a misstatement in our prior public disclosures, including within the NOTES TO CONSOLIDATED FINANCIAL STATEMENTS of our Annual Report on Form 10-K for the year ended December 31, 2010. A Related Party transaction was accurately reported that we paid Retreat House, LLC $123,200 in 2010 for the use of the property at various times for off-site meetings and lodging. It was determined in September 2011 that the property was owned individually by Dr. William A. Carter, our Chief Executive Officer, through April 28, 2010, at which time it was transferred to Retreat House, LLC, a Virginia limited liability company that is owned by three of the children of William A. Carter and a Senior Primary Revocable Trust in which William A. Carter is the Trustee. Dr. Carter also is the Manager of Retreat House, LLC. It had been previously reported by the Company that Retreat House, LLC was an entity wholly owned by the children of our CEO, William A. Carter and that Retreat House LLC was owner of the property since 2004; these statements were inaccurate. As an element of Dr. Carter’s Amended Employment Contract, effective November 15, 2011, he will continue to conduct Company business from Retreat House and the Company shall supply the equipment necessary for full telephone, telefax, computer and internet access. As an element of his employee compensation within this amended contract, Dr. Carter agreed to designate the Retreat House as both his home office and as a meeting place for a variety of Company business and social activities at no additional expense to the Company and agreed not to bill, either personally or through Retreat House LLC, or any other entity, for use of the Retreat House. Additionally, Dr. Carter shall be responsible for paying for all secretarial and receptionist services related to his work conducted in Florida and provide said services at no further expense to the Company.

For greater detail of each related transaction for 2011 and 2010, please see PART III, ITEM 13. “Certain Relationships and Related Transactions, and Director Independence.”

New Accounting Pronouncements

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

Disclosure About Off-Balance Sheet Arrangements

None.

Critical Accounting Policies

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

Revenue

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

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

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 historical data to estimate expected dividend yield, expected life, which represents the period of time the options are expected to be outstanding until they are exercised, and forfeiture rates.

Redeemable Warrants

We utilize the guidance contained in 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, 2011 and 2010 there were no receivables.

All sales for years ended December 31, 2011 and 2010 were prepaid by the customer related to the Ampligen® cost recovery treatment program.

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

We had approximately $34,391,000 in cash, cash equivalents and Marketable Securities (restricted and non-restricted) at December 31, 2011. 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 twelve 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, 2011 and 2010, and our consolidated statements of comprehensive loss, changes in stockholders' equity and comprehensive loss and cash flows for each of the years in the three year period ended December 31, 2011, 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, 2011, 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 Exchange Act. 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 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, 2011 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, 2011. 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, 2011. 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, 2011, 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, 2011 has been audited by McGladrey and Pullen, LLP, an independent registered public accounting firm, as stated in their report which appears herein.

ITEM 9B. Other Information.

None.

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.	74	Chairman of the Board, Chief Executive Officer, President and Chief Scientific Officer
Thomas K. Equels, Esq.	59	Executive Vice Chairman of the Board, Secretary and General Counsel
Richard C. Piani	85	Lead Independent Director
William M. Mitchell, M.D., Ph.D.	77	Director
Iraj Eqhbal Kiani, N.D., Ph.D.	66	Director
Charles T. Bernhardt, CPA	50	Chief Financial Officer and Chief Accounting Officer
David R. Strayer, M.D.	66	Chief Medical Officer and Medical Director, Regulatory Affairs
Robert Dickey IV	56	Senior Vice President
Wayne Springate	40	Senior Vice President of Operations

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' business and its future:

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, Esq., 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, Esq. - 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 and 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 Yasoug, 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, and his 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 from 2003 to 2006 and earlier in his career a member of the Internal Audit management teams for 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.

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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 was promoted to Senior Vice President of Operations on May 1, 2011. Mr. Springate joined Hemispherx in 2002 as Vice President of Business Development 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.

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, 2011, only one 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 2011. Specifically, Dr. Carter filed one Forms 4 late concerning his receipt of reissued Options.

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 Dr. 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. This Committee formally met nine times in 2011 with all committee members in attendance for at least 80% of the meetings. Our General Counsel and Chief Financial Officer support the Audit Committee in its work.

In September 2011, the Audit Committee engaged the services of a consultant who meets the SEC criteria of a Financial Expert to enhance the current structure and expertise of the Committee. After an extensive search, the Audit Committee selected Stewart L. Appelrouth, a Florida and North Carolina licensed Certified Public Accountant to directly support the efforts of the Audit Committee. Mr. Appelrouth is a Certified Valuation Analyst, Accredited in Business Valuation and a Diplomate of the American Board of Forensic Accounting. Mr. Appelrouth has a Masters Degree in Finance from Florida International University and an undergraduate degree in Business Administration from Florida State University. He is one of the founding partners of Appelrouth Farah & Co., which serves Southern Florida as a full service accounting and international business advisory firm specializing in auditing, domestic and international taxation, litigation support, forensic accounting, fraud examination and business valuation. The Firm is affiliated with MGI, a worldwide association of independent auditing and accounting firms.

Disclosure Control Committee

In August 2011, our Board formed the Disclosure Controls Committee (“DCC”). The DCC reports to the Audit Committee and is responsible for procedures and guidelines on managing disclosure information.

The purpose of the DCC is to make certain that information required to be publicly disclosed is properly accumulated, recorded, summarized and communicated to the Board and management. This process is intended to allow for timely decisions regarding communications and disclosures and to help ensure that we comply with related SEC rules and regulations. Robert Dickey, one of our Senior Vice Presidents, is the DCC’s Investor Relations Coordinator and Chairperson. The other members of the DCC are Thomas K. Equels, our General Counsel, Charles Bernhardt, our Chief Financial Officer, William A. Carter, our Chief Scientific Officer, William Mitchell, one of our Independent Directors. Nancy McGrory is the DCC’s Deputy Investor Relations Coordinator.

Code of Ethics

Our Board of Directors adopted a revision to the 2003 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. On an annual basis, this Code is reviewed and signed by each Officer, Director, employee and strategic consultants with none of the amendments constituting a waiver of provision of the Code of Ethics on behalf of 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.

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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"), President and Chief Scientific Officer ("CSO");
- Charles T. Bernhardt, Chief Financial Officer ("CFO") & Chief Accounting Officer ("CAO");
- Thomas K. Equels, General Counsel and Litigation Counsel;
- Dr. David Strayer, Chief Medical Officer ("CMO") and Medical Director;
- Robert Dickey, IV, Senior Vice President ("SVP");
- Ralph C. Cavalli, Vice President of Quality Control (joining the Company effective April 15, 2010); and
- Ronald Ritz, Senior Director of Manufacturing (joining the Company effective February 11, 2011 and separating on February 10, 2012).

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 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 of Compensation Committee

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 Exchange Act, and an “Outside Director” as defined under the U.S. Treasury regulations promulgated under Section 162(m) of the Internal Revenue Code of 1986, as amended (the “Internal Revenue Code”): Dr. Iraj E. Kiani, N.D (Chair), Dr. William Mitchell, M.D. and Richard C. Piani. 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 formally met five times in 2011 and all committee members were in attendance for at least 80% of the meetings. Our General Counsel, Chief Financial Officer and Director of Human Resources support the Compensation Committee in its work.

Results of Stockholder Advisory Vote on Executive Compensation

At the 2010 and 2011 Annual Meetings of Stockholders, Stockholders did not approve the annual, non-binding "say-on-pay" advisory vote on Executive Compensation. Comparable to the vote at the 2010 Annual Meeting, there was very little stockholder voting on this resolution at the 2011 meeting. In 2011, only 20.7% of the outstanding shares voted on this proposal. In addition, 44.1% of the votes cast were in favor of executive compensation, while 37.0% of the votes cast were against and 18.9% of the votes cast abstained. With 2010 and 2011 advisory votes taking place approximately seven months apart, it is our understanding that shareholder base has remained consistent with approximately 40% of the shares held in Europe and the majority of our stock held in the United States owned by non-institutional investors.

Our Compensation Committee reviewed its executive compensation policies to take into account the results of the most recent say-on-pay advisory vote. As a result, the Committee:

- Developed Company-wide goals and objectives with the intent to increase Stockholder value, enhance the "pay for performance" concept, attempt to address the needs of patients and enhance financial factors such as raising capital, reestablishing revenue streams, cost containment and/or improving the results of operations;
- Attempted to reinforce a Pay for Performance environment for the Executive Team with emphasis of sharing the economic goals of the Stockholders;
- Reviewed the Executive Team's Company-wide goals and individuals specific goals in relation to each job performance for a given year. In its review of each member of the Executive Team, the Committee utilized a weighted-average rating process regarding the goals and responsibilities specific to each individual as well as their contribution in meeting corporate goals;
- Reviewed peer group financial data of comparable publicly-traded companies for 2009 and 2010 with emphasis on a comparison of executive compensation as a factor to various Balance Sheet ratios to determine reasonableness to the respective companies;
- Considered the change in the market value of the Company's stock during the year in relation to Management's efforts and ability to impact the results;
- Mandated that the standard terms of future employee options issued by the Company require that such options not vest sooner than one year from the date of issuance and that, to the extent that any such options have not vested on the date of an Executive's termination, the options will expire; and
- Adopted a policy to facilitate compliance with Dodd-Frank's Claw-Back Compensation Recoupment provisions.

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.

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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 their 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, our own strategic goals, governmental regulations and the results of Stockholder Advisory Votes regarding executive compensation.

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. In 2011 and 2010, the Committee did not engage the services of an independent compensation consultant, but alternatively utilized web-based organizations and data bases such as Salary.com, to help them analyze compensation data and compare our programs with the practices of 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 overall Company performance;
- Performance incentive bonus based on the accomplishment of Company sales milestones;
- Long-term bonus incentive programs consisting of the Employee Bonus Pool Program;
- Stock option grants with exercise prices set in excess of fair market value at the time of grant and, effective December 2011, not vesting sooner than one year from the date of issuance; and
- Adoption of a policy to facilitate compliance with Dodd-Frank’s Claw-Back Compensation Recoupment provisions.

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, in recent years this review has occurred when NEO's employment agreements required restatement, amendment or replacement. 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 December 31, 2010 and 2011 at the rate of 3.0% and 3.6%, respectively. Additional changes to our NEO's base salaries could be undertaken in a future determination by the Compensation Committee at its discretion. During 2011, employment agreements were amended and restated for the following NEOs: Dr. William Carter, Charles Bernhardt, Thomas Equels and Dr. Ralph Cavalli. Additionally effective February 11, 2011 and through his separation with the Company on February 10, 2012, an employment agreement existed with Ronald Ritz. Robert Dickey's employment agreement was last renewed in September 2010, and Dr. David Strayer does not currently have an employment agreement with the Company.

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, 2011, the following NEO were eligible for an annual performance bonus based on 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%);
- Ralph C. Cavalli, Vice President of Quality Control (bonus opportunity up to 20%); and
- Ronald Ritz, Senior Director of Manufacturing (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 overall staff in order to determine each respective annual incentive opportunity including an analysis by the Compensation Committee that provides the following information:

1. The Company-wide goals and 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 quantitatively and/or quantitatively 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/her individually;
7. If applicable, whether the Committee reviewed any report(s) from compensation consultant(s) and/or web based organizations and data bases;
8. How this level of achievement translated into the actual bonuses awarded for the 2011 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, 2011. 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. Continued progress towards non-USA approval of Ampligen® for Chronic Fatigue Syndrome;
C. An overall strategic plan for Ampligen® and Alferon® to be submitted to the Board;
D. Strategic plans for the marketing and partners for Ampligen® to be submitted to the Board;
E. Continued development of enhancement of vaccines requiring Ampligen®;
F. Success in the protection of Company Intellectual Property;
G. Continued development of Alferon® LDO;
H. Progress in the return to commercialization of Alferon N Injection®;
I. Continued development of Ampligen® and Alferon N Injection® for treatment of influenza;
J. Maintaining the overall financial strength of the Company and operations consistent with the budget;
K. Implementation of research & development partnerships;
L. Implementation of Ampligen® clinical trials in cancer with commercial partner(s);
M. Implementation of Ampligen® clinical trials in cancer with academic partner(s);

N. Increase in clinical trials of Alferon N Injection® for additional indications; and
O. Acquisition of complimentary pharmaceutical technologies and/or drugs/vaccines.

On an annual basis and at the sole discretion of the Compensation Committee, with input from the CEO or the Executive's direct supervisor, the Committee evaluates 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 is utilized to determine if a bonus is 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 2011, the Compensation Committee reviewed the Executive Team's Company-wide goals as detailed in the Committee's Meeting Minutes of March and May 2011 and specific goals documented in each individual's job description. Upon individual review of each member of the Executive Team, the Committee concluded that the Executive Team members 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. Additionally upon analysis of publicly-traded Peer Group companies, the Committee observed that, for 2009 and 2010, Hemispherx' Officer Compensation Expense as compared to various Balance Sheet ratios were consistently less than that of the average of the Peer Group. Finally, the Committee considered the change in the market value of the Company's stock during 2011 and reached a consensus that the impact of the 2011 stock trading value should be considered to have a neutral effect on employees' performance evaluation due to their conclusion of the following observations:

1. The overall devaluation in the trading value of U.S. bio-pharmaceutical companies;
2. An overall depression in the global investment markets;
3. The current market value of the Company's stock is less than either its book value or cash value;
4. A belief that the current adverse impact of the Company's stock value is short-term;
5. Confidence that Company's employees were working diligently in an attempt to return the market value to the stock;

6. The Senior Management team had a net loss of two members from 2010 to 2011, for which the remaining executives had assumed those respective duties and responsibilities; and
7. The recognition that a performance bonus would be desirable to acknowledge the persistence, loyalty, effort and dedication of the Senior Management team.

The Compensation Committee in light of pre-established individual, along with position appropriate Company-wide goals (A. through O. as disclosed above) and objectives, undertook a weighted-average evaluation of the performance of each key executive in order to determine respective annual incentive opportunities considering base salary and fees, short and long-term incentive opportunity and any special/supplemental benefits or payments. Based upon all of the foregoing, the Committee determined that the following 2011 Performance Bonuses were granted and paid in 2012:

1. At the rate of 25% of their respective 2011 year-end base compensation:
   - William Carter (Chairman, CEO, President, Chief Scientific Officer) for $233,500;
   - Thomas Equels (Executive Vice Chairman, Secretary & General Counsel) for $125,000;
   - Charles Bernhardt (CFO & Chief Accounting Officer) for $56,250; and
   - Wayne Springate (Senior Vice President of Operations) for $46,740.

2. At the rate of 20% of their respective 2011 year-end base compensation:
   - David Strayer (Medical Director) for $50,199;
   - Adam Pascale (Corporate Controller) for $24,931;
   - Ralph C. Cavalli (Vice President of Quality Control) for $36,053; and
   - Ronald Ritz (Senior Director of Manufacturing) for $39,375.

