

HEMISPHERX BIOPHARMA INC  
Form 10-K  
March 18, 2013

**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, 2012**

**OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File No. 1-13441**

**HEMISPHERX BIOPHARMA, INC.**

(Exact name of registrant as specified in its charter)

Delaware 52-0845822  
(State or other jurisdiction of (I.R.S. Employer Identification  
incorporation or organization) Number)

1617 JFK Boulevard Philadelphia, Pennsylvania 19103  
(Address of principal executive offices) (Zip Code)

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

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

Common Stock, \$.001 par value

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

(Title of Each Class)

NONE

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

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

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  No

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

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  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

The aggregate market value of Common Stock held by non-affiliates at June 30, 2012, the last business day of the registrant's most recently completed second fiscal quarter was \$37,155,742.

The number of shares of the registrant's Common Stock outstanding as of March 1, 2013 was 166,784,590.

**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 note generally 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. With regard to Hemispherx’ New Drug Application (“NDA”) for Ampligen® to treat Chronic Fatigue Syndrome (“CFS”), we note that there are additional steps which the U.S. Food and Drug Administration (“FDA”) has advised Hemispherx to take in our seeking approval. The final results of these and other ongoing activities, and of the FDA review, could vary materially from Hemispherx’ expectations and could adversely affect the chances for approval of the Ampligen® NDA. Any failure to satisfy the FDA’s requirements could significantly delay, or preclude outright, approval of the Ampligen® NDA.

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. The inclusion of forward-looking statements should not be regarded as a representation by Hemispherx that any of its plans will be achieved. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond Hemispherx’ control, which could cause actual results to differ materially from those contemplated in these forward-looking statements. 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 CFS and as an influenza vaccine enhancer (adjuvant) for both therapeutic and preventative vaccine development. Alferon N Injection® is a FDA approved product with an indication for refractory or recurring genital warts. Alferon® LDO (Low Dose Oral) is a formulation 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 the facility enhancement project to focus on upgrading 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, and then again in June 2012 to \$7.2 million. The facility enhancement project is in its final stage with construction complete and a Certificate of Approval issued by the Construction Official of New Brunswick, NJ for the work completed. Approximately \$7,051,000 has been spent to date through December 31, 2012 and financed through a Margin Account with an effective interest rate of approximately 2.75%, as compared to \$1,695,000 at December 31, 2011. While facility upgrades are being undertaken to the Alferon® manufacturing process, this project has not impacted our capability to manufacture the Ampligen® drug substance intermediates needed for the final production steps. The production of new Alferon® Active Pharmaceutical Ingredient (“API”) inventory will not commence until the capital improvement and validation phases are complete. Due to the necessity to redirect our resources to the Ampligen® NDA application process and efforts towards the pre-approval inspection for Ampligen® manufacturing, the validation phase of the Alferon® manufacturing project had been delayed but is now underway. 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 prior to commercial sale of newly produced Alferon®. Once we have obtained a reaffirmation of FDA BLA status and have begun production of new Alferon® API, the FDA will be required to provide approval as to the quality and stability of the final product. We anticipate that it will take until the second half of 2014 before we will have newly produced Alferon® that can be commercially sold. We outsource certain components of our research and development, manufacturing, marketing and distribution while maintaining control over the entire process through our quality assurance group and our clinical monitoring group. We cannot provide any guarantee that the facility will necessarily pass a pre-approval inspection for Ampligen® or Alferon® manufacture, which are conducted in separately dedicated areas within the overall New Brunswick manufacturing complex.

On February 1, 2013, we received a Complete Response Letter (“CRL”) from the FDA declining to approve our new drug application (“NDA”) for Ampligen® for CFS. The FDA said Hemispherx should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses. In its CRL, the FDA set forth the reasons for this action and provided recommendations to address certain of the outstanding issues. The Agency stated that the submitted data do not provide substantial evidence of efficacy of Ampligen® for the treatment of CFS and that the data does not provide sufficient information to determine whether the product is safe for use in CFS due to the limited size of the safety database and multiple discrepancies within the submitted data.



In the two randomized double-blind, placebo-controlled clinical studies that form the basis of the Ampligen® NDA, AMP-502 and AMP-516, Hemispherx believes that the primary efficacy endpoints were met and that they showed a statistically significant improvement (i.e., with a p-value of less than 0.05). The FDA and Hemispherx agree that in clinical study AMP-502, the primary endpoint was met (p=0.02). In clinical study AMP-516, the FDA's analysis resulted in a p-value of 0.10, while Hemispherx' calculation resulted in a p-value of <0.05, and yet both analyses suggest that those patients on Ampligen® improved over those on placebo. With regard to safety, we have provided data from the 845 subjects who have received Ampligen®, including 589 subjects suffering from severe CFS and over 100 CFS patients who have received Ampligen® for at least one year or longer. The Company believes that these data are sufficient to determine the safety profile of Ampligen®. At the December 20, 2012, FDA Advisory Committee meeting, 8 of the 13 members voted "yes" on the question of "Is the safety profile of Ampligen® adequate for approval for the treatment of CFS?" though the majority of the Advisory Committee members did not vote in favor of the other questions presented.

We plan to request an end-of-review conference with the FDA as a precursor to a possible submission of a formal appeal to the Office of New Drugs in the FDA's Center for Drug Evaluation and Research regarding the Agency's decision. The purpose of the conference would be to review all of the issues raised in the Agency's CRL as well as to discuss the corroborating data and experiences of clinicians and patients who have seen the benefits of Ampligen® therapy.

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 for SEC Filings or by contacting the Investor Relations Department by calling (518) 398-6222 or sending an e-mail message to [ir@hemispherx.net](mailto: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 Chronic Fatigue Syndrome (“CFS”). As noted above and discussed below, the FDA in its recent CRL declined to approve our NDA for the treatment of CFS with Ampligen®. 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 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.

We believe that nucleic acid compounds represent a potential new class of pharmaceutical products as they 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(C12U).

Clinical trials of Ampligen® already conducted by us include studies of the potential treatment of 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 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, provide safety information regarding the use of Ampligen® in patients with CFS. As of December 31, 2012, we had twenty-eight patients participating in this open label treatment protocol with twenty taking treatment and eight on drug holiday. We are establishing an enlarged data base of clinical safety information which we believe will provide further documentation regarding the absence of autoimmune disease associated with Ampligen® treatment. We believe that continued efforts to understand existing data, and to advance the development of new data and information, will ultimately support our filings of the Ampligen® NDA and/or the design of future clinical studies.

In July 2008, the FDA accepted for review our NDA for Ampligen® to treat CFS, originally submitted in October 2007. We continue to seek marketing approval for the first-ever treatment for CFS, and the NDA for Ampligen® is the first-ever NDA accepted for review by the FDA for systemic use of a toll-like receptor 3 ("TLR-3") therapy to treat any condition. In November 2009, we received a 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.

On June 8, 2012, we and our consultants met with the FDA to discuss certain aspects of the CRL. At that meeting, the FDA agreed to accept, for review, in Hemispherx' complete response new analyses of data from the AMP-516 Trial. However, the FDA noted that whether the new analyses provide adequate evidence of Ampligen®'s efficacy in treating CFS would ultimately be an issue to be resolved during the review.



As a result of the FDA meeting, Hemispherx redirected many of its resources to the Ampligen® NDA submission and our preparation for the FDA pre-approval inspections by reassigning personnel, hiring additional staff, consultants and various independent contractors. The Company submitted the complete response to the FDA on July 31, 2012.

On December 20, 2012, the FDA held a meeting of its Arthritis Advisory Committee (“AAC”) to discuss the Ampligen® NDA. The AAC questions and the results of the members’ voting thereon were as follows:

“Considering the totality of the data, is there substantial evidence of efficacy for Ampligen for the treatment of patients with chronic fatigue syndrome (CFS)?” The AAC voted 9 no, 4 yes and 1 AAC member did not vote;  
“Has the safety of Ampligen been adequately assessed and characterized for the treatment of chronic fatigue syndrome (CFS)?” The AAC voted 9 no, 4 yes and 1 AAC member did not vote;  
“Is the safety profile of Ampligen adequate for approval for the treatment of CFS?” The AAC voted 8 yes, 5 no and 1 non-vote; and  
“Based on the information included in the briefing materials and presentations, has the applicant provided sufficient efficacy and safety data to support marketing of Ampligen for the treatment of CFS?” The AAC voted 8 no, 5 yes and 1 non-vote.

The AAC based its voting on a review of data from the Ampligen® clinical development program included as part of our NDA submission. This submission included data on nine studies conducted in patients with CFS, including two randomized double-blind, placebo-controlled studies and seven open-label studies. The trials were designed to evaluate safety, tolerability and efficacy in the approximately 845 patients (589 unique subjects suffering from severely debilitating CFS) who received Ampligen®.

On February 1, 2013, we received a CRL from the FDA declining to approve Hemispherx’ NDA for Ampligen® for CFS. In its CRL, the FDA communicated that Hemispherx should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses. The additional clinical study should address, among other things, Ampligen®’s efficacy in treating CFS patients, be of sufficient size and duration to assess the safety of Ampligen® and be sufficient to determine appropriate dosing. The FDA set forth the reasons for this action and provided recommendations to address certain of the outstanding issues. The FDA stated that the submitted data do not provide substantial evidence of efficacy of Ampligen® for the treatment of CFS and that the data do not provide sufficient information to determine whether the product is safe for use in CFS due to the limited size of the safety database and multiple discrepancies within the submitted data. In addition to the safety and effectiveness issues recommended to be addressed in at least one additional clinical trial, the CRL states that Hemispherx should conduct complete rodent carcinogenicity studies in two species prior to approval and also conduct additional animal toxicology studies providing more comprehensive evaluation of Ampligen® fragments and degradation products. The CRL also requests evaluation of variation between lots of Ampligen® tested in the development process and recommends tighter control of the Ampligen® manufacturing process.

In response to the CRL, we plan to avail ourselves of the opportunity for an “end-of-review” meeting with representatives of the Office of Drug Evaluation II which issued the CRL, in order to clarify and seek to narrow the outstanding issues regarding the further development of Ampligen® for the treatment of CFS.



FDA regulations provide a formal dispute resolution process to obtain review of any FDA decision, including a decision not to approve an NDA, by raising the matter with the supervisor of the FDA office that made the decision. The formal dispute resolution process exists to encourage open, prompt discussion of scientific (including, medical) disputes and procedural (including, administrative) disputes that arise during the drug development, new drug review, and post-marketing oversight processes of the FDA. Depending on the results of the “end-of-review” meeting, we will determine whether or not to submit a formal appeal regarding the FDA’s decision under applicable FDA regulations and guidance. Please see “Risks Associated With Our Business” in Item 1A. Risk Factors below.

Until we undertake the end-of-review conference(s) with the FDA, we are unable to reasonably estimate the nature, costs, necessary efforts to obtain FDA clearance or anticipated completion dates of any additional clinical study or studies. Utilizing the industry norms for undertaking a Phase III clinical study, we estimate upon acceptance of the study’s design that it would take approximately 18 months to three years to complete a new well-controlled Ampligen® clinical study for resubmission to the FDA. Industry norms suggest that it will require 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 acceptable Phase III clinical study design, availability of suitable participants and clinical sites along with other factors that could impact the implementation of the study, analysis of results or requirements of the FDA and/or other governmental organizations. The actual duration to complete the clinical study may be different based on the length of time it takes to design the study and obtain FDA’s acceptance of the design, the final design of an acceptable Phase III clinical study design, availability of suitable participants and clinical sites along with other factors that could impact the implementation of the study, analysis of results or requirements of the FDA and/or other governmental organizations.

There are multiple reasons for fatigue and the accurate diagnosis of CFS remains one of exclusion and adherence to strict diagnostic guidelines. In that regard, we have evaluated a blood test for CFS using a new technology being developed by Chronix Biomedical and continue to be interested in such diagnostic platform that may include next generation sequencing, gene expression or immune assays of dysfunction. While we believe that finding an accurate diagnostic for CFS is useful, we do not believe that development of new diagnostic tools is a prerequisite to FDA approval of a CFS treatment or design of a successful clinical study.

On July 12, 2012, we filed a new drug application for Ampligen® with the ANMAT (Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica), the agency responsible for the national regulation of drugs, foods and medical technology in Argentina, under the ANMAT’s Orphan Drug regulations. We believe that the approval of Ampligen® as an Orphan Drug may allow reimbursement by the Health Services Authority (SSS), the central health authority in Argentina for patients seeking treatment for CFS.

**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 U.S. Centers for Disease Control and Prevention (“CDC”) estimates that “approximately twenty million Americans are currently infected with HPV with another six million becoming newly infected each year. HPV is so common that at least 50% of sexually active men and women get it at some point in their lives.” Although they do not usually result in death, genital warts recurrence is common, cause significant morbidity and entail substantial health care costs.



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 neutralizing antibody formation. Neutralizing antibody formation has not been reported with the use of Alferon N Injection®.

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 formulate, fill, finish and package (“fill and finish”) Alferon N Injection® Drug Product, we require a FDA approved third party Contract Manufacturing Organization (“CMO”). In January 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea Technologies, Inc. (“Althea”) of San Diego, CA, regarding the fill and finish process for Alferon N Injection®. In April 2012, FDA reviewers raised certain questions about the status of our existing lots of older Work-In-Process Alferon® materials and Alferon® “API”, which would need to be released by the FDA before those materials could be used in commercial product.



As of December 31, 2012, all of our existing lots of Alferon® Work-In-Process Inventory have completed the fill, finish and packaging process with the need to undertake product quality and stability tests, the results of which would be submitted to the FDA for review. We are unable to provide any assurances that the FDA will approve the fill and finish product lots produced by Althea. In the absence of FDA approvals for commercial sale of product manufactured from existing Work-In-Process inventory, commercial sales of Alferon® will not resume until new batches of API can be produced and released by the FDA (see “MANUFACTURING” and “MARKETING/DISTRIBUTION” below for more information).

The production of new Alferon® API inventory will not commence until the capital improvement and validation phases are complete at our New Brunswick, NJ manufacturing facility. Due to the necessity to redirect resources to the Ampligen® NDA application process, the validation phase of the Alferon® manufacturing project had been delayed but is currently underway. 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 prior to commercial sale of newly produced inventory product. Once we have obtained a reaffirmation of FDA BLA status and have begun production of new Alferon® API, we will need FDA approval as to the quality and stability of the final product. We anticipate that it will take until the second half of 2014 before we will have newly produced Alferon® that can be commercially sold (see “MANUFACTURING” below for more information).

### **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.

In December 2010, the FDA authorized a protocol 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. Our Phase II study has been delayed as we have redirected many of our resources to the Ampligen® NDA submission.

### **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, 2012

## Costs and Expenses

	Ampligen® NDA	Alferon N Injection®	Alferon® LDO	Other	Total
Production/cost of goods sold	\$0	\$ 1,989	\$ 0	\$0	\$1,989
Research and development	6,775	0	2,245	488	9,508
General and administrative	5,337	1,567	1,768	384	9,056
Total	\$12,112	\$ 3,556	\$ 4,013	\$ 872	\$20,553

(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

### **PATENTS AND NON-PATENT EXCLUSIVITY RIGHTS**

As of December 31, 2012, we had 20 patents worldwide with 70 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 2012, we were granted two new patents, one in Australia and the other in New Zealand, both for the use of Ampligen to initiate innate immunity and to treat or prevent viral infections and tumors. In December 2011, we were granted two new United States Patents for the use of Alferon® LDO for the treatment in a number of different human diseases.

Alferon® composition patent #5,503,828 relates to the manufacturing process for Alferon® Active Pharmaceutical Ingredient (“API”), a complex mixture of natural interferon species that is manufactured from human leukocytes obtained from human blood donors. In addition, while it is the current standard by the FDA to treat biological drug products like interferon as “Well Characterized” biologics, a process for which chemical entities can have their identity, purity, impurities, potency, and quality controlled by chemical testing, Alferon®, as a natural interferon, does not lend itself well to such testing. Moreover, FDA continues to require that each lot of Alferon we produce be tested and released by the FDA before it can be distributed for commercial sales. Because of the complexity of the Alferon manufacturing process and these additional regulatory requirements, we believe that potential manufacturers of generic, or so-called “bio-similar,” drug products are focused on developing recombinant interferon products, rather than natural interferon products. For these reasons, we believe the expiration of this Alferon® composition patent in April 2013 should have no or little impact on the Company. Additionally at the completion of the facility enhancement and receipt of the FDA certification for the revised Alferon® manufacturing process and techniques in New Brunswick, NJ, it is our intention to file for additional patent protection.

Alferon® patent #5,676,942 relates to a manufacturing methodology which is no longer in use.

With respect to Ampligen®, the main U.S. CFS treatment patent (#6,130,206) expires October 10, 2017. Our main patents covering HIV treatment (#4,820,696, #5,063,209, and #5,091,374) expired on April 11, 2006, November 5, 2008, and February 25, 2009, respectively; Hepatitis treatment coverage is conveyed by U.S. patent #5,593,973 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 CFS, HIV/AIDS, and renal cell carcinoma and malignant melanoma. Orphan drug status grants us protection against the potential subsequent 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.

## **RESEARCH AND DEVELOPMENT (“R&D”)**

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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 CFS, HIV, HPV, Cancer and Influenza. Our current R&D projects are targeting treatment therapies for 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 2012, 2011 and 2010 by project:

	2012	2011	2010
Ampligen® New Drug Application for the treatment of Chronic Fatigue Syndrome	\$6,775	\$2,310	\$2,787
Alferon® LDO for influenza	2,245	4,080	4,658
Alferon N Injection® for influenza	0	0	168
Other projects	488	332	0
Total research and development	\$9,508	\$6,722	\$7,613



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, 2012, we had approximately \$43,953,000 in Cash, Cash Equivalents and Marketable Securities, (inclusive of approximately \$14,500,000 in Marketable Securities collateralizing certain debts). Please see ITEM 1A. Risk Factors; “We may require additional financing which may not be available” below.

In its CRL, the FDA communicated that Hemispherx should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analysis. Until we undertake the end-of-review conference(s) with the FDA, we are unable to reasonably estimate the nature, costs, necessary efforts to obtain FDA clearance or anticipated completion dates of any additional clinical study or studies. Utilizing the industry norms for undertaking a Phase III clinical study, we estimate upon acceptance of the study’s design that it would take approximately 18 months to three years to complete a new well-controlled Ampligen® clinical study for resubmission to the FDA. It can be reasonably anticipated that the time and cost to undertake clinical trial(s), studies and data analysis are beyond our current financial resources without gaining access to additional funding. The actual duration to complete the clinical study may be different based on the length of time it takes to design the study and obtain FDA’s acceptance of the design, the final design of an acceptable Phase III clinical study design, availability of suitable participants and clinical sites along with other factors that could impact the implementation of the study, analysis of results or requirements of the FDA and/or other governmental organizations. Please see “*We most likely will require additional financing which may not be available. The limitation on the number of shares of common stock available for financing without prior stockholder approval eventually may hinder our ability to raise additional funding.*” in Item 1A. Risk Factors below.

### **Chronic Fatigue Syndrome ("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. CFS is recognized by both the government and private sector as a major health problem, including the U.S. National Institutes of Health (“NIH”), FDA and the 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 CFS patients become completely disabled or totally bedridden and are afflicted with severe pain and mental confusion even at rest. 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 three criteria:

- The individual has had severe chronic fatigue for six or more consecutive months that is not due to ongoing exertion
1. or other medical conditions associated with fatigue (these other conditions need to be ruled out by a doctor after diagnostic tests have been conducted);
  2. The fatigue significantly interferes with daily activities and work; and
  3. The individual concurrently has four or more of the following eight symptoms:
    - post-exertion malaise lasting more than twenty-four hour;
    - unrefreshing sleep;
    - significant impairment of short-term memory or concentration;
    - muscle pain;
    - pain in the joints without swelling or redness;
    - headaches of a new type, pattern, or severity;
    - tender lymph nodes in the neck or armpit; or
    - a sore throat that is frequent or recurring.
- These symptoms should have persisted or recurred during six or more consecutive months of illness and they cannot have first appeared before the fatigue.

Because no cause for 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 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 and 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 CFS that 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 CFS are being developed.

When she served as director of the CDC, Dr. Julie Gerberding 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. In June 2012, U.S. Senators Robert P. Casey, Richard Blumenthal and Kay R. Hagan sent a letter to Health and Human Services Secretary Kathleen Sebelius requesting the FDA hold a stakeholders meeting on CFS. Senators Casey and Hagan serve on the Committee on Health, Education, Labor & Pensions, which has Congressional oversight responsibility for FDA. The letter stated, "CFS/ME represents a significant unmet medical need, one that confers on patients a lifetime of illness. A stakeholder meeting would be of great benefit, as it would offer an opportunity to examine existing treatment protocols known to FDA, address how risk/benefit determinations should be made in relation to CFS/ME treatments and identify a path forward for regulatory science in this area."

