HEMISPHERX BIOPHARMA INC
Form 10-K
March 14, 2012

FORM 10-K

SECURITIES AND EXCHANGE COMMISSION

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2011

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File No. 1-13441

HEMISPHERX BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

Common Stock, $.001 par value

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

(Title of Each Class)

NONE

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

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

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

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

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

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

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

The aggregate market value of Common Stock held by non-affiliates at June 30, 2011, the last business day of the registrant's most recently completed second fiscal quarter was $51,514,392.

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

DOCUMENTS INCORPORATED BY REFERENCE: None.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

PART I

ITEM 1. Business.

GENERAL

We are a specialty pharmaceutical company based in Philadelphia, Pennsylvania and engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. We were founded in the early 1970s doing contract research for the National Institutes of Health. Since that time, we have established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of natural interferon and nucleic acids to enhance the natural antiviral defense

system of the human body and to aid the development of therapeutic products for the treatment of certain chronic diseases. We have three domestic subsidiaries BioPro Corp., BioAegean Corp., and Core BioTech Corp., all of which are incorporated in Delaware and are dormant. Our foreign subsidiary is Hemispherx Biopharma Europe N.V./S.A. established in Belgium in 1998, which has minimal activity. All significant intercompany balances and transactions have been eliminated in consolidation.

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

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ that produces Alferon® and Ampligen®. In December 2011, our Board of Directors (the "Board") reevaluated its facility enhancement project to focus on converting the facility to provide for a high volume, more cost effective manufacturing process for Alferon N Injection®, Alferon® LDO and Ampligen®. In this regard, the Board increased the funding allocated to this project from $4.4 million to $6.5 million. The project is in an active construction phase with approximately $1,695,000 spent to date and financed through a Margin Account with an effective interest rate of 2.75%. As of December 31, 2011, construction in progress on this project was $1,484,000 as compared to $485,000 at December 31, 2010. While facility enhancements are being undertaken, this project has not impacted our capability to manufacture Ampligen®. The production of new Alferon® inventory product will not commence until the capital improvement phase is completed, which is projected for mid-2012. While the facility had been granted approval of its Biological License Application ("BLA") by the FDA for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements. Provided we receive a Release Approval from the FDA as to quality and consistency of our existing inventory and final product, we believe that our current lots of Active Pharmaceutical Ingredient ("API") will be sufficient to meet the short-term patient demand for Alferon N Injection® until production of an FDA approved product can recommence. We outsource certain components of our research and development, manufacturing, marketing and distribution while maintaining control over the entire process through our quality assurance group and our clinical monitoring group.

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

AVAILABLE INFORMATION

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

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

OUR PRODUCTS

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

Ampligen®

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

Nucleic acid compounds represent a potential new class of pharmaceutical products that are designed to act at the molecular level for treatment of human diseases. There are two forms of nucleic acids, DNA and RNA. DNA is a group of naturally occurring molecules found in chromosomes, the cell's genetic machinery. RNA is a group of naturally occurring informational molecules which orchestrate a cell's behavior which, in turn, regulates the action of groups of cells, including the cells which compromise the body's immune system. RNA directs the production of proteins and regulates certain cell activities including the activation of an otherwise dormant cellular defense against viruses and tumors. Our drug technology utilizes specifically-configured RNA. Our double-stranded RNA drug product, trademarked Ampligen®, is an experimental, unapproved drug, that would be administered intravenously. Ampligen® has been assigned the generic name rintatolimod by the United States Adopted Names Council (USANC) and has the chemical designation poly(I) poly(C_{12},U).

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

In July 2008, the FDA accepted for review our NDA for Ampligen® to treat CFS, originally submitted in October 2007. We are seeking marketing approval for the first-ever treatment for CFS. At present, only supportive, symptom-based care is available for CFS patients. The NDA for Ampligen® is also the first ever accepted for review by the FDA for systemic use of a toll-like receptor therapy to treat any condition. In November 2009, we received a Complete Response Letter ("CRL") from the FDA which described specific additional recommendations related to the Ampligen® NDA. In accordance with its 2008 Complete Response procedure, the FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues. We intend to take the appropriate steps to seek approval and commercialization of Ampligen®. Most notably, the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen® and recommended at least one additional clinical study which shows convincing effect and confirms safety in the target population. The FDA indicated that the additional study should be of sufficient size and sufficient duration (six months) and include appropriate monitoring to rule out the generation of autoimmune

disease. In addition, patients in the study should be on more than one dose regimen, including at least 300 patients on dose regimens intended for marketing. We are examining those two major studies for further insight into efficacy and safety. In the Non-Clinical area, the FDA recommended among other things that we complete rodent carcinogenicity studies in two species. While as part of the NDA submission we had requested that these studies be waived, this waiver had not been granted by the FDA in their CRL.

Under the Product Quality section of the CRL, the FDA recommended that we submit additional data and complete various analytical procedures. The collection of these data and the completion of these procedures is already part of our ongoing Quality Control, Quality Assurance program for Ampligen® manufacturing under current Good Manufacturing Practice ("cGMP") guidelines and our manufacturing enhancement program. On January 14, 2010, we submitted reports of new preclinical data regarding Ampligen® to the FDA that we believed to be sufficient to address certain preclinical issues in the FDA's CRL. We do not anticipate receiving feedback until we submit our complete response to the CRL. The preclinical studies discussed in these reports were the combined work-product of the staffs at Hemispherx and Lovelace Respiratory Research Institute in Albuquerque, New Mexico, and included pharmacokinetic analyses in two lower animal species (primate and rodent). The new preclinical data showed no evidence of antibodies against Ampligen® in primates nor evidence of an increase in certain undesirable cytokines (specific modulators of the immune system) at clinically used doses of Ampligen® for CFS. Although most other experimental immunomodulators have been associated with one or more features of aberrant immune activity, including toll-like receptor activators (of which Ampligen® is one), this was specifically not seen with Ampligen® in primates.