Employee Appraisal And Merit Bonus Program

For the year ending 2011, the Compensation Committee approved 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 year-end, department-wide merit bonuses. This 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 ending 2011, granted and paid in 2012, the average employee bonus from this Program was 3.4% of the respective non-executive employee's year-end Base Salary. Accordingly, the total cost of this non-NEO bonus program for 2011 was approximately $29,500.

Executive Performance Incentive Bonus

As an element of their current employment contracts, William Carter (Chairman, CEO, President, Chief Scientific Officer) and Thomas Equels (Executive Vice Chairman, Secretary and General Counsel) are eligible for performance incentive bonus based on a percent, 2.5% and 5.0% respectively, of the Gross Proceeds paid to the Company as a result of sales of Alferon N Injection®, Alferon® LDO, Ampligen® or other Company products, or from any joint ventures or corporate partnering arrangements. For bonus purposes, Gross Proceeds is defined as cash amounts paid to the Company by the other parties to the joint venture or corporate partnering arrangement, but shall not include any amounts paid to the Company as reimbursement of expenses incurred; and any amounts paid to the Company in consideration for the Company's assets (i.e., plant, property, equipment, investments, etc.), equity or other securities. After the termination of this Agreement, for any reason, Dr. Carter and Mr. Equels shall be entitled to receive the incentive bonus based upon Gross Proceeds received by the Company during the three year period commencing on the termination of their Agreement with respect to any joint ventures or corporate partnering arrangements entered into by the Company during the term of the Agreement. Furthermore, Dr. Carter and Mr. Equels shall be entitled to a 5% bonus related to any sale of the Company, or any sale of a substantial portion of Company assets not in the ordinary course of its business. The aggregate incentive bonus hereunder as set forth above shall be capped not to exceed $5,000,000 annually. For the year ending 2011, no compensation was granted or paid related to the Executive Performance Incentive Program.

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. For the year ending 2011, the Employee Bonus Pool Program continued to exist 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.

Employee Bonus Pool Program

An element of 2009's 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 2011, no compensation was granted or paid 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, and continue to use, stock options as the primary long-term equity 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 executives 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.

As a reinforcement to employees that one of the Company’s priorities continues to be that of increasing shareholder value, the Compensation Committee and Board have historically granted the replacement of expired stock options to all current employees at the same number of shares and exercise price as had been originally issued. While the Company filed with the SEC on Form 8-K (No. 1-13411) on March 7, 2011 that options were being reissued to Dr. William Carter and Dr. David Strayer to replace those that had expired on January 3, 2011, it was subsequently determined that the options did not expire until 2012. Therefore, these options were not reissued in 2011. For the year ending December 31, 2011, the Company did not reissue any expiring employee stock options.

Effective as of December 2011, the Compensation Committee mandated that the standard terms of options to be issued to Company Executives to require that such options not vest sooner than one year from the date of issuance and that, to the extent that any such options have not vested on the date of an Executive’s termination, the options shall be void as to such unvested portion.

On May 31, 2011, we granted options to purchase 90,000 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 May 1, 2011 and with immediate vesting, to Wayne Springate, Senior Vice President of Operations, consistent with his employment agreement.

On June 24, 2011, we granted options to purchase 300,000 shares of our common stock at an exercise price of $0.41 per share, or 110% of the $0.37 closing price of the stock on the NYSE Amex as of June 9, 2011 with immediate vesting, to Thomas K. Equels, Executive Vice Chairman, Secretary and General Counsel, consistent with his employment agreement.

On July 15, 2011, we granted options to purchase 500,000 shares of our common stock at an exercise price of $0.41 per share, or 110% of the $0.37 closing price of the stock on the NYSE Amex as of July 14, 2011 with immediate vesting, to William A. Carter, Chairman, Chief Executive Officer and Chief Scientific Officer, consistent with his employment agreement.

On September 23, 2011, we granted options to purchase 40,000 shares of our common stock at an exercise price of $0.37 per share, or 110% of the $0.34 closing price of the stock on the NYSE Amex as of July 15, 2011 with proportionate vesting over 18 months, to Ralph C. Cavalli, Vice President of Quality Control, consistent with his employment agreement.

On December 22, 2011, we granted options to purchase 100,000 shares of our common stock at an exercise price of $0.31 per share, or 110% of the $0.28 closing price of the stock on the NYSE Amex as of December 5, 2011 with total vesting in twelve months, to Charles T. Bernhardt, Chief Financial Officer and Chief Accounting Officer consistent with his employment agreement.

Claw-Back Compensation Recoupment Provisions

Effective December 2011, all Executive compensation including and without limitation to base salary, bonuses, stock options, and fringe benefits, shall be subject to recoupment from the Employee by the Company pursuant to the Company's Executive Compensation Recoupment Policies adopted December 1, 2011, as may be amended by the Company's Board of Directors from time to time to remain in compliance with the claw-back compensation recoupment provisions of the Dodd-Frank Act.

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 or to the extent of IRS regulations, whichever is lower.

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 2011 NEO as an element of their respective employment:

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

- Automobile allowance;
- Predetermined allowance for the Company's utilization of property owned by Retreat House LLC (effective November 15, 2011);
- Reimbursement of home office, computer, internet, phone and telefax expenses;
- Health, vision and dental insurance fully paid by the Company (effective November 15, 2011); and
- Supplementary life and disability insurance policies.

Thomas Equels, General Counsel and Litigation Counsel, as an element of his employment agreement:

- Automobile allowance (effective November 15, 2011);
- Predetermined allowance for the Company's utilization of Florida offices of Equal Law;
- Reimbursement of home office, computer, internet, phone and telefax expenses;
- Health, vision and dental insurance fully paid by the Company (effective November 15, 2011); and
- Supplementary life and disability insurance policies.

Charles Bernhardt, CFO and CAO, as an element of his employment agreement effective November 15, 2011:

- Reimbursement of home office, computer, internet, phone and telefax expenses; and
- Health, vision and dental insurance fully paid by the Company.

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.

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, to the dollar extent permitted by IRS regulations, 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)**.** This agreement with Mr. Peterson expired without replacement on December 31, 2011.

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, President and Chief Scientific Officer;
- Thomas K. Equels, Executive Vice Chairman of the Board, Secretary and General Counsel; and
- Charles T. Bernhardt, Chief Financial Officer and Chief Accounting Officer.

The Compensation Committee believes that severance agreements provided to these individuals are generally in line with severance packages offered to executive officers of companies of similar size. Alternately, Robert Dickey, Dr. David Strayer, Dr. Ralph C. Cavalli and Ronald Ritz 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, 2011.

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, 2011 and Hemispherx' Proxy Statement to be filed in connection with Hemispherx' 2012 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 or the Exchange Act, 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, 2011, 2010 and 2009 of our Chief Executive Officer, Chief Financial Officers, three other most highly compensated Executive Officers and two mostly highly compensated non-executives, constituting the Company's Named Executive Officers, based on the year-ending 2011 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 Chief Executive Officer (1)	2011	$1,007,714	$233,500 (11)	$-0-	$143,749 (1)	$-0-	—$132,052 (12)		$1,517,0
	2010	$951,837	$200,000 (9)	$405,083 (19)	$253,721 (1)	$-0-	—$100,699 (12)		$1,911,3
	2009	$554,105	$482,072 (6)(7)	$188,311 (19)	$-0-	$-0-	—$76,896 (12)		$1,301,3
Thomas K. Equels General Counsel (2)	2011	$572,957	$125,000 (11)	$-0-	$91,504 (2)	$-0-	—$48,813 (13)		$838,274
	2010	$398,333	$250,000 (8)(9)	$-0-	$140,528 (2)	$-0-	—$39,973 (13)		$828,834
	2009	$-0-	$-0-	$-0-	$-0-	$-0-	—$-0-		$-0-
Charles T. Bernhardt Chief Financial Officer (3)	2011	$208,389	$81,250 (10)(11)	$-0-	$14,291 (3)	$-0-	—$25,935 (14)		$329,865
	2010	$194,133	$50,000 (9)	$117,296 (19)	$37,301 (3)	$-0-	—$24,273 (14)		$423,003
	2009	$134,662	$44,000 (7)	$45,334 (19)	$-0-	$-0-	—$9,380 (14)		$233,376
Robert Dickey (4) Sr. Vice President	2011	$302,500	$-0-	$0-	$-0-	$-0-	—$7,797 (15)		$310,297
	2010	$302,500	$-0-	$-0-	$-0-	$-0-	—$8,232 (15)		$310,732
	2009	$152,131	$-0-	$-0-	$252,312 (4)	$-0-	—$4,824 (15)		$409,267
David Strayer Medical Director	2011	$251,000	$51,199 (11)	$-0-	$-0-	$-0-	—$13,098 (16)		$315,297
	2010	$243,685	$48,737 (9)	$132,587 (19)	$-0-	$-0-	—$13,227 (16)		$438,236
	2009	$167,484	$194,306 (6)(7)	$53,054 (19)	$-0-	$-0-	—$3,229 (16)		$418,073

Ralph Cavalli (20)	2011	$180,264	$36,059	(11)	$-0-	$9,207	(20)	$-0-	—$18,472	(17) $244,001
Vice President	2010	$169,791	$31,500	(9)	$-0-	$9,369	(20)	$-0-	—$4,026	(17) $214,686
	2009	$-0-	$-0-		$-0-	$-0-		$-0-	—$-0-	$-0-
Ronald Ritz (21)	2011	$119,424	$39,375	(11)	$16,369	$-0-		$-0-	—$3,548	(18) $178,716
Senior Director	2010	$-0-	$-0-		$-0-	$-0-		$-0-	—$-0-	$-0-
	2009	$-0-	$-0-		$-0-	$-0-		$-0-	—$-0-	$-0-

Notes:

(1) Dr. Carter renewed his Employment Agreements on June 11, 2010, which was amended on July 15, 2010, then amended and restated on December 6, 2011, that granted him the annual Option 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, then amended and restated December 6, 2011, that granted him the annual Option to purchase 300,000 shares of Hemispherx common stock as an element of his Employment Agreement.

(3) Mr. Bernhardt became Chief Financial Officer effective January 1, 2009. He entered into an Employment Agreement on December 6, 2010, that was amended and restated on December 6, 2011, that 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 then granted the Options to purchase 150,000 shares of Hemispherx common stock as an element of his Employment Agreement. His Executive Employment Agreement was amended and restated on February 1, 2010 and then again effective September 1, 2010.

(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) Stock- 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, 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.

(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 2010 Company-wide and individual goals.

(10) On March 3, 2011, our Board of Directors awarded an extraordinary bonus of $25,000 to Mr. Bernhardt related to his effort in financial reporting.

(11) On December 19, 2011, our Board of Directors awarded bonuses to certain NEO and senior, non-officer Executives in recognition for their achievement towards of 2011 Company-wide and individual goals.

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

	2011	2010	2009
Life and Disability Insurance	$86,386	$64,707	$38,679
Healthcare Insurance	16,696	24,139	28,586
Company Car Expenses / Car Allowance	11,535	11,853	9,631
Outside Office Expenses	0	-0-	-0-
401(k) matching funds	17,435	-0-	-0-
	$132,052	$100,699	$76,896

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

	2011	2010	2009
Life and Disability Insurance	$24,170	$34,140	$ -0-
Healthcare Insurance	11,623	5,833	-0-
Car Expenses / Allowance	-0-	11,853	-0-
Outside Office Expenses	-0-	-0-	-0-
401(k) matching funds	13,020	-0-	-0-
	$48,813	$39,973	$ -0-

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

2011	2010	2009

Life and Disability Insurance	$-0-	$-0-	$-0-
Healthcare Insurance	9,074	9,985	9,380
Outside Office Expenses	-0-	-0-	-0-
401(k) matching funds	16,861	14,288	-0-
	$25,935	$24,273	$9,380

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

	2011	2010	2009
Life and Disability Insurance	$-0-	$-0-	$-0-
Healthcare Insurance	7,797	8,232	4,824
401(k) matching funds	-0-	-0-	-0-
	$7,797	$8,232	$4,824

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

	2011	2010	2009
Life and Disability Insurance	$-0-	$-0-	$-0-
Healthcare Insurance	3,598	3,727	3,229
401(k) matching funds	9,500	9,500	-0-
	$13,098	$13,227	$3,229

(17) Dr. Cavalli's All Other Compensation consists of:

	2011	2010	2009
Life and Disability Insurance	$-0-	$-0-	$-0-
Healthcare Insurance	10,360	4,026	-0-
401(k) matching funds	8,112	-0-	-0-
	$18,472	$4,026	$-0-

(18) Mr. Ritz' All Other Compensation consists of:

	2011	2010	2009
Life and Disability Insurance	$-0-	$-0-	$-0-
Healthcare Insurance	3,548	-0-	-0-
401(k) matching funds	0	-0-	-0-
	$3,548	$-0-	$-0-

(19) Hemispherx' "Employee Wage Or Hours Reduction Program" allowed an individual to elect a 50% reduction in salary/fees which would allow 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).

(20) Ralph C. Cavalli joined the Company as an employee effective April 15, 2010. He entered into an employment agreement on June 11, 2010 and was granted the option to purchase 20,000 of Hemispherx common stock. The employment agreement was amended on September 15, 2011 and he was granted the option to purchase 40,000 of Hemispherx common stock.

(21) Ronald Ritz joined the Company as an employee effective February 11, 2011 and separated from the Company on February 10, 2012.

Grants Of Plan Based Awards

Name	Grant Date (2)(5)	Estimated Future Payouts Under Non-Equity Incentive Plan Awards(1)			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)(2)	Exercise or Base Price of Option Awards ($/Sh)	Grant Date Fair Value of Stock and Option Awards ($)
		Threshold ($)	Target ($)	Maximum ($)	Threshold ($)	Target ($)(3)	Maximum ($)				
William A. Carter, Chief Executive Officer	07/15/11	—	193,525	241,906	—	— 75,756	—	—	— 500,000	$ — $0.40	— 143,749
Thomas K. Equels, General Counsel	06/24/11	—	103,600	129,500	—	— 45,453	—	—	— 300,000	$ — $0.40	— 91,504
Charles T. Bernhardt, Chief Financial Officer	12/22/11	—	46,620	58,275	—	— -0-	— (4)	—	— 100,000	$ — $0.30	— 14,291
Robert Dickey, Senior Vice President	N/A	—	62,678	78,348	—	—	—	—	—	$ —	—
David Strayer, Medical Director	N/A	—	52,006	65,008	—	—	—	—	—	$ —	—
Ralph Cavalli, Vice President	09/23/11	—	44,371	55,464	—	— -0-	— (4)	—	— 40,000	$ — $0.37	— 9,207

Ronald Ritz (5), Senior Director	N/A	—	-0-	(5)	-0-	(5)	—	—	—	—	—$	—

Notes:

(1) For 2011 or 2012, 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, 2011, the "Target" was estimated at 20% of the Base Salary and "Maximum" was estimated at 25% of Base Salary. Details reported as Non-Equity Incentive Plan Compensation in 2011 are reported in the Summary Compensation Table above.

(2) Consists of stock options 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 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).