Accordingly, the FDA's Center for Drug Evaluation and Research has announced a public workshop on April 25 and 26, 2013, to discuss how best to facilitate and expedite the development of safe and effective drug therapies to treat signs and symptoms related to CFS and ME. On April 25, 2013, as part of FDA's Patient-Focused Drug Development initiative, patients will provide feedback to FDA on issues like the disease impact on quality of life and individual experiences with current treatment options. On April 26, 2013, there will be discussions with academic and government experts, patient advocates, patients, and clinicians on how to identify sound, quantitative outcome measures that can be used in clinical trials to determine whether disease symptoms improve with specific drug interventions. For more information, see <http://www.fda.gov/Drugs/NewsEvents/ucm319188.htm>.

While CFS strikes people in all age, racial, ethnic, and socioeconomic groups, it is most prevalent amongst women. Research has shown that 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, CFS is over four times more common than HIV infection in women, and the rate of CFS in women is considerably higher than a woman's lifetime risk of getting lung cancer as published by the CFIDS Association of America.

### **Other Viral Diseases**

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. On April 16, 2012, a clinical trial was initiated in which Ampligen® is being nasally administered in conjunction with FluMist® to healthy human volunteers at the University of Alabama at Birmingham under the auspices of Dr. Paul Goepfert, Associate Professor of Medicine in the Division of Infectious Diseases and Director of the Alabama Vaccine Research Clinic. This study is a first use of Ampligen® with a seasonal vaccine in humans to assess the safety of Ampligen® when nasally delivered as a vaccine adjuvant. Another objective of this study is to determine the extent to which Ampligen® mobilizes potential protections against pandemic influenza by utilization of a seasonal flu vaccine. The study will evaluate the potential immunologic enhancement of Ampligen® by comparing immune parameters in the group receiving Ampligen® plus FluMist® with another group receiving FluMist® plus placebo. We intend to conduct a broad array of immune tests to compare the immune response for both its magnitude and breadth. It is our

objective to qualify and enroll 72 patients for this clinical trial. As of December 31, 2012, eight subjects have participated in this study. As required by the study's protocol, a Data Monitoring Committee has reviewed the safety data on these subjects and approved the study to proceed at the next higher dosage level.

In April 2010, we began the process to undertake a clinical placebo-controlled 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. As of June 2012, we had ten operational Clinical Investigative Sites. Thirty patients, of the planned total of sixty, 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 experiencing an unusually mild flu season during the past year. Due to the unexpectedly slow enrollment rate for this study, on June 20, 2012, we notified Max Neeman International that this study was suspended, pending an interim analysis of results to date on the thirty completed patients of the planned sixty patient study. Our interim analysis of results has been delayed as we have redirected many of our resources to the Ampligen® NDA submission. Upon completion of the Ampligen® NDA effort, we intend to undertake this analysis.

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, 2012, three patients have participated in this study. Further treatment of the existing three patients, as well as new enrollment into this study, are currently suspended pending additional data analyses and non-clinical experimentation by the University of Pennsylvania's School of Medicine in an attempt to modify the immune response elicited by the vaccine adjuvant combination. To date, this treatment has been generally well-tolerated with no tumor regression seen in the first three patients.

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, 2012, forty patients have enrolled in this ninety-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.

## **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 the facility enhancement project to focus on upgrading 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, and then again in June 2012 to \$7.2 million. The facility enhancement project is in its final stage with construction complete and a Certificate of Approval issued by the Construction Official of New Brunswick, NJ for the work completed. Approximately \$7,051,000 has been spent to date through December 31, 2012 and financed through a Margin Account with an effective interest rate of approximately 2.75%, as compared to \$1,695,000 at December 31, 2011. While facility upgrades are being undertaken to the Alferon® manufacturing process, this project has not impacted our capability to manufacture the Ampligen® drug substance intermediates needed for the final production steps.

An element of the June 8, 2012 meeting with the FDA was the requirement that our New Brunswick manufacturing facility would be ready for the FDA to undertake a cGMP pre-approval inspection related to Ampligen® at the time of submission of our complete response submission. The FDA did not complete the inspection before the February 1, 2013 CRL and, as a result of the CRL, we do not anticipate a preapproval inspection at this time. We cannot provide any guarantee that the facility will pass a FDA pre-approval inspection for Ampligen® or Alferon® manufacture, which are conducted in separately dedicated areas within the overall New Brunswick manufacturing complex (see “Risks Associated With Our Business” in Item 1A. Risk Factors below for more information).

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. Accordingly 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®. The Technology Transfer process with Althea was completed in May 2012 and included the 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. As of December 31, 2012, all of our lots of Alferon® Work-In-Process Inventory have completed the fill, finish and packaging process. With the completion of the fill, finish and packaging protocol, Process Validation of Alferon® Work-In-Process lots need to be completed. With our redirection of resources to the Ampligen® NDA submission, this process had been delayed but is now underway. A minimum of three months of stability tests is required in a Pre-Approval Supplement (“PAS”). Upon submission of the PAS, the data would then be subjected to FDA review. The FDA could take up to six months to render an opinion as to the quality of the product as suitable for commercial sales. We are unable to provide any assurances that the FDA will approve the existing inventory finish product lots produced by Althea (see “MARKETING/DISTRIBUTION” below for more information).



The production of new Alferon® API inventory will not commence until the capital improvement and validation phases are complete at the New Brunswick, NJ manufacturing facility. Due to the necessity to redirect our resources to the Ampligen® NDA application process and efforts towards the pre-approval inspection for Ampligen® manufacturing, the validation phase of the Alferon® manufacturing project had been delayed, but we are now again dedicated to this process. 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 prior to commercial sale of newly produced inventory product. Once we have obtained a reaffirmation of FDA BLA status and have begun production of new Alferon® API, we will be required to obtain FDA approval as to the quality and stability of the final product. We anticipate that it will take until the second half of 2014 before we will have newly produced Alferon® that can be commercially sold to meet potential patient demand in the United States and abroad.

While at December 31, 2011 and 2012, the Work-In-Process Inventory had no manufacturing steps to be undertaken at our New Brunswick, NJ facility, it will not be classified as Finished Goods unless and until the FDA confirms that the product can be commercially sold. We are unable to provide any assurances that the FDA will approve the finish product lots produced by Althea. In the absence of FDA approvals for commercial sale of product manufactured from existing Work-In-Process inventory, commercial sales of Alferon® will not resume until new batches of Alferon® API can be produced and formulated in order that finished product can be filled, finished, packaged and released by the FDA for commercial sale (see “Risks Associated With Our Business” in Item 1A. Risk Factors below for more information).

In the absence of FDA approvals for commercial sale of product manufactured from existing Work-In-Process inventory, commercial sales of Alferon® in the United States will not resume until new batches of Alferon® API can be produced and formulated in order that finished product can be filled, finished, packaged and released by the FDA for commercial sale.

## **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. We expect that, subject to receipt of FDA, ANMAT and/or other regulatory approval, Ampligen® may be utilized in four medical arenas: physicians’ offices; clinics; hospitals; and the home treatment setting. In preparation for the FDA’s consideration of our Ampligen® NDA, we undertook early stage development of pre-launch and launch driven marketing plans focusing on audience development, medical support and payor reimbursement initiatives which could facilitate product acceptance and utilization at the time of regulatory approval, if obtained. Similarly, we continued to consider distribution scenarios for the Specialty Pharmacy/Infusion channel which could provide 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. As a possible option, we considered a 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 could 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 any approach considered should enable us to retain multiple options for future marketing strategies.

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, reimbursement of preapproved expense, 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 our Stock on the NYSE MKT at the close of the day preceding the execution date of the agreement. The Agreement also allows us at our sole discretion to award a bonus for extraordinary performance or special projects not to exceed \$250,000 per year, and provides 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 a five year 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 seeking regulatory approval in Mexico for Ampligen®, an experimental therapeutic, to treat CFS in Mexico and, if approval is obtained, 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.

Also on November 15, 2010, we executed a five year exclusive Alferon N Injection® Sales, Marketing, Distribution and Supply Agreement for Argentina and other Latin American countries with GP Pharm. The ANMAT (Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica) is the agency responsible for the national regulation of drugs, foods and medical technology in Argentina. In December 2010, GP Pharm exercised this right and in July 2011 GP Pharm submitted an application for approval to ANMAT. As a result of the efforts of GP Pharm, in January 2012 the 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. In February 2013, the ANMAT approved the use of Naturaferon for any patient in Argentina who fails or becomes intolerant to treatment with recombinant interferon (see "MANUFACTURING" above for more information).



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. On August 14, 2012, the agreement with Armada was extended for one year under the same terms and conditions. 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. On August 14, 2012, the agreement with Bio Ridge was extended for one year under the same terms and conditions.

## **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 before we do. 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 & Co., 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 & Co. 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® is a herbal product made from green tea leaves which is self-administered as an ointment and is used to treat external genital warts in adult patients;

Condylox® Solution (podofilox) and Podofin® (podophyllin resin) are liquids applied externally using a cotton applicator or finger which attempts to destroy genital warts by halting cell growth; and

Trichloroacetic acid (TCA) or Dichloroacetic acid (DCA) are chemical treatments which attempt to externally 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 we believe 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. For information about the current status of our Ampligen® NDA please see "Our Products; Ampligen®" above.

## **HUMAN RESOURCES**

As of February 1, 2013, we had personnel consisting of 34 full-time employees and 3 part-time employees. Our employees are supported by 30 full-time and 11 part-time consultants, mostly undertaking regulatory, research and/or medical projects. Part-time personnel are paid on a per diem or monthly basis. Consultants are independent contractors that are paid on an hourly basis. 58 of the combined personnel are engaged in our research, development, clinical, and manufacturing effort with 20 performing regulatory, general administration, data processing, including bio-statistics, financial and investor relations functions. We have no union employees.

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**

Although we had a Scientific Advisory Board to conduct periodic meetings as needed, as previously disclosed, no Scientific Advisory Board meetings were held in the last four years. We do meet with experts from time to time in areas of clinical and scientific interest.



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. During 2011 and 2012, the DMC focused its attention on the clinical trial (AMP-600) in which Ampligen® is being nasally administered in conjunction with FluMist® to healthy human volunteers at the University of Alabama at Birmingham under the auspices of Dr. Paul Goepfert. As of December 31, 2012, eight subjects have participated in this study. As required by the study’s protocol, the DMC held two meetings and has reviewed the safety data on these subjects and approved the study to proceed at the next higher dosage level.

#### **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 and PART 1, ITEM I Business, “OUR PRODUCTS” “Ampligen®” above for more information).

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. (Please see the next Risk Factor and PART 1, ITEM I Business, “OUR PRODUCTS” “Alferon N Injection®” above for more information).

***Our drug and related technologies are investigational and subject to regulatory approval. If we are unable to obtain regulatory approval in a timely manner, or at all, our operations will be materially harmed and our stock 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, the Agency for the European Medicines Agency (“EMA”) in Europe and the Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica (“ANMAT”) in Argentina. 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 and efficacious. While Ampligen® is authorized for use in clinical trials in the U.S., we cannot assure you that additional clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials. In addition, although Ampligen® has been authorized by the FDA for treatment use under certain conditions, including provision for cost recovery, there can be no assurance that such authorization will continue in effect.

On February 1, 2013, we received a Complete Response Letter (“CRL”) from the FDA declining to approve our Ampligen® NDA for the treatment of CFS. The FDA communicated that we should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analysis. For more detailed information about the current status of our Ampligen® NDA please see “Our Products; Ampligen®” in Item 1. Business above.

The FDA's regulatory review and approval process is extensive, lengthy, expensive and inherently uncertain. To receive approval for a product candidate, we must, among other things, demonstrate to the FDA's satisfaction with substantial evidence from well-controlled pre-clinical and clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. Before we can sell Ampligen® for any use, or Alferon® for any use other than as Alferon N Injection® for treatment of refractory or recurring genital warts, we will need to file the appropriate NDA with the FDA in the U.S. and the appropriate regulatory agency outside of the U.S. where we intend to market and sell such products. At present the only NDA we have filed with the FDA is the NDA for the use of Ampligen® to treat CFS. As discussed in the prior paragraph, the FDA declined to approve this NDA and indicated that we needed to conduct additional work. Therefore, ultimate FDA approval, if any, may be delayed by several years and may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be successful or considered sufficient by the FDA for approval or even to make our applications approvable. If any of these outcomes occur, we may be forced to abandon one or more of our future applications for approval, which might significantly harm our business and prospects. As a result, we cannot predict if or when we might receive regulatory approval for the use of Ampligen® to treat CFS or for the use of any other products. Even if regulatory approval from the FDA is received for the use of Ampligen® to treat CFS or eventually, for the use of any other product, any approvals that we obtain could contain significant limitations in the form of narrow indications, patient populations, warnings, precautions or contra-indications or other conditions of use, or the requirement that we implement a risk evaluation and mitigation strategy. In such an event, our ability to generate revenues from such products could be greatly reduced and our business could be harmed.

Even if we believe that data collected from our preclinical studies and clinical trials of our product candidate are promising, these data have not been, and may not be in the future, sufficient to support marketing approval by the FDA, and regulatory interpretation of these data and procedures may continue to be unfavorable.

To the extent that we are required by the FDA pursuant to the Ampligen® NDA to conduct additional studies and take additional actions, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be successful or considered sufficient by the FDA for approval or even to make our applications approvable. If any of these outcomes occur, we may be forced to abandon one or more of our future applications for approval, which might significantly harm our business and prospects. As a result, we cannot predict when or whether regulatory approval will be obtained for any product candidate we develop.

Obtaining approval of a NDA by the FDA, or a comparable foreign regulatory authority, is inherently uncertain. Even after completing clinical trials and other studies, a product candidate could fail to receive regulatory approval for many reasons, including the following:

- not be able to demonstrate to the satisfaction of the FDA that our product candidate is safe and effective for any indication;
- the FDA may disagree with the design or implementation of our clinical trials or other studies;
- the results of the clinical trials or other studies may not demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from clinical trials or other studies;
- the data collected from clinical trials and other studies of a product candidate may not be sufficient to support the submission of a NDA;
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical and other study data insufficient for approval; and
- the FDA may not approve the proposed manufacturing processes and facilities for a product candidate.

In April 2012, FDA reviewers raised certain questions about the status of our existing lots of older Work-In-Process Alferon® materials and API, which would need to be released by FDA before those materials could be used in commercial product. We are unable to provide any assurances that the FDA will approve the final inventory lots produced by Althea. In the absence of FDA approvals for product manufactured from existing inventory, commercial sales of Alferon® will not resume until new batches of Alferon® inventory and API can be produced, filled and finished, and released by the FDA for commercial sale. (Please see PART 1, ITEM I Business, “OUR PRODUCTS” “Alferon N Injection®” above for more information).

Alferon® LDO has been approved for 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. The outcome of this confirmatory study, if and when resumed, will allow us to better evaluate 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 the Phase II Alferon® LDO study for the prophylaxis and treatment of seasonal and pandemic influenza will be undertaken.

If we are unable to gain necessary FDA approvals related to Ampligen® and Alferon® on a timely basis, our operations most likely will be materially and/or adversely affected. Additionally, if we are unable to generate the additional data, successfully complete inspections or obtain approvals as required by the FDA on a timely manner, or at all, 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 ability to generate revenues to sustain our operations will be substantially impaired, which would increase the likelihood that we would need to obtain additional financing for our other development efforts;

Our reputation among investors might be harmed, which might make it more difficult for us to obtain equity capital on attractive terms or at all; and

Our profitability would be delayed, our business will be materially harmed and our stock price may be adversely affected.

Biotechnology stock prices, including our stock price, have declined significantly in certain instances where companies have failed to meet expectations with respect to FDA approval or the timing for FDA approval.

***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, 2012, our accumulated deficit was approximately \$(244,094,000). 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.

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***We most likely will require additional financing which may not be available. The limitation on the number of shares of common stock available for financing without prior stockholder approval eventually may hinder our ability to raise additional funding.***

The development of our products requires the commitment of substantial resources to conduct the time consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of December 31, 2012, we had approximately \$43,953,000 in cash, cash equivalents and marketable securities (inclusive of approximately \$14,500,000 in Marketable Securities collateralizing certain debts). However, if we are unable to commercialize and sell Ampligen® or Alferon® LDO and/or recommence material sales of Alferon N Injection®, our operations, financial position and liquidity may be adversely impacted.

In its CRL, the FDA communicated that Hemispherx should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analysis. Until we undertake the end-of-review conference(s) with the FDA, we are unable to reasonably estimate the nature, costs, necessary efforts to obtain FDA clearance or anticipated completion dates of any additional clinical study or studies. Utilizing the industry norms for undertaking a Phase III clinical study, we estimate upon acceptance of the study's design that it would take approximately 18 months to three years to complete a new well-controlled Ampligen® clinical study for resubmission to the FDA. It can be reasonably anticipated that the time and cost to undertake clinical trial(s), studies and data analysis are beyond our current financial resources without gaining access to additional funding. The actual duration to complete the clinical study may be different based on the length of time it takes to design the study and obtain FDA's acceptance of the design, the final design of an acceptable Phase III clinical study design, availability of suitable participants and clinical sites along with other factors that could impact the implementation of the study, analysis of results or requirements of the FDA and/or other governmental organizations.

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® along with the manufacturing, marketing and distribution of our products, including Alferon N Injection®. We may also need additional funds to eventually commercialize and sell Ampligen® or Alferon® LDO and/or recommence and increase sales of Alferon N Injection® or our other products. We anticipate considering multiple options as to securing other sources of funding, including but not limited to such methods as the sales of additional equity, licensing agreements, partnering with other organizations debt financing or other sources of capital.

In this regard, on July 23, 2012, we entered into a New Equity Distribution Agreement with Maxim (the "New Maxim EDA") pursuant to which we may sell up to \$75,000,000 worth of our shares of Common Stock from time to time through Maxim, as sales agent (See Part I; Item 2: "Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources" above). We cannot assure how much funding will be obtained from the New Maxim EDA or whether it will be sufficient in conjunction with current financial resources to permit us to take all actions needed to obtain FDA approval for Ampligen® and manufacturing, commercialization, marketing and distribution of our products.

Our ability to raise additional funds from the sale of equity securities may be limited due to limitations on our ability to sell stock for funding purposes. Pursuant to our Amended and Restated Certificate of Incorporation, the purpose for which 75,000,000 of 150,000,000 of our authorized shares (the “Restricted Shares”) may be utilized is limited. Specifically, without stockholder approval, the Restricted Shares can only be issued where such issuance would be primarily in connection with strategic transactions or other non-fundraising purpose that met certain significant criteria. In this regard, approximately 66,862,000 shares are authorized but unissued and unreserved at December 31, 2012 with an additional 75,000,000 of the Restricted Shares approved by Stockholders for certain generally defined business purposes.



There can be no assurances that we can obtain the requisite stockholder approval to use any additional Restricted Shares for funding purposes or raise adequate funds from other sources. If we are unable to obtain additional funding, through the New Maxim EDA or otherwise, our ability to develop our products, commercially produce inventory or continue our operations may be materially adversely affected.

***Our Alferon N Injection® Commercial Sales were halted due to lack of finished goods inventory. If we are unable to gain the necessary FDA approvals related to Alferon®, our operations most likely will be materially and/or adversely affected.***

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 required a FDA approved third party CMO in Althea.

In April 2012, FDA reviewers raised certain questions about the status of our existing lots of older Work-In-Process Alferon® materials and API, which would need to be released by FDA before those materials could be used in commercial product. We are unable to provide any assurances that the FDA will approve the final inventory lots of Alferon® produced by Althea. In the absence of FDA approvals for commercial sale of product manufactured from existing inventory, commercial sales of Alferon® will not resume until new batches of Alferon® inventory and API can be produced, filled and finished, and released by the FDA for commercial sale. Please see *“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”* below for more information.

While the facility had been granted approval of its Biological License Application by the FDA for Alferon®, this status will need to be reaffirmed upon the completion of the facility’s upgrades for Alferon®. We cannot provide any guarantee that the facility will necessarily pass a pre-approval inspection for Ampligen® or Alferon® manufacture, which are conducted in separately dedicated areas within the overall New Brunswick manufacturing complex.

If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon® inventory, our operations most likely will be materially and/or adversely affected. For more information on Alferon N Injection® regarding potential commercial sales, please see “Alferon N Injection®” in Item 2: “Management’s Discussion and Analysis of Financial Condition and Results of Operations; Overview; General”.

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.

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

We need to preserve and acquire enforceable patents covering the use of Ampligen® for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen® for such disease. We obtained all rights to Alferon N Injection®, and we plan to preserve and acquire enforceable patents covering its use for existing and potentially new diseases. Our success depends, in large part, on our ability to preserve and obtain patent protection for our products and to obtain and preserve our trade secrets and expertise. Certain of our know-how and technology is not patentable, particularly the procedures for the manufacture of our experimental drug, Ampligen®. We also have been issued patents on the use of Ampligen® in combination with certain other drugs for the treatment of chronic Hepatitis B virus, chronic Hepatitis C virus, and a patent which affords protection on the use of Ampligen® in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of Ampligen® as a sole treatment for any of the cancers which we have sought to target.