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

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

In 2009, we had estimated that the approximate cost to undertake the Ampligen® Phase III clinical study could range from $12,000 to $18,500 per each of the 600 participating patients, for an estimated range of total incremental costs of $7,200,000 to $11,100,000. Our estimate is based on the belief that our experience from the prior Phase III study and established teams (e.g., Medical, Data Processing, Clinical Monitors, Statisticians, Medical Reporting) along with existing inventory and investigational protocol, could produce financial efficiencies. We believe that these efficiencies could permit our costs of undertaking a Phase III CFS study to be discounted as compared to a potential $28,500 per patient cost approximated as an industry average for running a Phase III study from scratch, as estimated and adjusted for inflation, utilizing data from the business intelligence firm Cutting Edge Information. The actual costs of a Phase III investigation study for CFS may differ based on final design of an accepted FDA Phase III clinical study, prevailing costs to undertake clinical studies, qualification and access to CFS patients, insurance and government requirements along with other potential costs or reimbursements unknown at this time. Aside from the foregoing, we cannot estimate what additional studies and/or additional testing or information that the FDA may require. Accordingly, as of this time, we are unable to estimate the nature, timing, costs and necessary efforts to obtain FDA clearance, the anticipated completion dates or whether we will obtain FDA clearance.

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

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

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

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

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Alferon N Injection®

Alferon N Injection® is the registered trademark for our injectable formulation of natural alpha interferon, which is approved by the FDA in 1989 for the treatment of certain categories of genital warts. Alferon® is the only natural-source, multi-species alpha interferon currently approved for sale in the U.S. for the intralesional (within lesions) treatment of refractory (resistant to other treatment) or recurring external genital warts in patients 18 years of age or older. Certain types of human papilloma viruses ("HPV") cause genital warts, a sexually transmitted disease ("STD"). The CDC estimates that approximately twenty million Americans are currently infected with HPV with another six million becoming newly infected each year. The CDC states that HPV is so common, that at least 50% of sexually active men and women get it at some point in their lives. According to a World Health Organization report on HPV, "Genital warts are very common and are highly infectious, and between 90% and 100% are caused by HPV genotypes 6 and 11. Although they do not usually result in death, genital warts cause significant morbidity and entail substantial health care costs. Recurrence is common."

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

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

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

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

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

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

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

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

Alferon® LDO (Low Dose Oral)

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

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In October 2009, we originally submitted a protocol to the FDA proposing to conduct a Phase II, double-blind, adaptive-design, randomized, placebo-controlled, dose-ranging study of Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. In December 2010, the FDA authorized this Phase II. Our Phase II study has been delayed as we are undertaking a confirmatory study using gene expression measures to identify the systemic gene activation effects in peripheral blood leukocytes following treatment with Alferon® LDO. The outcome of this confirmatory study will allow us to evaluate better the potential effectiveness of this product and to proceed with this study of seasonal and pandemic influenza.

HISTORICAL COSTS RELATED TO OUR PRODUCTS

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

(dollars in thousands)
Year Ended December 31, 2011

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

(dollars in thousands)
Year Ended December 31, 2010

Costs and Expenses	Ampligen® NDA	Alferon N Injection®	Alferon® LDO	Other	Total
Production/cost of goods sold	$0	$ 1,341	$ 0	$0	$1,341
Research and development	2,787	0	4,658	168	7,613
General and administrative	2,356	1,133	3,937	142	7,568
Total	$5,143	$ 2,474	$ 8,595	$310	$16,522

(dollars in thousands)

Costs and Expenses	Year Ended December 31, 2009				
	Ampligen® NDA	Alferon N Injection®	Alferon® LDO	Other	Total
Production/cost of goods sold	$0	$ 584	$ 0	$0	$584
Research and development	5,026	0	1,784	185	6,995
General and administrative	3,844	447	1,364	141	5,796
Total	$8,870	$ 1,031	$ 3,148	$326	$13,375

PATENTS AND NON-PATENT EXCLUSIVITY RIGHTS

On March 1, 2012, we had 16 patents worldwide with 85 additional pending patent applications comprising our intellectual property. Please see “Note 7: Patents, Trademark Rights and Other Intangibles (FASB ASC 350 General Intangibles Other than Goodwill)” under Notes To Consolidated Financial Statements for more information on these patents.

We continually review our patents' rights to determine whether they have continuing value. Such review includes an analysis of the patent's ultimate revenue and profitability potential. In addition, Management's review addresses whether each patent continues to fit into our strategic business plans for Ampligen®, Alferon N Injection® and Alferon® LDO. The U.S. patents relating to our Alferon® products expire April 2, 2013 (5,503,828) October 14, 2014 (5,676,942) and December 22, 2017 (5,989,441). In December 2011, the Company was granted two new United States Patents for the use of Alferon® LDO for the treatment in a number of different human diseases. We believe that oral administration of Alferon® LDO, with its anticipated affordability, low toxicity, expected non-production of antibodies, and broad range of potential bioactivity, could be a breakthrough treatment for prevention for viral diseases including influenza. New therapeutic use patent applications are pending.

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

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

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

RESEARCH AND DEVELOPMENT ("R&D")

Our general focus during the past three fiscal years has been on developing drugs for use in treating viral and immune based chronic disorders and diseases such as ME/CFS, HIV, HPV and West Nile Virus, Cancer and Influenza. Our current R&D projects are targeting treatment therapies for ME/CFS, various cancers (as adjunctive therapy) and other viral diseases such as prevention and treatment of seasonal and pandemic H1N1 or influenza.

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

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

Due to the inherent uncertainty involved in the design and conduct of clinical trials and the applicable regulatory requirements, including the factors discussed above in “OUR PRODUCTS”, we cannot predict what additional studies and/or additional testing or information may be required by the FDA. Accordingly, we are unable to estimate the nature, timing, costs and necessary efforts to complete these projects nor the anticipated completion dates. In addition, we have no basis for estimating when material net cash inflows may commence. We have yet to generate significant revenues from the sale of these developmental products. As of December 31, 2011, we had approximately $34.4 million in Cash, Cash Equivalents and Marketable Securities. Based upon our current anticipated financial needs, absent unexpected circumstances or new opportunities, we anticipate, but cannot assure, that we will be able to fund operations for at least the next three years. However, if we are unable to timely commercialize and sell Ampligen® for the treatment of CFS or Alferon® LDO and/or recommence material sales of Alferon N Injection®, our operations, financial position and liquidity may be adversely affected (see ITEM 1A. Risk Factors; “We may require additional financing which may not be available” below).