(3) Consists of stock options contractually required per the NEO's respective Employment Agreement to be granted during 2012 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 our common stock on the date of grant. For the purpose of this schedule, a NYSE Amex closing price at January 1, 2012 of $0.20 was assumed with an estimated exercise price of $0.22. The value was obtained using the Black-Scholes pricing model for stock-based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

(4) The term of the NEO's current Employment Agreement is at least through December 31, 2012, with the stock options related to the contract already awarded in 2011. Therefore for the purpose of this schedule, there is no estimated future payout under the Equity Incentive Plan calculated for 2012.

(5) Ronald Ritz joined the Company as an employee effective February 11, 2011 and separated from the Company on February 10, 2012. Therefore, his estimated bonus for 2012 is to be considered $-0-.

(6) 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 Carter, Chief Executive Officer	1,450,000	0	0	2.20	09/17/18				
	1,000,000	0	0	2.00	09/09/17				
	190,000	0	0	4.00	02/18/18				
	73,728	0	0	2.71	12/12/20				
	10,000	0	0	4.03	01/03/12				
	167,000	0	0	2.60	09/07/14				
	153,000	0	0	2.60	12/07/14				
	100,000	0	0	1.75	04/26/15				
	465,000	0	0	1.86	06/30/15				
	70,000	0	0	2.87	12/09/15				
	300,000	0	0	2.38	01/01/16				
	10,000	0	0	2.61	12/08/15				
	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				
	500,000	0	0	0.41	07/15/21				
Thomas Equels, General Counsel	300,000	0	0	0.66	06/11/20				
	300,000	0	0	0.41	06/24/21				
Charles Bernhardt Chief Financial Officer	100,000	0	0	0.55	12/06/20				
	0	100,000	0	0.31	12/22/21				
Robert Dickey,	93,750	56,250	0	2.55	06/11/19				

Sr. Vice President					
David Strayer,	50,000	0	0	2.00	09/09/17
Medical	50,000	0	0	4.00	02/28/18
Director	10,000	0	0	4.03	01/03/12
	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
Ralph Cavalli,	20,000	0	0	0.66	06/11/20
Vice President	6,667	33,333	0	0.37	09/15/21
Ronald Ritz, Sr. Director	0	0	0		

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	—	—	—	—
Ralph Cavalli, Vice President	—	—	—	—
Ronald Ritz, Sr. Director	—	—	—	—

Payments on Disability

At December 31, 2011, we had employment agreements with Dr. Carter, Mr. Equels and Mr. Bernhardt which entitled them Base Salary and applicable benefits otherwise due and payable through the last day of the month in which disability occurs and for an additional twelve month period. 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 older as of the date of the claim. In June 2010 through 2011, 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.

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Payments on Death

At December 31, 2011, we had employment agreements with Dr. Carter, Mr. Equels and Mr. Bernhardt which entitled them Base Salary and applicable benefits otherwise due and payable through the last day of the month in which death occurs and for an additional twelve month period. 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. In June 2010 and through 2011, 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, 2011, we had employment agreements with Dr. Carter, Mr. Equels and Mr. Bernhardt which entitled them to severance benefits on certain types of employment terminations not related to a change in control. Based on their employment agreements, Mr. Dickey, Dr. Cavalli and Mr. Ritz do not have severance benefits, but are required to be provided either one month or two weeks' notice of termination. Dr. Strayer is not covered by an employment agreement and therefore would only receive severance as determined by the Compensation Committee in its discretion.

The dollar amounts below assume that the termination occurred on January 1, 2012. 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 Chief Executive Officer	Involuntary (no cause)	4,517,996	378,778	70,705	444,705	5,412,184
	Termination (for cause)	-0-	-0-	-0-	-0-	-0-
	Death or disability	967,624	75,756	14,141	88,941	1,146,462
	Termination by employee or retirement	967,624	75,756	14,141	88,941	1,146,462
Thomas K. Equels General Counsel	Involuntary (no cause)	2,590,000	227,267	52,615	126,350	2,996,232
	Termination (for cause)	-0-	-0-	-0-	-0-	-0-
	Death or disability	518,000	45,453	10,523	25,271	599,246
	Termination by employee or retirement	518,000	45,453	10,523	25,270	599,246
Charles T. Bernhardt Chief Financial Officer	Involuntary (no cause)	233,100	-0-	6,035	3,039	242,174
	Termination (for cause)	-0-	-0-	-0-	-0-	-0-
	Death or disability	233,100	-0-	6,035	3,039	242,174
	Termination by employee or retirement	233,100	-0-	6,035	3,039	242,174
Robert Dickey Senior Vice President	Involuntary (no cause)	-0-	-0-	-0-	-0-	-0-
	Termination (for cause)	-0-	-0-	-0-	-0-	-0-
	Death or disability	-0-	-0-	-0-	-0-	-0-
	Termination by employee or retirement	-0-	-0-	-0-	-0-	-0-
David Strayer Medical Director	Involuntary (no cause)	-0-	-0-	-0-	-0-	-0-
	Termination (for cause)	-0-	-0-	-0-	-0-	-0-
	Death or disability	-0-	-0-	-0-	-0-	-0-
	Termination by employee or retirement	-0-	-0-	-0-	-0-	-0-
Ralph Cavalli Vice President	Involuntary (no cause)	-0-	-0-	-0-	-0-	-0-
	Termination (for cause)	-0-	-0-	-0-	-0-	-0-
	Death or disability	-0-	-0-	-0-	-0-	-0-
	Termination by employee or retirement	-0-	-0-	-0-	-0-	-0-
Ronald Ritz Sr. Director	Involuntary (no cause)	-0-	-0-	-0-	-0-	-0-
	Termination (for cause)	-0-	-0-	-0-	-0-	-0-
	Death or disability	-0-	-0-	-0-	-0-	-0-
	Termination by employee or retirement	-0-	-0-	-0-	-0-	-0-

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 at December 31, 2011 of $0.20 was utilized with an estimated exercise price of $0.22. The value was obtained using the Black-Scholes pricing model for stock-based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

(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, 2011, we had employment agreements with Dr. Carter, Mr. Equels and Mr. Bernhardt which entitled them to severance benefits on certain types of employment terminations related to a change in control thereby the term of their respective agreements would automatically be extended for three additional years. Based on their employment agreements, Mr. Dickey, Dr. Cavalli and Mr. Ritz do not have severance benefits resulting from a change in control, but are required to be provided either one month or two weeks' notice of termination. Dr. Strayer is not covered by an employment agreement and therefore would only receive severance from a change in control as determined by the Compensation Committee in its discretion. Any specific benefits for these four NEO would be determined by the Compensation Committee in its discretion.

The dollar amounts in the chart below assume that change in control termination occurred on January 1, 2012, 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 January 1, 2012 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 ($)	PVSU Acceleration (2) ($)	Early Vesting of Restricted Stock (3) ($)	Early Vesting of Stock Options and SARs (3) ($)	Acceleration and Vesting of Supplemental Award (5) ($)	Welfare Benefits Continuation (6) (7) ($)	Outplacement Assistance ($)
William A. Carter	7,420,868 (1)	-0-	-0-	-0-	606,045 (4)	918,350 (1)	-0-

Thomas K. Equels	4.144,000	(1)	-0-	-0-	-0-	363,627	(4)	708,715	(1) -0-
Charles Bernhardt	932,400	(1)	-0-	-0-	-0-	-0-		298,646	(1) -0-
Robert Dickey	-0-		-0-	-0-	-0-	-0-		-0-	-0-
David Strayer	-0-		-0-	-0-	-0-	-0-		-0-	-0-
Ralph Cavalli	-0-		-0-	-0-	-0-	-0-		-0-	-0-
Ronald Ritz	-0-		-0-	-0-	-0-	-0-		-0-	-0-

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 payout of all outstanding performance-vesting share units ("PVSU") awarded 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.

(3) This amount is the intrinsic value [fair market value on January 1, 2012 ($0.20 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.

(4) This amount represents the options to be issued annually for the 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 January 1, 2012 of $0.20 with an estimated exercise price of $0.22. The value was obtained using the Black-Scholes pricing model for stock-based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

(5) Any purchase rights represented by the Option not then vested shall, upon a change in control, shall become vested.

(6) This amount represents the employer-paid portion of the premiums for medical, dental, vision, life and disability insurance coverage utilizing the costs as of January 1, 2012.

(7) This amount also includes the estimated cost of Company matching 401(k) contributions of $15,000 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.

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, Chief Executive Officer and Chief Scientific Officer; an employment agreement with Thomas K. Equels, our Executive Vice Chairman, Secretary and General Counsel; and Charles T. Bernhardt, our Chief Financial Officer and Chief Accounting Officer.

The following is a description of post-employment compensation payable to the respective NEO. If a NEO does not have a specific benefit, they will not be 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 willful engaging in illegal conduct, 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 employee's part shall be deemed "willful" unless done intentionally by employee and not in good faith and without reasonable belief that employee's action or omission was in the best interest of the Company. Notwithstanding the foregoing, employee shall not be deemed to have been terminated for

Cause unless and until the Company delivers to the employee 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 employee and an opportunity for Employee, together with counsel, to be heard before the Board) finding that, in the good faith opinion of the Board, employee 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 them through the last day of their actual employment by the Company.

Termination Without Cause

Dr. Carter, Mr. Equels and Mr. Bernhardt are each entitled to the compensation and benefits otherwise due and payable to them through the last day of the then current term of their respective agreements**.** In the event that they are terminated at any time without "Cause" the Company shall pay to them, at the time of such termination, the compensation and benefits otherwise due and payable through the last day of the then current term of their Agreement. However, benefit distributions that are made due to a “separation from service” occurring while they are 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 them during such period shall be accumulated and paid to them 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 their inability to effectively carry out substantially all of their duties under their 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 their employment is terminated due to his death or disability, the Company will pay to each (or their respective 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.

Termination by Officer and Employee

All NEO employment agreements have the right to terminate their respective agreement upon thirty (30) days or less of prior written notice of termination. In such event, Dr. Carter, Mr. Equels and Mr. Bernhardt are specifically 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 NEO are entitled to the fees due to them through the last day of the month in which such termination occurs.

Change in Control

As an element of their employment agreements, Dr. Carter, Mr. Equels and Mr. Bernhardt are entitled to benefits upon a Change in Control or Constructive Termination that include that any unvested Options immediately vest and the

term of their respective employment 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 2010 and 2011, all Board members received Directors' fees of $165,000 and $169,950, respectively. 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 were issued under the our 2007 and 2009 Equity Incentive Plans.

Commencing as of January 1, 2011, with a 3.0% cost of living increase granted, Board member Directors' fee compensation was increased to an annual retainer of $169,950. Director's fees will continue to be paid quarterly in cash at the end of each calendar quarter and fee as granted a 3.06% cost of living adjustment for calendar year 2012.

Director Compensation - 2011

Name and Title of Director	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
W. Carter, Chairman & Chief Executive Officer	169,950	0	143,749 (1)	0	0	1,203,366 (2)	1,517,065
T. Equels, Executive Vice Chairman, Secretary & General Counsel	169,950	0	91,504 (3)	0	0	576,870 (4)	838,324
W. Mitchell, Director (5)	169,950	0	0	0	0	0	169,950
R. Piani, Director (5)	169,950	0	0	0	0	0	169,950
I. Kiani, Director (5)	169,950	0	0	0	0	0	169,950

Notes:

(1) Ten year Option to purchase 500,000 shares at $0.41 per share is awarded consistent with Employment Agreement of July 15, 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)

Compensation consists of salary and benefits for his role as Chief Executive Officer, President and Chief Scientific Officer in accordance with his Employment Agreements of June 11, 2010 and December 6, 2011 along with the year-end performance bonus for 2010 paid in 2011.

(3) Ten year Option to purchase 300,000 shares at $0.41 per share awarded consistent with Employment Agreement of June 24, 2011. The value was obtained using the Black-Scholes pricing model for stock-based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

(4) Compensation consists of salary and benefits as General Counsel in accordance with his Employment Agreements June 11, 2010 and December 6, 2011 along with the year-end performance bonus for 2010 paid in 2011.

(5) Independent Director of the Company.

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

The following table sets forth as of March 1, 2012, 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 Officers; 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)	5.62	%
Thomas K. Equels	1,728,622	(3)	1.27	%
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	377,420	(7)	*	
David R. Strayer, M.D.	410,932	(8)	*	
Robert Dickey, IV	152,500	(9)	*	
Ralph C. Cavalli, Ph.D.	60,000	(10)	*	
Ronald Ritz	39,032	(11)	*	
All directors and executive officers as a group (11 persons)	12,102,381		8.91	%

* Ownership of less than 1%

(1) Dr. Carter is our Chairman, Chief Executive Officer and Chief Scientific Officer. He owns 890,585 shares of common stock and beneficially owns 7,256,574 shares issuable or issued upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	2004	12/07/01	$4.03	10,000	01/04/12
	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
	2009	07/15/11	$0.41	500,000	07/15/21
Total Options				6,765,378	
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. Dr. Kovari 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 1,091,196 shares issuable or issued upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	2009	06/11/10	$0.66	300,000	06/11/20
	2009	06/24/11	$0.41	300,000	06/24/21
Total Options				600,000	

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 who 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 200,000 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	2009	12/06/10	$0.55	100,000	12/06/20
	2009	12/22/11	$0.31	100,000	12/22/21
Total Options				200,000	

(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. 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

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(10) Dr. Ralph C. Cavalli is our Vice President of Quality Control who beneficially owns 60,000 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	2009	06/11/10	$0.66	20,000	06/11/20
	2009	09/23/11	$0.37	40,000	09/15/21
Total Options				60,000	

(11) Ronald Ritz was our Senior Director of Manufacturing (joining the Company effective February 11, 2011 and separating on February 10, 2012) who beneficially owns 39,032 shares.

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

Review, Approval or Ratification of Transactions with Related Persons

Our policy is to require that any transaction with a related party required to be reported under applicable SEC rules, other than compensation related matters and waivers of our code of business conduct and ethics, be reviewed and approved or ratified by a majority of independent, disinterested Directors. We have adopted procedures in which the Audit Committee shall conduct an appropriate review of all related party transactions for potential conflict of interest situations on an annual and case-by-case basis with the approval of this Committee required for all such transactions.

We have employment agreements with certain of our executive officers and have granted such Officers and Directors options and warrants to purchase our common stock, as discussed under the headings, “ITEM 11. Executive Compensation,” and “ITEM 12. Security Ownership of Certain Beneficial Owners and Management,” as noted above.