One of our Alferon® composition patents (#5,676,942) expires in April 2013. This patent relates to the manufacturing process for Alferon® API, a complex mixture of natural interferon species that is manufactured from human leukocytes obtained from human blood donors. In addition, while it is the current standard by the FDA to treat biological drug products like interferon as “Well Characterized” biologics, a process for which chemical entities can have their identity, purity, impurities, potency, and quality controlled by chemical testing, Alferon®, as a natural interferon, does not lend itself well to such testing. Moreover, FDA continues to require that each lot of Alferon we produce be tested and released by the FDA before it can be distributed for commercial sales. Because of the complexity of the Alferon manufacturing process and these additional regulatory requirements, we believe that potential manufacturers of generic, or so-called “bio-similar,” drug products are focused on developing recombinant interferon products, rather than natural interferon products. For these reasons, we believe the expiration of this Alferon® composition patent in April 2013 should have no or little impact on the Company.

Alferon® composition patent #5,676,942, relates to a methodology by which we no longer produce the product.

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 CFS, if and when it is approved for marketing and sale by the FDA, 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. It is our current intention 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 both Ampligen® and Alferon® in Argentina along with other South and Latin American 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 that are used in the production of Ampligen® and packaging materials are used in the fill and finish process. 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 and packaging materials for use in manufacturing Ampligen®. At present, we do not have any agreements with third parties for the supply of any of these 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. For more information on Ampligen®, please see the “Ampligen®” and “Manufacturing” sections in Item 2: Management's Discussion and Analysis of Financial Condition and Results of Operations; Overview; General.

If we are unable to obtain or manufacture the required 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 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, ownership of intellectual property, FDA and other governmental regulations. 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 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.

In January 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea Technologies, Inc. regarding the fill and finish process for Alferon N Injection® (see “MANUFACTURING” in Item 1.

Business above). As of December 31, 2012, all of our lots of Alferon® Work-In-Process Inventory have completed the fill, finish and packaging process. However, Process Validation of Alferon® Work-In-Process lots need to be completed. With our redirection of resources to the Ampligen® NDA submission, this process had been delayed but is now underway. We are unable to provide any assurances that the FDA will approve finish product lots produced by Althea.

Pursuant our Supply Agreement with Hollister-Stier, they 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. This Supply Agreement, as amended extends through March 11, 2014.

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. For more information on Ampligen® and Alferon N Injection®, please see “Ampligen®”, “Alferon N Injection®” and “Manufacturing” in Item 2: “Management's Discussion and Analysis of Financial Condition and Results of Operations; Overview; General”.

***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.

The production of new Alferon® API inventory will not commence until the capital improvement and validation phases are complete at the New Brunswick, NJ manufacturing facility. Due to the necessity to redirect our resources to the Ampligen® NDA application, the validation phase of the Alferon® manufacturing project has been delayed but is again underway. 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 prior to commercial sale of newly produced inventory product. Once we have obtained a reaffirmation of FDA BLA status and have begun production of new Alferon® API, the FDA will be required to provide approval as to the quality and stability of the final product. We anticipate that it will take until the second half of 2014 before we will have newly produced Alferon® that can be commercially sold in the United States. For more information, please see “Alferon N Injection®” and “Manufacturing” in Item 1: “Business”. 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 completed on a timely basis or successfully, that any given product will be determined to be safe and effective, or capable of being manufactured under applicable quality standards.

Only if and when our BLA status is recertified by the FDA to produce new lots of Alferon® at our enhanced manufacturing facility can batches of Alferon® API can be produced, formulated, filled, finished, packaged and then approved for release by the FDA. We are unable to provide any assurances that the FDA will approve our enhanced manufacturing process and/or newly created finish product lots. Without FDA approval, our Alferon N Injection® will not be considered suitable for commercial sales.



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 is no assurance that upon 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 upgrade our 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® and Alferon®. We may not be profitable unless we can produce Ampligen®, Alferon® or other products in commercial quantities at costs acceptable to us.***

Satisfactory inspection by the FDA of both our Ampligen® and Alferon® manufacturing process is required before commercial sale of project would be allowed. The CRL from the FDA on February 1, 2013 requests evaluation of variation between lots of Ampligen® tested in the development process and recommends tighter control of the Ampligen® manufacturing process. We cannot provide any guarantee that the facility will pass a FDA pre-approval inspection for Ampligen® or Alferon® manufacture, which are conducted in separately dedicated areas within the overall New Brunswick manufacturing complex. The failure to obtain FDA approval for either of our manufacturing process would most likely have a materially adverse impact upon us.

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.

We continue to undertake at our New Brunswick, NJ facility a major capital improvement program to upgrade our manufacturing capability to produce bulk quantities of Alferon N Injection® API. The facility enhancement project is in its final stage with construction complete and a Certificate of Approval issued by the Construction Official of New Brunswick, NJ for the work completed. The production of new API inventory will not commence until the capital improvement and validation phases are complete. Due to the necessity to redirect our resources to the Ampligen® NDA application process and efforts towards the pre-approval inspection for Ampligen® manufacturing, the validation phase of the Alferon® manufacturing project has been delayed. 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 upgrades for Alferon®. 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. The failure to obtain FDA approval of

any of our manufacturing process would most likely have a materially adverse impact upon us.

Also to be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. We believe, but cannot assure, that our enhancements to our manufacturing facilities will be adequate for our future needs 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 have never produced Ampligen®, Alferon® 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® and/or Alferon®, or continue to maintain third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. If and when the Ampligen® NDA is 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® and/or Alferon® 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 CFS in the United States. The dominant competitors with drugs to treat disease indications in which we plan to address include Pfizer, GlaxoSmithKline, Merck & Co., 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, 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.

The FDA in its February 1, 2013, CRL set forth the reasons for not approving Ampligen at this time and provided recommendations to address certain of the outstanding issues. The Agency stated that the submitted data do not provide substantial evidence of efficacy of Ampligen® for the treatment of CFS and that the data do not provide sufficient information to determine whether the product is safe for use in CFS due to the limited size of the safety database and multiple discrepancies within the submitted data.

If approved, one or more of the potential side effects of the drug might deter usage of Ampligen® in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

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

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

We 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.

***A Securities Federal Class Action and Two Shareholder Derivative Actions Have Been Filed Against Us and We May Be Subject to Civil Liabilities.***

As described below in Item 3. Legal Proceedings, paragraphs (a), (b) and (c), three actions have been filed against Hemispherx and certain of its Officers and Directors: a putative class action alleging violations of the federal securities laws and seeking monetary damages, costs, and attorneys' fees; and two shareholder derivative actions alleging various state law breach of fiduciary duty claims and seeking monetary damages, costs, attorneys' fees, and equitable and injunctive relief. Defending against these suits, even if meritless, can result in substantial costs to us and could divert the attention of our management.

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

**Risks Associated With an Investment in Our Common Stock:**

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

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

- announcements of the results of clinical trials by us or our competitors;
- announcement of legal actions against us and/or settlements or verdicts adverse to us;
- adverse reactions to products;  
governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental
- approvals or public or regulatory agency comments regarding the safety or effectiveness of our products, or the adequacy of the procedures, facilities or controls employed in the manufacture of our products;
- changes in U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards;
- overall investment market fluctuation;
- restatement of prior financial results;
- notice of NYSE MKT 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 MKT. For the 12 month period ended December 31, 2012, the closing price of our common stock has ranged from \$0.19 to \$1.10 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. In this regard, please see "A Federal Securities Class Action and Two Shareholder Derivative Actions Have Been Filed Against Us and We May Be Subject to Civil Liabilities" above.

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

In May 2009, we issued an aggregate of 25,543,339 shares and warrants to purchase an additional 14,708,687 shares under a Universal Shelf Registration Statement. 4,895,000 of these warrants have been exercised as of December 31, 2012. 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 statement and we have been selling shares under this shelf registration statement and the New Maxim EDA. Through December 31, 2012, we had sold an aggregate of approximately 29,500,000 shares under this EDA.

Pursuant to the New Maxim EDA, we may sell up to \$75,000,000 worth of our shares of Common Stock from time to time through Maxim, as sales agent. While we have no obligation to sell any of the Shares and may at any time suspend offers under the New Maxim EDA or terminate the EDA, the sale of substantial numbers of Shares under the EDA may have an adverse impact on the trading value of the stock.

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 New Maxim EDA or otherwise under the universal shelf registration statement or upon exercise of outstanding options, could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in Management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, on November 2, 2012, we amended and restated our 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, 2012. Each Right initially entitles holders to buy one-hundredth unit of preferred stock for \$30.00 and may be redeemed prior to November 19, 2017, the expiration date, at \$0.001 per Right under certain circumstances. 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 4.99% of our common stock, the Rights Plan’s threshold will be 20%, instead of 15%. For more information, see Part II; Item 5: “Other Information”.

***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 are currently evaluating various options with regards to the leasing of offices for our headquarters.

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.**

- (a) *Stephanie A. Frater v. Hemispherx Biopharma, Inc., William A. Carter, Thomas Equels and Charles Bernhardt, U.S. District Court for Eastern District of Pennsylvania, Case No. 2:12-cv-07152-WY.*
- Mark Zicherman v. Hemispherx Biopharma, Inc., William A. Carter, Thomas K. Equels, Iraj E. Kiani, William M. Mitchell, Richard C. Piani and Charles T. Bernhardt, U.S. District Court for Eastern District of Pennsylvania, Case No. 2:13-cv-00243-WY.*
- (c) *Michael Desclos v. Hemispherx Biopharma, Inc., William A. Carter, Charles T. Bernhardt, Thomas K. Equels, David R. Strayer, Richard C. Piani, William M. Mitchell, and Iraj E. Kiani, First Judicial District of Pennsylvania, Court of Common Pleas of Philadelphia, March 2013 Term, No. 110.*

On December 21, 2012, a putative federal securities class action complaint was filed against the Company and three of its officers in the United States District Court for the Eastern District of Pennsylvania. This action, *Stephanie A. Frater v. Hemispherx Biopharma, Inc., et al.*, was purportedly brought on behalf of a putative class of Hemispherx investors who purchased the Company's publicly traded securities between March 19, 2012 and December 17, 2012. The complaint generally asserts that Defendants made material misrepresentations and omissions regarding the status of the Company's New Drug Application for Ampligen®, which had been filed with the United States Food and Drug Administration, in alleged violation of Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), Rule 10b-5 promulgated thereunder, and Section 20(a) of the Exchange Act. On February 22, 2013, several putative members of the alleged plaintiff class filed motions to be appointed Lead Plaintiff pursuant to the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4. Pursuant to Court order, within 15 calendar days following the Court's appointment of a lead plaintiff and approval of the lead plaintiff's selection of lead counsel, the parties will submit an additional stipulation and proposed order setting forth a mutually agreeable schedule for the filing of any amended complaint and the briefing of Defendants' motion to dismiss. Under the PSLRA, discovery will be stayed pending the Court's decision on Defendants' motion to dismiss.

On January 15, 2013, a shareholder derivative complaint was filed against the Company, as nominal defendant, and certain of its Officers and Directors in the United States District Court for the Eastern District of Pennsylvania. The complaint in this action, *Mark Zicherman v. Hemispherx Biopharma, Inc., et al.*, alleges violations of state law, including breaches of fiduciary duties, waste of corporate assets, and unjust enrichment, arising from the alleged federal securities violations asserted in the securities class action. On February 22, 2013, the Court entered an order staying this case pending the outcome of Defendants' motion to dismiss the securities class action.

On March 4, 2013, a shareholder derivative and putative class action complaint was filed against the Company, as nominal defendant, and certain of its officers and directors in the First Judicial District of Pennsylvania of the Court of Common Pleas of Philadelphia. The complaint alleges violations of state law, including breaches of fiduciary duties, waste of corporate assets, and unjust enrichment. As of today's date, none of the defendants has been served with the complaint.

The Company intends to vigorously defend these actions. The potential impact of these actions, which seek unspecified damages, equitable relief, attorneys' fees and expenses, is uncertain. There can be no assurance that an adverse result in these proceedings would not have a potentially material adverse effect on the Company's business, results of operations and financial condition.

(d) *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. Keble 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 security bond of \$66,873 related to the JCI proceedings and a second bond of \$25,200 was posted in July 2012 related our proceedings against the Estate of Keble.

*(e)MidSouth Capital, Inc. v. Hemispherx Biopharma, 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 (Adam Cabibi and Robert Rosenstein) 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 were 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 was assigned Case No. 11-11618-E and the Company's Cross-Appeal was assigned Case No. 11-11650-E. Mediation ordered by the Court of Appeals was unsuccessful. Oral arguments on consolidated appeals took place before the Eleventh Circuit Court of Appeals on February 1, 2012.

In early April 2012, the Company received notice that Robert Rosenstein, a principal of MidSouth, filed a petition under Chapter 7 of the Bankruptcy Code in the Northern District of Georgia. The Company elected not to contest the dischargability of its claim against Mr. Rosenstein.

On August 14, 2012, the panel to which the Appeal and Cross-Appeal had been assigned issued an opinion affirming in part and reversing in part the decisions of the Trial Court. The Court of Appeals affirmed both the Trial Judge's grant of Summary Judgment in favor of the Company and Sage on MidSouth's fraud Counterclaim and the grant of Summary Judgment in favor of MidSouth, Cabibi, and Rosenstein on the Company's tortious interference claims. The Court of Appeals reversed the Trial Court's Order dismissing MidSouth's Counterclaim for breach of contract and the Order granting Summary Judgment in favor of the Company on MidSouth's Counterclaims based on promissory estoppel, quantum meruit, and unjust enrichment.



After remand to the District Court, a Scheduling Order proposed by the parties was entered by the Court on October 17, 2012. In light of the Court of Appeals' Ruling, the parties were realigned with MidSouth as the Plaintiff and the Company as the Defendant. The Company deposed representatives of two more of the investors to preserve their testimony for trial. Neither witness testified that MidSouth's activity significantly influenced the decision to invest. The Company has moved for leave to designate an expert witness, and that Motion is awaiting a decision by the Trial Court. If leave is granted, there will be an additional period of discovery limited to expert issues. If the Motion is denied, the parties will prepare and submit a proposed pretrial Order together with any other pretrial Motions. In either event, the Company will vigorously defend the remaining claims. No date has been set for trial.

As of March 6, 2013, 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 MidSouth claims or a range of potential recovery or loss.

*(f) 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 sought 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. 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 was 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. On August 30, 2011, the Company and the Sage Group filed an Answer with Affirmative Defenses to the Plaintiff's Amended Complaint. 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. In accordance with a Scheduling Order set by the Court, the parties concluded fact and expert discovery on April 16, 2012. On April 30, 2012 the Company filed Motions for Summary Judgment seeking dismissal of all counts. The Sage Group also filed a Motion for Summary Judgment seeking dismissal of all counts asserted against Sage.

The parties concluded Fact and Expert Discovery on April 16, 2012. On April 30, 2012 the Company filed Motions for Summary Judgment seeking dismissal of all counts. The Sage Group (“Sage”) also filed a Motion for Summary Judgment seeking dismissal of all counts asserted against Sage. On September 10, September 12, and September 13, 2012 the Court entered Orders denying all pending Motions by all parties.

The Parties had a Non-Jury trial on March 4, 5 and 6, 2013, before the United States District Court for the District of Delaware. The Court has Ordered the Parties to submit additional briefing and other documentation to the Court on or before April 22, 2013. There can be no estimate of when the Court may rule on the case.

As of March 6, 2013, no informed judgment can be made as to the likely outcome and Counsel is unable to provide an estimate of the merits or probability of success of the Cato claims or a range of potential recovery or loss.

**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 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. In 2012, we issued 1,111,397 shares of common stock in payment to vendors and consultants for services rendered along with 189,674 shares and 50,073 shares issued to two individuals formerly serving as our Senior Director of Manufacturing, in payment of 50% of their respective 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 MKT (formerly 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 MKT. Such prices reflect inter-dealer prices, without retail mark-up, mark-downs or commissions and may not necessarily represent actual transactions.

	High	Low
<b>COMMON STOCK</b>		
Time Period:		
January 1, 2012 through March 31, 2012	\$0.50	\$0.19
April 1, 2012 through June 30, 2012	\$0.40	\$0.25
July 1, 2012 through September 30, 2012	\$1.10	\$0.27
October 1, 2012 through December 31, 2012	\$0.85	\$0.25
January 1, 2011 through March 31, 2011	\$0.61	\$0.45
April 1, 2011 through June 30, 2011	\$0.57	\$0.33
July 1, 2011 through September 30, 2011	\$0.44	\$0.24
October 1, 2011 through December 31, 2011	\$0.33	\$0.17

As of March 1, 2013, 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, 2013, the last sale price for our common stock on the NYSE MKT was \$0.22 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, 2012:

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:	13,069,912	\$ 1.87	6,936,892
Equity compensation plans not approved by security holders:	11,128,246	\$ 1.44	0
Total	24,198,158	\$ 1.67	6,936,892

## PERFORMANCE GRAPH

Total Return To Shareholders  
(Includes reinvestment of dividends)

ANNUAL RETURN PERCENTAGE

Company Name / Index	Years Ending				
	Dec. 2008	Dec. 2009	Dec. 2010	Dec. 2011	Dec. 2012
Hemispherx Biopharma, Inc.	-52.63	55.56	-11.88	-60.47	28.55
S&P SmallCap 600 Index	-31.07	25.57	26.31	1.02	16.33
Peer Group	-70.17	67.87	-44.07	-60.97	-29.17



Company Name / Index	Base		INDEXED RETURNS			
	Period		Years Ending			
	Dec. 2007	Dec. 2008	Dec. 2009	Dec. 2010	Dec. 2010	Dec. 2011
Hemispherx Biopharma, Inc.	100	43.37	73.68	64.93	25.67	33.00
S&P SmallCap 600 Index	100	68.93	86.55	109.32	110.43	128.46
Peer Group	100	29.83	50.07	28.00	10.93	7.74

## Peer Group Companies

CARDIUM THERAPEUTICS INC

CYTRX CORP

GENVEC INC

OXIGENE INC

REGENERX BIOPHARMACEUTICALS

**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, 2012 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	2008	2009	2010	2011	2012
Statement of Operations Data:					
Revenues and License fee Income	\$265	\$111	\$135	\$161	\$213
Total Costs and Expenses <sup>(1)</sup>	13,076	13,375	16,522	14,456	20,553
Interest Expense and Financing Costs <sup>(2)</sup>	0	241	11	41	24
Redeemable warrants valuation adjustment	0	(6,258 )	(879 )	(2,425 )	(85 )
Net loss	(12,219 )	(7,180 )	(13,136 )	(9,015 )	(17,354 )
Net loss applicable to common stockholders	(12,219 )	(7,180 )	(13,136 )	(9,015 )	(17,354 )
Basic and diluted net loss per share	\$(0.16 )	\$(0.07 )	\$(0.10 )	\$(0.07 )	\$(0.12 )
Shares used in computing basic and diluted net loss per share	75,142,075	109,514,401	134,018,243	135,432,395	141,016,935
Balance Sheet Data:					
Working Capital	\$5,646	\$55,789	\$33,842	\$26,717	\$32,079
Total Assets	13,211	64,994	51,680	43,513	57,699
Debt, net of discount	0	0	0	1,695	7,051
Stockholders' Equity	11,544	58,695	45,947	37,965	44,700
Cash Flow Data:					
Cash used in operating activities	(9,358 )	(9,297 )	(11,886 )	(10,096 )	(13,136 )
Capital expenditures	\$(73 )	\$(332 )	\$(729 )	\$(1,802 )	\$(5,755 )

(1) General and Administrative expenses include stock compensation expense of \$573, \$826, \$740, \$377 and \$356 for the years ended December 31, 2008, 2009, 2010, 2011 and 2012, respectively.

(2) For information concerning our financing see Note 20 "Margin Account Loan" to our consolidated financial statements for the year ended December 31, 2012 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, 2012. 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 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-Merton value 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.