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

Chronic Fatigue Syndrome (“CFS”), also known as Chronic Immune Dysfunction Syndrome (“CFIDS”) and, Myalgic Encephalomyelitis (“ME”) is a serious and debilitating chronic illness and a major public health problem. ME/CFS is recognized by both the government and private sector as a major health problem, including the National Institutes of Health, FDA and the U.S. Centers for Disease Control and Prevention (“CDC”). The CDC states on its website at http://www.cdc.gov/cfs/index.html that “Chronic fatigue syndrome, or CFS, is a devastating and complex disorder characterized by overwhelming fatigue that is not improved by bed rest and that may be worsened by physical or mental activity. People with CFS most often function at a significantly lower level of activity than they were capable of before the onset of illness.”

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

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

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

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

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

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

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

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

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Other Viral Diseases

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

A Phase II Trial for intramuscular administration of Ampligen® for seasonal influenza was conducted in Australia through St. Vincent's Hospital with the final patient completing the study in September 2008. This open-label study (Phase IIa Trial) utilized Ampligen® as a potential immune-enhancer in Australia with thirty-eight subjects age 60 or greater with the standard trivalent seasonal influenza vaccines. We continue in good faith to work towards obtaining the clinical data and retrieve the study samples from St. Vincent's recently restructured Clinical Trials Centre and related Clinical Network Services. As a prerequisite of payment, we had requested the confirmation that samples were properly maintained utilizing cGCP and Good Laboratory Practice ("cGLP") for the controlled environment as per our agreement. On February 5, 2010, our Counsel advised representatives of St. Vincent's business units in correspondence that, due to the failure to meet the condition precedent to payment, we had no choice but to declare them in breach of the study agreement and that it was our intention to terminate the relationship between the parties. Since February 18, 2010, various offers and counteroffers have been made between us and Clinical Trials Centre and/or Clinical Network Services, to permit us to retrieve the data by making certain payments to each organization or a third party escrow account with funds equal to the disputed amount placed in escrow. Upon agreement of the payment terms, we would then be granted access to review some or all of the data. Following our satisfaction that the clinical study was conducted utilizing cGCP along with samples properly maintained utilizing cGLP, the escrow funds could be released to Clinical Trials Centre and Clinical Network Services so that pathology samples could be collected by us. The proposals for data collection and the dollar value of the disputed fees continue to be reviewed by the respective parties.

Ampligen® as a mucosal adjuvant with vaccine had been studied at Japan's National Institute of Infectious Disease ("NIID") and at Biken (the for profit operational arm of the Foundation for Microbial Diseases of Osaka University). Investigators from Japan's NIID had conducted studies in animals that suggested that Ampligen® could stimulate a sufficiently broad immune response to provide cross-protection against a range of virus genetic types, including H5N1 and derivative clades. Japan's Council for Science & Technology Policy ("CSTP"), a cabinet level position, awarded funds from Japan's CSTP to advance research with influenza vaccines utilizing Ampligen®.

A Material Evaluation Agreement ("MEA") regarding Ampligen® with Biken that was initiated on August 19, 2009, effectively expired on September 1, 2010. Pursuant to the MEA, we supplied Biken with proprietary information related to Ampligen® and Biken purchased Ampligen® from us for use solely in connection with evaluating Ampligen® as a candidate for adjuvant incorporated into potential influenza virus vaccines in the form of intranasal mucosal administration, including conducting further animal studies of intranasal prototype vaccines containing antigens from various influenza sub-types, including H5N1, H1N1, H3N2 and B.

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

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

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

Dr. Hideki Hasegawa, M.D., Ph.D., Chief of Laboratory of Infectious Disease Pathology for the Department of Pathology for the NIID, undertook studies in 2009 and 2010 that focused on mucosal immunity and the inherent advantages of a vigorous immune response to respiratory pathogens. Dr. Hasegawa has published data that the formulation of pandemic vaccine mixed with Ampligen® increases immuno-genicity and may demonstrate cross protection against mutated strains. Dr. Hasegawa has expressed a desire to continue preclinical development of this concept, and as such, he continues to organize and participate in meetings with other qualified corporate vaccine partners in Japan who have intranasal vaccines under development along with necessary facilities to test, develop and commercialize the vaccine enhancement utilizing Ampligen® in an attempt to achieve cross-protection against pandemic strains in a commercial environment.

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

In April 2010, we began the process to undertake a clinical study with Max Neeman International, a leading and large clinical research organization in India. This collaborative clinical research effort is intended to utilize Alferon N Injection® for treatment of seriously ill patients hospitalized with either seasonal influenza or pandemic influenza. The Indian site selection process was initiated and we obtained approval to begin the study from the Indian Drugs Controller General on July 13, 2010. We continue to enroll subjects with expectation of greater patient participation in the upcoming flu season. As of December 31, 2011, we have eight operational Clinical Investigative Sites, with the intention of adding additional sites. Twenty-five patients have completed the study. Our study has progressed at a rate slower than originally projected due to difficulties encountered in the process of screening for subjects with influenza, rather than other illnesses with symptoms similar to influenza, along with India currently experiencing an unusually mild flu season. In an attempt to expedite the process to qualify study subjects, we added a second "point of care" screening test which has been implemented at the sites as we attempt to qualify subjects for the upcoming flu season. It is our objective to qualify and enroll sixty patients for the study.

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

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

MANUFACTURING

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

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

We outsource certain components of our research and development, manufacturing, marketing and distribution while maintaining control over the entire process through our quality assurance group and our clinical monitoring group.