During the quarter ended September 30, 2011, our internal controls identified a misstatement in our prior public disclosures, including within the NOTES TO CONSOLIDATED FINANCIAL STATEMENTS of our Annual Report on Form 10-K for the year ended December 31, 2010. A Related Party transaction was accurately reported that we paid Retreat House, LLC $123,200 in 2010 for the use of the property at various times for off-site meetings and lodging. It was determined in September 2011 that the property was owned individually by Dr. William A. Carter, our Chief Executive Officer, through April 28, 2010, at which time it was transferred to Retreat House, LLC, a Virginia limited liability company that is owned by three of the children of William A. Carter and a Senior Primary Revocable Trust in which William A. Carter is the Trustee. Dr. Carter also is the Manager of Retreat House, LLC. It had been

previously reported by the Company that Retreat House, LLC was an entity wholly owned by the five children of our CEO, William A. Carter and that Retreat House LLC was owner of the property since 2004; these statements were inaccurate. We paid Retreat House, LLC $137,200 and $123,200 in 2011 and 2010, respectively, for the use of the property at various times for use of the property, off-site meetings and lodging. Upon analysis in the Fall of 2011 by the Audit Committee's Financial Expert, we were unable to gain assurance that the fees charged for conference and lodging by the Retreat House, LLC were reasonable when compared to commercially available alternatives in the same geographic market. As a result and effective November 15, 2011, Dr. Carter agreed to designate the property owned by Retreat House, LLC as both his home office and as a meeting place for a variety of Company business and social activities at no additional expense to the Company and agreed not to bill, either personally or through Retreat House LLC, or any other entity, for use of the Retreat House. Additionally, Dr. Carter shall be responsible for paying for all secretarial and receptionist services related to his work conducted in Florida and provide said services at no further expense to the Company. In return as reflected in his Amended Employment Contract, Dr. Carter was granted an increase in his base salary compensation and the Company shall supply the equipment necessary for full telephone, telefax, computer and internet access.

For her part-time services to us as Assistant Medical Director, Katalin Kovari, M.D. was paid $28,000 and $26,000 in 2011 and 2010, respectively. Dr. Kovari is the spouse of Dr. William A. Carter, our CEO.

On September 19, 2011, we engaged Peter Kovari as an independent consultant related to coordinating, programming, analyzing and evaluating clinical for the Company at the rate of $20 per hour. For the year ended 2011, we paid Mr. Kovari $5,760. Mr. Kovari is the nephew of Dr. Katalin Kovari, spouse of Dr. William Carter, our CEO.

In December 2011, the Compensation Committee passed an exception to the Nepotism Policy and approved the full-time hiring of Kyle Carter as a Data Control Clerk at the annual salary of $37,950. Kyle Carter is the son of Dr. William A. Carter, our CEO.

Thomas Equels was elected to the Board of Directors at the Annual Stockholders Meeting on November 17, 2008 and join the Company as an Officer effective June 1, 2010. 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 2011 and 2010, we paid Equels Law Firm approximately $144,000 and $729,000 respectfully, for services rendered. Upon analysis in the Fall of 2011 by the Audit Committee's Financial Expert, it was deemed that the hourly rates charged by Equels Law were reasonable when compared to the fee structure of a possible arms-length transaction from comparable firms in practice in the same market and of the similar size.

Richard C. Piani has been a Director since 1995 and our Lead director since April, 2005. For the benefit of our foreign subsidiary, Hemispherx Biopharma Europe N.V./S.A., the Company subleases a 2,000 square foot, fully furnished and equipped office with part-time administrative assistance located at 97 Rue Jean Jaures, Levallois, Perret, France (a suburb of Paris). The landlord for this sub-lease is Synholon Corporation, of which the son of Richard Piani is affiliated. For our convenience and benefit, we pay $3,000 each month to Mr. Piani to reimburse him for his direct rental of this office facility. For 2011 and 2010, we reimbursed Mr. Piani approximately $48,000 each respective year for the rental of this office. Upon analysis in the Fall of 2011 by the Audit Committee's Financial Expert, it was deemed that the rental fee charged to the Company was reasonable as compared to a possible arms-length transaction with comparable office facilities in the same geographic vicinity for similar commercial space of comparable quality and size in the same market.

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 2011 and 2010 were $274,750 and $304,000, respectively. The following table shows the aggregate fees for professional services rendered during the year ended December 31, 2011 and 2010.

	Amount ($)	
Description of Fees:	2011	2010*

Audit Fees	$268,250	$270,000
Audit-Related Fees	6,500	34,000
Tax Fees	0	0
All Other Fees	0	0
Total	$274,750	$304,000

* Includes fees related to the restatement of our audited financial statements for the fiscal year ended December 31, 2009 along with the quarterly unaudited financial statements for 2011 and 2010.

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 2011 and 2010.

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 (11)
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. (7)
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.
10.3	Biken Activating Agreement. (6)
10.4	Biken Material Evaluation Agreement. (6)
10.5	Employee Wage Or Hours Reduction Program. (7)
10.6	Standby Financing Agreement. (7)
10.7	Goal Achievement Incentive Award Program. (8)
10.8	Form of Securities Purchase Agreement entered into on May 10, 2009. (1)
10.9	Form of Securities Purchase Agreement entered into on May 18, 2009. (5)
10.10	Amended and Restated Employment Agreement with Robert Dickey IV, dated September 1, 2010. (9)
10.11	Supply Agreement with Hollister-Stier Laboratories LLC dated December 5, 2005. (10)
10.12	Amendment to Supply Agreement with Hollister-Stier Laboratories LLC dated February 25, 2010. (11)
10.13	Amended and Restated Employment Agreement of Dr. William A. Carter dated June 11, 2010 (10)
10.14	Vendor Agreement with Bio Ridge Pharma, LLC dated August 11, 2011.(14) (Confidential Treatment granted with respect to portions of the Agreement).
10.15	Vendor Agreement with Armada Healthcare, LLC dated August 11, 2011. (14) (Confidential Treatment granted with respect to portions of the Agreement).
10.16	Amended and restated employment agreement with Wayne Springate dated May 1, 2011. (13)
10.17	Amended and restated employment agreement with Ralph Christopher Cavalli dated September 15, 2011. (15)
10.18	Amended and restated employment agreement with William A. Carter dated December 6, 2011. (16)
10.19	Amended and restated employment agreement with Thomas K. Equels dated December 6, 2011. (16)
10.20	Amended and restated employment agreement with Charles T. Bernhardt dated December 6, 2011. (16)
10.21	Second Amended and Restated Advisor’s Agreement with The Sage Group dated December 14, 2011. *
10.22	Amendment to Supply Agreement with Hollister-Stier Laboratories LLC executed September 9, 2011. * (Confidential portions of this exhibit have been redacted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended).
21	Subsidiaries of the Registrant. *
23.1	McGladrey & Pullen, LLP consent. *
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer. *
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer. *
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer. *
32.2	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer. *
101	The following materials from Hemispherx’ Annual Report on Form 10-K for the year ended December 31, 2011, formatted in eXtensible Business Reporting Language (“XBRL”): (i) the Condensed Consolidated Statements of Income; (ii) the Condensed Consolidated Balance Sheets; (iii) the Condensed Consolidated Statements of Cash Flows; and (iv) Notes to Condensed Consolidated Financial Statements.

* 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 June 24, 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 Current Report on Form 8-K (No. 1-13441) dated December 13, 2007 and is hereby incorporated by reference.

(7) 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.

(8) 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.

(9) 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.

(10) 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, 2005 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, 2009 and is hereby incorporated by reference.

(12) 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.

(13) 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, 2011 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 September 30, 2011 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 September 23, 2011 and is hereby incorporated by reference.

(16) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) filed December 12, 2011 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 14, 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, Director, Chief Executive Officer, President and Chief Scientific Officer	March 14, 2011
/s/ Richard Piani Richard Piani	Director	March 14, 2011
/s/ Charles T. Bernhardt Charles T. Bernhardt CPA	Chief Financial Officer and Chief Accounting Officer	March 14, 2011
/s/ Thomas K. Equels Thomas Equels	Executive Vice Chairman of the Board, Director, Secretary and General Counsel	March 14, 2011
/s/ William Mitchell	Director	March 14, 2011

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

/s/ Iraj E. Kiani Iraj E. Kiani, N.D., Ph.D.	Director	March 14, 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, 2011 and 2010, and the related consolidated statements of comprehensive loss, changes in stockholders' equity and comprehensive loss and cash flows for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, 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 14, 2012, 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 14, 2012

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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, 2011, 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, 2011 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, 2011 consolidated financial statements of Hemispherx Biopharma, Inc. and our report dated March 14, 2012 expressed an unqualified opinion.

/s/ McGladrey & Pullen, LLP
Blue Bell, Pennsylvania
March 14, 2012

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

December 31, 2011 and 2010

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

	2011	2010
ASSETS		
Current assets:		
Cash and cash equivalents	$3,103	$2,920
Marketable securities- unrestricted	26,229	32,689
Marketable securities- restricted	1,026	0
Inventories	897	787
Prepaid expenses and other current assets	531	278
Total current assets	31,786	36,674
Property and equipment, net	5,276	4,876
Patent and trademark rights, net	863	794
Marketable securities unrestricted	1,958	8,778
Marketable securities- restricted	2,075	0
Construction in progress	1,484	485
Other assets	71	73
Total assets	$43,513	$51,680
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,681	$1,328
Accrued expenses	1,644	1,443
Margin Account Loan	1,695	0
Current portion of capital lease	49	61
Total current liabilities	5,069	2,832
Long-term liabilities:		
Long-term portion of capital lease	99	96
Redeemable warrants	380	2,805
Total liabilities	5,548	5,733
Commitments and contingencies (Notes 11, 13, 14, 20 & 21)		

Stockholders' equity :		
Preferred stock, par value $0.01 per share, authorized 5,000,000; issued and outstanding; none	0	0
Common stock, par value $0.001 per share, authorized 350,000,000 shares in 2011, and 200,000,000 in 2010; issued and outstanding 135,642,303 and 135,241,609, respectively	136	135
Additional paid-in capital	264,958	264,511
Unrealized loss	(389)	(974)
Accumulated deficit	(226,740)	(217,725)
Total stockholders' equity	37,965	45,947
Total liabilities and stockholders' equity	$43,513	$51,680

See accompanying notes to consolidated financial statements.

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss

(in thousands, except share and per share data)

	Years ended December 31,		
	2011	2010	2009
Revenues:			
Clinical treatment programs	$161	$135	$111
Total Revenues	161	135	111
Costs and Expenses:			
Production/cost of goods sold	1,043	1,341	584
Research and development	6,722	7,613	6,995
General and administrative	6,691	7,568	5,796
Total Costs and Expenses	14,456	16,522	13,375
Operating loss	(14,295)	(16,387)	(13,264)
Interest and other income	624	2,383	67
Interest expense	(41)	(11)	0
Financing costs from standby financing agreement	0	0	(241)
Funds received from sale of income tax operating losses	2,272	0	0
Redeemable warrants valuation adjustment	2,425	879	6,258
Net loss	$(9,015)	$(13,136)	$(7,180)
Other Comprehensive Income:			
Unrealized losses on securities	(311)	(1,013)	0
Less: Premium amortization and realized losses	896	39	0
Net comprehensive loss	$(8,430)	$(14,110)	$(7,180)
Basic and diluted loss per share	$(.07)	$(.10)	$(.07)
Weighted average shares outstanding basic and diluted	135,432,395	134,018,243	109,514,401

See accompanying notes to consolidated financial statements.

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Loss

(in thousands except share data)

	Common Stock Shares	Common Stock .001 Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
Balance January 1, 2009	78,750,995	$ 79	$ 208,874	$ 0	$ (197,409)	$ 11,544
Shares issued for:						
Warrants exercised	5,589,790	6	6,133	0	0	6,139
Options exercised	293,831	0	130	0	0	130
Private placement, net of issuance costs	45,591,304	46	55,524	0	0	55,570
Settlement of accounts payable	1,925,408	2	1,365	0	0	1,367
Stock-based compensation	636,119	0	826	0	0	826
Standby Finance- finance costs	0	0	241	0	0	241
Redeemable warrants valuation adjustment	0	0	(9,942)	0	0	(9,942)
Net comprehensive loss	0	0	-	-	(7,180)	(7,180)
Balance December 31, 2009	132,787,447	133	263,151	0	(204,589)	58,695
Shares issued for:						
Settlement of accounts payable	498,867	0	329	0	0	329
Shares sold at the market	520,000	0	292	0	0	292
Stock-based compensation	1,435,295	2	739	0	0	741
Net comprehensive loss	0	0	0	(974))	(13,136)	(14,110)
Balance December 31, 2010	135,241,609	135	264,511	(974)	(217,725)	45,947
Shares issued for:						
Settlement of accounts payable and accrued expenses	145,440	0	71	0	0	71
Stock-based compensation	255,254	1	376	0	0	377
Net comprehensive loss	0	0	0	585)	(9,015)	(8,430)
Balance December 31, 2011	135,642,303	$ 136	$ 264,958	$ (389)	$ (226,740)	$ 37,965

See accompanying notes to consolidated financial statements

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(in thousands)

	Years ended December 31		
	2011	2010	2009
Cash flows from operating activities: Net loss	$(9,015)	$(13,136)	$(7,180)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of property and equipment	465	407	359
Amortization of patent, trademark rights, and royalty interest	165	373	381
Finance costs amortization and for Standby Financing	0	0	241
Redeemable warrants valuation adjustment	(2,425)	(879)	(6,258)
Equity based compensation (stock option, warrant and service expense)	377	740	826
Other-than-temporary impairment of marketable securities	69	0	0
Gain on disposal of equipment	0	0	(83)
Changes in assets and liabilities:			
Inventories	(110)	77	0
Prepaid expenses and other current assets	(253)	54	93
Other assets	6	(7)	(5)
Accounts payable	424	362	1,884
Accrued expenses	201	123	445
Net cash used in operating activities	(10,096)	(11,886)	(9,297)
Cash flows from investing activities:			
Purchases of property, equipment and construction in progress	(1,802)	(729)	(332)
Additions to patent and trademark rights	(234)	(337)	(242)
Deposits on capital leases	(4)	(9)	0
Maturities of short-term and long-term investments	20,896	7,448	0
Purchase of short-term and long-term investments	(10,201)	(49,889)	0
Net cash provided by (used in) investing activities	$8,655	$(43,516)	$(574)

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows (Continued)

(in thousands)

	Years ended December 31,		
	2011	2010	2009
Cash flows from financing activities:			
Proceeds from sale of common stock, net of issuance costs	$0	$293	$55,570
Payments on capital leases	(71)	(43)	0
Proceeds from Margin Account Loan	1,695	0	0
Proceeds from exercise of stock warrants and options	0	0	6,254
Net cash provided by financing activities	1,624	250	61,824
Net (decrease) increase in cash and cash equivalents	183	(55,152)	51,953
Cash and cash equivalents at beginning of year	2,920	58,072	6,119
Cash and cash equivalents at end of year	$3,103	$2,920	$58,072
Supplemental disclosures of cash flow information:			
Issuance of common stock for accounts payable and accrued expenses	$71	$329	$1,382
Equipment acquired by capital leases	$62	$200	$0
Unrealized losses on investments	$(585)	$(974)	$0
Redeemable warrants valuation adjustment	$(2,425)	$(879)	$(6,258)
Supplemental disclosure of cash flow information:			
Cash paid for interest expense	$41	$11	$0

See accompanying notes to consolidated financial statements.