Fair value at measurement dates during the period from Warrants' issued May 10, 2009, May 18, 2009 and May 21, 2009 to December 31, 2010, 2011 and 2012, were estimated using the following assumptions:

	2010	2011	2012
Underlying price per share	\$0.47-\$0.74	\$0.20-\$0.46	\$0.25-\$0.80
Exercise price per share	\$1.31-\$1.65	\$1.31-\$1.65	\$1.31-\$1.65
Risk-free interest rate	0.83%-2.36%	0.29%-1.58%	0.19%-0.44%
Expected holding period	3.38-4.63 years	2.38-3.63 years	1.38-2.63 years
Expected volatility	112.16%-122.02%	74.55%-120.55%	69.21%-110.27%
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:

- The Company only has one product that is FDA approved for sale, but such product will not be available for commercial sales any sooner than the second half of 2013;
- a.
  - b. The production of new Alferon N Injection® API inventory will not commence until the capital improvement and validation phases are complete;

- c. The Company is expected to be required to perform additional clinical trials for FDA approval of its flagship product as well as to diversify the applications of its FDA approved product;
- d. Industry and market conditions continue to include a global market recession, adding risk to any transaction;
- e. Available capital for a potential buyer in a cash transaction continues to be limited;
- f. The nature of a life sciences company is heavily dependent on future funding and high fixed costs, including Research & Development;
- g. 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
- h. 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, 2012 versus December 31, 2011

#### Net Loss

Our net loss of approximately \$17,354,000 for the year ended December 31, 2012 was 93% higher when compared to the same period in 2011. This \$8,339,000 increase in loss was primarily due to:

- 1) an increase in Research and Development costs in 2012 of approximately \$2,786,000 or 41% as compared to the same period in 2011;
- 2) an increase in Production/Cost of Goods Sold in 2012 of approximately \$946,000 or 91%;
- 3) an increase in General and Administrative expenses of approximately \$2,365,000 or 35% as compared to the same period in 2011;
- 4) the revaluation of the Liability related to the Redeemable Warrants resulting in a non-cash gain of approximately \$85,000 in 2012 as compared to non-cash gain of approximately \$2,425,000 for the same period in 2011, resulting in an increased loss of \$2,340,000;
- 5) sale in January 2012 of \$16,000,000 of our New Jersey state Net Operating Loss carry-forwards (for the years 2009 and 2010) for approximately \$1,328,000 as compared to February 2011, when we effectively sold \$28,000,000 of our New Jersey state Net Operating Loss carry-forwards (for the years 2003 through 2008) for approximately \$2,272,000, representing a decrease in income of \$944,000 or 42%; offset by
- 6) an increase in interest and other income of approximately \$973,000 from funds invested in marketable securities.

Net loss per share was \$(0.12) for the current twelve month period versus \$(0.07) per share for the same period in 2011. The weighted average number of shares of our common stock outstanding as of December 31, 2012 was 141,016,935 as compared to 135,432,395 as of December 31, 2011.

### Revenues

Revenues from our Ampligen® Cost Recovery Treatment Program for the year ended December 31, 2012 were approximately \$213,000 compared to revenues of \$161,000 for the same period in 2011, an increase of \$52,000 or 32%. The number of patients increased 25% in 2012. There were 45 patients in 2012 and 36 patients in 2011 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 2012 or 2011 and all sales revenue in 2012 and 2011 has been generated from the Ampligen® Cost Recovery Treatment Program.

### Production/Cost of Goods Sold

Production/Cost of Goods Sold was approximately \$1,989,000 and \$1,043,000, respectively, for the twelve months ended December 31, 2012 and 2011. This increase of \$946,000 or 91% was primarily due to cost of fill, finish and packaging of Alferon N Injection® Work-In-Process inventory along with a related valuation write-down reserve of approximately \$1,024,000 to the lower of cost or market.

### Research and Development Costs

Overall Research and Development (“R&D”) costs for the year ended December 31, 2012 were approximately \$9,508,000 as compared to \$6,722,000 for the same period a year ago, reflecting an increase of approximately \$2,786,000 or 41%. The increased R&D efforts during the year 2012 were primarily due to approximately \$2,290,000 spent on our efforts regarding the Ampligen® NDA and preparedness for the FDA pre-approval inspections of the New Brunswick manufacturing facility along with approximately \$1,159,000 of employment agreement incentive payment to Dr. William A. Carter, our Chief Executive Officer, President and Chief Scientific Officer, with these expenses offset by approximately \$663,000 of cost savings achieved by suspending Alferon® related R&D projects.

### General and Administrative Expenses

General and Administrative (“G&A”) expenses for the year ended December 31, 2012 and 2011 were approximately \$9,056,000 and \$6,691,000, respectively, reflecting an increase of approximately \$2,365,000 or 35%. The higher G&A expenses in 2012 consisted primarily of an increase of approximately \$446,000 in legal fees due to the Cato Capital, LLC litigation and efforts to domesticate the judgment against JCI in South Africa, approximately \$229,000 of prior year’s Director’s fees paid to Dr. Iraj E. Kiani, approximately \$1,159,000 of employment agreement incentive payment to Thomas K. Equels, in his role as our General Counsel, and \$250,000 bonus to The Sage Group for consulting fees. For detailed information on the sources of legal fees, see “Note 16 – Contingencies” under Notes to Consolidated Financial Statements.

### Interest and Other Income

Interest and other income for the years ended December 31, 2012 and 2011 was approximately \$1,597,000 and \$624,000, respectively, representing an increase of \$973,000 or 156%. The primary causes for the increase of investment income was a higher rate of return from our portfolio of short and long-term bond and fixed-income type investments during 2012, an increase in the size of our portfolio as proceeds were realized from sale of stock through the Maxim ATM in the latter part of 2012 and capital gain distributions of approximately \$409,000 from the mutual funds investments. The interest income from the investments is recognized over the life of the instrument.

### Interest Expense

In 2010 and 2011, we financed through capital leases some office equipment vital to our overall operations as well as manufacturing equipment utilized in the production of Alferon®. For the years ended December 31, 2012 and 2011, we had interest expense of approximately \$24,000 and \$41,000, respectively from these capital leases.

### Sale of New Jersey Tax Net Operating Loss

In January 2012, we effectively sold \$16,000,000 of our approximately \$25,000,000 of New Jersey state Net Operating Loss carry-forwards (for the years 2009 and 2010) for approximately \$1,328,000 as compared to February 2011, when we effectively sold \$28,000,000 of our New Jersey state Net Operating Loss carry-forwards (for the years 2003 through 2008) for approximately \$2,272,000, representing a decrease in gain of approximately \$944,000 or 42% (see “Note 15: Income Taxes (FASB ASC 740 Income Taxes) and Subsequent Event”).

Redeemable Warrants Valuation Adjustment

The quarterly fiscal revaluations resulted in non-cash adjustments to the redeemable warrants liability for the twelve months ended December 31, 2012 and 2011 of approximately \$85,000 gain and \$2,425,000 gain, respectively, representing a decrease of \$2,339,000 (see “Note 19: Fair Value”).

## 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. a decrease in Research and Development costs in 2011 of approximately \$891,000 or 12% as compared to the same period in 2010;

2. a decrease in Production/Cost of Goods Sold in 2011 of approximately \$298,000 or 22%;

3. a decrease in 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. The weighted average number of shares of our common stock outstanding as of December 31, 2011 was 135,432,395 as compared to 134,081,243 as of December 31, 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 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.

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 approximately \$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 approximately \$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 a 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 approximately \$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 our overall operations 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.

Sale of New Jersey Tax Net Operating Loss

In February 2011, we received approximately \$2,272,000 from the sale of the State of New Jersey tax net operating losses for years 2003 to 2008. 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.



### Liquidity and Capital Resources

Cash used in operating activities for the twelve months ended December 31, 2012, was approximately \$13,136,000 compared to \$10,096,000 for the same period in 2011, an increase of \$3,040,000 or 30%. 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, 2012, was approximately \$14,464,000 compared to \$12,368,000. Cash used in operating activities increased by approximately \$2,096,000 or 17% over the comparable period in 2011. This increase was primarily due to our efforts regarding the Ampligen® NDA and preparedness for the FDA pre-approval inspections of the New Brunswick manufacturing facility.

In January 2012, we effectively sold \$16,000,000 of our New Jersey state Net Operating Loss carry-forwards (for the years 2009 and 2010) for approximately \$1,328,000 as compared to February 2011, when we effectively sold \$28,000,000 of our New Jersey state Net Operating Loss carry-forwards (for the years 2003 through 2008) for approximately \$2,272,000. As of December 31, 2012, we had approximately \$8,500,000 of New Jersey state net operating loss carry forwards (expiring in the years 2021 through 2022) available to offset future state taxable income or possibly sell through the State of New Jersey's Corporate Business Tax Transfer Program.

As of December 31, 2012, we had approximately \$43,953,000 in Cash, Cash Equivalents and Marketable Securities (inclusive of \$14,500,000 in Marketable Securities collateralizing certain debts), or an increase of approximately \$9,562,000 from December 31, 2011. However, if we are unable to commercialize and sell Ampligen® or Alferon® LDO and/or recommence material sales of Alferon N Injection®, our operations, financial position and liquidity may be adversely impacted, and additional financing may be required, however, there is no assurance that such financing will be available.

In its CRL, the FDA communicated that Hemispherx should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analysis. Until we undertake the end-of-review conference(s) with the FDA, we are unable to reasonably estimate the nature, costs, necessary efforts to obtain FDA clearance or anticipated completion dates of any additional clinical study or studies. Utilizing the industry norms for undertaking a Phase III clinical study, we estimate upon acceptance of the study's design that it would take approximately 18 months to three years to complete a new well-controlled Ampligen® clinical study for resubmission to the FDA. It can be reasonably anticipated that the time and cost to undertake clinical trial(s), studies and data analysis are beyond our current financial resources without gaining access to additional funding. The actual duration to complete the clinical study may be different based on the length of time it takes to design the study and obtain FDA's acceptance of the design, the final design of an acceptable Phase III clinical study design, availability of suitable participants and clinical sites along with other factors that could impact the implementation of the study, analysis of results or requirements of the FDA and/or other governmental organizations. 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"*.



A “Margin Account” loan was established with Wells Fargo Advisors for which the proceeds of this flexible form of indebtedness effectively serves us 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, we needed to pledge, restrict from sale and segregate to a Margin Account our Marketable Securities at an approximate ratio of two to one, based on the diversity of securities pledged as collateral, for debt undertaken. With the exception of collateral requirements, we maintain 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, from its inception in October 2011 through September 2012, it carried an effective interest rate of 2.75% per annum applied against the “Margin Debit Balance” (i.e., those funds withdrawn and outstanding), based on the prevailing “Wells Fargo Base Rate” less 2.50%. Currently, an effective interest rate of 2.50% per annum is being applied against the Margin Debit Balance by Wells Fargo Advisors. As of December 31, 2012, the principal loan balance of the Margin Account was approximately \$7,051,000, for which approximately \$14,500,000 in Marketable Securities were restricted as dedicated collateral for the indebtedness. 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 were restricted as dedicated collateral. The finance and construction period interest charges were approximately \$85,000 and \$6,000 for the twelve months ended December 31, 2012 and three months ended December 31, 2011, respectively. (see “Note 20: Margin Account Loan”).

On July 23, 2012, we entered into a new EDA with Maxim (the New EDA”) pursuant to which we may sell up to \$75,000,000 worth of our shares of common stock from time to time through Maxim, as sales agent. Under the New EDA, Maxim is entitled to a fixed commission rate of 4.0% of the gross sales price of Shares sold under the New EDA, up to aggregate gross proceeds of \$10,000,000, and thereafter, at a fixed commission rate of 3.0% of the gross sales price of Shares sold under the EDA. Sales of the Shares, if any, may be made in transactions that are deemed to be “at-the-market” offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers’ transactions, including on the NYSE MKT, at market prices or as otherwise agreed with Maxim. We have no obligation to sell any of the Shares and may at any time suspend offers under the New EDA or terminate the New EDA. The Shares are being sold pursuant to our Universal Shelf Registration Statement on Form S-3, declared effective by the Securities and Exchange Commission on July 2, 2012. On September 14, 2012, we filed a Prospectus Supplement with the Securities and Exchange Commission related to the offering of 20,000,000 shares under the ATM. On October 5, 2012, we filed an updated Prospectus Supplement. As a result, as of the date of this report, an aggregate of 40,000,000 shares are allocated for public sale under the Prospectus Supplement pursuant to the ATM. As of December 31, 2012, we had sold an aggregate of approximately 29,500,000 shares that resulted in net cash proceeds of approximately \$23,003,000 after direct expenses along with commissions paid to Maxim of approximately \$820,000. (see “Note 9: Stockholders’ Equity”). During the twelve months ended December 31, 2011, we sold no shares through this program and received no net cash proceeds.

There can be no assurances that, if needed, we will be able to raise adequate funds from these or other sources or enter into licensing, partnering or other arrangements to advance our business goals. Our inability to raise such funds or enter into such arrangements, 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. 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.”

The proceeds from our financing have been used to fund infrastructure growth including manufacturing, regulatory compliance and market development along with our efforts regarding the Ampligen® NDA and preparedness for the FDA pre-approval inspections of the New Brunswick manufacturing facility. 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.

Contractual Cash Obligations	(dollars in thousands)				
	Obligations Expiring by Period				
	Total	2013	2014	2015	2016
Margin Account Loan	\$7,051	\$7,051	\$ 0	\$ 0	\$ 0
Capital Leases	125	61	40	23	1
Operating Leases	65	65	0	0	0
Total	\$7,241	\$7,177	\$ 40	\$ 23	\$ 1

### **Certain Relationships and Related Transactions**

Refer to 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-Merton pricing 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 January 1, 2011, 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, 2012 and 2011 there were no receivables.

All sales for years ended December 31, 2012 and 2011 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 \$43,953,000 in cash, cash equivalents and Marketable Securities (restricted and non-restricted) at December 31, 2012. 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, 2012 and 2011, and our consolidated statements of comprehensive loss, changes in stockholders' equity, and cash flows for each of the years in the three year period ended December 31, 2012, together with the report of McGladrey LLP (formerly known as 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, 2012, 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, 2012 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, 2012. 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, 2012. 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, 2012, 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, 2012 has been audited by McGladrey 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:

<b>Name</b>	<b>Age</b>	<b>Position</b>
William A. Carter, M.D.	75	Chairman of the Board, Chief Executive Officer, President and Chief Scientific Officer
Thomas K. Equels, Esq.	60	Executive Vice Chairman of the Board, Secretary and General Counsel
Richard C. Piani	86	Lead Independent Director
William M. Mitchell, M.D., Ph.D.	78	Director
Iraj E. Kiani, N.D., Ph.D.	67	Director
Charles T. Bernhardt, CPA	51	Chief Financial Officer and Chief Accounting Officer
David R. Strayer, M.D.	67	Chief Medical Officer and Medical Director
Robert Dickey IV	57	Senior Vice President
Wayne Springate	41	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, CEO, President and Chief Scientific Officer 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. Mr. Equels is the President and Managing Director of the Equels Law Firm headquartered 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 E. 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. Dr. Kiani received his Ph.D. degree from the University of Ferdosi in Iran, and his ND from American University.

**IRAJ E. 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.

**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, 2012, all of our Officers and Directors had complied with all applicable Section 16(a) filing requirements on a timely basis with regard to transactions occurring in 2012.

### 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 E. 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 MKT 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 MKT 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 seven times in 2012 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. The full text of the Audit Committee’s Charter, as approved by the Board, is available on our website: [www.hemispherx.net](http://www.hemispherx.net) in the “Investor Relations” tab under “Corporate Governance”.

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 on an as-needed basis. 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 Controls 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 Richardson, of Providence Management & Communication, serves the DCC as Deputy Investor Relations Coordinator. The full text of the DCC's Charter, as approved by the Board, is available on our website: [www.hemispherx.net](http://www.hemispherx.net) in the "Investor Relations" tab under "Corporate Governance".

## 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](http://www.hemispherx.net) (Investor Relations / Corporate Governance) or by written request to our office at 1617 JFK Boulevard, Suite 660, Philadelphia, PA 19103.

## **ITEM 11. Executive Compensation.**

### **COMPENSATION DISCUSSION AND ANALYSIS**

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

- Dr. William A. Carter, Chief Executive Officer ("CEO"), President and Chief Scientific Officer ("CSO");
- Charles T. Bernhardt, Chief Financial Officer ("CFO") & Chief Accounting Officer ("CAO");
- Thomas K. Equels, General Counsel;
- Dr. David Strayer, Chief Medical Officer ("CMO") and Medical Director; and
- Robert Dickey, IV, Senior Vice President ("SVP").

### **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 that is currently approved to undertake clinical testing targeting influenza.

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## **Governance of Compensation Committee**

The Compensation Committee consists of the following three directors, each of whom is “independent” under applicable NYSE MKT 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’s Charter, as approved by the Board, is available on our website: [www.hemispherx.net](http://www.hemispherx.net) in the “Investor Relations” tab under “Corporate Governance”. This Committee formally met four times in 2012 and all committee members were in attendance for at least 75% 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 September 19, 2012 Annual Meeting of Stockholders, the Stockholders approved the annual, non-binding “say on pay” advisory vote on Executive Compensation with 85.35% of the shares cast to affirm the plan.

Our Compensation Committee reviews its executive compensation policies annually and takes into account the results of prior say-on-pay advisory votes. After reviewing the results of the 2011 say-on-pay advisory vote, the Committee had:

- Developed Company-wide goals and objectives with the intent to increase Stockholder value, enhance the “pay for performance” concept, attempted 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 each 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 Company’s overall goals;

- Reviewed peer group financial data of comparable publicly-traded companies for 2011 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;

Issued new options to employees at the rate of 110% of the Company's NYSE MKT stock market trading value at the time of award; 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.

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

Compensation Committee	<ul style="list-style-type: none"> <li>•Fulfills the Board of Directors' responsibilities relating to compensation of Hemispherx' NEO, other non-officer Executives and non-Executives.</li> <li>•Oversees implementation and administration of Hemispherx' compensation and employee benefits programs, including incentive compensation and equity compensation plans.</li> <li>•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.</li> <li>•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.</li> <li>•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.</li> <li>•Reviews and approves employment agreements, severance arrangements, issuances of equity compensation and change in control agreements.</li> </ul>
Chairman and CEO	<ul style="list-style-type: none"> <li>•Presents to the Compensation Committee the overall performance evaluation of, and compensation recommendations for, each of the NEO and other non-officer Executives.</li> </ul>
Chief Financial Officer and Director of Human Resources	<ul style="list-style-type: none"> <li>•Reports directly or indirectly to the Chief Executive Officer.</li> <li>•Assists the Compensation Committee with the data for competitive pay and benchmarking purposes.</li> </ul>

- 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 2012 and 2011, 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 or activity;

- 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, 2012, 2011 and 2010 at the rates of 2.1%, 3.6% and 3.0%, respectively. Additional changes to our NEO's base salaries could be undertaken in a future determination by the Compensation Committee at its discretion. During 2012, none of the employment contracts of NEOs were created, amended or restated. During 2011, employment agreements were amended and restated for the following NEOs: Dr. William Carter, Charles Bernhardt and Thomas Equels. 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, 2012, 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%); and
- Charles Bernhardt, Chief Financial Officer and Chief Accounting Officer (bonus opportunity up to 25%).

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 review and reestablish goals and objectives for the Executive Team regarding possible bonuses for the year ending December 31, 2012. 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® and 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 cumulative 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 2012 and January 2013, the Compensation Committee reviewed the Executive Team's Company-wide goals as detailed in the Committee's prior 2012 Meeting Minutes along with 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 2011 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 2012 and reached a consensus that the impact of the stock's 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. The market value of the Company's stock had been volatile during 2012 and traded from a high of \$1.10 to a low of \$0.19;
3. Confidence that Company's employees were working diligently in an attempt to return the market value to the stock;
4. Recognition that employees had worked tirelessly over the second half of 2012 related to the Ampligen® NDA and preparedness of the manufacturing facility in New Brunswick; and
5. 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 2012 Performance Bonuses were granted and paid in 2012 to the following NEO at the rate of 25% of their respective 2012 year-end base compensation:

- William Carter (Chairman, CEO, President, Chief Scientific Officer) for \$241,906;
- Thomas Equels (Executive Vice Chairman, Secretary & General Counsel) for \$129,500;
- Charles Bernhardt (CFO & Chief Accounting Officer) for \$58,275;
- David Strayer (Chief Medical Officer & Medical Director) for \$65,800; and
- Seven non-NEO employees included in 2012 Performance Bonuses for total of \$186,170.

### **Employee Appraisal And Merit Bonus Program**

For the year ending 2012, 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 2012, the Compensation Committee granted ten employee bonus related to this Program for an approximate total of \$24,000.

### **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.



During 2012, the Compensation Committee and Board of Directors sought out and received an opinion of independent legal counsel regarding the elements of the Executive Performance Incentive Bonus created by the current employment contracts of William Carter and Thomas Equels in relation to the shares of Company stock sold through the Maxim ATM. It was the opinion of independent counsel that Section 3(c)(ii) of Dr. Carter and Mr. Equels respective agreements could reasonably be interpreted to require the Company to pay them a 5% bonus on the net proceeds resulting from the sale of securities of the Maxim ATM Offering as either (a) constitutes any sale of the Company, or (b) is a sale of substantial portion of Company assets not in the ordinary course of its business. On November 26, 2012, all of the members of the Compensation Committee authorized the payment of bonus for the Company stock sold through the Maxim ATM based on the contractual obligation and opinion of independent counsel. For the year ending 2012, compensation was granted or paid related to the Executive Performance Incentive Program, as set forth in Section 3(c)(ii) of their respective Employment Agreements, for approximately \$1,159,000 to each Dr. Carter and Mr. Equels, respectively.