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

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

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

MARKETING/DISTRIBUTION

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

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

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

In January 2010, we engaged an Argentinean regulatory and business design entity to explore the possibility of initiating clinical trials of Alferon N Injection®, Ampligen® and Alferon® LDO during the influenza season in Argentina. On June 14, 2010, we executed an exclusive Sales, Marketing, Distribution and Supply Agreement for Argentina with GP Pharm Latinoamerica ("GP Pharm"), an affiliate company of Spanish GP Pharm SA. Under this Agreement, GP Pharm will be responsible for gaining regulatory approval in Argentina for Ampligen® to treat CFS in Argentina and for commercializing Ampligen® for this indication in Argentina. We granted GP Pharm the right to expand rights to sell this experimental therapeutic into other Latin America countries based upon GP Pharm achieving certain performance milestones. We also granted GP Pharm an option to market Alferon N Injection® in Argentina and other Latin America countries. Under these agreements, we will manufacture and supply Ampligen® and Alferon N Injection® to GP Pharm. On November 15, 2010, we amended our June 15, 2010 agreement with GP Pharm to include Mexico in the Territory under the Sales, Marketing, Distribution and Supply Agreement. Under this Agreement, GP Pharm Mexico will be responsible for gaining regulatory approval in Mexico for Ampligen®, an experimental therapeutic, to treat CFS in Mexico and for commercializing Ampligen® for this indication in Mexico. We have granted GP Pharm the right to expand rights to sell this experimental therapeutic into other Latin America countries based upon GP Pharm achieving certain performance milestones. In December 2010, GP Pharm exercised this right and in July 2011 GP Pharm submitted an application for approval to ANMAT, the agency responsible for the national regulation of drugs, foods and medical technology in Argentina. As a result of the efforts of GP Pharm, in January 2012, ANMAT approved the sale and distribution of Alferon N Injection® (under the brand name "Naturaferon") in Argentina. The receipt of the ANMAT approval is the first step of a regulatory process towards the commercial sales of Naturaferon.

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

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

COMPETITION

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

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

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

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

GOVERNMENT REGULATION

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

We are subject to various federal, state and local laws, regulations and recommendations relating to such matters as safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use of and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. Prior to our construction phase, our laboratory and production facility in New Brunswick, New Jersey was approved for the manufacture of Alferon N Injection®. While our facility had been granted approval of its BLA by the FDA for the manufacture of Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements. Upon completion of our enhanced manufacturing process, we believe it will again be able to obtain FDA approval. However, there can be no assurance that this facility, or facilities owned and operated by third parties that are utilized in the manufacture of our products, will obtain and/or continue to maintain FDA approval.

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HUMAN RESOURCES

As of March 1, 2012, we had 59 personnel consisting of 47 full-time employees or consultants and 12 regulatory/research medical personnel on a part-time basis. Part-time personnel are paid on a per diem or monthly basis. 41 personnel are engaged in our research, development, clinical, and manufacturing effort. 18 of our personnel perform regulatory, general administration, data processing, including bio-statistics, financial and investor relations functions. We have no union employees and we believe our relationship with our employees is good.

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

SCIENTIFIC ADVISORY BOARD AND DATA MONITORING COMMITTEE

With the unfortunate June 2011 passing of Dr. James Rahal, formally Director of the Infectious Disease Section of New York Hospital Queens and one of the nation's foremost experts on the West Nile Virus, our Scientific Advisory Board is presently being reorganized. It is the role of this Board to advise us about current and long-term scientific planning including research and development. The Scientific Advisory Board conducts periodic meetings as needed. No Scientific Advisory Board meetings were held in the last three years, primarily due to fewer active scientific projects. Individual Scientific Advisory Board Members may informally consult with and/or meet with our employees or Board Members. Members of the Scientific Advisory Board could be employed by others and may have commitments to and/or consulting agreements with other entities, including our potential competitors.

In May 2010, we formed a Data Monitoring Committee (“DMC”) that consists of two independent regulatory and medical experts along with a Biostatistics expert. The function of the DMC is to perform independent safety and efficacy analyses on our clinical trials.

ITEM 1A. Risk Factors.

The following cautionary statements identify important factors that could cause our actual results to differ materially from those projected in the forward-looking statements made in this Form 10-K. Among the key factors that have a direct bearing on our results of operations are:

Risks Associated With Our Business

No assurance of successful product development.

Ampligen® and related products. The development of Ampligen® and our other related products is subject to a number of significant risks. Ampligen® may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale, be uneconomical to market or be precluded from commercialization by proprietary right of third parties. Our investigational products are in various stages of clinical and pre-clinical development and require further clinical studies and appropriate regulatory approval processes before any such products can be marketed. We do not know when, if ever, Ampligen® or our other products will be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale. Please see the next risk factor.

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

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

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

Our products, including Ampligen®, are subject to extensive regulation by numerous governmental authorities in the United States ("U.S.") and other countries, including, but not limited to, the FDA in the U.S., the Health Protection Branch ("HPB") of Canada, and the Agency for the European Medicines Agency ("EMA") in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen® or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen® will ultimately be demonstrated to be safe or efficacious. While Ampligen® is authorized for use in clinical trials in the U.S. and Europe, we cannot assure you that additional clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials. In addition, although Ampligen® has been authorized by the FDA for treatment use under certain conditions, including provision for cost recovery, there can be no assurance that such authorization will continue in effect.

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

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

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

Alferon® LDO is undergoing pre-clinical testing for possible use as prophylaxis against influenza. While the studies to date have been encouraging, preliminary testing in the laboratory and in animal models is not necessarily predictive of successful results in clinical testing or human treatment. No assurance can be given that similar results will be observed in clinical trials. Use of Alferon® as a possible treatment of influenza requires prior regulatory approval. In October 2009, we originally submitted a protocol to the FDA proposing to conduct a Phase II, double-blind, adaptive-design, randomized, placebo-controlled, dose-ranging study of Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. In December 2010, the FDA authorized this Phase II, double-blind, adaptive-design, randomized, placebo-controlled, dose-ranging study of Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. Our Phase II study has been delayed as we are undertaking a confirmatory study using gene expression measures to identify the systemic gene activation effects in peripheral blood leukocytes following treatment with Alferon® LDO. The outcome of this confirmatory study will allow us to evaluate better the potential effectiveness of this product and to proceed with this study of seasonal and pandemic influenza. We are unable to provide any assurances that Phase II Alferon® LDO study for the prophylaxis and treatment of seasonal and pandemic influenza will be undertaken. Please see Part 1, ITEM 1. "Business; MANUFACTURING above for more detailed information.

If we are unable to generate the additional data, successfully complete inspections or obtain approvals as required by the FDA, determine that any of our clinical studies are not cost/justified to undertake or if, for that or any other reason, Ampligen®, Alferon® or one of our other products or production processes do not receive necessary regulatory approval in the U.S. or elsewhere, our operations may be materially adversely affected.

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

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, with a major emphasis on new drug diagnostic and development, we have incurred substantial operating losses, as we pursued our clinical trial effort to get our experimental drug, Ampligen®, approved. As of December 31, 2011, our accumulated deficit was approximately $(226,740,000). We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

We may require additional financing which may not be available. The limited number of shares of common stock available for financing without prior stockholder approval may hinder our ability to raise additional funding.