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) Business

Hemispherx Biopharma, Inc. (“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, 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 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 (“CRL”) from the U.S. Food and Drug Administration (“FDA”) of 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 based on the submission of new data concerning the potential viral etiology of CFS. In January 2012, the FDA granted an additional extension to file a response to the CRL. Unless communicated otherwise by the FDA, the extension will remain open while the Company continues to amend the NDA. The Company is currently conducting an open-label treatment protocol in the U.S. and evaluating new diagnostic modalities to provide additional insights into the CFS disorder. It is their plan that the new analyses and other insights will supplement the original study findings. The Company believes that continued efforts to understand existing data and to advance the development of new data and information, will ultimately support a re-filing of the NDA.

(2) Summary of Significant Accounting Policies

(a) Cash and Cash Equivalents

Cash and Cash Equivalents consist of cash and money market accounts and total $3,103,000 and $2,920,000 at December 31, 2011 and 2010, respectively.

(b) Marketable Securities

The Company’s securities are classified as available for sale and are stated at fair value. Unrealized gains and losses on securities available for sale are excluded from results of operations and are reported as other comprehensive income (loss), a separate component of shareholders’ equity, net of taxes. Securities classified as available for sale include securities that may be sold in response to changes in interest rates, changes in prepayment risks or for portfolio management purposes. The cost of securities sold is determined on a specific identification basis. Gains and losses on sales of securities are recognized in the statements of comprehensive loss on date of sale.

(c) Property and Equipment	(in thousands) December 31, 2011	2010
Land, buildings and improvements	$4,209	$4,193
Furniture, fixtures, and equipment	4,002	3,154
Leasehold improvements	85	85
Total property and equipment	8,296	7,432
Less: accumulated depreciation and amortization	(3,020)	(2,556)
Property and equipment, net	$5,276	$4,876

Property and equipment are recorded at cost. Depreciation and amortization are 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 Brunswick, NJ facility. As of December 31, 2011, construction in progress was $1,484,000 as compared to $485,000 at December 31, 2010.

(d) Patent and Trademark Rights

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

(e) Revenue

Revenue from the sale of Ampligen® under a cost recovery, open-label 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.

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

Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws in effect when the differences are expected to reverse. The measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance for any tax benefits which are not expected to be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

The Company applies the provisions of FASB ASC 740-10 Uncertainty in Income Taxes. 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.

(g) Comprehensive loss

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

(h) Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Actual results could differ from those estimates. Accounts requiring the use of significant estimates include valuation allowances for inventory, determination of other-than-temporary impairment on securities, valuation of deferred taxes, patent and trademark valuations, stock options calculations, building valuation, fair value of warrants and contingency accruals.

(i) Recent Accounting Standards and Pronouncements

In 2011, the Financial Accounting Standards Board (“FASB”) published FASB Accounting Standards Updates 2011-01 through 2011-12. With the exception of Update 2011-05, Management deemed them to have no material effect on the Company’s financial statements for the twelve months ended December 31, 2011. FASB Accounting Standards Update 2011-05, “Comprehensive Income (Topic 220)”, effective for fiscal years beginning after December 15, 2011, is related to the revision of the traditional “Consolidated Statements of Operation” to a “Consolidated Statement of Comprehensive Income”. In transitioning to this new presentation prior to the mandatory conversion date of 2012, Management deemed that the only material change to be the reflection of our “unrealized gain or (loss) on investments” after our traditional Net Loss reporting. For the reporting period ended December 31, 2011, the new Consolidated Statement of Comprehensive Loss reporting approach has been utilized for our presentation of financial results for both current and prior periods.

FASB ASU 2011-12, “Comprehensive Income (Topic 220) Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05” was issued in December 2011. ASU 2011-12 amends ASU 2011-05 to reflect only those changes that relate to the presentation of reclassification adjustments. The amendments are being made to allow the FASB time to re-deliberate whether to present on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income for all periods presented. While the FASB is considering the operational concerns about the presentation requirements for reclassification adjustments and the needs of financial statement users for additional information about reclassification

adjustments, entities should continue to report reclassifications out of accumulated other comprehensive income consistent with the presentation requirements in effect before Update 2011-05.

(j) Stock-Based Compensation

The Company accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, “Compensation – Stock Compensation”, which requires recognition of compensation expense related to stock-based compensation awards over the period during which an employee is required to provide service for the award. Compensation expense is equal to the fair value of the award, net of estimated forfeitures.

(k) Accounts Receivable

Concentration of credit risk, with respect to accounts receivable, is limited due to the Company’s credit evaluation process. The Company does not require collateral on its receivables. The Company did not have any receivables as of December 31, 2011 and 2010.

(l) 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 54,242,702 52,796,158 and 21,241,453 shares, are excluded from the calculation of diluted net loss per share for the years ended December 31, 2011, 2010 and 2009, 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)	
	2011	2010
Inventory work-in-process, January 1	$787	$0
Transfer from Other Assets	0	864
Production	302	373
Spoilage	(192)	(450)
Inventory work-in-process, December 31	$897	$787

The production of Alferon N Injection® from the Work-In-Process Inventory was restarted in May 2010, continued into January 2011 with its conversion into Active Pharmaceutical Ingredient ("API") and is completed for the related Final Lot Release Test. To formulate, fill, finish and package ("fill and finish") Alferon N Injection® Drug Product, the Company requires an FDA approved third party Contract Manufacturing Organization ("CMO"). The Work-In-Process Inventory has expiration dates of September 30, 2012 through March 10, 2013. Upon the expected mid-2012 completion of the fill and finish process, it is projected that Alferon N Injection® will then have an expected shelf life of 42 months. In January 2012, the Company agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea Technologies, Inc. ("Althea") regarding the fill and finish for Alferon N Injection®. Provided the Company receives a Release Approval from the FDA as to quality and consistency of its current inventory and final product, as well as Althea is successful in the fill and finish process, the Company estimates that commercial sales of Alferon N Injection® could commence in the later part of 2012. While at December 31, 2011 the Work-In-Process Inventory has no manufacturing steps to be undertaken at its New Brunswick, NJ facility, it will not be classified as Finished Goods until the fill and finish process is completed to create a product that can be commercially sold.

(4) Options

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 2009 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 in 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, life and forfeiture rates. The expected life of the options was estimated based on historical option holder's behavior and represents the period of time that options are expected to be outstanding. The fair values of the options granted, were estimated based on the following weighted average assumptions:

	December 31, 2011	2010	2009
Risk-free interest rate	0.83 - 2.24%	1.02 - 2.06%	1.76 - 2.69%
Expected dividend yield	0	0	0
Expected life	5 yrs.	5 yrs.	2 - 5 yrs.
Expected volatility	104.29%-105.91%	106.28%-110.01%	86.78-137.47%
Weighted average grant date fair value of options and warrants issued	$0.26 per option for	$0.42 per option for	$1.09 per option for 491,250

1,310,000 options	1,618,428 options	options

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, 2009, 2010 and 2011 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, 2009	6,258,608	$ 2.60	7.92	0
Granted	0	0	0	0
Forfeited	(29,856)	2.24	5.75	0
Outstanding December 31, 2009	6,228,752	$ 2.60	6.95	0
Granted	993,728	.80	9.42	0
Forfeited	0	0	0	0
Outstanding December 31, 2010	7,222,480	$ 2.35	6.21	0
Granted	1,030,000	.41	9.51	0
Forfeited	0	0	0	0
Outstanding December 31, 2011	8,252,480	$ 2.11	5.75	0
Vested and expected to vest at December 31, 2011	8,252,480	$ 2.11	5.75	0
Exercisable at December 31, 2011	8,104,147	$ 2.13	5.70	0

The weighted-average grant-date fair value of employee options granted during the year 2011 was $293,000 for 1,030,000 options at $0.28 per option, during the year 2010 was $441,000 for 993,728 options at $.44 per options and during 2009 no options were granted.

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2009	76,944	$ 1.41	3.89	0
Granted	0	0	0	0
Vested	(38,611)	1.28	7.92	0
Forfeited	0	0	0	0

Outstanding December 31, 2009	38,333	$ 1.54	8.00	0
Granted	20,000	0.66	9.50	0
Vested	(7,778)	0.66	9.50	0
Forfeited	0	0	0	0
Outstanding December 31, 2010	50,555	$ 1.33	7.60	0
Granted	140,000	0.33	9,93	0
Vested	(42,222)	0.95	7.38	0
Forfeited	0	0	0	0
Outstanding December 31, 2011	148,333	$ 0.49	9.52	0

The weighted-average grant-date fair value of employee unvested stock options granted during the year 2011 was $24,000 for 140,000 options at $0.17 per option, during the year 2010 was $9,000 for 20,000 options at $.45 per option and during 2009 no options were granted.

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, 2009	2,417,482	$ 2.35	6.98	0
Granted	361,250	2.12	7.00	0
Exercised	(293,831)	1.56	7.93	0
Forfeited	(251,469)	2.14	7.43	0
Outstanding December 31, 2009	2,233,432	$ 2.44	5.73	0
Granted	625,000	0.55	9.52	0
Exercised	0	0		0
Forfeited	(10,000)	2.46	0	0
Outstanding December 31, 2010	2,848,432	$ 2.03	5.80	0
Granted	280,000	0.27	9.88	0
Exercised	0	0	0	0
Forfeited	0	0	0	0
Outstanding December 31, 2011	3,128,432	$ 1.87	5.25	0
Vested and expected to vest at December 31, 2011	3,128,432	$ 1.87	5.25	0
Exercisable at December 31, 2011	2,872,182	$ 1.97	5.12	0

The weighted-average grant-date fair value of non-employee options granted during the year 2011 was $51,000 for 280,000 options at $0.18 per option, during the year 2010 was $233,000 for 625,000 options at $.37 per options and during the year 2009 was $458,788 for 361,250 options at $1.27 per option.

Unvested stock option activity for non-employees:

Number of Options	Weighted Average Exercise Price	Weighted Average Remaining	Aggregate Intrinsic Value

			Contracted Term (Years)	
Outstanding January 1, 2009	26,667	$ 1.43	9.00	0
Granted	131,250	2.81	3.42	0
Vested	(18,333)	1.79	7.45	0
Forfeited	0	0	0	0
Outstanding December 31, 2009	139,584	$ 2.68	3.76	0
Granted	0	0	0	0
Vested	(37,500)	2.81	2.50	0
Forfeited	0	0	0	0
Outstanding December 31, 2010	102,084	$ 2.63	3.54	0
Granted	200,000	0.21	10.00	0
Vested	(45,834)	2.81	1.50	0
Forfeited	0	0	0	0
Outstanding December 31, 2011	256,250	$ 0.71	8.55	0

The impact on the Company's results of operations of recording stock-based compensation for the year ended December 31, 2011 was to increase general and administrative expenses by approximately $377,000 and reduce earnings per share by $0.00 per basic and fully diluted share, for 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 fully diluted share and for year ended December 31, 2009 was to increase general and administrative expenses by $353,000 and reduce earnings per share by $.01 per basic and fully diluted share.

As of December 31, 2011, there was $147,000 of unrecognized stock-based compensation cost related to options granted under the Equity Incentive Plans.

(5) Marketable Securities - Unrestricted

Marketable securities consist of fixed income securities with remaining maturities of greater than three months at the date of purchase, debt securities and equity securities. For the twelve months ended December 31, 2011 and 2010, it was determined that some of the Marketable Securities had other than temporary impairments of approximately $69,000 and $-0-, respectively, which has been included with interest and other income for reporting purposes. At December 31, 2011, all of these securities were classified as available for sale investments and $26,022,000 were measured as Level 1 instruments and $2,165,000 were measured as level 2 instruments of the fair value measurements standard (see Note 19: Fair Value).

Securities classified as available for sale consisted of:

December 31, 2011

(in thousands)

Securities	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 22,087	$ 0	$ (334)	$ 21,753	$ 21,753	$ 0
Certificates of Deposit	2,155	10	0	2,165	1,707	458
Corporate Bonds	4,320	0	(51)	4,269	2,769	1,500
Totals	$ 28,562	$ 10	$ (385)	$ 28,187	$ 26,229	$ 1,958

December 31, 2010

(in thousands)

Securities	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 22,200	$ 0	$ (490)	$21,710	$ 21,710	$ 0
Certificates of Deposit	4,327	12	(5)	4,334	2,052	2,282
Corporate Bonds	13,092	0	(444)	12,648	8,173	4,475
Foreign Bonds	2,822	0	(47)	2,775	754	2,021
Totals	$ 42,441	$ 12	$ (986)	$41,467	$ 32,689	$ 8,778

Unrealized losses on investments

Investments with continuous unrealized losses for less than 12 months and 12 months or greater and their related fair values were as follows:

December 31, 2011

(in thousands)

Securities	Total Number In Loss Position	Less Than 12 Months		12 Months or Greater		Totals	
		Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	1	$0	$ 0	$21,753	$ (334)	$21,753	$ (334)
Certificates of Deposit		0	0	0	0	0	0
Corporate Bonds	4	997	(16)	3,272	(35)	4,268	(51)
Totals	5	$997	$ (16)	$25,025	$ (369)	$26,021	$ (385)

December 31, 2010

(in thousands)

Securities	Total Number In Loss Position	Less Than 12 Months		12 Months or Greater		Totals	
		Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	1	$21,710	$ (490)	$0	$ 0	$21,710	$ (490)
Certificates of Deposit	5	721	(5)	0	0	721	(5)
Corporate Bonds	15	12,649	(444)	0	0	12,649	(444)
Foreign Bonds	3	2,775	(47)	0	0	2,775	(47)
Totals	24	$37,855	$ (986)	$0	$ 0	$37,855	$ (986)

Unrealized losses from fixed-income securities (bonds) are primarily attributable to changes in interest rates and/or a reduction in their rating of credit worthiness as determined by independent financial rating services. Unrealized losses from domestic and international equities are due to market price movements. Management does not believe any remaining losses represent other-than- temporary impairment based on our evaluation of available evidence as of

December 31, 2011.

Realized gains, realized losses and other-than-temporary impairment totaled $203, $(713), and $69 for 2011 and $19, $(58), and $0 for 2010, respectively.

(6) Marketable Securities - Restricted

A Margin Account was established on July 26, 2011 for which the Company needs to pledge, restrict from sale and segregate marketable securities at an approximate ratio of two to one to serve as collateral for those funds withdrawn and outstanding (see Note 21: Margin Account Loan).

These restricted marketable securities consist of corporate bonds with remaining maturities of greater than three months at the date of purchase, debt securities and bond funds. As of December 31, 2011, it was determined that none of the Marketable Securities had other-than-temporary impairments. At December 31, 2011, all restricted securities were classified as restricted from sale investments and $3,101,000 was measured as level 1 instruments of the fair value measurements standard (see Note 19: Fair Value).

Securities classified as restricted from sale consisted of:

December 31, 2011

(in thousands)

Securities	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Corporate Bonds	$ 3,115	$ 0	$ (14)	$3,101	$ 1,026	$ 2,075
Totals	$ 3,115	$ 0	$ (14)	$3,101	$ 1,026	$ 2,075

There were no restricted marketable securities as of December 31, 2010.