### **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 2012, 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. For the year ending 2012, no compensation was granted or paid in relation to Long-Term Bonus Programs.

### **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 2012, 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.

Effective as of December 2011, the Compensation Committee mandated that the standard terms of options to be issued to individuals in their role as Company employees 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.

The following Options were issued to NEO in their role as employees during 2012:

On April 13, 2012, we granted 10 year term replacement options to purchase 10,000 shares of our common stock at an exercise price of \$4.03 per share that vested immediately to both Dr. William Carter, Chairman, Chief Executive Officer and Chief Scientific Officer, and Dr. David Strayer, Chief Medical Officer and Medical Director, respectively;

On June 5, 2012, we granted options to purchase 50,000 shares of our common stock at an exercise price of \$0.29 per share, or 110% of the closing price of the stock on the NYSE MKT as of June 4, 2012 with total vesting in twelve months, to Robert Dickey, Senior Vice President;

On June 11, 2012, we granted options to purchase 500,000 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 MKT as of June 10, 2012 with total vesting in twelve months, to William A. Carter, Chairman, Chief Executive Officer and Chief Scientific Officer, consistent with his employment agreement; and

On June 11, 2012, we granted options to purchase 300,000 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 MKT as of June 10, 2012 with total vesting in twelve months, to Thomas K. Equels, Executive Vice Chairman, Secretary and General Counsel, 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 2012 NEO as an element of their respective employment:

Dr. William Carter, Chief Executive Officer and Chief Scientific Officer:

Automobile allowance;

Reimbursement of home office, computer, internet, phone and telefax expenses;

Health, vision and dental insurance fully paid by the Company; and

Supplementary life and disability insurance policies.

Thomas Equels, General Counsel:

Automobile allowance;

Predetermined allowance for the Company's utilization of Florida offices of Equels Law Firm;

Reimbursement of home office, computer, internet, phone and telefax expenses;

Health, vision and dental insurance fully paid by the Company; and

Supplementary life and disability insurance policies.

Charles Bernhardt, Chief Financial Officer and Chief Accounting Officer:

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 was to be equal to 120% of the closing price of our stock on the NYSE MKT on the last trading day of the calendar quarter for which the Options are being issued.

Additionally, the severance/consulting agreement remains in effect until passage of one of the following events:

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 \$540,000 (two times the amount of compensation agreed upon with Mr. Peterson by us for calendar year 2008 compensation); or

On the occurrence of a "Change In Control, the Company shall pay to Peterson three times the amount of compensation paid to Peterson by the Company for calendar year 2008.

As a result of Financial Transactions completed through the sale of Company stock in the Maxim ATM, Mr. Peterson was paid \$231,839 in 2012 towards the Peterson One Per Cent Fee, for which \$139,214 remains outstanding at December 31, 2012 for the agreement to terminate as fulfilled.

### **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 and Dr. David Strayer are currently not covered under an existing severance agreement. 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, 2012.

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, 2012 and Hemispherx' Proxy Statement to be filed in connection with Hemispherx' 2013 Annual Meeting of Stockholders.

**COMPENSATION COMMITTEE**

Dr. Iraj E. Kiani, Committee Chairman

Dr. William M. Mitchell

Mr. 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 E. 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, 2012, 2011 and 2010 of our Chief Executive Officer, Chief Financial Officers, three other most highly compensated Executive Officers constituting the Company's Named Executive Officers, based on the year-ending 2012 for each fiscal year.

**Summary Compensation Table**

Name & Principal Position	Year	Salary / Fees (3)	Bonus	Stock Awards (15)	Option Awards (3) (15)	Change in Pension and Other Compensation			Total Compensation (3)		
						Non-Executive Incentive Plan Compensation	Valued Additions	Other Earnings (\$)			
William A. Carter CEO, President & CSO (1) (3)	2012	\$1,143,692	\$1,401,099	(4)(8)	\$-0-	\$133,627	(1)(5)	\$-0-	—\$148,938	(16)	\$2,827,3
	2011	\$1,007,714	\$233,500	(9)	\$-0-	\$143,749	(1)	\$-0-	—\$132,052	(16)	\$1,517,0
	2010	\$951,837	\$200,000	(10)	\$405,083	(13)	\$253,721	(1)(14)	\$-0-	—\$100,699	(16)
Thomas K. Equels General Counsel (2) (3)	2012	\$694,068	\$1,288,693	(4)(8)	\$-0-	\$87,246	(2)	\$-0-	—\$101,450	(17)	\$2,171,4
	2011	\$572,957	\$125,000	(9)	\$-0-	\$91,504	(2)	\$-0-	—\$48,813	(17)	\$838,27
	2010	\$398,333	\$250,000	(10)(11)	\$-0-	\$140,528	(2)	\$-0-	—\$39,973	(17)	\$828,83
Charles Bernhardt CFO & CAO (6)	2012	\$233,100	\$58,275	(8)	\$-0-	\$-0-		\$-0-	—\$41,959	(18)	\$333,33
	2011	\$208,389	\$81,250	(9)(12)	\$-0-	\$14,291	(6)	\$-0-	—\$25,935	(18)	\$329,86
	2010	\$194,133	\$50,000	(10)	\$117,296	(13)	\$37,301	(6)	\$-0-	—\$24,273	(18)
Robert Dickey (7) Sr. Vice President	2012	\$313,390	\$-0-		\$-0-	\$9,987	(7)	\$-0-	—\$10,429	(19)	\$333,80
	2011	\$302,500	\$-0-		\$-0-	\$-0-		\$-0-	—\$7,797	(19)	\$310,29
	2010	\$302,500	\$-0-		\$-0-	\$-0-		\$-0-	—\$8,232	(19)	\$310,73
David Strayer CMO & Medical Director	2012	\$260,032	\$65,008	(8)	\$-0-	\$1,534	(5)	\$-0-	—\$10,030	(20)	\$336,60
	2011	\$251,000	\$51,199	(9)	\$-0-	\$-0-		\$-0-	—\$13,098	(20)	\$315,29
	2010	\$243,685	\$48,737	(10)	\$132,587	(13)	\$-0-		\$-0-	—\$13,227	(20)

Notes:

Dr. Carter renewed his Employment Agreements on June 11, 2010, which was amended on July 15, 2010, then  
(1) 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.

Mr. Equels transitioned from the role of external to internal General Counsel and Litigation Counsel effective June  
(2) 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.

For Named Executive Officers, who are also Directors that receive compensation for their services as a Director, the Salary/Fees and Option Awards columns include compensation that was received by them for their role as a  
(3) member of the Board of Directors. As is required by Regulation S-K, Item 402(c), compensation for services as a Director have been reported within the "Summary Compensation Table" (above) for fiscal years of 2012, 2011 and 2010 as well as reported separately in the "Compensation of Directors" section (see below) for calendar year 2012. On November 26, 2012, the Compensation Committee authorized the payment of a bonus of 5% on the net dollar proceeds resulting from the sale of Company stock sold through the Maxim ATM to Dr. Carter and Mr. Equels  
(4) based on the contractual obligation and opinion of independent legal counsel, as set forth in Section 3(c)(ii) of their respective Employment Agreements. Amounts include for 2012, compensation was granted or paid to each Dr. Carter and Mr. Equels, respectively, pursuant to this bonus.



(5) On April 13, 2012, the Compensation Committee granted 10 year term replacement options to purchase 10,000 shares of our common stock at an exercise price of \$4.03 per share that vested immediately to both Dr. Carter and Dr. Strayer.

(6) 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 in 2010 and 2011 as an element of each of his Employment Agreement.

(7) Mr. Dickey entered into an Employment Agreement with Hemispherx effective June 11, 2009 that was amended and restated on February 1, 2010 and then again effective September 1, 2010. On June 5, 2012, the Compensation Committee granted him an Option to purchase 50,000 shares of our common stock at the exercise price of \$0.26 per share that will vest one year after issuance.

(8) On January 10, 2013, our Compensation Committee of the Board of Directors awarded bonuses to certain NEO and senior, non-officer Executives in recognition for their achievement towards of 2012 Company-wide and individual goals.

(9) December 19, 2011, our Compensation Committee of the 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.

(10) On December 22, 2010, our Compensation Committee of the 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.

(11) On December 6, 2010, our Compensation Committee of the 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.

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

(13) 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 MKT 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).

(14) On December 22, 2010, the Compensation Committee granted 10 year term replacement options to purchase 73,728 shares of our common stock at an exercise price of \$2.71 per share that vested immediately to both Dr. Carter.

(15) The value was obtained using the Black-Scholes-Merton 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.

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

	2012	2011	2010
Life and Disability Insurance	\$79,322	\$86,386	\$64,707
Healthcare Insurance	24,616	16,696	24,139
Company Car Expenses / Car Allowance	30,000	11,535	11,853
Outside Office Expenses	-0-	-0-	-0-
401(k) matching funds	15,000	17,435	-0-
	\$148,938	\$132,052	\$100,699

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

	2012	2011	2010
Life and Disability Insurance	\$27,350	\$24,170	\$34,140
Healthcare Insurance	41,100	11,623	5,833
Car Expenses / Allowance	18,000	-0-	11,853
Outside Office Expenses	-0-	-0-	-0-
401(k) matching funds	15,000	13,020	-0-
	\$101,450	\$48,813	\$39,973

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

	2012	2011	2010
Life and Disability Insurance	\$-0-	\$-0-	\$-0-
Healthcare Insurance	25,228	9,074	9,985
Outside Office Expenses	1,731	-0-	-0-
401(k) matching funds	15,000	16,861	14,288
	\$41,959	\$25,935	\$24,273

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

	2012	2011	2010
Life and Disability Insurance	\$-0-	\$-0-	\$-0-
Healthcare Insurance	10,429	7,797	8,232
401(k) matching funds	-0-	-0-	-0-
	\$10,429	\$7,797	\$8,232

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

	2012	2011	2010
Life and Disability Insurance	\$-0-	\$-0-	\$-0-
Healthcare Insurance	10,030	3,598	3,727
401(k) matching funds	-0-	9,500	9,500
	\$10,030	\$13,098	\$13,227

## 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 of 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 (\$)				
William A. Carter, Chief Executive Officer		—	197,589	246,986	—	—	—	—	\$—	\$—
	04/13/12				-0-	(5)		10,000	4.03	1,534
	06/11/12				77,022	(3)		500,000	0.31	112,119
Thomas K. Equels, General Counsel		—	105,776	132,220	—	—	—	—	\$—	\$—
	06/11/12				46,213	(3)		300,000	0.31	67,272
Charles T. Bernhardt, Chief Financial Officer	N/A(4)	—	47,599	59,499	—	—	—	—	\$—	\$—
Robert Dickey, Senior Vice President		—	63,994	79,993	—	—	—	—	\$—	\$—
	06/05/12				-0-	(6)		50,000	0.29	9,987
David Strayer, Medical Director		—	53,099	66,373	—	—	—	—	\$—	\$—
	04/13/12				-0-	(5)		10,000	4.03	1,534

Notes:

For 2012, the Compensation Committee continued its practice of not establishing or estimating possible future payouts to the NEO under a Cash Bonus Plan. All Bonuses are at the discretion of the Compensation Committee.

- (1) Utilizing existing Employment Agreements as a benchmark and the respective employees' Base Salary at January 1, 2013, 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 2012 are reported in the Summary Compensation Table above.

- (2) Consists of stock options 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 NYSE MKT closing market price of our common stock on the date of grant. The value was obtained using the Black-Scholes-Merton 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 NYSE MKT closing market price of our common stock on the date of grant. For the purpose of this schedule, a NYSE MKT closing price at December 31, 2012 of \$0.20 was assumed with an estimated exercise price of \$0.25. The value was obtained using the Black-Scholes-Merton pricing model for stock-based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

The term of the NEO's current Employment Agreement is at least through December 31, 2013, with the stock (4) 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) Issued to replace previously expired options, 10 year term replacement options to purchase 10,000 shares of our common stock at an exercise price of \$4.03 per share that vested immediately.

(6) The NEO's current Employee Agreement does not require the issuance of options as a form of compensation. All stock options issued are at the discretion of the Compensation Committee.

### Outstanding Equity Awards At Fiscal Year End

Name	Option Awards					Stock Awards		Equity Incentive Plan Awards:	Equity Incentive Plan Awards:
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised 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 (\$)	Number of Shares, Units or Rights That Have Not Vested (#)	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	04/13/22				
	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				
	0	100,000	0	0.29	06/06/22				
	0	500,000	0	0.31	06/11/22				
Thomas Equels, General Counsel	300,000	0	0	0.66	06/11/20				
	300,000	0	0	0.41	06/24/21				
	0	100,000	0	0.29	06/06/22				
	0	300,000	0	0.31	06/11/22				

Charles

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Bernhardt	100,000	0	0	0.55	12/06/20
Chief Financial Officer	100,000	0	0	0.31	12/22/21
Robert	131,250	18,750	0	2.81	06/11/19
Dickey Sr. Vice President	0	50,000	0	0.29	06/06/22
David	50,000	0	0	2.00	09/09/17
Stayer,	50,000	0	0	4.00	02/28/18
Medical	10,000	0	0	4.03	04/13/22
Director	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

**Option Exercises And Stock Vested**

Name and Principal Position	Option Awards		Stock Awards	
	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	—	—	—	—

**Payments on Disability**

At December 31, 2012, 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 2012 pursuant to their respective employment agreements and payable by us, Dr. Carter is entitled to receive total disability coverage of \$500,000 and Mr. Equels is entitled to receive total disability coverage of \$400,000.

**Payments on Death**



At December 31, 2012, 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 2012 pursuant to their respective 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, 2012, 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. Mr. Dickey's employment agreement does not have severance benefits, but the Company is required to provide with one month's 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, 2013. 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)	3,624,930	435,078	89,984	325,764	4,475,756
	Termination (for cause)	-0-	-0-	-0-	-0-	-0-
	Death or disability	987,944	108,770	22,496	81,441	1,200,641
	Termination by employee or retirement	987,944	108,770	22,496	81,441	1,200,651
Thomas K. Equels General Counsel	Involuntary (no cause)	2,115,512	269,037	153,764	120,036	2,658,349
	Termination (for cause)	-0-	-0-	-0-	-0-	-0-
	Death or disability	528,878	67,260	38,441	30,009	664,588
	Termination by employee or retirement	528,878	67,260	38,441	30,009	664,588
Charles T. Bernhardt Chief Financial Officer	Involuntary (no cause)	237,995	-0-	22,576	2,652	263,223
	Termination (for cause)	-0-	-0-	-0-	-0-	-0-
	Death or disability	237,995	-0-	22,576	2,652	263,223
	Termination by employee or retirement	237,995	-0-	22,576	2,652	263,223
Robert Dickey	Involuntary (no cause)	26,664	-0-	-0-	-0-	26,664
	Termination (for cause)	-0-	-0-	-0-	-0-	-0-

Senior Vice  
President

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-

Notes:

- 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 MKT closing price at December 31, 2012 of \$0.25 was utilized with an estimated exercise price of \$0.28. The value was obtained using the Black-Scholes-Merton pricing model for stock-based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).
- (1)
  - (2) This amount reflects the current premium incremental cost to the Company for continuation of elected benefits to the extent required under an applicable agreement.
  - (3) The life insurance benefit represents life insurance paid for by the Company including the standard coverage offer to all full-time employees.

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

At December 31, 2012, 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 his employment agreement, Mr. Dickey is not entitled to severance benefits resulting from a change in control, but the Company is required to provide one month's 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, 2013, 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, 2012**

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, 2012. The amounts assume a January 1, 2013 termination date regarding base pay and use of the opening price of \$0.25 on the NYSE MKT for our common stock at that date.

Name	Aggregate Severance Pay (\$)	PVSU Acceleration (3) (\$)	Early Vesting of Restricted Stock (4) (\$)	Early Vesting of Stock Options and SARs (4) (\$)	Acceleration and Vesting of Supplemental Award (6) (\$)	Welfare Benefits Continuation (7) (\$)	Outplacement Assistance (\$)	Parachute Tax Gross-up Payment (\$)	Total (\$)
William A. Carter	6,588,732	(1) -0-	-0-	-0-	530,223	(5) 832,564	(1) -0-	-0-	7,951,519
Thomas K. Equels	3,702,146	(1) -0-	-0-	-0-	315,134	(5) 584,150	(1) -0-	-0-	4,601,430
Charles Bernhardt	951,980	(1) -0-	-0-	-0-	-0-	293,714	(1) -0-	-0-	1,245,694
Robert Dickey	26,664	(2) -0-	-0-	-0-	-0-	-0-	-0-	-0-	26,664
David Strayer	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-

**Notes:**

- This amount represents the base salary or benefits for remaining term of the NEO's employment agreement plus a three year extension in the term upon the occurrence of a termination from a change in control. The existing employment agreements with Dr. Carter and Mr. Equels have a term through December 31, 2016 and Mr. Bernhardt through December 31, 2013.
- (1) This amount represents one month's base salary related to notice required 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, 2013 (\$0.25 per share) minus the per share exercise price of 110%] 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 MKT closing price for December 31, 2012 of \$0.25 with an estimated exercise price of \$0.28 (110% prior NYSE MKT closing value). The value was obtained using the Black-Scholes-Merton pricing

model for stock-based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

- (6) Any purchase rights represented by the Option not then vested shall, upon a change in control, shall become vested.
- (7) 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, 2013.
- (8) This amount also includes the estimated cost of Company's 100% match 401(k) contributions up to 6% of Base Pay to a maximum 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](http://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](http://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 as a condition of their respective employment agreements: Dr. William Carter, our Chairman, Chief Executive Officer, President and Chief Scientific Officer; 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. In the event of a Change in Control, the Company is responsible for the base salary or benefits for remaining term of the NEO's employment agreement plus an automatic three year extension in the term of the agreement. The existing employment agreements with Dr. Carter and Mr. Equels have a term through December 31, 2016 and Mr. Bernhardt through December 31, 2013.

### **Compensation of Directors**

Our Compensation, Audit and Corporate Governance and Nomination Committees, consist of Dr. Iraj E. 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.

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.

Commencing as of January 1, 2012, a 3.06% cost of living increase granted to Board member Directors' fee compensation, increasing 2011's annual retainer from \$169,950 to \$176,068 for 2012. Director's fees will continue to be paid quarterly in cash at the end of each calendar quarter and the fee for calendar year 2013 was granted a 2.1% cost of living increase adjustment.

In 2012, it was identified that one of our non-employee Directors, Dr. Iraj E. Kiani, had not been compensated for his service to the Company from his joining of the Board of Directors on May, 1, 2002 through December 31, 2004. Through July 24, 2012, the Board of Directors has researched this issue, taking into account payments made to other non-employee Directors during that time. As a result, the Company has dispensed the following to Dr. Kiani regarding his previously unpaid services:

- \$28,667 for 2002, proportionate to his seven months of service;
- \$50,000 for 2003;
- \$50,000 for 2004;
- 16,270 shares in Restricted Company Common Stock as partial payment, based on the June 6, 2012 NYSE MKT closing price of \$0.26 per share as compensation for the \$100,000 worth of stock that had been previously distributed to other non-employee Directors for services provided in 2003 and 2004, during which time, the stock traded from \$1.83 to \$3.47 per share; and

368,345 shares of Restricted Company Common Stock as balance due for services provided in 2003 and 2004 that had previously been paid in stock to non-employee Directors, during which time the stock traded from \$1.83 to \$3.47 per share, based on the June 6, 2012, NYSE MKT closing price of \$0.26 per share.

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.

In recognition of that the Board members' commitment of time and effort has increased over time for the benefit of the Company as the demand for specific expertise has grown and corporate governance issues require greater attention in a highly regulated environment, each Director was granted an Option to purchase 100,000 shares of Company common stock. The respective Options were granted with an exercise price equal to 110% of the final closing price of the Company's common stock on the NYSE MKT LLC as of June 5, 2012 (\$0.26), will vest one year after issuance, contain a cashless exercise provision, have a ten year term and were issued from the Company's 2009 Equity Incentive Plan.

### Director Compensation - 2012

Name and Title of Director	Fees Earned or Paid in Cash (\$)	Stock Award (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation As Director (\$)	Total (\$)
W. Carter, Chairman	176,068(5)	0	19,974 (1)(5)	0	0	0	196,042
T. Equels, Executive Vice Chairman & Secretary	176,068(5)	0	19,974 (1)(5)	0	0	0	196,042
W. Mitchell, Director (4)	176,068	0	19,974 (1)	0	0	0	196,042
R. Piani, Director (4)	176,068	0	19,974 (1)	0	0	0	196,042
I. Kiani, Director (4)	304,735(2)	100,000(3)	19,974 (1)	0	0	0	324,709

#### Notes:

Ten year Option to purchase 100,000 shares at \$0.26 per share. The value was obtained using the (1)Black-Scholes-Merton pricing model for stock-based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

- (2) In addition to his 2012 Director's fee of \$176,068, the Company has dispensed the fees in cash to Dr. Kiani regarding his previously unpaid services as discussed above.
- (3) In addition to his 2012 Director's fee, the Company has dispensed 384,615 shares of Restricted Company Stock as discussed above.