The development of our products will require the commitment of substantial resources to conduct the time consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of December 31, 2011, we had approximately $34,391,000 in Cash, Cash Equivalents and Marketable Securities (inclusive of $3,101,000 in Marketable Securities collateralizing certain debts). Given the challenging economic conditions, we continue to review every aspect of our operations for cost and spending reductions to assure our long-term financial stability while maintaining the resources necessary to achieve our primary objectives of obtaining NDA approval of Ampligen®, and securing a strategic partner.

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

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

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

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

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

Commercial sales of Alferon N Injection® were halted in March 2008 when our finished goods inventory expired. The production of Alferon N Injection® from the Work-In-Process Inventory was restarted in May 2010, continued into January 2011 with its conversion into API and is completed for the related Final Lot Release Test. To fill and finish Alferon N Injection® Drug Product, we require a FDA approved third party CMO. In January 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea regarding the fill and finish process for Alferon N Injection®. Our Work-In-Process Inventory has expiration dates of September 30, 2012 through March 10, 2013. Upon the expected mid-2012 completion of the fill and finish process, it is projected that Alferon N Injection® will have an expected shelf life of 42 months. Provided we receive a Release Approval from the FDA as to quality and consistency of our current inventory and final product, as well as Althea is successful in the fill and finish process, we estimate that commercial sales of Alferon N Injection® could commence in the later part of 2012. We are unable to provide any assurances that the Work-In-Process Inventory will be converted into Finished Goods prior to the product's expiration nor that the FDA will approve the final inventory lots manufactured by us or produced by Althea. If this Finished Goods inventory does not complete the fill and finish steps prior to their expiration or the inventory is not granted approval by the FDA for clinical sales, our operations most likely will be materially adversely affected. (see "MANUFACTURING" in ITEM 1. Business).

We continue to undertake at our New Brunswick, NJ facility a major capital improvement program to enhance our manufacturing capability to produce bulk quantities of Alferon N Injection® API. The production of new Alferon® inventory product will not commence until the capital improvement phase is completed, which is projected for mid-2012. While the facility had been granted approval of its BLA by the FDA for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements. Provided we receive a Release Approval from the FDA as to quality and consistency of our existing inventory and final product, we believe that our current lots of API will be sufficient to meet the short-term patient demand for Alferon N Injection® until production of an FDA approved product can recommence. We outsource certain components of our research and development, manufacturing, marketing and distribution while maintaining control over the entire process through our quality assurance group and our clinical monitoring group. Certain of the plant and equipment improvements being implemented for production of Alferon N Injection® may require FDA review prior to commercial sale of the resulting new product, and each production lot of Alferon N Injection® using this new process is subject to FDA review and approval prior to releasing the lots to be sold.

In light of these contingencies, there can be no assurances that the approved Alferon N Injection® product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

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

Ampligen® has been tested as a vaccine adjuvant for H5N1, a pathogenic avian influenza virus, in the laboratories of Dr. Hasegawa at the National Institute of Infectious Diseases in Japan, where the preclinical data has shown activity in preventing lethal challenge with the original N5N1 viral strain used for vaccination as well as the other related, but not identical, isolates of H5N1 virus (i.e., cross-reactivity). We had an agreement regarding Ampligen® with Biken pursuant to which we supplied Biken with proprietary information related to Ampligen® and Biken purchased Ampligen® from us for use solely in connection with evaluating Ampligen® as a candidate for adjuvant incorporated into potential influenza virus vaccines in the form of intranasal mucosal administration. Biken concluded that it was possible that Ampligen® would not satisfy the requirements for safety as an adjuvant for influenza vaccines in Japan. Biken's primary concern was related to a single intravenous high dose study in rats that resulted in an apparent toxicity when doses of Ampligen® were combined with a whole viron influenza vaccine and Carboxyl Vinyl Polymer ("CVP") or CVP alone. Additionally in both cases of Ampligen® being combined with other product(s), the dosage utilized was several hundred times higher than the intended dosage for humans by body weight and delivered intravenously, rather than the prescribed mucosal (nasal) method. While we have disputed Biken's findings, the relationship has effectively ended with no further resolution to the dispute expected. See Part 1, ITEM 1. "Business; RESEARCH AND DEVELOPMENT ("R&D"); Other Viral Diseases" above.

No assurance can be given that positive results will be observed in clinical trials. Use of Ampligen® or Alferon® in the treatment of influenza requires prior regulatory approval. Only the FDA or other corresponding regulatory agencies world-wide can determine whether a drug is safe, effective and appropriate for treating a specific application. As discussed above, obtaining regulatory approvals is a rigorous and lengthy process (see "*Our drugs and related technologies are investigational and subject to regulatory approval. If we are unable to obtain regulatory approval, our operations will be significantly adversely affected*" above). If we are unable to obtain the necessary regulatory approval in the U.S. or elsewhere, generate the data of successfully completed clinical studies, or determine that a clinical study is not cost/justified to undertake, or if for that or any other reason, our operations most likely will be materially and/or adversely impacted.

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

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

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

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

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

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

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

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

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

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

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

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

We cannot assure that our U.S. or foreign marketing strategy will be successful or that we will be able to establish future marketing or third party distribution agreements on terms acceptable to us, or that the cost of establishing these arrangements will not exceed any product revenues. Our inability to establish viable marketing and sales capabilities would most likely have a materially adverse effect on us. There can be no assurances that the approved Alferon N Injection® product will be returned to prior sales levels.

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

A number of essential raw materials are used in the production of Ampligen®. We do not have, but continue to work towards having long-term agreements for the supply of such materials, when possible. There can be no assurance we can enter into long-term supply agreements covering essential materials on commercially reasonable terms, if at all.

There are a limited number of suppliers in the United States available to provide the raw materials for use in manufacturing Ampligen®. At present, we do not have any agreements with third parties for the supply of any of these raw materials. We have established relevant manufacturing operations within our New Brunswick, New Jersey facility for the production of Ampligen® polymers from raw materials in order to obtain a more consistent manufacturing basis in the quantities necessary for clinical testing. In September 2011 and similar to our prior agreements, Hollister-Stier has agreed to undertake the manufacturing sets to formulate, fill, finish and package Ampligen® from the key polymers that we would supply. Hollister-Stier would have the right of first refusal to manufacture certain Ampligen® related products.