Unrealized losses on investments restricted from sale

Investments restricted from sale with continuous unrealized losses for less than 12 months and 12 months or greater and their related fair values were as follows:

December 31, 2011

(in thousands)

	Less Than 12 Months		12 Months or Greater		Totals	
Securities	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Corporate Bonds	$2,075	$ (14)	$0	$ 0	$2,075	$ (14)
Totals	$2,075	$ (14)	$0	$ 0	$2,075	$ (14)

Unrealized losses from fixed-income securities (bonds) are primarily attributable to changes in interest rates and/or a reduction in their rating of credit worthiness as deemed by independent financial rating services. Unrealized losses from domestic and international equities are due to market price movements. Management does not believe any remaining losses represent other than temporary impairment based on our evaluation of available evidence as of December 31, 2011.

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

During the years ended December 31, 2011, 2010 and 2009, the Company decided not to pursue certain patents in various countries for strategic reasons and recorded abandonment charges of $147,000, $198,000 and $228,000 respectively, which are included in research and development. Amortization expense was $17,000, $176,000 and $153,000 in 2011, 2010 and 2009, respectively. The total cost of the patents was $967,000 and $1,100,000 as of December 31, 2011 and 2010, respectively. The accumulated amortization as of December 31, 2011 and 2010 is $104,000 and $306,000, respectively. In 2011, additions to patent costs were $234,000 and adjustments for fully amortized and abandoned patents had costs of $367,000 and accumulated amortization of $220,000. In 2010, additions to patent costs for patent maintenance were $337,000 and adjustments for fully amortized and abandoned patents had costs of $1,052,000 and accumulated amortization of $854,000.

Amortization of patents and trademarks for each of the next five years is as follows: 2012 - $17,000; 2013 - $17,000; 2014 – $17,000; 2015 - $17,000; and 2016 - $17,000.

(8) Accrued Expenses

Accrued expenses at December 31, 2011 and 2010 consists of the following:

	(in thousands) December 31,	
	2011	2010
Compensation	$821	$995
Professional fees	215	207
Other expenses	495	128
Other liability	113	113
	$1,644	$1,443

(9) Stockholders' Equity

(a) Preferred Stock

The Company is authorized to issue 5,000,000 shares of $0.01 par value preferred stock with such designations, rights and preferences as may be determined by the Board of Directors. There were no Preferred Shares issued and outstanding at December 31, 2011 and 2010.

(b) Common Stock

The Company’s stockholders approved an amendment to the Company’s corporate Charter at the Annual Shareholder Meeting held in Philadelphia, PA that concluded on December 8, 2011. This amendment increased the Company’s authorized shares from 200,000,000 to 350,000,000 with specific limitations and restrictions on the usage of those newly authorized shares.

As of December 31, 2011 and 2010, 135,642,303 shares and 135,241,609, shares were outstanding, respectively.

(c) Equity Financings

On May 8, 2009, the Company 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, the Company entered into Securities Purchase Agreements with two institutional investors. Pursuant to the Securities Purchase Agreements, the Company issued to these investors in the aggregate: (a) 13,636,363 shares of our common stock; (b) Series I warrants to purchase an additional 6,136,363 shares of common stock at an exercise price of $1.65 per share (“Series I Warrants”); and (c) Series II warrants to purchase up to 3,000,000 shares of common stock at an exercise price of $1.10 per share (“Series II Warrants”, and together with the Series I Warrants, the “Warrants”). The 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, 2011, all Series II Warrants have been 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 outstanding 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. As of December 31, 2011, none of the Series I Warrants have been exercised.

On May 18, 2009, the Company entered into Securities Purchase Agreements with two institutional investors. Pursuant to the Securities Purchase Agreements, the Company issued to these investors in the aggregate: (a) 11,906,976 shares of common stock; and (b) warrants to purchase an additional 4,167,440 shares of common stock at an exercise price $1.31 per share ("Warrants"). The Warrants 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, 2011, 1,895,000 of these Warrants had been exercised.

Rodman, as placement agent for the May 18, 2009 Securities Purchase Agreements 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, 2011, none of the Warrants have been exercised.

Pursuant to their May 28, 2010 Equity Distribution Agreement (the "Agreement") with Maxim Group LLC ("Maxim"), they established an At-The-Market ("ATM") Equity Program pursuant to which the Company may sell up to 32,000,000 shares of their Common Stock from time to time through Maxim as their 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. The Company has no obligation to sell any shares under this program, and may at any time terminate the Agreement. During the twelve months ended December 31, 2011, the Company sold no shares through this program and received no net cash proceeds. All sales related to the ATM took place in 2010. As of December 31, 2011, the Company had sold an aggregate of 520,000 shares through the ATM that resulted in net cash proceeds of approximately $293,000 and commissions paid to Maxim of approximately $12,000.

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

(d) Common Stock Options and Warrants

(i) Stock Options

The 1990 Stock Option Plan provides for the grant of options to purchase up to 460,798 shares of the Company's Common Stock to employees, Directors, and Officers of the Company and to consultants, advisors, and other persons whose contributions are important to the success of the Company. The recipients of options granted under the 1990 Stock Option Plan, the number of shares to be converted by each option, and the exercise price, vesting terms, if any, duration and other terms of each option shall be determined by the Company's Board of Directors or, if delegated by

the Board, its Compensation Committee. No option is exercisable more than 10 years and one month from the date as of which an option agreement is executed. These shares become vested through various periods not to exceed four years from the date of grant. The option price represents the fair market value of each underlying share of Common Stock at the date of grant, based upon the public trading price. This plan is no longer in effect and no further options will be issued from this plan.

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

	2009			2010			2011		
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price
Outstanding, beginning of year	345,728	$ 2.71-4.03	$ 3.01	335,728	$ 2.71-4.03	$ 2.98	262,000	$ 2.75-4.03	$ 3.05
Granted	0	0	0	0	0	0	0	0	0
Canceled	(10,000)	$ 4.03	$ 4.03	(73,728)	$ 2.71	0		0	0
Exercised	0	0	0	0	0	0	0	0	0
Outstanding, end of year	335,728	$ 2.71-4.03	$ 2.98	262,000	$ 2.75-4.03	$ 3.05	262,000	$ 2.75-4.03	$ 3.05
Exercisable	335,728	$ 2.71-4.03	$ 2.98	262,000	$ 2.75-4.03	$ 3.05	262,000	$ 2.75-4.03	$ 3.05
Weighted average remaining contractual life (years)	3.86 yrs.			2.86 yrs.			1.86 yrs.		
Exercised in current and prior years	(27,215)			(27,215)			(27,215)		
Available for future grants	0			0			0		

In December 1992, the Board of Directors approved the 1992 Stock Option Plan (the 1992 Stock Option Plan) which provides for the grant of options to purchase up to 92,160 shares of the Company's Common Stock to employees, Directors, and Officers of the Company and to consultants, advisors, and other persons whose contributions are important to the success of the Company. The recipients of the options granted under the 1992 Stock Option Plan, the number of shares to be covered by each option, and the exercise price, vesting terms, if any, duration and other terms of each option shall be determined by the Company's Board of Directors. No option is exercisable more than 10 years and one month from the date as of which an option agreement is executed. To date, no options have been granted under the 1992 Stock Option Plan.

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

The 1993 Purchase Plan is administered by the Compensation Committee of the Board of Directors. Under the 1993 Purchase Plan, Company employees are eligible to participate in semi-annual plan offerings in which payroll deductions may be used to purchase shares of Common Stock. The purchase price for such shares is equal to the lower of 85% of the fair market value of such shares on the date of grant or 85% of the fair market value of such shares on the date such right is exercised. There have been no offerings under the 1993 Purchase Plan to date and no shares of Common Stock have been issued thereunder.

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 Incentive Plan. Unless sooner terminated, the Equity Incentive Plan will continue in effect for a period of 10 years from its effective date.

The Equity Plan is administered by the Board of Directors. The Equity Incentive Plan provides 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 Equity Plan 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 Equity Incentive Plan 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 shareholders 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 in control.

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

	December 31, 2009			December 31, 2010			December 31, 2011		
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price
Outstanding beginning at year	7,226,090	$ 0.68-6.00	$ 2.59	6,650,934	$ 1.30-6.00	$ 2.66	6,640,934	$ 1.30-6.00	$ 2.66
Granted	0	0	0	0	0	0	0	0	0
Canceled	(281,325)	$ 0.68– 2.20	$ 1.86	(10,000)	2.46	0	0	0	0
Exercised	(293,831)	$ 0.68-2.20	$ 1.56	0	0	0	0	0	0
Outstanding end of year	6,650,934	$ 1.30-6.00	$ 2.66	6,640,934	$ 1.30-6.00	$ 2.66	6,640,934	$ 1.30-6.00	$ 2.66
Exercisable	6,604,267	$ 1.30-6.00	$ 2.66	6,594,267	$ 1.30-6.00	$ 2.66	6,625,934	$ 1.30-6.00	$ 2.66
Weighted average remaining contractual life (years)	6-7 yrs.			5-6 yrs.			4-5 yrs.		

Available for future grants	5.575	10,019	10,019

On June 20, 2007, the Stockholders approved the 2007 Equity Incentive Plan at our Annual Shareholder Meeting. This plan, effective June 1, 2007, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other awards. A maximum of 9,000,000 shares of common stock is reserved for potential issuance pursuant to awards under this plan. Unless sooner terminated, this plan will continue in effect for a period of 10 years from its effective date. As of year-end, option awards under this plan were:

	December 31, 2009			December 31, 2010			December 31, 2011		
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price
Outstanding beginning at year	1,450,000	$ 2.20	$ 2.20	1,530,000	$ 0.72-3.05	$ 2.19	1,550,000	$ 0.72-3.05	$ 2.17
Granted	80,000	$ 0.72-3.05	$ 1.96	20,000	$ 0.89	$ 0.89	0	0	0
Canceled	0	0	0	0	0	0	0	0	0
Exercised	0	0	0	0	0	0	0	0	0
Outstanding end of year	1,530,000	$ 0.72-3.05	$ 2.19	1,550,000	$ 0.72 –3.05	$ 2.17	1,550,000	$ 0.72 –3.05	$ 2.17
Exercisable	1,530,000	$ 0.72-3.05	$ 2.19	1,550,000	$ 0.72-3.05	$ 2.17	1,550,000	$ 0.72-3.05	$ 2.17
Remaining contractual life	8.1 years			7.81 years			6.81 years		
Available for future grants	107,225			19,626			19,626		

On June 24, 2009, the Stockholders approved the 2009 Equity Incentive Plan at our Annual Shareholder Meeting. This plan, effective September 15, 2009, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other awards. A maximum of 15,000,000 shares of common stock is reserved for potential issuance pursuant to awards under this plan. Unless sooner terminated, this plan will continue in effect for a period of 10 years from its effective date. As of year-end, option awards under this plan were:

	December 31, 2009			December 31, 2010			December 31, 2011		
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price
Outstanding beginning	0	0	$0	281,250	$ 1.42-2.81	$2.16	1,879,978	$ 0.52-2.81	$.92

at year									
Granted	281,250	$ 1.42-2.81	$2.16	1,598,758	$ 0.52-2.71	$0.70	1,310,000	$ 0.21-0.55	$0.38
Canceled	0	0	0	0	0	0	0	0	0
Exercised	0	0	0	0	0	0	0	0	0
Outstanding end of year	281,250	$ 1.42-2.81	$2.16	1,879,978	$ 0.52–2.81	$.92	3,189,978	$ 0.21 –2.81	$0.70
Exercisable at end of year	281,250	$ 1.42-2.81	$2.16	1,879,978	$ 0.52-2.81	$.92	2,856,645	$ 0.21-2.81	$1.57
Remaining contractual life	9.5 years			8.1 years			6.81 years		
Available for future grants	13,642,525			11,618,085			9,765,847		

(ii) Stock Warrants

Information regarding warrants outstanding and exercisable into shares of common stock is summarized below:

	December 31, 2009			December 31, 2010			December 31, 2011		
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price
Outstanding beginning at year	5,266,187	$ 0.35-4.25	$3.13	11,008,246	$ 0.51-3.60	$1.44	10,983,246	$ 0.51-3.60	$ 1.61
Granted	15,821,080	$ 0.51-1.65	$1.44	0	0	0	0	0	0
Canceled	(3,347,777)	$ 2.08-4.25	$3.37	(25,000)	$ 2.50	$2.50	(5,000)	$ 3.60	$ 3.60
Exercised	(6,753,244)	$ 0.35-3.33	$1.56	0	0	0	0	0	0
Outstanding end of year	11,008,246	$ 0.51-3.60	$1.44	10,983.246	$ 0.51 –3.60	$1.61	10,978.246	$ 0.51 –1.65	$ 1.55
Exercisable	11,008,246	$ 0.51-3.60	$1.44	10,983,246	$ 0.51-3.60	$1.61	10,978,246	$ 0.51-1.65	$ 1.55
Weighted average remaining contractual life	4.5 years			3.9 years			2.9 years		
Years exercisable	2010-2019			2011-2019			2012-2019		

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

Net proceeds received from the exercise of stock warrants were $6,139,000 for 2009. No warrants were exercised during 2010 or 2011.

(e) Rights Offering

On November 19, 2002, the Board of Directors of the Company declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002 (the "Record Date"). Each Right entitles the registered holder to purchase from the Company a unit consisting of one one-hundredth of a share (a "Unit") of Series A Junior Participating Preferred Stock, par value $.01 per share (the "Series A Preferred Stock") at a Purchase Price of $30.00 per Unit, subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement (the "Rights Agreement") between the Company and Continental Stock Transfer & Trust Company, as Rights Agent.

Initially, the Rights are attached to all Common Stock certificates representing shares then outstanding, and no separate Rights Certificates will be distributed. Subject to certain exceptions specified in the Rights Agreement, the Rights will separate from the Common Stock and a Distribution Date will occur upon the earlier of (i) 10 days following a public announcement that a person or group of affiliated or associated persons (an "Acquiring Person") has acquired beneficial ownership of 15% or more (or 20% or more for William A. Carter, M.D.) of the outstanding shares of Common Stock (the "Stock Acquisition Date"), other than as a result of repurchases of stock by the Company or certain inadvertent actions by institutional or certain other stockholders or (ii) 10 business days (or such later date as the Board shall determine) following the commencement of a tender offer or exchange offer that would result in a person or group becoming an Acquiring Person. Until the Distribution Date, (i) the Rights will be evidenced by the Common Stock certificates and will be transferred with and only with such Common Stock certificates, (ii) new Common Stock certificates issued after the Record Date will contain a notation incorporating the Rights Agreement by reference and (iii) the surrender for transfer of any certificates for Common Stock outstanding will also constitute the transfer of the Rights associated with the Common Stock represented by such certificate. Pursuant to the Rights Agreement, the Company reserves the right to require prior to the occurrence of a triggering event that, upon any exercise of Rights, a number of Rights be exercised so that only whole shares of Preferred Stock will be issued.

(10) Segment and Related Information

The Company operates in one segment, which performs research and development activities related to Ampligen® and other drugs under development, and sales and marketing of Alferon®. The Company's revenues for the three year period ended December 31, 2011, were earned in the United States.