(4) Independent Director of the Company.

- (5) Only includes compensation received in the role as member of the Board of Directors and does not include compensation received in the capacity of a Named Executive Officer. As is required by Regulation S-K, Item 402(c), compensation as a Director has also been reported within the "Summary Compensation Table" regarding Named Executive Officer Compensation during fiscal years of 2012, 2011 and 2010 (see above).

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

The following table sets forth as of March 1, 2013, 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.	8,708,174	(1)(2)	4.99	%
Thomas K. Equels	2,496,640	(3)	1.48	%
Richard C. Piani 97 Rue Jeans-Jaures Levaillois-Perret, France 92300	857,420	(4)	*	
William M. Mitchell, M.D.  Vanderbilt University  Department of Pathology  Medical Center North  21 <sup>st</sup> and Garland  Nashville, TN 37232	716,025	(5)(6)	*	
Iraj E. Kiani, N.D., Ph.D. Orange County Immune Institute 18800 Delaware Street Huntingdon Beach, CA 92648	807,886	(7)	*	
Charles T. Bernhardt CPA	377,420	(8)	*	
David R. Strayer, M.D.	477,681	(9)	*	
Robert Dickey, IV	202,500	(10)	*	
All directors and executive officers as a group (8 persons)	14,643,746		8.24	%

\* Ownership of less than 1%

(1) Dr. Carter is our Chairman, Chief Executive Officer and Chief Scientific Officer. He beneficially owns 850,585 shares of common stock and beneficially owns 7,856,574 shares issuable or issued upon exercise of:





Options	Plan	Date	Exercise	Number	Expiration
		Issued	Price	Of Shares	Date
	2004	04/13/12	\$ 4.03	10,000	04/13/22
	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
	2009	06/05/12	\$ 0.29	100,000	06/06/22
	2009	06/11/12	\$ 0.31	500,000	06/11/22
Total Options				7,365,378	

## Warrants

Total Warrants	2009	02/1/09	\$ 0.51	491,196	02/01/19
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(2) Katalin Kovari, M.D, 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.

Mr. Equels is Executive Vice Chairman of our Board of Directors, Secretary and General Counsel who beneficially (3) owns 1,005,444 shares of common stock and beneficially owns 1,491,196 shares issuable or issued upon exercise of:

Options	Plan	Date	Exercise	Number	Expiration
		Issued	Price	Of Shares	Date
	2009	06/11/10	\$ 0.66	300,000	06/11/20
	2009	06/24/11	\$ 0.41	300,000	06/24/21
	2009	06/05/12	\$ 0.29	100,000	06/06/22
	2009	06/11/12	\$ 0.31	300,000	06/11/22
Total Options				1,000,000	

Warrants	Plan	Date	Exercise	Number	Expiration
		Issued	Price	Of Shares	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 424,608 shares issuable upon exercise of:

Options	Plan	Date	Exercise	Number	Expiration
		Issued	Price	Of Shares	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
	2009	06/05/12	\$ 0.29	100,000	06/06/22
Total Options				424,608	

- (5) Dr. Mitchell is a member of our Board of Directors who owns 104,364 shares of common stock and beneficially owns 412,000 shares issuable upon exercise of:

Options	Plan	Date	Exercise	Number	Expiration
		Issued	Price	Of Shares	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
	2009	06/05/12	\$ 0.29	100,000	06/06/22
Total Options				412,000	

- (6) Dr. Mitchell beneficially owns 199,661 shares of common stock of which 150,487 shares are held by Shirley Mitchell (Spouse) and 49,174 shares are held by the Aesclepius Irrevocable Trust (Shirley Mitchell Trustee).

- (7) Dr. Kiani is a member of our Board of Directors who owns 630,886 shares of common stock and beneficially owns 177,000 shares issuable upon exercise of:

Options	Plan	Date	Exercise	Number	Expiration
		Issued	Price	Of Shares	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
	2009	06/05/12	\$ 0.29	100,000	06/06/22
Total Options				177,000	

(8) Mr. 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	

(9) Dr. Strayer is our Medical Director that has ownership of 287,681 shares of common stock and beneficially owns 190,000 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
	2009	04/13/12	\$ 4.03	10,000	04/13/22
	2004	11/20/06	\$ 2.20	15,000	11/20/16
	2004	01/23/07	\$ 2.37	20,000	01/23/17
	2004	09/10/07	\$ 2.00	50,000	09/09/17
	2004	12/06/07	\$ 1.30	25,000	12/06/17
	2004	02/18/08	\$ 4.00	50,000	09/18/18
Total Options				190,000	

(10) Mr. Dickey is our Senior Vice President and owns 2,500 shares of common stock and beneficially owns 200,000 shares issuable upon exercise of:

Options	Plan	Date	Exercise	Number	Expiration
		Issued	Price	Of Shares	Date
	2009	07/01/09	\$ 2.81	150,000	07/01/19
	2009	06/05/12	\$ 0.29	50,000	06/06/22
Total Options				200,000	

### 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.

The Company used at various times the property owned by Retreat House, LLC, for off-site meetings and lodging. 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. We paid Retreat House, LLC approximately \$0- and \$137,000 for the use of the property, off-site meetings and lodging at various times in 2012 and 2011, respectively. Upon analysis in the Fall of 2011 by the Audit Committee’s Financial Expert consultant, 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 for the use of the property or lodging 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.

In December 2011, Kyle Carter was hired as a Data Control Clerk at the annual salary of \$37,950. Mr. Carter is the Son of Dr. William A. Carter, our CEO. From December 2011 through June 2012, we employed Kyle Carter and paid approximately \$8,000 and \$3,000 in 2012 and 2011, respectively.

In June 2012, William Kramer was hired as a Clinical Research Associate at the annual salary of \$68,284. Mr. Kramer is the Son-In-Law of Dr. William A. Carter, our CEO, and was paid approximately \$38,000 in 2012 in salary. Additionally in 2012 on an as-needed basis, the Company utilized the services of Kramer Environmental Management, Inc. to develop standard operating procedures, compliance assessments, testing and obtain permits related to environmental issues. William Kramer is also the President of Kramer Environmental Management, Inc. and this organization was paid approximately \$20,000 and \$-0- by us during 2012 and 2011, respectively.

Katalin Kovari, M.D. was paid approximately \$25,000 and \$28,000 in 2012 and 2011, respectively, for her part-time services to the Company as Assistant Medical Director. Dr. Kovari is the spouse of Dr. William A. Carter, our CEO.

Since October 2011, Peter Kovari was utilized as a part-time independent contractor for Hemispherx Biopharma Europe to undertake projects as a Clinical Programmer related to coordinating, programming, analyzing and evaluating clinical data for the Company at the rate of \$20 per hour and was paid by us approximately \$12,000 and \$6,000 in 2012 and 2011, respectively. Mr. Kovari is the nephew of Dr. Katalin Kovari, our Assistant Medical Director and spouse 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 2012 and 2011, we paid Equels Law Firm approximately \$147,000 and \$159,000, 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. The hourly rate fees from Equels Law Firm to us have remained the same for 2011 and 2012. Additionally beginning December 2012 with the approval of the Audit Committee, the Company began renting an office at Equels Law Firm for \$3,000 per month for dedication to and utilization by Hemispherx personnel. For 2012 and 2011, we paid Equels Law Firm \$3,000 and \$-0-, respectfully, for office rent based on a proration of the Firm's current leasing fee less the cost for common area.

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 \$4,000 each month to Mr. Piani to reimburse him for his direct rental of this office facility. For 2012 and 2011, 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. The office rental fee of \$4,000 per month to us has remained constant since 2010.



**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 LLP ("McGladrey" and formerly known as McGladrey & Pullen, LLP) for 2012 and 2011 were \$312,223 and \$274,750, respectively. The following table shows the aggregate fees for professional services rendered during the year ended December 31, 2012 and 2011.

Description of Fees:	Amount (\$)	
	<u>2012</u>	<u>2011</u>
Audit Fees	\$280,350	\$268,250
Audit-Related Fees	31,873	6,500
Tax Fees	0	0
All Other Fees	0	0
Total	\$312,223	\$274,750

*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. Audit-related fees include professional services related to the Company's filing of SEC Form S-3 and S-8 (i.e., stock shelf offering procedures).

The Audit Committee has determined that McGladrey's rendering of these audit-related services and all other fees were 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 2012 and 2011.

The Audit Committee pre-approves all auditing and accounting 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	July 23, 2012 Equity Distribution Agreement with Maxim Group LLC (1)
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended, along with Certificates of Designations. (2)
3.2	Amended and Restated By-laws of Registrant. (19)
4.1	Specimen certificate representing our Common Stock.
4.2	Amended and Restated Rights Agreement, dated as of November 2, 2012, between the Company and Continental Stock Transfer & Trust Company. The Amended and Restated 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)
4.4	Form of Indenture filed with Form S-3 Universal Shelf Registration Statement. (4)
4.5	Form of Series I common stock purchase warrant pursuant to May 10, 2009 Securities Purchase Agreement. (5)
4.6	Form of Series II common stock purchase warrant pursuant to May 10, 2009 Securities Purchase Agreement. (5)
4.7	Form of common stock purchase warrant pursuant to May 18, 2009 Securities Purchase Agreement. (6)
10.1	Form of Confidentiality, Invention and Non-Compete Agreement.
10.2	Form of Clinical Research Agreement.
10.3	Employee Wage Or Hours Reduction Program. (7)
10.4	Form of Securities Purchase Agreement entered into on May 10, 2009. (1)
10.5	Form of Securities Purchase Agreement entered into on May 18, 2009. (5)
10.6	Amended and Restated Employment Agreement with Robert Dickey IV, dated September 1, 2010. (8)
10.7	Supply Agreement with Hollister-Stier Laboratories LLC dated December 5, 2005. (9)
10.8	Amendment to Supply Agreement with Hollister-Stier Laboratories LLC dated February 25, 2010. (10)
10.9	Amended and Restated Employment Agreement of Dr. William A. Carter dated June 11, 2010 (11)
10.10	Vendor Agreement with Bio Ridge Pharma, LLC dated August 11, 2011. (14) (Confidential Treatment granted with respect to portions of the Agreement).
10.11	Vendor Agreement with Armada Healthcare, LLC dated August 11, 2011. (14) (Confidential Treatment granted with respect to portions of the Agreement).
10.12	Amended and restated employment agreement with Wayne Springate dated May 1, 2011. (13)
10.13	Amended and restated employment agreement with Ralph Christopher Cavalli dated September 15, 2011. (15)
10.14	Amended and restated employment agreement with William A. Carter dated December 6, 2011. (16)
10.15	Amended and restated employment agreement with Thomas K. Equels dated December 6, 2011. (16)
10.16	Amended and restated employment agreement with Charles T. Bernhardt dated December 6, 2011. (16)
10.17	Second Amended and Restated Advisor's Agreement with The Sage Group dated December 14, 2011. (17)
10.18	

Amendment to Supply Agreement with Hollister-Stier Laboratories LLC executed September 9, 2011. (17)  
(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).

10.19 Vendor Agreement extension with Bio Ridge Pharma, LLC dated August 14, 2012. (18)

- 10.20 Vendor Agreement extension with Armada Healthcare, LLC dated August 14, 2012. (18)
- 21 Subsidiaries of the Registrant. \*
- 23.1 McGladrey 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, 2012, 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 Current Report on Form 8-K (No. 1-13441) filed July 23, 2012 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 2, 2012 as an exhibit to the Company's Registration Statement on Form 8-A12G/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. 333-182216) on June 19, 2012 and is hereby incorporated by reference.
- (5) 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.
- (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 May 18, 2009 and is hereby incorporated by reference.

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- (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 quarterly report on Form 10-Q (No. 1-13441) for the period ended June 30, 2010 and is hereby incorporated by reference.
- (9) 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.
- (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, 2009 and is hereby incorporated by reference.
- (11) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) dated June 15, 2010 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.
- (17) 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, 2011 and is hereby incorporated by reference.
- (18) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) filed August 15, 2012 and is hereby incorporated by reference.
- (19) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) filed August 23, 2012 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 18, 2013

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 18, 2013
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/s/ Thomas K. Equels Thomas K. Equels	Executive Vice Chairman of the Board, Director, Secretary and General Counsel	March 18, 2013
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/s/ Richard Piani Richard Piani	Director	March 18, 2013
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/s/ William Mitchell William Mitchell, M.D., Ph.D.	Director	March 18, 2013
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/s/ Iraj E. Kiani Iraj E. Kiani, N.D., Ph.D.	Director	March 18, 2013
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/s/ Charles T. Bernhardt Charles T. Bernhardt CPA	Chief Financial Officer and Chief Accounting Officer	March 18, 2013
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**HEMISPHERx BIOPHARMA, INC AND SUBSIDIARIES**

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**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, 2012 and 2011, and the related consolidated statements of comprehensive loss, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2012. 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 and schedule 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, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012, 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, 2012, 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 18, 2013, expressed an unqualified opinion on the effectiveness of Hemispherx Biopharma, Inc.'s internal control over financial reporting.

/s/ McGladrey LLP  
Blue Bell, Pennsylvania  
March 18, 2013

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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, 2012, 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, 2012 based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

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We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the December 31, 2012 consolidated financial statements of Hemispherx Biopharma, Inc. and our report dated March 18, 2013 expressed an unqualified opinion.

/s/ McGladrey LLP  
Blue Bell, Pennsylvania  
March 18, 2013

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**HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES****Consolidated Balance Sheets****December 31, 2012 and 2011**

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

	2012	2011
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$2,212	\$3,103
Marketable securities- unrestricted	27,241	26,229
Marketable securities- restricted	14,500	1,026
Inventories	453	897
Prepaid expenses and other current assets	322	531
Total current assets	44,728	31,786
Property and equipment, net	5,292	5,276
Patent and trademark rights, net	1,034	863
Marketable securities unrestricted	0	1,958
Marketable securities- restricted	0	2,075
Construction in progress	6,580	1,484
Other assets	65	71
Total assets	\$57,699	\$43,513
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$2,157	\$1,681
Accrued expenses	3,395	1,644
Margin account loan	7,051	1,695
Current portion of capital lease	46	49
Total current liabilities	12,649	5,069
Long-term liabilities:		
Long-term portion of capital lease	55	99
Redeemable warrants	295	380
Total liabilities	12,999	5,548
Commitments and contingencies (Notes 11, 13, 14, 19 & 20)		
Stockholders' equity :		
Preferred stock, par value \$0.01 per share, authorized 5,000,000; issued and outstanding;	0	0
none		



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Common stock, par value \$0.001 per share, authorized 350,000,000 shares; issued and outstanding 166,490,190 and 135,642,303, respectively	166	136
Additional paid-in capital	288,671	264,958
Unrealized loss	(43 )	(389 )
Accumulated deficit	(244,094)	(226,740)
Total stockholders' equity	44,700	37,965
Total liabilities and stockholders' equity	\$57,699	\$43,513

See accompanying notes to consolidated financial statements.

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**HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES****Consolidated Statements of Comprehensive Loss**

(in thousands, except share and per share data)

	Years ended December 31,		
	2012	2011	2010
Revenues:			
Clinical treatment programs	\$213	\$161	\$135
Total Revenues	213	161	135
Costs and Expenses:			
Production/cost of goods sold	1,989	1,043	1,341
Research and development	9,508	6,722	7,613
General and administrative	9,056	6,691	7,568
Total Costs and Expenses	20,553	14,456	16,522
Operating loss	(20,340 )	(14,295 )	(16,387 )
Interest and other income	1,597	624	2,383
Interest expense	(24 )	(41 )	(11 )
Funds received from sale of income tax operating losses	1,328	2,272	0
Redeemable warrants valuation adjustment	85	2,425	879
Net loss	(17,354 )	(9,015 )	(13,136 )
Other Comprehensive Income (Loss)			
Unrealized gain (loss) on securities	340	(311 )	(1,013 )
Less: Premium amortization and realized losses	6	896	39
Net comprehensive loss	\$(17,008 )	\$(8,430 )	\$(14,110 )
Basic and diluted loss per share	\$(0.12 )	\$(0.07 )	\$(0.10 )
Weighted average shares outstanding basic and diluted	141,016,935	135,432,395	134,018,243

See accompanying notes to consolidated financial statements.

**HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES****Consolidated Statements of Changes in Stockholders' Equity**

(in thousands except share data)

	Common Stock Shares	Common Stock Par Value	Additional .001 Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
Balance January 1, 2010	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
Equity-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
Equity-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
Shares issued for:						
Settlement of accounts payable	1,111,397	1	383	0	0	384
Shares sold at the market	29,496,743	29	22,974	0	0	23,003
Equity-based compensation	239,747	0	356	0	0	356
Net comprehensive loss	0	0	0	346	(17,354 )	(17,008 )
Balance December 31, 2012	166,490,190	\$ 166	\$ 288,671	\$ (43 )	\$ (244,094 )	\$ 44,700

See accompanying notes to consolidated financial statements

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

	Years ended December 31		
	2012	2011	2010
Cash flows from operating activities:			
Net loss	\$(17,354)	\$(9,015 )	\$(13,136)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation of property and equipment	643	465	407
Amortization and abandonment of patent and trademark rights	40	165	373
Redeemable warrants valuation adjustment	(85 )	(2,425 )	(879 )
Equity based compensation (stock option, warrant and service expense)	356	377	741
Other-than-temporary impairment of marketable securities	9	69	0
Inventory reserve	1,023	0	0
Changes in assets and liabilities:			
Inventories	(579 )	(110 )	77
Prepaid expenses and other assets	200	(247 )	46
Accounts payable	860	424	362
Accrued expenses	1,751	201	123
Net cash used in operating activities	(13,136)	(10,096)	(11,886)
Cash flows from investing activities:			
Purchases of property, equipment and construction in progress	(5,755 )	(1,802 )	(729 )
Additions to patent and trademark rights	(211 )	(234 )	(337 )
Deposits on capital leases refunded (paid)	6	(4 )	(9 )
Maturities of short-term and long-term marketable securities	22,658	20,896	7,448
Purchase of short-term and long-term marketable securities	(32,765)	(10,201)	(49,889)
Net cash (used in) provided by investing activities	\$(16,067)	\$8,655	\$(43,516)

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

	Years ended December 31,		
	2012	2011	2010
Cash flows from financing activities:			
Proceeds from sale of common stock, net of issuance costs	\$23,003	\$0	\$292
Payments on capital leases	(47 )	(71 )	(42 )
Proceeds from Margin Account Loan	5,356	1,695	0
Net cash provided by financing activities	28,312	1,624	250
Net (decrease) increase in cash and cash equivalents	(891 )	183	(55,152)
Cash and cash equivalents at beginning of year	3,103	2,920	58,072
Cash and cash equivalents at end of year	\$2,212	\$3,103	\$2,920
Supplemental disclosures of non-cash investing and financing cash flow information:			
Issuance of common stock for accounts payable and accrued expenses	\$384	\$71	\$329
Equipment acquired by capital leases	\$0	\$62	\$200
Unrealized gain (loss) on marketable securities	\$346	\$(585 )	\$(974 )
Redeemable warrants valuation adjustment	\$(85 )	\$(2,425)	\$(879 )
Supplemental disclosure of cash flow information:			
Capitalized construction interest	\$85	\$0	\$0
Cash paid for interest expense	\$24	\$41	\$11

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 submitted the complete response to the FDA on July 31, 2012 in support of Ampligen®'s NDA for CFS. On December 20, 2012, the FDA held an Arthritis Advisory Committee ("AAC") meeting to discuss the Ampligen® NDA for CFS. The voting results in three of the four questions posed were not in favor of the Company's position with the AAC voting on a review of data from the Ampligen® clinical development program included as part of the Company's NDA submission. The majority of the AAC members expressed the view that an additional controlled clinical trial of Ampligen® should be conducted prior to the FDA granting approval. The FDA uses committees, like the AAC, to obtain independent expert advice on scientific, technical and policy matters to assist in its mission to protect and promote public health. The FDA is not bound by the AAC's recommendation, but is believed to consider their recommendation in its review.

On February 1, 2013, the Company received a CRL from the FDA declining to approve its NDA for Ampligen® for CFS. The FDA said Hemispherx should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses. In its CRL, the FDA set forth the reasons for this action and provided recommendations to address certain of the outstanding issues. The FDA stated that the submitted data do not provide substantial evidence of efficacy of Ampligen® for the treatment of CFS and that the data do not provide sufficient information to determine whether the product is safe for use in CFS due to the limited size of the safety database and multiple discrepancies within the submitted data.