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

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

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

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

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

In light of these contingencies, there can be no assurances that the approved Alferon N Injection® product will be returned to commercial production or sale on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

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

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

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

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

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

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

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

We have limited manufacturing experience for Ampligen®.

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

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

We have never produced Ampligen® or any other products in large commercial quantities. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen® or continue to maintain third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Should the NDA be approved, we may need to find an additional vendor to manufacture the product for commercial sales. Also, each production lot of Alferon N Injection® is subject to FDA review and approval prior to releasing the lots to be sold. This review and approval process could take considerable time, which would delay our having product in inventory to sell, nor can we provide any assurance as to the receipt of FDA approval of our finished inventory product. There can be no assurances that the Ampligen® can be commercially produced at costs acceptable to us.

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

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

Our products may be subject to substantial competition.

Ampligen®. Competitors may be developing technologies that are, or in the future may be, the basis for competitive products. Some of these potential products may have an entirely different approach or means of accomplishing similar therapeutic effects to products being developed by us. These competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments may offer competition to our products. Furthermore, many of our competitors have significantly greater experience than us in preclinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, HPB or other regulatory product approvals more rapidly than us. There are no drugs approved for commercial sale with respect to treating ME/CFS in the United States. The dominant competitors with drugs to treat disease indications in which we plan to address include Pfizer, GlaxoSmithKline, Merck, Novartis and AstraZeneca. Biotech competitors include Baxter International, Fletcher/CSI, AVANT Immunotherapeutics, AVI BioPharma and Genta. These potential

competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Although we believe our principal advantage is the unique mechanism of action of Ampligen® on the immune system, we cannot assure that we will be able to compete.

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

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

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

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

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

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

We maintain Products Liability and Clinical Trial insurance coverage world-wide for Ampligen® and Alferon®. However even with retaining Products Liability and Clinical Trial insurance coverage for Ampligen®, Alferon N Injection® and Alferon® LDO, a claim against the products could have a materially adverse effect on our business and financial condition.

We face an inherent business risk of exposure to product liability claims in the event that the use of Ampligen®, Alferon N Injection® or other of our products results in adverse effects. This liability might result from claims made directly by patients, hospitals, clinics or other consumers, or by pharmaceutical companies or others manufacturing these products on our behalf. Our future operations may be negatively affected from the litigation costs, settlement expenses and lost product sales inherent to these claims. While we will continue to attempt to take appropriate precautions, we cannot assure that we will avoid significant product liability exposure.

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

Our success is dependent on the continued efforts of our staff, especially certain doctors and researchers along with the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen®, and his knowledge of our overall activities, including patents and clinical trials. The loss of the services of Dr. Carter or other personnel key to our operations, could have a material adverse effect on our operations and chances for success. As a cash conservation measure, we have elected to discontinue the Key Man life insurance on the life of Dr. Carter. An employment agreement continues to exist with Dr. Carter that, as amended, runs until December 31, 2016. However, Dr. Carter has the right to terminate his employment upon not less than 30 days prior written notice. The loss of Dr. Carter or other key personnel or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

Uncertainty of health care reimbursement for our products.

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

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

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

Risks Associated With an Investment in Our Common Stock:

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

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

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

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

- overall investment market fluctuation;
- restatement of prior financial results;
- notice of NYSE Amex non-compliance with requirements; and
- occurrence of any of the risks described in these "Risk Factors".

Our common stock is listed for quotation on the NYSE Amex. For the 12 month period ended December 31, 2011, the closing price of our common stock has ranged from $0.18 to $0.55 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry.

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

In May 2009, we issued an aggregate of 25,543,339 shares and warrants to purchase an additional 14,708,687 shares under a Universal Shelf Registration Statement. 4,895,000 of these warrants have been exercised as of December 31, 2011. Depending upon market conditions, we anticipate selling 9,813,687 shares pursuant to the conversion of remaining warrants.

Additionally, we registered with the SEC on September 29, 2009, 1,038,527 shares issuable upon exercise of certain other warrants. To the extent the exercise price of our outstanding warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the exercise price of certain of these warrants are adjusted pursuant to anti-dilution protection, the warrants could be exercisable or convertible for even more shares of common stock. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. In this regard we have registered $150,000,000 of securities for public sale pursuant to a universal shelf registration. We have allocated 32,000,000 shares under this registration statement to an At-The-Market equity offering and, as of December 31, we have sold a total of 520,000 shares pursuant to this offering.

We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. Sales of substantial amounts of our common stock in the public market, including additional sale of securities pursuant to the universal shelf registration statement or upon exercise of outstanding options, could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in Management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November 2002, we adopted a Stockholder Rights Plan ("Rights Plan") and, under the Rights Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one-hundredth unit of preferred stock for $30.00. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Dr. Carter, our Chief Executive Officer, who already beneficially owns 5.65% of our common stock, the Rights Plan's threshold will be 20%, instead of 15%. The Rights Plan will expire on November 19, 2012, and may be redeemed prior thereto at $0.01 per Right under certain circumstances.

Special Note Regarding Forward Looking Statements

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

ITEM 1B. Unresolved Staff Comments.

None.

ITEM 2. Properties.

We currently lease through April 2013, our headquarters located in Philadelphia, Pennsylvania consisting of a suite of offices of approximately 9,000 square feet. We also own, occupy and use our New Brunswick, New Jersey laboratory and production facility that we acquired from ISI. These facilities consist of two buildings located on 2.8 acres. One building is a two story facility consisting of a total of 31,300 square feet. This facility contains offices, laboratories and production space. It also contains space designated for research and development, packaging, quality assurance and quality control laboratories. Building Two has 11,670 square feet consisting of offices, laboratories, warehouse space, shipping, receiving and packaging areas. The property has parking space for approximately 100 vehicles.

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

ITEM 3. Legal Proceedings.

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

ITEM 4. Mine Safety Disclosures.

Not Applicable.

PART II

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

In 2010, we issued shares of common stock consisting of: 1) 498,867 shares in payment to vendors and consultants for services rendered; 2) 520,000 shares sold at the market; and 3) 1,435,295 shares to our employees for final distribution of shares from the stock for pay program started in 2009. In 2011, we issued 145,440 shares of common stock in payment to vendors and consultants for services rendered and 255,254 shares to Ronald Ritz, Sr. Director of Manufacturing in payment of 50% of his compensation.