The Company employs an insignificant amount of net property and equipment in its foreign operations, which has minimal activity.

(11) Research, Consulting and Supply Agreements

On June 6, 2008, the Company engaged the services of Warren C. Bogard, Jr., Ph.D. as a consultant for Business and Product. Dr. Bogard had agreed to spend at least 70% of his time working on product and business development matters. His compensation from the agreement included $5,000 per work week and 100,000 stock options with a five year term exercisable at $0.68 per share. Dr. Bogard was a participant in the Goal Achievement Incentive Award Program and consistent with the Company's "Employee Wage Or Hours Reduction Program", he elected to receive 50% of his fee in Incentive Rights on a three-to-one conversion basis for the period of January 1 to May 31, 2009. His agreement expired May 31, 2009 and had been extended by informal mutual consent through March 2011. The Company incurred approximately $132,000, $307,000 and $365,000 in fees for the years ended December 31, 2011, 2010 and 2009.

The Biken Material Evaluation Agreement ("MEA") concluded on September 1, 2010 and had been effectively extended through December 1, 2010 in order to determine whether the parties could agree on the next phase of the collaboration, which included, without limitation, a proposed clinical trial. In April 2011, the Company received correspondence from Biken confirming that the MEA had expired without completion of the Evaluation Program along with their intention not to extend or replace the expired MEA with another agreement. Biken (the for profit operational arm of the Foundation for Microbial Diseases of Osaka University) had purchased Ampligen® for use in conducting animal studies of intranasal prototype vaccines containing antigens from influenza sub-types H1N1, H3N2 and B. The Company sold approximately $-0-, $-0- and $45,000, of specially formulated Ampligen® to Biken for the years ended December 31, 2011, 2010 and 2009, respectively.

Since October 2005, the Company has engaged the Sage Group, Inc. ("Sage"), a health care, technology oriented, strategy and transaction advisory firm, to assist the Company in obtaining a strategic alliance in Japan for the use of Ampligen® in treating Chronic Fatigue Syndrome ("CFS"). On December 14, 2011, the Company agreed to a Second Amended Adviser's Agreement for twenty-four months with The Sage Group, Inc. ("Sage"), effective June 15, 2011, that amends and supersedes all other agreements and arrangements between the parties. Further, this Agreement may

be terminated by the Company for cause after the Company delivers written notice to Adviser of a failure to perform and such failure is not cured within fifteen (15) days. Sage will assist the Company to identify, qualify, negotiate and close one or more licensing, partnering, alliance or similar transactions pertaining to the Company's products and technology including, but not limited to, any and all uses of Ampligen®, Alferon® and related intellectual property as well as acquisition of companies in whole or in part and the sale or the merger of Company ("Transactions"). In consideration for services performed or attributed to Sage resulting in Transactions, Sage is entitled to a monthly "Adviser's Fee" of $20,000, a one-time distribution of 200,000 Options that vest proportionately over 18 months with an exercise price of 110% of the closing price of the Company Stock on the NYSE Amex on the closing price of the day preceding the execution date of the agreement plus preapproved expenses along with the potential for a "Success Fee" of five percent (5%) of all consideration that is capped at $5,000,000 per annum for Transactions introduced to the Company by Sage. However, it is the intention of the parties that Sage be an active participant in all material Transactions of the Company. A Transaction can occur during the Term of the agreement or 18 months thereafter. The Company incurred approximately $314,000, $290,000 and $507,000 in fees to Sage for the years ended December 31, 2011, 2010 and 2009 respectively, pursuant to this and earlier agreements. R. Douglas Hulse, the Company's former President and Chief Operating Officer, is a member and an Executive Director of Sage.

On October 2, 2011, the Company finalized their Fourth Amendment to a Supply Agreement, effective through March 11, 2014, with Jubilant 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 Hemispherx would supply to them. The Company incurred approximately $-0-, $-0- and $225,000 in fees for the years ended December 31, 2011, 2010 and 2009, respectively, pursuant to this agreement.

On September 6, 2011 the Company executed an amended agreement with Armada Healthcare, LLC (“Armada”) to undertake the marketing, education and sales of Alferon N Injection® throughout the United States. Armada will also provide start up and ongoing sales and marketing support to the Company. The Company incurred no fees for the years ended December 31, 2011, 2010 and 2009, pursuant to original and amended agreements.

On September 6, 2011 the Company executed a new agreement with specialty distributor, BioRidge Pharma, LLC (”BioRidge”) to warehouse, ship, and distribute Alferon N Injection® on an exclusive basis in support of U.S. sales. The Company incurred approximately $5,250 fees for the year ended December 31, 2011, pursuant to the agreement.

The Company has entered into agreements for consulting services, which are performed at medical research institutions and by medical and clinical research individuals. The Company's obligation to fund these agreements can be terminated after the initial funding period, which generally ranges from one to three years or on an as-needed monthly basis. During the years ending December 31, 2011, 2010 and 2009, the Company incurred approximately $1,580,000, $1,607,000 and $801,000 respectively, of consulting service fees under these agreements. These costs are charged to research and development expense as incurred.

(12) 401(k) Plan

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

Each participant immediately vests in his or her deferred salary contributions, while Company contributions will vest over one year. The 6% Company matching contribution was terminated as of March 15, 2008 and then was reinstated effective January 1, 2010. For 2011, 2010 and 2009, the Company contributions towards the 401(k) Plan were $148,000, $122,000 and $-0- respectively.

(13) Royalties, License and Employment Agreements

The Company had contractual agreements with five Officers in 2011, four Officers in 2010 and two Officers at December 31, 2009. The aggregate annual base compensation for these Officers under their respective contractual agreements for 2011, 2010 and 2009 were $2,299,000, $2,369,000 and $928,000 respectively. In addition, certain of these Officers were entitled to receive performance bonuses of up to 25% or 20% of their respective annual base salary, at the sole discretion of the Compensation Committee of the Board of Directors. In 2011, 2010 and 2009, Officers' bonuses of $486,000, $500,000 and $527,000 respectively were granted. The Chief Executive Officer and General Counsel's employment agreements provided for bonuses based on gross proceeds received by the Company from any joint venture or corporate partnering agreement.

In 2011, equity was granted as a form of compensation to these Officers:

- Chief Executive Officer was granted 500,000 ten year options to purchase common stock at $0.41 per share which vested immediately;
- General Counsel was granted 300,000 ten year options to purchase common stock at $0.41 per share.
- Chief Financial Officer was granted 100,000 ten year options to purchase common stock at $0.31 per share which vest over one year;
- Senior Vice President of Operations was granted 90,000 ten year options to purchase common stock at $0.55 per share; and
- Vice President of Quality Control was granted 40,000 ten year options to purchase common stock at $0.37 per share which vest over one year.

In 2010, equity was granted as a form of compensation to these Officers:

- Chief Executive Officer was granted 573,728 ten year options to purchase common stock at $2.71 - $0.66 per share which vested immediately;
- General Counsel was granted 300,000 ten year options to purchase common stock at $0.66 per share which vested immediately; and
- Chief Financial Officer was granted 100,000 ten year options to purchase common stock at $0.55 per share which vested immediately.

In 2009, no Officer was granted equity as a form of compensation.

The Company recorded stock compensation expense of $271,000, $495,000 and $32,000, respectively, during the years ended December 31, 2011, 2010 and 2009 with regard to these issuances.

An agreement was made and entered into as of the 31st day of December, 2008 with Robert E. Peterson which expired upon reaching term on December 31, 2011 without replacement. Mr. Peterson was previously engaged by the Company as its Chief Financial Officer pursuant to an Amended And Restated Engagement Agreement (“Engagement Agreement”) made as of March 11, 2005.

(14) Leases

The Company has a non-cancelable operating lease for the space in which its principal office is located. Future minimum lease payments under the non-cancellable operating lease are as follows:

	(in thousands)
Year Ending December 31,	
2012	$ 197
2013	65
Total minimum lease payment	$ 262

Rent expense charged to operations for the years ended December 31, 2011, 2010 and 2009 amounted to approximately $215,000, $205,000 and $214,000 respectively. The term of the lease for the Philadelphia, Pennsylvania offices is currently through April 30, 2013.

(15) Income Taxes (FASB ASC 740 Income Taxes) And Subsequent Event

The Company applies 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.

In February 2011, the Company effectively sold $28,000,000 of its New Jersey state net operating loss carryforwards (for the years 2003 through 2008) for approximately $2,272,000.

As of December 31, 2011, the Company has approximately $108,000,000 of federal net operating loss carryforwards (expiring in the years 2012 through 2030) available to offset future federal taxable income. The Company also has approximately $39,000,000 of Pennsylvania state net operating loss carryforwards (expiring in the years 2018 through 2030) and approximately $25,000,000 of New Jersey state net operating loss carryforwards (expiring in the years 2016 through 2018 available to offset future state taxable income.

In January 2012, the Company effectively sold $16,000,000 of its approximately $25,000,000 of New Jersey state net operating loss carryforwards (for the years 2009 and 2010) for approximately $1,328,000. The utilization of certain state net operating loss carryforwards may be subject to annual limitations. 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.

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

Deferred income taxes reflect the net tax effects of temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the carrying amounts used for income tax purposes. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences representing net future deductible amounts become deductible. Due to the uncertainty of the Company's ability to realize the benefit of the deferred tax asset, the deferred tax assets are fully offset by a valuation allowance at December 31, 2011 and 2010.

The components of the net deferred tax asset of December 31, 2011 and 2010 consist of the following:

Deferred tax assets:	(in thousands) December 31, 2011	2010
Net operating losses	$36,612	$34,514
Amortization & depreciation	(1,282)	(1,095)
Research and development costs	2,285	2,477
Stock compensation	123	252
Inventory reserve	65	0
Total	37,803	36,148
Less: Valuation allowance	(37,803)	(36,148)
Balance	$-0-	$-0-

(16) Contingencies

(a) Hemispherx Biopharma, Inc. v. Johannesburg Consolidated Investments, et al.,U.S. District Court for the Southern District of Florida, Case No. 04-10129-CIV.

In December 2004, the Company filed a multi-count complaint in U.S, Federal Court (Southern District of Florida) which was granted by the Court in August 2010 whereby Hemispherx was awarded $188 million, plus interest against Johannesburg Consolidated Investments ("JCI") and former JCI officers R.B. Kebble and H.C. Buitendag. The Company is attempting to domesticate the Final Judgment in South Africa and is being assisted by the South African law firm of Webber Wentzel. The action to domesticate has been filed in South Africa. No gain has been recorded for this judgment as it is too early in these proceedings to predict an outcome. As required by South African law, on October 11, 2011, Hemispherx has posted a security bond of $66,873 for these proceedings.

(b) ***Hemispherx Biopharma, Inc. v. MidSouth Capital, Inc., Adam Cabibi, And Robert L. Rosenstein v. Hemispherx Biopharma, Inc. and The Sage Group, Inc.,*** **Civil Action No. 1:09-CV-03110-CAP.**

On June 4, 2009, the Company filed suit in the United States District Court for the Southern District of Florida against MidSouth Capital, Inc. (“MidSouth”) and its principals seeking monetary and injunctive relief against MidSouth's tortious interference with certain financing transactions in which the Company was engaged. The case was transferred to the Northern District of Georgia, and Holland & Knight was engaged as local counsel for the Company on November 13, 2009. On November 19, 2009, MidSouth answered the Company's Complaint and filed a Counterclaim against the Company and The Sage Group, Inc. (“Sage”) seeking to recover between $3,900,000 and $4,800,000 for fees allegedly owed to it as a result of the same financing transactions, plus attorneys' fees and punitive damages, under various contractual, quasi contractual, and tort theories. On January 12, 2010, the Company and Sage filed a Motion for Judgment on the Pleadings as to all parts of MidSouth's Counterclaim. By Order dated March 31, 2010, the Court granted the Motion with respect to MidSouth's contract claim but denied it with respect to MidSouth's other claims.

The parties conducted Discovery and subsequently, all parties filed Motions for Summary Judgment. By Order dated March 9, 2011, the Court granted the Company's Motion on all the remaining counts of MidSouth's counterclaim, granted Sage's Motion with respect to MidSouth's claims against Sage, and granted MidSouth's Motion with respect to the Company's original Complaint against MidSouth. Costs have been taxed in the Trial Court in favor of the Company and against MidSouth in the amount of $8,631.82, and in favor of MidSouth and against the Company in the amount of $7,916.90.

In April 2011, MidSouth filed a Notice of Appeal from the Order disposing of its claims against the Company and Sage, and the Company filed a Notice of Cross Appeal from the Order granting the Defendants' Motion for Summary Judgment on the original Complaint. MidSouth’s appeal has been assigned Case No. 11-11618-E and the Company’s Cross-Appeal has been assigned Case No. 11-11650-E. Mediation ordered by the Court of Appeals was unsuccessful. The appeal and cross appeal have been fully briefed.

Oral arguments on consolidated appeals took place before the Eleventh Circuit Court of Appeals on February 1, 2012. The Judges’ questions primarily focused on whether it was proper for the District Court to grant Summary Judgment as to MidSouth’s claim for quantum meruit. The Judges did not express any opinions as to the merits of the claim, but questioned whether issues of material fact exist that should be determined by a jury as opposed to the District Court. Hemispherx’ claim for Tortious Interference was also briefly discussed with very little time spent discussing the other claims. Counsel is unable to express an opinion as to how the Court will ultimately rule regarding this litigation.

(c) Cato Capital, LLC v. Hemispherx Biopharma, Inc., U.S. District Court for the District of Delaware, Case No. 09-549-GMS.

On July 31, 2009, Cato Capital LLC ("Cato") filed suit asserting that under a November 2008 agreement, the Company owes Cato a placement fee for certain investment transactions. The Complaint seeks damages in the amount of $5,000,000 plus attorneys' fees. The Company filed an Answer on August 20, 2009. On October 13, 2009, Cato filed a Motion seeking leave to file an Amended Complaint which proposed that Cato be permitted to add The Sage Group as an additional defendant and to bring additional causes of action against the Company arising from the defenses contained in the Answer, and increase the total amount sought to $9,830,000, plus attorneys' fees and punitive damages. The Company filed a response objecting to the Motion, and also filed a Motion to Disqualify Cato's Delaware attorneys on basis of a conflict of interest. On September 14, 2010, the Court granted the Company's Motion to Disqualify Cato's Delaware attorneys. Also on September 14, 2010, the Court granted Cato's Motion for Leave to file an Amended Complaint, but specifically indicated that the Company could file a Motion to Dismiss, raising the arguments that the Company had previously made in response to Cato's Motion for Leave to file an Amended Complaint. On September 16, 2010, Cato filed its Amended Complaint, and on September 30, 2010, the Company filed a Motion to dismiss all the counts of the Amended Complaint against the Company other than the breach of contract count. In addition, pursuant to an indemnification responsibility, the Company has also retained counsel to undertake the defense of the Sage Group, and a motion to dismiss has been filed on behalf of the Sage Group seeking to dismiss all claims against the Sage Group. On July 28, 2011, the Court denied the Company's motion to dismiss and the motion to dismiss of the Sage Group. On August 11, 2011, the Court entered a Scheduling Order that set Discovery, Motion and other applicable dates, including a trial date of October 1, 2012. On August 30, 2011, the Company and the Sage Group filed an Answer with Affirmative Defenses to the Plaintiff's Amended Complaint. The Company and other parties to the litigation are now in the discovery phase of the litigation. On October 24, 2011, Cato filed a Motion for a Partial Summary Judgment, seeking a determination that two of the Company's affirmative defenses to Cato's breach of contract cause of action should be stricken. On November 10, 2011, the Company filed a response controverting Cato's Motion on factual and legal basis. Also on November 10, 2011, the Company filed its own Motion for Partial Summary Judgment, seeking dismissal of Cato's claim for breach of contract. The time frame for the Court's determination of the respective Motions for Partial Summary Judgment cannot be ascertained. The parties are currently engaged in Discovery and a number of depositions have been taken, with others scheduled to be taken in the near future. As of March 1, 2012, no informed judgment can be made as to the likely outcome and Counsel is unable to provide a precise estimate of the merits or probability of success of the Cato claims or a range of potential recovery or loss.