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In response to the CRL, the Company plans to avail itself of the opportunity for an “end-of-review” meeting with representatives of the Office of Drug Evaluation II which issued the CRL, in order to clarify and seek to narrow the outstanding issues regarding the further development of Ampligen® for the treatment of CFS. FDA regulations provide a formal dispute resolution process to obtain review of any FDA decision, including a decision not to approve an NDA, by raising the matter with the supervisor of the FDA office that made the decision. Depending on the results of the “end-of-review” meeting, the Company will determine whether or not to submit a formal appeal regarding the FDA’s decision under applicable FDA regulations and guidance.

The Company owns and operates a 43,000 sq. ft. manufacturing facility in New Brunswick, NJ that produces Alferon® and Ampligen®. Their Board of Directors had approved \$7.2 million towards facility upgrades being undertaken to the Alferon® manufacturing process. The production of new Alferon® Active Pharmaceutical Ingredient (“API”) inventory will not commence until the capital improvement and validation phases are complete. Due to the necessity to redirect many of their resources to the Ampligen® NDA application process and efforts towards the pre-approval inspection for Ampligen® manufacturing, the validation phase of the Alferon® manufacturing project has been delayed.

## **(2) Summary of Significant Accounting Policies**

### **(a) Cash and Cash Equivalents**

Cash and Cash Equivalents consist of cash and money market accounts and total \$2,212,000 and \$3,103,000 at December 31, 2012 and 2011, 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) on the Statement of Comprehensive Loss, 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,	
	2012	2011
Land, buildings and improvements	\$4,209	\$4,209
Furniture, fixtures, and equipment	4,662	4,002
Leasehold improvements	85	85
Total property and equipment	8,956	8,296
Less: accumulated depreciation and amortization	(3,664)	(3,020)
Property and equipment, net	\$5,292	\$5,276

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, 2012, construction in progress was \$6,580,000 as compared to \$1,484,000 at December 31, 2011. The Company capitalized \$85,000 of interest charges in 2012 related to the construction in progress.

#### (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 and title is transferred to the customer. The Company has no other obligation associated with its products once shipment has been shipped to the customer.

(f) Accounting for Income Taxes

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

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, net unrealized gains (losses) on securities and premium amortization and related losses 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 June 2011, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update 2011-05, Presentation of Comprehensive Income (ASU 2011-05). This standard eliminated the option to report other Comprehensive Income (Loss) and its components in the Statement of Changes in Stockholders’ Equity. Under this standard, an entity can elect to present items of Net Income (Loss) and other comprehensive income (loss) in one continuous statement referred to as the Consolidated Statements of Comprehensive Income (Loss), or in two separate but consecutive, statements.

In December 2011, the FASB issued Accounting Standards Update No. 2011-12, 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 (ASU 2011-12). ASU 2011-12 defers the effective date of the requirement in ASU 2011-05 to disclose on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income (loss) on the components of net income(loss) and other comprehensive income (loss). All other requirements of ASU 2011-05 are not affected by ASU 2011-12. The Company adopted ASU 2011-05 effective September 30, 2011 and indefinitely deferred certain disclosures as allowed under ASU 2011-12. In transitioning to this new presentation prior to the mandatory conversion date of 2012, Management deemed that the only material change is the reflection of our “unrealized gain or (loss) on investments” after our traditional Net Loss reporting. The expiration of deferral allowed by ASU 2011-12 is not expected to have a significant impact on our consolidated financial statements.

In 2012 and 2013, the FASB issued Accounting Standards Updates (“ASU”) 2012-01 through 2013-05. Additionally, FASB issued ASU 2013-02 has superseded ASI 2011-05 and 2011-12. These updates had no material impact on our consolidated financial statements.

#### (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, 2012 and 2011.

#### (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 related to 34,701,415, 54,242,702 and 52,796,158 shares, are excluded from the calculation of diluted net loss per share for the

years ended December 31, 2012, 2011 and 2010, respectively, since their effect is antidilutive.

**(3) Inventories and Other Assets**

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

Inventories consist of the following:	(in thousands)	
	2012	2011
Inventory work-in-process, January 1	\$897	\$787
Production	579	302
Spoilage	(1,023)	(192)
Inventory work-in-process, December 31	\$453	\$897

As of December 31, 2012, all of our lots of Alferon® Work-In-Process Inventory have completed the fill, finish and packaging process. With the completion of the fill, finish and packaging protocol, Process Validation of Alferon® Work-In-Process lots need to be completed. With our redirection of resources to the Ampligen® NDA submission, this process had been delayed but is now underway. We are unable to provide any assurances that the FDA will approve the existing inventory finish product lots produced by Althea.

While at December 31, 2012 and 2011, the Work-In-Process Inventory had no manufacturing steps to be undertaken at the Company's New Brunswick, NJ facility, it will not be classified as Finished Goods until all stability and release testing are concluded and it is confirmed by the FDA that the product can be commercially sold as is.

#### **(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 pricing 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:

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	December 31, 2012	2011	2010
Risk-free interest rate	0.61%- 0.86%	0.83%- 2.24%	1.02%- 2.06%
Expected dividend yield	0	0	0
Expected life	5 yrs.	5 yrs.	5 yrs.
Expected volatility	108.76%-112.35%	104.29%-105.91%	106.28%-110.01%
Weighted average grant date fair value of options issued	\$0.23 per option for 1,499,000 options	\$0.26 per option for 1,310,000 options	\$0.42 per option for 1,618,428 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 pricing 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, 2010, 2011 and 2012 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, 2010	6,228,752	\$ 2.60	6.95	0
Granted	993,728	0.80	9.42	0
Forfeited	0	0	0	0
Outstanding December 31, 2010	7,222,480	\$ 2.35	6.21	0
Granted	1,030,000	0.41	9.51	0
Forfeited	0	0	0	0
Outstanding December 31, 2011	8,252,480	\$ 2.11	5.75	0
Granted	1,199,000	0.45	9.51	0
Forfeited	(10,000 )	1.30	5.50	0
Outstanding December 31, 2012	9,441,480	\$ 1.90	5.35	0
Vested and expected to vest at December 31, 2012	9,441,480	\$ 1.90	5.35	0



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Exercisable at December 31, 2012	8,925,107	\$ 1.98	5.12	0
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The weighted-average grant-date fair value of employee options granted during the year 2012 was \$284,000 for 1,199,000 options at \$0.24 per option, the year 2011 was \$293,000 for 1,030,000 options at \$0.28 per option and during the year 2010 was \$441,000 for 993,728 options at \$0.44 per option.

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Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2010	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
Granted	509,708	0.43	9.52	0
Vested	(131,668 )	0.36	9.04	0
Forfeited	(10,000 )	1.30	5.50	0
Outstanding December 31, 2012	516,373	\$ 0.45	9.43	0

The weighted-average grant-date fair value of employee unvested stock options granted during the year 2012 was \$120,558 for 509,708 options at \$0.24 per option, during the year 2011 was \$24,000 for 140,000 options at \$0.17 per option and during the year 2010 was \$9,000 for 20,000 options at \$0.45 per option.

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, 2010	2,233,432	\$ 2.44	5.73	0
Granted	625,000	0.55	9.52	0
Exercised	0	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

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Outstanding December 31, 2011	3,128,432	\$ 1.87	5.25	0
Granted	300,000	0.29	9.50	0
Exercised	0	0	0	0
Forfeited	0	0	0	0
Outstanding December 31, 2012	3,428,432	\$ 1.73	4.71	0
Vested and expected to vest at December 31, 2012	3,428,432	\$ 1.73	4.71	0
Exercisable at December 31, 2012	3,218,010	\$ 1.82	4.53	0

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The weighted-average grant-date fair value of non-employee options granted during the year 2012 was \$59,922 for 300,000 options at \$0.20 per option, during the year 2011 was \$51,000 for 280,000 options at \$0.18 per option and during the year 2010 was \$233,000 for 625,000 options at \$0.37 per option.

Unvested stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2010	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
Granted	300,000	0.29	9.50	0
Vested	(345,828 )	0.53	7.95	0
Forfeited	0	0	0	0
Outstanding December 31, 2012	210,422	\$ 0.40	9.68	0

The impact on the Company's results of operations of recording stock-based compensation for the year ended December 31, 2012 was to increase general and administrative expenses by approximately \$356,000 and reduce earnings per share by \$0.00 per basic and fully diluted share, 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 and for year ended December 31, 2010 was to increase general and administrative expenses by approximately \$741,000 and reduce earnings per share by \$0.01 per basic and fully diluted share.

As of December 31, 2012 and 2011, there was \$232,000 and \$147,000, respectively, 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, 2012 and 2011, it was determined that some of the Marketable Securities had other than temporary impairments of approximately \$9,000 and \$69,000, respectively, which has been included with interest and other income for reporting purposes. At December 31, 2012, all of these securities were classified as available for sale investments and \$27,241,000 were measured as Level 1 instruments of the fair value measurements standard (see Note 19: Fair Value).

Securities classified as available for sale consisted of:

December 31, 2012

(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	\$ 27,230	\$ 11	\$ (0 )	\$27,241	\$ 27,241	\$ 0
Totals	\$ 27,230	\$ 11	\$ (0 )	\$27,241	\$ 27,241	\$ 0

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December 31, 2011

(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross 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

**(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 range of two to one, based on the diversity of securities pledged as collateral, for those funds withdrawn and outstanding (see Note 20: 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 mutual funds. As of December 31, 2012, it was determined that none of the Marketable Securities had other-than-temporary impairments. At December 31, 2012, all restricted securities were classified as restricted from sale investments and \$13,499,000 was measured as level 1 instruments and \$1,001,000 were measured as level 2 instruments of the fair value measurements standard (see Note 19: Fair Value).

Securities classified as restricted from sale consisted of:

December 31, 2012

(in thousands)

Securities	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Corporate Bonds	\$ 3,503	\$ 1	\$ 0	\$3,504	\$ 3,504	\$ 0

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Mutual Funds	11,049	0	(53 )	10,996	10,996	0
Totals	\$ 14,552	\$ 1	\$ (53 )	\$ 14,500	\$ 14,500	\$ 0

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.

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**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, 2012

(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	\$ 10,996	\$ (54 )	\$ 0	\$ 0	\$10,996	\$ (54 )
Totals	1	\$ 10,996	\$ (54 )	\$ 0	\$ 0	\$10,996	\$ (54 )

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	996	(16 )	3,272	(35 )	4,268	(51 )
Totals	5	\$ 996	\$ (16 )	\$ 25,025	\$ (369 )	\$26,021	\$ (385 )

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, including mutual funds, are due to market price movements. Management believes that any of 2012's unrealized losses attributed to the Mutual Funds were limited to temporary impairment based on our evaluation of available evidence as of December 31, 2012.



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

During the years ended December 31, 2012, 2011 and 2010, the Company decided not to pursue certain patents in various countries for strategic reasons and recorded abandonment charges of \$25,000, \$147,000 and \$198,000, respectively, which are included in research and development. Amortization expense was \$15,000, \$17,000 and \$176,000 in 2012, 2011 and 2010, respectively. The total cost of the patents was \$1,131,000 and \$967,000 as of December 31, 2012 and 2011, respectively. The accumulated amortization as of December 31, 2012 and 2011 is \$97,000 and \$104,000, respectively. In 2012, additions to patent costs were \$211,000 and adjustments for fully amortized and abandoned patents had costs of \$47,000 and accumulated amortization of \$22,000. 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.

Amortization of patents and trademarks for each of the next five years is as follows: 2013 - \$15,000; 2014 - \$15,000; 2015 - \$15,000; 2016 - \$15,000 and 2017 - \$15,000. No amortization expense is recognized related to patents that are pending.

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**(8) Accrued Expenses**

Accrued expenses at December 31, 2012 and 2011 consists of the following:

	(in thousands)	
	December 31,	
	2012	2011
Compensation	\$2,131	\$821
Professional fees	466	215
Accrued Alferon production costs	70	0
Other expenses	615	495
Due for returned product	113	113
	\$3,395	\$1,644

**(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, 2012 and 2011.

**(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 75,000,000 of the 150,000,000 newly authorized shares.

As of December 31, 2012 and 2011, 166,490,190 shares and 135,642,303 shares were outstanding, respectively.

**(c) Equity Financings**

Pursuant to a May 28, 2010 Equity Distribution Agreement (the “Old EDA”) with Maxim Group LLC (“Maxim”), the Company established an At-The-Market (“ATM”) Equity Program pursuant to which the Company could 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 Old EDA, the Agent was 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 had no obligation to sell any shares under this program, and could at any time terminate the Agreement. For the years ended December 31, 2012 and 2011, the Company sold no shares through this Old EDA and received no net cash proceeds. All sales related to the Old EDA took place in 2010, in which 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. In June 2012, the Old EDA with Maxim expired.

On July 23, 2012, the Company entered into a new Equity Distribution Agreement (the “New EDA”) with Maxim pursuant to which the Company may sell up to \$75,000,000 worth of its shares of Common Stock from time to time through Maxim, as sales agent. Under the New EDA, Maxim is entitled to a fixed commission rate of 4.0% of the gross sales price of Shares sold under the EDA, up to aggregate gross proceeds of \$10,000,000, and thereafter, at a fixed commission rate of 3.0% of the gross sales price of Shares sold under the EDA. Sales of the Shares, if any, may be made in transactions that are deemed to be “at-the-market” offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers’ transactions, including on the NYSE MKT, at market prices or as otherwise agreed with Maxim. The Company has no obligation to sell any of the Shares and may at any time suspend offers under the New EDA or terminate the New EDA. The Shares are being sold pursuant to the Company’s Universal Shelf Registration Statement on Form S-3, declared effective by the Securities and Exchange Commission on July 2, 2012. On September 14, 2012, the Company filed a Prospectus Supplement with the Securities and Exchange Commission related to increasing the offering from 12,000,000 to 20,000,000 shares under the New ATM. On October 5, 2012, the Company filed an updated Prospectus Supplement to revise the New EDA for an aggregate of 40,000,000 shares to be allocated for public sale under the Prospectus Supplement pursuant to the ATM. As of December 31, 2012, the Company had sold an aggregate of approximately 29,500,000 shares that resulted in net cash proceeds of approximately \$23,003,000 after direct expenses along with commissions paid to Maxim for approximately \$820,000.

The proceeds from this financing are intended to be used to fund infrastructure growth including manufacturing, regulatory compliance, market development and general operating expenses.

(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:

	2010			2011			2012		
	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	335,728	\$2.71-4.03	\$ 2.98	262,000	\$2.75-4.03	\$ 3.05	262,000	\$2.75-4.03	\$ 3.05
Granted	0	0	0	0	0	0	0	0	0
Forfeited	(73,728 )	\$2.71	0		0	0	(62,000 )	4.03	0
Exercised	0	0	0	0	0	0	0	0	0
Outstanding, end of year	262,000	\$2.75-4.03	\$ 3.05	262,000	\$2.75-4.03	\$ 3.05	200,000	\$2.75	\$ 2.75
Exercisable	262,000	\$2.75-4.03	\$ 3.05	262,000	\$2.75-4.03	\$ 3.05	200,000	\$2.75	\$ 2.75
Weighted average remaining	3.86 yrs.			2.86 yrs.			0.83 yrs.		

contractual life  
(years)

Exercised in

current and prior (27,215 )

(27,215 )

(27,215 )

years

Available for  
future grants

-0-

-0-

-0-

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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, 2010			December 31, 2011			December 31, 2012		
	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	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
Granted	0	0	0	0	0	0	0	0	0
Forfeited	(10,000 )	2.46	0	0	0	0	(10,000 )	1.30	1.30
Exercised	0	0	0	0	0	0	0	0	0
Outstanding end of year	6,640,934	\$ 1.30-6.00	\$ 2.66	6,640,934	\$ 1.30-6.00	\$ 2.66	6,630,934	\$ 1.30-6.00	\$ 2.66
Exercisable	6,594,267	\$ 1.30-6.00	\$ 2.66	6,625,934	\$ 1.30-6.00	\$ 2.66	6,630,934	\$ 1.30-6.00	\$ 2.66
	5-6 yrs.			4-5 yrs.			3-4 yrs.		

Weighted average remaining contractual life (years) Available for future grants	10,019	10,019	10,019
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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, 2010			December 31, 2011			December 31, 2012		
	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	1,530,000	\$0.72-3.05	\$ 2.19	1,550,000	\$0.72-3.05	\$ 2.17	1,550,000	\$0.72-3.05	\$ 2.17
Granted	20,000	\$0.89	\$ 0.89	0	0	0	0	0	0
Forfeited	0	0	0	0	0	0	0	0	0
Exercised	0	0	0	0	0	0	0	0	0
Outstanding end of year	1,550,000	\$0.72-3.05	\$ 2.17	1,550,000	\$0.72-3.05	\$ 2.17	1,550,000	\$0.72-3.05	\$ 2.17
Exercisable	1,550,000	\$0.72-3.05	\$ 2.17	1,550,000	\$0.72-3.05	\$ 2.17	1,550,000	\$0.72-3.05	\$ 2.17
Remaining contractual life	7.81 years			6.81 years			5.81 years		
Available for future grants	19,626			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, 2010			December 31, 2011			December 31, 2012		
	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	281,250	\$1.42-2.81	\$ 2.16	1,879,978	\$0.52-2.81	\$ 0.92	3,189,978	\$0.21-2.81	\$ .70
Granted	1,598,758	\$0.52-2.71	\$ 0.70	1,310,000	\$0.21-0.55	\$ 0.38	1,499,000	\$0.29-4.03	\$ 0.42
Forfeited	0	0	0	0	0	0	0	0	0
Exercised	0	0	0	0	0	0	0	0	0
Outstanding end of year	1,879,978	\$0.52-2.81	\$ .92	3,189,978	\$0.21-2.81	\$ 0.70	4,688,978	\$0.21-4.03	\$ 0.61
Exercisable at end of year	1,879,978	\$0.52-2.81	\$ .92	2,856,645	\$0.21-2.81	\$ 1.57	3,962,183	\$0.21-4.03	\$ 0.61
Remaining contractual life	8.1 years			6.81 years			7.67 years		



Available for future grants	11,618,085	9,765,847	6,907,247
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(ii) Stock Warrants

Stock warrants are issued as needed by the Board of Directors and have no formal plan.

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The fair value of each warrant award is estimated on the date of grant using a Black-Scholes-Merton pricing 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 warrants 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 warrants granted in 2012, were estimated based on the following weighted average assumptions:

	December 31, 2012
Risk-free interest rate	0.61%- 0.073
Expected dividend yield	0
Expected life	5 yrs.
Expected volatility	112.18%-112.35%
Weighted average grant date fair value of options issued	\$0.57 per option for 150,000 options

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

	December 31, 2010		December 31, 2011			December 31, 2012			
	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	11,008,246	\$0.51-3.60	\$ 1.44	10,983,246	\$0.51-3.60	\$ 1.61	10,978,246	\$0.51-3.60	\$ 1.55
Granted	0	0	0	0	0	0	150,000	\$0.89-2.00	1.30
Forfeited	(25,000 )	\$2.50	\$ 2.50	(5,000 )	\$3.60	\$ 3.60	0	0	0
Exercised	0	0	0	0	0	0	0	0	0
Outstanding end of year	10,983,246	\$0.51 -3.60	\$ 1.61	10,978,246	\$0.51 -1.65	\$ 1.55	11,128,246	\$0.51 -3.60	\$ 1.44
Exercisable	10,983,246	\$0.51-3.60	\$ 1.61	10,978,246	\$0.51-1.65	\$ 1.55	11,128,246	\$0.51-3.60	\$ 1.44
Weighted average remaining contractual life	3..9 years			2.9 years			2.0 years		
Years exercisable	2011-2019			2012-2019			2013-2022		

Stock warrants are issued at the discretion of the Board. In 2012, warrants to purchase 150,000 shares were issued to independent contractors or consultants for services rendered.

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

No warrants were exercised during 2010, 2011 or 2012.

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(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 \$0.01 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.

On November 2, 2012, the Company executed an Amended and Restated Rights Agreement amending and restating the November 19, 2002 Rights Agreement between the Company and Continental Stock Transfer & Trust Company, as Rights Agent (as amended, the "Amended Rights Agreement"). The Amended Rights Agreement extends the term of the Rights Plan to November 18, 2017 and amends certain other provisions, as described in the Company's Amended Registration Statement on Form 8-A/A, filed on November 2, 2012 (the "Amended Form 8-A"). The Amended Rights Plan entitles holders to buy one-hundredth unit of preferred stock for \$30.00 and may be redeemed prior to November 19, 2017, the expiration date, at \$0.001 per Right under certain circumstances. 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 approximately 4.99% of our common stock, the Rights Plan's threshold will be 20%, instead of 15%.