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

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

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

July 1, 2011 through September 30, 2011	$0.40	$0.27
October 1, 2011 through December 31, 2011	$0.30	$0.18
January 1, 2010 through March 31, 2010	$0.84	$0.56
April 1, 2010 through June 30, 2010	$0.87	$0.44
July 1, 2010 through September 30, 2010	$0.62	$0.44
October 1, 2010 through December 31, 2010	$0.57	$0.46

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

On March 1, 2012, the last sale price for our common stock on the NYSE Amex was $0.31 per share.

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

The following table gives information about our Common Stock that may be issued upon the exercise of options, warrants and rights under all of our equity compensation plans as of December 31, 2011:

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

PERFORMANCE GRAPH

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

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

INDEXED RETURNS
Base Period
Years Ending

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

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

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

The selected consolidated financial data set forth below should be read in conjunction with our consolidated financial statements, and the related notes thereto, and "Management's Discussion and Analysis of Financial Condition and Results of Operations", included in this Annual Report. The statement of operations and balance sheet data presented below for, and as of the end of, each of the years in the five year period ended December 31, 2011 are derived from our audited consolidated financial statements. Historical results are not necessarily indicative of the results to be expected in the future.

Year Ended December 31	2007	2008	2009	2010	2011
Statement of Operations Data:	$1,059	$265	$111	$135	$161
Revenues and License fee Income					
Total Costs and Expenses[1]	20,348	13,076	13,375	16,522	14,456
Interest Expense and Financing Costs[2]	396	0	241	11	41
Redeemable warrants valuation adjustment	0	0	(6,258)	(879)	(2,425)
Net loss	(18,139)	(12,219)	(7,180)	(13,136)	(9,015)
Deemed Dividend	0	0	0	0	0
Net loss applicable to common stockholders	(18,139)	(12,219)	(7,180)	(13,136)	(9,015)
Basic and diluted net loss per share	$(0.25)	$(0.16)	$(0.07)	$(0.10)	$(0.07)
Shares used in computing basic and diluted net loss per share	71,839,782	75,142,075	109,514,401	134,018,243	135,432,395
Balance Sheet Data:					
Working Capital	$14,412	$5,646	$55,789	$33,842	$26,717
Total Assets	23,142	13,211	64,994	51,680	43,513

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

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

(2) For information concerning our financing see Note 21 “Margin Account Loan” to our consolidated financial statements for the year ended December 31, 2011 contained herein.

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis is related to our financial condition and results of operations for the three years ended December 31, 2011. This information should be read in conjunction with ITEM 6 – “Selected Financial Data” and our consolidated financial statements and related notes thereto beginning on F-1 of this Form 10-K.

Statement of Forward-Looking Information

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

Background

We are a specialty pharmaceutical company based in Philadelphia, Pennsylvania and engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. Our flagship products include Alferon N Injection® and the experimental therapeutic Ampligen®. Alferon N Injection® is approved for a category of STD infection, and Ampligen® represents an experimental RNA nucleic acid being developed for globally important viral diseases and disorders of the immune system. Hemispherx' platform technology includes large and small agent components for potential treatment of various severely debilitating and life threatening diseases. We have 16 patents comprising our core intellectual property estate and a FDA approved product (Alferon N Injection®).

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

Fair Value

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

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

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

	2011	2010	2009
Underlying price per share	$0.20-$0.46	$0.47-$0.74	$0.56 - $2.54
Exercise price per share	$1.31-$1.65	$1.31-$1.65	$1.10 – $1.65
Risk-free interest rate	0.29%-1.58%	0.83%-2.36%	0.19% - 2.67%
Expected holding period	2.38-3.63 years	3.38-4.63 years	0.122-5.50 years
Expected volatility	74.55%-120.55%	112.16%-122.02%	94.99%–226.46%
Expected dividend yield	None	None	None

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

(i) *Risk-Free Interest Rate*. The risk-free interest rates for the Warrants are based on U.S Treasury constant maturities for periods commensurate with the remaining expected holding periods of the warrants.

(ii) *Expected Holding Period*. The expected holding period represents the period of time that the Warrants are expected to be outstanding until they are exercised. The Company utilizes the remaining contractual term of the Warrants at each valuation date as the expected holding period.

(iii) *Expected Volatility*. Expected stock volatility is based on daily observations of the Company's historical stock values for a period commensurate with the remaining expected holding period on the last day of the period for which the computation is made.

(iv) *Expected Dividend Yield*. Expected dividend yield is based on the Company's anticipated dividend payments over the remaining expected holding period. As the Company has never issued dividends, the expected dividend yield is $-0- and this assumption will be continued in future calculations unless the Company changes its dividend policy.

(v) *Expected Probability of a Fundamental Transaction.* The possibility of the occurrence of a Fundamental Transaction triggering a Put right is extremely remote. As discussed above, a Put right would only arise if a Fundamental Transaction 1) is an all cash transaction; (2) results in the Company going private; or (3) is a transaction involving a person or entity not traded on a national securities exchange. The Company believes such an occurrence is highly unlikely because:

a. The Company only has one product that is FDA approved for sale, but such product will not be available for commercial sales until at least the second half of 2012;

b. The Company will have to perform additional clinical trials for FDA approval of its flagship product as well as to diversify the applications of its FDA approved product;

c. Industry and market conditions continue to include a global market recession, adding risk to any transaction;

d. Available capital for a potential buyer in a cash transaction continues to be limited;

e.

The nature of a life sciences company is heavily dependent on future funding and high fixed costs, including Research & Development;

f. The Company has minimal revenue streams which are insufficient to meet the funding needs for the cost of operations or construction at their manufacturing facility; and

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g. The Company's Rights Plan and Executive Employment Agreements make it less attractive to a potential buyer.

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

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

The Monte Carlo Simulation has incorporated a 5.0% probability of a Fundamental Transaction for the life to date for these securities.