(d) Summation.

In reference to Contingencies identified above, there can be no assurance that an adverse result in these proceedings would not have a potentially material adverse effect on our business, results of operations, and financial condition. The Company believes it has meritorious defenses and is vigorously defending against the claims identified in Contingency (b) and (c). There is currently no projection as to the likely outcome of the cases and the Company has not recorded any gain or loss contingencies as a result of the above matters for the years ended December 31, 2011 or 2010.

(17) Certain Relationships and Related Transactions

The Company has employment agreements with certain of their Executive Officers and has granted such officers and directors options and warrants to purchase their common stock. Please see details of these Employment Agreements in Note 13 - Royalties, License and Employment Agreements.

The Company used at various times the property owned by Retreat House, LLC, for off-site meetings and lodging. It was determined in September 2011 that the property was owned individually by Dr. William A. Carter, Hemispherx' Chief Executive Officer, through April 28, 2010, at which time it was transferred to Retreat House, LLC, a Virginia limited liability company that is owned by three of the children of William A. Carter and a Senior Primary Revocable Trust in which William A. Carter is the Trustee. Dr. Carter also is the Manager of Retreat House, LLC. The Company paid Retreat House, LLC approximately $137,000, $123,200 and $82,400 for the use of the property, off-site meetings and lodging at various times in 2011, 2010 and 2009, respectively. Upon analysis in the Fall of 2011 by the Audit Committee's Financial Expert, the Company was unable to gain assurance that the fees charged for conference and lodging by the Retreat House, LLC were reasonable when compared to commercially available alternatives in the same geographic market. As a result and effective November 15, 2011, Dr. Carter agreed to designate the property owned by Retreat House, LLC as both his home office and as a meeting place for a variety of Company business and social activities at no additional expense to the Company and agreed not to bill, either personally or through Retreat House LLC, or any other entity, for use of the Retreat House. Additionally, Dr. Carter shall be responsible for paying for all secretarial and receptionist services related to his work conducted in Florida and provide said services at no further expense to the Company. In return as reflected in his Amended Employment Contract, Dr. Carter was granted an increase in his base salary compensation and the Company shall supply the equipment necessary for full telephone, telefax, computer and internet access. For his Board fees, Dr. Carter received approximately $170,000, $165,000 and $-0- for 2011, 2010 and 2009, respectively.

Katalin Kovari, M.D. was paid approximately $28,000, $26,000 and $13,000 in 2011, 2010 and 2009, respectively for her part-time services to the Company as Assistant Medical Director. Dr. Kovari is the spouse of William A. Carter, CEO. In December 2011, the Company hired Kyle Carter as a Data Control Clerk. Mr. Carter is the Son of Dr. William A. Carter, and was paid approximately $3,000, $-0- and $-0- in 2011, 2010 and 2009, respectively.

Thomas Equels was elected to the Board of Directors at the Annual Stockholders Meeting on November 17, 2008 and joined the Company as General Counsel effective June 1, 2010. Mr. Equels had provided external legal services for several years through May 31, 2010 and Equels Law Firm continues to support the Company. In 2011, 2010 and 2009, the Company paid Equels Law Firm approximately $159,000, $729,000 and $387,000, respectfully, for services rendered. Upon analysis in the Fall of 2011 by the Audit Committee's Financial Expert, it was deemed that the hourly rates charged by Equels Law to the Company were reasonable when compared to the fee structure of a possible arms-length transaction from comparable firms in practice in the same market and of the similar size. For his Board fees, Mr. Equels received approximately $170,000 and $165,000 in cash for 2011 and 2010, respectively, and $150,000 in cash and stock in 2009.

On a quarterly basis, the Company reimbursed Director Richard Piani for his rental of a 2,000 square foot, fully furnished and equipped office with part-time administrative assistance located at 97 Rue Jean Jaures, Levallois, Perret, France used exclusively for Hemispherx Europe N.V./S.A. In 2011, 2010 and 2009, the Company paid reimbursements to Mr. Piani for approximately $48,000, $48,000 and $46,000, respectfully, for the sublease. Upon analysis in the Fall of 2011 by the Audit Committee's Financial Expert, it was deemed that the rental fee charged to the Company was reasonable as compared to a possible arms-length transaction with comparable office facilities in the same geographic vicinity for similar *commercial space of comparable quality and size in the same market.* For his Board fees, Mr. Piani received approximately $170,000 and $165,000 in cash for 2011 and 2010, respectively, and

approximately $150,000 in cash and stock in 2009.

(18) Concentrations of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash, cash equivalents, investments and accounts receivable. The Company places its cash with high-quality financial institutions. At times, such amounts may be in excess of Federal Deposit Insurance Corporation insurance limits of $250,000.

There were no credit based sales for 2011, 2010 or 2009.

(19) Fair Value

The Company is required under GAAP to disclose information about the fair value of all the Company's financial instruments, whether or not these instruments are measured at fair value on the Company's consolidated balance sheet.

The Company estimates that the fair values of cash and cash equivalents, other assets, accounts payable and accrued expenses approximate their carrying values due to the short-term maturities of these items. The Company also has certain warrants with a cash settlement feature in the unlikely occurrence of a Fundamental Transaction. The fair value recalculation of the Liability resulting from the issuance of the Warrants ("Call") and existence of the Fundamental Transaction ("Put") related to the May 2009 issuance, are calculated using a Monte Carlo Simulation. While the Monte Carlo Simulation is one of a number of possible pricing models, the Company has determined it to be industry accepted and fairly presented the Fair Value of the Warrants. As an additional factor to determine the Fair Value of the Put's Liability, the occurrence probability of a Fundamental Transaction event was factored into the valuation.

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' issued May 10, 2009, May 18, 2009 and May 21, 2009 to December 31, 2011, 2010 and 2009, were estimated using the following assumptions:

	December 31, 2011	2010	2009
Underlying price per share	$0.20-$0.46	$0.47-$0.74	$0.56 - $2.54
Exercise price per share	$1.31-$1.65	$1.31-$1.65	$1.10 – $1.65
Risk-free interest rate	0.29%-1.58%	0.83%-2.36%	0.19% - 2.67%
Expected holding period	2.38-3.63 years	3.38-4.63 years	0.122-5.50 years
Expected volatility	74.55%-120.55%	112.16%-122.02%	94.99%–226.46%
Expected dividend yield	None	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 for which will not be available for commercial sales until no sooner than the second half of 2012;
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. The Company has minimal revenues streams which are insufficient to meet the funding needs for the cost of operations or construction at their manufacturing facility; and
g. The Company's Rights Agreement and Executive Agreements make 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 has incorporated a 5.0% probability of a Fundamental Transaction to date for the life of the securities.

(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.

While the assumptions remain consistent from period to period (e.g., utilizing historical stock prices), the numbers input change from period to period (e.g., the actual historical prices input for the relevant period). The carrying amount and estimated fair value of the above warrants were approximately $380,000 and $2,805,000 at December 31, 2011 and 2010, respectively. There were no other financial instruments at December 31, 2011 or 2010.

The Company applies FASB ASC 820 (formerly Statement No. 157 *Fair Value Measurements*) that defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The guidance does not impose any new requirements around which assets and liabilities are to be measured at fair value, and instead applies to asset and liability balances required or permitted to be measured at fair value under existing accounting pronouncements. The Company measures its warrant liability for those warrants with a cash settlement feature at fair value.

FASB ASC 820-10-35-37 (formerly SFAS No. 157) establishes a valuation hierarchy based on the transparency of inputs used in the valuation of an asset or liability. Classification is based on the lowest level of inputs that is significant to the fair value measurement. The valuation hierarchy contains three levels:

- Level 1 – Quoted prices are available in active markets for identical assets or liabilities at the reporting date. Generally, this includes debt and equity securities that are traded in an active market.
- Level 2 – Observable inputs other than Level 1 prices such as quote prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Generally, this includes debt and equity securities that are not traded in an active market.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or other valuation techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation. As of December 31, 2011 and 2010, the Company has classified the warrants with cash settlement features as Level 3. Management evaluates a variety of inputs and then estimates fair value based on those inputs. As discussed above, the Company utilized the Monte Carlo Simulation Model in valuing these warrants.

The table below presents the balances of assets and liabilities measured at fair value on a recurring basis by level within the hierarchy as of December, 31, 2011 and 2010:

	(in thousands) 2011			
	Total	Level 1	Level 2	Level 3
Assets				
Marketable Securities	$28,187	$26,022	$2,165	$0
Marketable Securities - restricted	3,101	3,101	0	0
Liabilities				
Warrants	380	0	0	380
Total	$31,668	$29,123	$2,165	$380

	2010			
	Total	Level 1	Level 2	Level 3
Assets				
Marketable Securities	$41,467	$33,257	$8,210	$0
Liabilities				
Warrants	2,805	0	0	2,805
Total	$44,272	$33,257	$8,210	$2,805

The changes in Level 3 Liabilities measured at fair value on a recurring basis are summarized as follows:

	2011	2010	2009
Balance at January 1	$2,805	$3,684	
Fair value adjustment at March 31	(301)	1,336	
Balance March 31	2,504	5,020	
Value at issuance			$17,359
Less: value of warrants exercised in May and June 2009			(3,742)
Fair value adjustment at June 30	(643)	(2,260)	7,185
Balance at June 30,	1,861	2,760	20,803
Fair value adjustment at September 30	(614)	583	(4,951)
Balance at September 30	1,247	3,343	15,852
Fair value adjustment at December 31	(867)	(538)	(12,168)
Balance at December 31	$380	$2,805	$3,684

(20) Capital Leases

The Company has acquired equipment under capital leases as follows:

	(in thousands) Asset Balance at December 31, 2011
Leased Equipment included with property and equipment	$ 263
Less: accumulated depreciation	(62)
	$ 201

The following is a schedule by year of future minimum lease payments under the capital leases as of December 31, 2011:

2012	$71
2013	60
2014	39
2015	23
2016	1
Total lease payments remaining	194
Less: amount representing interest	(46)
Present value of remaining minimum lease payments	148
Less: current obligations under lease obligations	(49)
Long-term capital lease obligations	$99

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Minimum lease payments under the capital leases range from $576 per to $2,994 per month and the lease periods range from 24 months to 60 months. Aggregate security deposits of $7,041 were paid and are included in other assets.

(21) Margin Account Loan

A “Margin Account” loan was established with Wells Fargo Advisors for which the proceeds of this flexible form of indebtedness effectively serves the Company as a line of credit to finance the capital improvement project underway at the New Brunswick, New Jersey Manufacturing facility. In order to maintain this Margin Account, established on July 26, 2011 with an estimated maximum dollar value of $6.5 million, the Company needs to pledge, restrict from sale and segregate to a dedicated Margin Account its Marketable Securities at an approximate ratio of two to one of security collateral to debt undertaken. With the exception of collateral requirements, the Company maintains all the rights and benefits of ownership including receipt of interest, dividends or proceeds from the securities. While this Margin Account has no material establishment or maintenance fees, it currently carries an effective interest rate of approximately 3% per annum applied against the “Margin Debit Balance” (i.e., those funds withdrawn and outstanding), based on the prevailing “Wells Fargo Base Rate” less 2.75%. At December 31, 2011, the principal loan balance of the Margin Account was approximately $1,695,000, for which approximately $3,101,000 in Marketable Securities became restricted as dedicated collateral for the indebtedness. As a result of the loan being outstanding for only three months at December 31, 2011, the finance charge was approximately $6,000 for 2011. (see Note 6: Marketable Securities - Restricted).

(22) Subsequent Events

The Company evaluated subsequent events through the date on which these financial statements were issued, and other than the Company’s Commercial Supply Agreement with Althea regarding the fill and finish process for Alferon N Injection® as disclosed in *Note 3 Inventories and Other Assets* and the sale of net operating losses as disclosed in *Note 15 Income Taxes (FASB ASC 740 Income Taxes) And Subsequent Event*, determined that no subsequent event constituted a matter that required disclosure or adjustment to the financial statements for the year ended December 31, 2011.

(23) Quarterly Results of Operation (unaudited and restated)

The following is a summary of the unaudited quarterly results of operations:

2011
(in thousands except per share data)

	March 31, 2011	June 30, 2011	September 30, 2011	December 31, 2011	Total
Revenues	$ 42	$ 36	$ 45	$ 38	$ 161
Costs and expenses	(3,632)	(3,284)	(3,602)	(3,938)	(14,456)
Interest & other Income (expense)	151	311	203	(82)	583
Sales of tax NOL	2,272	0	0	0	2,272
Redeemable warrants valuation adjustment	301	643	614	867	2,425
Net loss	$ (866)	$ (2,294)	$ (2,740)	$ (3,115)	$ (9,015)
Basic and diluted loss per share	$ (.01)	$ (.02)	$ (.02)	$ (.02)	$ (.07)

2010
(in thousands except per share data)

	March 31, 2010	June 30, 2010	September 30, 2010	December 31, 2010	Total
Revenues	$ 32	$ 41	$ 35	$ 27	$ 135
Costs and expenses	(4,105)	(3,810)	(3,727)	(4,880)	(16,522)
Interest & other Income (expense)	29	93	438	1,812	2,372
Redeemable warrants valuation adjustment	(1,336)	2,260	(584)	539	879
Net loss	$ (5,380)	$ (1,416)	$ (3,838)	$ (2,502)	$ (13,136)
Basic and diluted loss per share	$ (.04)	$ (.01)	$ (.02)	$ (.02)	$ (.10)

Hemispherx Biopharma, Inc.

Schedule II -Valuation and Qualifying Accounts

(dollars in thousands)

Description	**Balance at beginning of period**	**Charge to expense**	**Write-offs**	**Balance at end of period**
Year Ended December 31, 2009 Reserve for inventory	$ 286	$ 0	$ (4)	$ 282
Year Ended December 31, 2010 Reserve for inventory	$ 282	$ 0	$ (33)	$ 249
Year Ended December 31, 2011 Reserve for inventory	$ 249	$ 192	$ (249)	$ 192