**(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, 2012, 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**

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 \$545,000, \$314,000 and \$290,000 in fees to Sage for the years ended December 31, 2012, 2011 and 2010, 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 no fees for the years ended December 31, 2012, 2011 and 2010, 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. This agreement also provides start-up along with ongoing sales and marketing support to the Company. On August 14, 2012, it was mutually agreed upon to extend this agreement for one year subject to the same terms and conditions. The Company incurred no fees for the years ended December 31, 2012, 2011 and 2010, 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. On August 14, 2012, it was mutually agreed upon to extend this agreement for one year subject to the same terms and conditions. The Company incurred approximately fees of \$21,000 and \$5,250 for the years ended December 31, 2012 and 2011, respectively, 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, 2012, 2011 and 2010, the Company incurred approximately \$1,561,000, \$1,580,000 and \$1,607,000, 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 effective as of January 1, 2010. For 2012, 2011 and 2010, the Company contributions towards the 401(k) Plan were \$138,000, \$148,000 and \$122,000 respectively.

**(13) Royalties, License and Employment Agreements**

The Company had contractual agreements with the same five Officers in 2012 and 2011, and four of those Officers in 2010. The aggregate annual base compensation for these Officers under their respective contractual agreements for 2012, 2011 and 2010 were \$2,578,000, \$2,299,000 and \$2,369,000 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 2012, 2011 and 2010, Executive Officers' bonuses of \$478,000, \$486,000 and \$500,000 respectively were granted. Additionally, on November 26, 2012, the Company's Compensation Committee authorized the payment per Section 3(c)(ii) of their respective Employment Agreements to Dr. Carter and Mr. Equels based on the contractual obligation and opinion of independent legal counsel of approximately \$1,159,000 to each Dr. Carter and Mr. Equels, respectively.

In 2012, equity was granted as a form of compensation to these Officers:

Chief Executive Officer was granted 100,000 ten year options to purchase common stock at \$0.29 per share which vest in entirety in one year;

Chief Executive Officer was granted 500,000 ten year options to purchase common stock at \$0.31 per share which vested immediately;

Chief Executive Officer was granted 10,000 ten year options, as replacement for similar options that had expired, to purchase common stock at \$4.03 per share which vested immediately;

General Counsel was granted 100,000 ten year options to purchase common stock at \$0.29 per share which vest in entirety in one year;

General Counsel was granted 300,000 ten year options to purchase common stock at \$0.31 per share;

Chief Medical Officer was granted 10,000 ten year options, as replacement for similar options that had expired, to purchase common stock at \$4.03 per share which vested immediately;

Senior Vice President of Operations was granted 50,000 ten year options to purchase common stock at \$0.29 per share which vest in entirety in one year;

Senior Vice President was granted 50,000 ten year options to purchase common stock at \$0.29 per share which vest in entirety in one year; and

Vice President of Quality Control was granted 30,000 ten year options to purchase common stock at \$0.85 per share which vest in entirety in one year.

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 vests in entirety in 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.

The Company recorded stock compensation expense of \$262,000, \$271,000 and \$495,000, respectively, during the years ended December 31, 2012, 2011 and 2010 respectively with regard to these issuances.



An agreement was made and entered into as of the 31st day of December, 2008 with Robert E. Peterson. 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.

For a period of thirty six (36) months following the Effective Date of December 31, 2008, shall engage Peterson as a part time advisor to the Company’s Chief Executive Officer and shall pay to Peterson for such services (“Advisory Services”) the sum of four thousand dollars (\$4,000) per month, payable monthly with the first monthly payment being due and payable one month after the Effective Date. These payments and services concluded on December 31, 2011;

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On the occurrence of a “Change In Control, the Company shall pay to Peterson three times the amount of compensation paid to Peterson by the Company for calendar year 2008. A “Change In Control” shall be deemed to have occurred as set forth the Engagement Agreement Regarding Change In Control made as of March 11, 2005 between the Company and Peterson, with the definition of “Change In Control” as therein set forth;

Peterson is to receive Options to purchase 20,000 shares of the Company’s common stock at the end of each calendar quarter following the Effective Date. Peterson may terminate the Advisory Services at any time. The issuance of Options concluded on December 31, 2011;

Upon executing a “Financial Transaction”, the Company shall pay to Peterson one (1) percent (the “Peterson One Per Cent Fee”) of the cash to be received by the Company from each Financial Transaction. Provided, however, the Peterson One Per Cent Fee shall in no event exceed in the aggregate two times the amount of compensation paid to Peterson by the Company for calendar year 2008. A “Financial Transaction” shall be any agreements entered into by the Company in which the Company is to receive cash from such third parties. A Financial Transaction does not include agreements whereby the Company receives cash as a result of (i) the Company only being reimbursed for expenses, not including expenses for prior research conducted by the Company, incurred by the Company, (ii) an agreement in which the only economic benefit to the Company is a loan or loans to the Company, (iii) any transactions with Fusion pursuant to the July 2, 2008, Common Stock Purchase Agreement between the Company and Fusion; and

This Agreement shall terminate upon Peterson having received full payment for a change in control or upon receiving the maximum one percent fee. The Agreement provides for a “gross-up” payment to make Peterson whole for any Federal taxes imposed as a result of change of control or one percent payments to him.

As a result of Financial Transactions completed through the sale of Company Stock, in accordance with the Peterson One Per Cent Fee, and his monthly consulting fee, Mr. Peterson was paid for \$231,839, \$48,000 and \$50,928 for 2012, 2011 and 2010.

#### **(14) Leases**

The Company has a non-cancelable operating lease for the space in which its principal office is located. The term of the lease for the Philadelphia, Pennsylvania offices is currently through April 30, 2013.

Rent expense charged to operations for the years ended December 31, 2012, 2011 and 2010 amounted to approximately \$210,000 \$215,000 and \$205,000 respectively.

#### **(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.

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In January 2012, the Company effectively sold \$16,000,000 of its New Jersey state Net Operating Loss carry-forwards (for the years 2009 and 2010) for approximately \$1,328,000 as compared to February 2011, when 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, 2012, the Company has approximately \$119,000,000 of federal net operating loss carryforwards (expiring in the years 2013 through 2032) available to offset future federal taxable income. The Company also has approximately \$36,000,000 of Pennsylvania state net operating loss carryforwards (expiring in the years 2018 through 2032) and approximately \$17,000,000 of New Jersey state net operating loss carryforwards (expiring in the years 2030 through 2032) available to offset future state taxable income.

In January 2013, the Company effectively sold \$8,500,000 of its New Jersey state net operating loss carryforwards for the years 2010 and 2011 for approximately \$685,000. 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, 2012 and 2011.

The components of the net deferred tax asset of December 31, 2012 and 2011 consist of the following:

	(in thousands)	
Deferred tax assets:	December 31,	
	2012	2011

Net operating losses	\$40,442	\$36,612
Amortization & depreciation	(1,503 )	(1,282 )
Research and development costs	3,233	2,285
Stock compensation	121	123
Inventory reserve	348	65
Total	42,641	37,803
Less: Valuation allowance	(42,641)	(37,803)
Balance	\$-0-	\$-0-

**(16) Contingencies**

- (a) *Stephanie A. Frater v. Hemispherx Biopharma, Inc., William A. Carter, Thomas Equels and Charles Bernhardt, U.S. District Court for Eastern District of Pennsylvania, Case No. 2:12-cv-07152-WY.*  
*Mark Zicherman v. Hemispherx Biopharma, Inc., William A. Carter, Thomas K. Equels, Iraj E. Kiani, William*
- (b) *M. Mitchell, Richard C. Piani and Charles T. Bernhardt, U.S. District Court for Eastern District of Pennsylvania, Case No. 2:13-cv-00243-WY.*  
*Michael Desclos v. Hemispherx Biopharma, Inc., William A. Carter, Charles T. Bernhardt, Thomas K. Equels,*
- (c) *David R. Strayer, Richard C. Piani, William M. Mitchell, and Iraj E. Kiani, First Judicial District of Pennsylvania, Court of Common Pleas of Philadelphia, March 2013 Term, No. 110.*

On December 21, 2012, a putative federal securities class action complaint was filed against the Company and three of its officers in the United States District Court for the Eastern District of Pennsylvania. This action, *Stephanie A. Frater v. Hemispherx Biopharma, Inc., et al.*, was purportedly brought on behalf of a putative class of Hemispherx investors who purchased the Company's publicly traded securities between March 19, 2012 and December 17, 2012. The complaint generally asserts that Defendants made material misrepresentations and omissions regarding the status of the Company's New Drug Application for Ampligen®, which had been filed with the United States Food and Drug Administration, in alleged violation of Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), Rule 10b-5 promulgated thereunder, and Section 20(a) of the Exchange Act. On February 22, 2013, several putative members of the alleged plaintiff class filed motions to be appointed Lead Plaintiff pursuant to the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4. Pursuant to Court order, within 15 calendar days following the Court's appointment of a lead plaintiff and approval of the lead plaintiff's selection of lead counsel, the parties will submit an additional stipulation and proposed order setting forth a mutually agreeable schedule for the filing of any amended complaint and the briefing of Defendants' motion to dismiss. Under the PSLRA, discovery will be stayed pending the Court's decision on Defendants' motion to dismiss.

On January 15, 2013, a shareholder derivative complaint was filed against the Company, as nominal defendant, and certain of its Officers and Directors in the United States District Court for the Eastern District of Pennsylvania. The complaint in this action, *Mark Zicherman v. Hemispherx Biopharma, Inc., et al.*, alleges violations of state law, including breaches of fiduciary duties, waste of corporate assets, and unjust enrichment, arising from the alleged federal securities violations asserted in the securities class action. On February 22, 2013, the Court entered an order staying this case pending the outcome of Defendants' motion to dismiss the securities class action.

On March 4, 2013, a shareholder derivative and putative class action complaint was filed against the Company, as nominal defendant, and certain of its officers and directors in the First Judicial District of Pennsylvania of the Court of Common Pleas of Philadelphia. The complaint alleges violations of state law, including breaches of fiduciary duties, waste of corporate assets, and unjust enrichment. As of today's date, none of the defendants has been served with the complaint.

The Company intends to vigorously defend these actions. The potential impact of these actions, which seek unspecified damages, equitable relief, attorneys' fees and expenses, is uncertain. There can be no assurance that an adverse result in these proceedings would not have a potentially material adverse effect on the Company's business, results of operations and financial condition.

*(d) 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 security bond of \$66,873 related to the JCI proceedings and a second bond of \$25,200 was posted in July 2012 related our proceedings against the Estate of Kebble.

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***(e) MidSouth Capital, Inc. v. Hemispherx Biopharma, 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 (Adam Cabibi and Robert Rosenstein) 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 were 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 was assigned Case No. 11-11618-E and the Company's Cross-Appeal was assigned Case No. 11-11650-E. Mediation ordered by the Court of Appeals was unsuccessful. Oral arguments on consolidated appeals took place before the Eleventh Circuit Court of Appeals on February 1, 2012.

In early April 2012, the Company received notice that Robert Rosenstein, a principal of MidSouth, filed a petition under Chapter 7 of the Bankruptcy Code in the Northern District of Georgia. The Company elected not to contest the dischargability of its claim against Mr. Rosenstein.

On August 14, 2012, the panel to which the Appeal and Cross-Appeal had been assigned issued an opinion affirming in part and reversing in part the decisions of the Trial Court. The Court of Appeals affirmed both the Trial Judge's grant of Summary Judgment in favor of the Company and Sage on MidSouth's fraud Counterclaim and the grant of Summary Judgment in favor of MidSouth, Cabibi, and Rosenstein on the Company's tortious interference claims. The Court of Appeals reversed the Trial Court's Order dismissing MidSouth's Counterclaim for breach of contract and the Order granting Summary Judgment in favor of the Company on MidSouth's Counterclaims based on promissory estoppel, quantum meruit, and unjust enrichment.



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After remand to the District Court, a Scheduling Order proposed by the parties was entered by the Court on October 17, 2012. In light of the Court of Appeals' Ruling, the parties were realigned with MidSouth as the Plaintiff and the Company as the Defendant. The Company deposed representatives of two more of the investors to preserve their testimony for trial. Neither witness testified that MidSouth's activity significantly influenced the decision to invest. The Company has moved for leave to designate an expert witness, and that Motion is awaiting a decision by the Trial Court. If leave is granted, there will be an additional period of discovery limited to expert issues. If the Motion is denied, the parties will prepare and submit a proposed pretrial Order together with any other pretrial Motions. In either event, the Company will vigorously defend the remaining claims. No date has been set for trial.

As of March 6, 2013, 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 MidSouth claims or a range of potential recovery or loss.

*(f) 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 sought 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. 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 was 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. On August 30, 2011, the Company and the Sage Group filed an Answer with Affirmative Defenses to the Plaintiff's Amended Complaint. 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. In accordance with a Scheduling Order set by the Court, the parties concluded fact and expert discovery on April 16, 2012. On April 30, 2012 the Company filed Motions for Summary Judgment seeking dismissal of all counts. The Sage Group also filed a Motion for Summary Judgment seeking dismissal of all counts asserted against Sage.

In accordance with a Scheduling Order set by the Court, the parties concluded Fact and Expert Discovery on April 16, 2012. On April 30, 2012, the Company filed Motions for Summary Judgment seeking dismissal of all counts. The Sage Group (“Sage”) also filed a Motion for Summary Judgment seeking dismissal of all counts asserted against Sage. On September 10, September 12, and September 13, 2012, the Court entered Orders denying all pending Motions by all parties.

The Parties had a Non-Jury trial on March 4, 5 and 6, 2013 before the United States District Court for the District of Delaware. The Court has Ordered the Parties to submit additional Briefing and other documentation to the Court on or before April 22, 2013. There can be no estimate of when the Court may rule on the case.

As of March 6, 2013, no informed judgment can be made as to the likely outcome and Counsel is unable to provide an estimate of the merits or probability of success of the Cato claims or a range of potential recovery or loss.

***(g) 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 (a), (b), (c), (e) and (f). 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, 2012 or 2011. Also with regards to Contingency (a), (b) and (c), the Company maintains a Directors and Officers Insurance Policy that provides coverage for claims and retention of legal counsel.

**(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. 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 \$-0-, \$137,000 and \$123,200 for the use of the property, off-site meetings and lodging at various times in 2012, 2011 and 2010, 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 for the use of the property or lodging 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 \$176,000, \$170,000 and \$165,000 for 2012, 2011 and 2010, respectively.

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From December 2011 through June 2012, the Company employed Kyle Carter as a Data Control Clerk. Kyle Carter is the Son of Dr. William A. Carter, and was paid approximately \$8,000, \$3,000 and \$-0- in 2012, 2011 and 2010, respectively.

In June 2012, William Kramer was hired as a Clinical Research Associate. Mr. Kramer is the Son-In-Law of Dr. William A. Carter, and was paid approximately \$38,000, \$-0- and \$-0- in 2012, 2011 and 2010, respectively. Additionally on an as-needed basis, the Company utilized the services of Kramer Environmental Management, Inc. to develop standard operating procedures, compliance assessments, testing and obtain permits related to environmental issues. William Kramer is also the President of Kramer Environmental Management, Inc. and the organization was paid approximately \$20,000, \$-0- and \$-0- in 2012, 2011 and 2010, respectively.

Katalin Kovari, M.D. was paid approximately \$25,000, \$28,000 and \$26,000 in 2012, 2011 and 2010, respectively for her part-time services to the Company as Assistant Medical Director. Dr. Kovari is the spouse of William A. Carter, CEO.

Since October 2011, Peter Kovari was utilized as a part-time independent contractor for Hemispherx Biopharma Europe to undertake projects as a Clinical Programmer. Mr. Kovari is the nephew of Dr. Katalin Kovari and was paid approximately \$12,000, \$6,000 and \$-0- in 2012, 2011 and 2010, 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 2012, 2011 and 2010, the Company paid Equels Law Firm approximately \$147,000, \$159,000 and \$729,000, respectively, 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. The hourly rate fees from Equels Law Firm remained the same for 2011 and 2012. For his Board fees, Mr. Equels received approximately \$176,000, \$170,000 and \$165,000 for 2012, 2011 and 2010, respectively. Additionally beginning December 2012 with the approval of the Audit Committee, the Company began renting an office at Equels Law Firm for \$3,000 per month for dedication to and utilization by Hemispherx personnel. For 2012, 2011 and 2010, the Company paid Equels Law Firm \$3,000, \$-0- and \$-0-, respectfully, for office rent based on a proration of the Firm's current leasing fee less the cost for common area.

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 2012, 2011 and 2010, the Company paid reimbursements to Mr. Piani for approximately \$48,000, \$48,000 and \$48,000, 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. The office rental fee of \$4,000 per month has remained constant since 2010. For his Board fees, Mr. Piani received approximately \$176,000, \$170,000 and \$165,000 for 2012, 2011 and 2010, respectively.

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**(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 2012, 2011 or 2010.

**(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, 2012, 2011 and 2010, were estimated using the following assumptions:

	December 31,		
	2012	2011	2010
Underlying price per share	\$0.25-\$0.80	\$0.20-\$0.46	\$0.47-\$0.74
Exercise price per share	\$1.31-\$1.65	\$1.31-\$1.65	\$1.31-\$1.65
Risk-free interest rate	0.19%-0.44%	0.29%-1.58%	0.83%-2.36%
Expected holding period	1.38-2.63 years	2.38-3.63 years	3.38-4.63 years
Expected volatility	69.21%-110.27%	74.55%-120.55%	112.16%-122.02%

Expected dividend yield	None	None	None
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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.

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(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 any sooner than the second half of 2013;

b. The Company may 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.

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(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 \$295,000, \$380,000 and \$2,805,000 at December 31, 2012, 2011 and 2010, respectively.

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, 2012, 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:

	(in thousands)			
	As of December 31, 2012			
	Total	Level 1	Level 2	Level 3
Assets				
Marketable Securities	\$27,241	\$27,241	\$0	\$0
Marketable Securities - restricted	14,500	13,499	1,001	0
Liabilities				
Warrants	(295 )	0	0	(295)
Total	\$41,446	\$40,740	\$1,001	\$(295)

	As of December 31, 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	\$30,908	\$29,123	\$2,165	\$(380)

	As of December 31, 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	\$38,662	\$33,257	\$8,210	\$(2,805)

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

	2012	2011	2010
Balance at January 1	\$380	\$2,805	\$3,684
Fair value adjustment at March 31	151	(301 )	1,336
Balance March 31	531	2,504	5,020
Fair value adjustment at June 30	(387 )	(643 )	(2,260)
Balance at June 30,	144	1,861	2,760

Fair value adjustment at September 30	1,968	(614 )	583
Balance at September 30	2,112	1,247	3,343
Fair value adjustment at December 31	(1,817)	(867 )	(538 )
Balance at December 31	\$295	\$380	\$2,805

**(20) 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 range of two to one, based on the diversity of securities, pledged as collateral for 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, from its inception in October 2011 through September 2012, it carried an effective interest rate of 2.75% per annum applied against the “Margin Debit Balance” (i.e., those funds withdrawn and outstanding), based on the prevailing “Wells Fargo Base Rate” less 2.50%. Currently, the effective interest rate of 2.50% per annum applied against the Margin Debit Balance. As of December 31, 2012, the principal loan balance of the Margin Account was approximately \$7,051,000, for which approximately \$14,500,000 in Marketable Securities that are restricted with them dedicated collateral for the indebtedness. 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 was restricted as dedicated collateral. The finance charges were approximately \$85,000 and \$6,000 for the twelve months ended December 31, 2012 and three months ended December 31, 2011, respectively (see Note 6: Marketable Securities - Restricted).

**(21) Subsequent Events**

The Company evaluated subsequent events through the date on which these financial statements were issued, and other than the sale of New Jersey state net operating losses for approximately \$685,000 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, 2012.

**(22) Quarterly Results of Operation (unaudited)**

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

	2012 (in thousands except per share data)				
	March 31, 2012	June 30, 2012	September 30, 2012	December 31, 2012	Total
Revenues	\$72	\$49	\$ 39	\$ 53	\$213
Costs and expenses	(3,819)	(3,682 )	(5,004 )	(8,048 )	(20,553)
Interest & other					
Income (expense)	262	246	346	719	1,573
Sales of tax NOL	1,328	0	0	0	1,328
Redeemable warrants valuation adjustment	(151 )	387	(1,968 )	1,817	85
Net loss	\$(2,308)	\$(3,000 )	\$(6,587 )	\$(5,459 )	\$(17,354)
Basic and diluted loss per share	\$(0.02 )	\$(0.02 )	\$(0.05 )	\$(0.03 )	\$(0.12 )

	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

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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	\$(0.01 )	\$(0.02 )	\$( 0.02 )	\$( 0.02 )	\$(0.07 )

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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	\$(0.04 )	\$(0.01 )	\$(0.02 )	\$(0.02 )	\$(0.10 )

### Hemispherx Biopharma, Inc.

#### Valuation and Qualifying Accounts Schedule

(dollars in thousands)

Description	Balance at beginning of period	Charge to expense	Write- offs	Balance at end of period
Year Ended December 31, 2010 Reserve for inventory	\$ 282	\$ 0	\$(33 )	\$ 249
Year Ended December 31, 2011 Reserve for inventory	\$ 249	\$ 192	\$(249 )	\$ 192
Year Ended December 31, 2012 Reserve for inventory	\$ 192	\$ 1,023	\$(0 )	\$ 1,215

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