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

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

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

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

RESULTS OF OPERATIONS

Year ended December 31, 2011 versus December 31, 2010

Net Loss

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

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

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

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

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

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

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

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

Revenues

Revenues from our Ampligen® cost recovery treatment program for the year ended December 31, 2011 were approximately $161,000 compared to revenues of $135,000 for the same period in 2010, an increase of $26,000 or 19% for approximately 36 patients in 2011 and 21 patients in 2010 participating in the program. Commercial sales of Alferon N Injection® were halted in March 2008 when our Finished Goods Inventory expired. As a result, we had no Alferon N Injection® product to commercially sell in 2011 or 2010 and all sales revenue in 2011 and 2010 has been generated from Ampligen® cost recovery clinical treatment programs. We currently have the financial resources to undertake manufacturing upgrades that have been undertaken throughout 2011 and 2010 (see “MANUFACTURING” in ITEM 1. Business).

Production/Cost of Goods Sold

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

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

Research and Development Costs

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

General and Administrative Expenses

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

Interest and Other Income

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

Interest Expense and Financing Costs

In 2011 and 2010 prior to the establishment of the Margin Account Loan, we financed through capital leases some office equipment vital to the overall operations of the Company as well as manufacturing equipment utilized in the production of Alferon®. For the year ended December 31, 2011 and 2010, we had interest expense of approximately $41,000 and $11,000, respectively. For detailed information on the Margin Account Loan and capital leases, see “Liquidity and Capital Resources” below.

Sale of New Jersey Tax Net Operating Loss

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

Redeemable Warrants Valuation Adjustment

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

RESULTS OF OPERATIONS

Year ended December 31, 2010 versus December 31, 2009

Net Loss

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

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

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

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

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

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

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

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

Revenues

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

In 2010 and 2009, production of Alferon N Injection® had been put on hold due to the resources needed to prepare our New Brunswick, NJ facility for the FDA preapproval inspection with respect to our Ampligen® NDA. We now have the financial resources to commence manufacturing upgrades that had been undertaken throughout 2010 and continue in 2011.

Production/Cost of Goods Sold

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

Research and Development Costs

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

General and Administrative Expenses

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

Interest and Other Income

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

Interest Expense and Financing Costs

In 2010, we financed through capital leases some office equipment vital to the overall operations of the Company as well as manufacturing equipment utilized in the production of Alferon®. Accordingly in 2010, we had interest expense of approximately $11,000 as compared to $-0- for 2009. In February 2009, we entered into a Standby Financing Agreement that produced finance costs of $241,000 in Common Stock Commitment Warrants for the twelve months ended December 31, 2009 for which no agreement of this type was undertaken in 2010. For detailed information on this agreement, see “Standby Financing Agreement” below.

Redeemable Warrants Valuation Adjustment

Cash Flows from Investing Activities:

Capital expenditures

(23,131) (23,131)

Intercompany

(15,963) 5,455 (71,377) 81,885 (15,963) 5,455 (94,508) 81,885 (23,131)

Cash Flows from Financing Activities:

Distribution paid to Limited Partners and General Partner

(31,591) (31,591)

Payments of statutory withholding on net issuance of Limited Partner units under restricted unit incentive plan

(1,278) (1,278)

Contribution from General Partner for Limited Partner unit transactions

76 76

Advances to affiliates, net

9,974 510 10,792 21,276

Borrowings under credit facility

5,000 5,000

Repayments under credit facility

(46,000) (46,000)

Contributions from affiliate

1,069 1,069 (21,541) (40,490) 10,583 (51,448)

Net change in cash and cash equivalents

Cash and cash equivalents at beginning of year

2,000 2,000

Cash and cash equivalents at end of year

$ $2,000 $ $ $2,000

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Condensed Consolidating Statement of Cash Flows

Three Months Ended March 31, 2007

(unaudited)

	Parent	Subsidiary Issuer	Subsidiary Guarantors	Non-Guarantor Subsidiaries	Consolidating Adjustments	Total
Net Cash Flows from Operating Activities	$ 22,224	$ 19,847	$ (15,284)	$ 3	$ (52,407)	$ (25,617)
Cash Flows from Investing Activities:						
Capital expenditures			(17,881)			(17,881)
Intercompany	(4,499)	(77,259)	29,354	(3)	52,407	
	(4,499)	(77,259)	11,473	(3)	52,407	(17,881)
Cash Flows from Financing Activities:						
Distribution paid to Limited Partners and General Partner	(28,253)					(28,253)
Payments of statutory withholding on net issuance of Limited Partner units under restricted unit incentive plan			(1,479)			(1,479)
Contribution from General Partner for Limited Partner unit transactions	58					58
Repayments from (advances to) affiliates, net	10,470		4,637			15,107
Borrowings under credit facility		48,000				48,000
Contributions from (distributions to) affiliate			653			653
	(17,725)	48,000	3,811			34,086
Net change in cash and cash equivalents		(9,412)				(9,412)
Cash and cash equivalents at beginning of year		9,412				9,412
Cash and cash equivalents at end of period	$	$	$	$	$	$

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations Three Months Ended March 31, 2008 and 2007

Sunoco Logistics Partners L.P.

Operating Highlights

Three Months Ended March 31, 2008 and 2007

	Three Months Ended March 31	
	2008	**2007**
Eastern Pipeline System:[1]		
Total shipments (barrel miles per day)[2]	60,383,731	63,491,427
Revenue per barrel mile (cents)	0.526	0.472
Terminal Facilities:		
Terminal throughput (bpd):		
Refined product terminals[3]	418,615	415,567
Nederland terminal	569,769	556,622
Refinery terminals[4]	675,196	613,511
Western Pipeline System:[1]		
Crude oil pipeline throughput (bpd)	550,424	533,906
Crude oil purchases at wellhead (bpd)	171,445	185,151
Gross margin per barrel of pipeline throughput (cents)[5]	50.4	24.9

(1) Excludes amounts attributable to equity ownership interests in corporate joint ventures.

(2) Represents total average daily pipeline throughput multiplied by the number of miles of pipeline through which each barrel has been shipped.

(3) Includes results from the Partnership s purchase of a 50% undivided interest in a refined products terminal in Syracuse, New York in June 2007.

(4) Consists of the Partnership s Fort Mifflin Terminal Complex, the Marcus Hook Tank Farm and the Eagle Point Dock.

(5) Represents total segment sales minus cost of products sold and operating expenses and depreciation and amortization divided by crude oil pipeline throughput.

Analysis of Consolidated Net Income

Net income was $37.5 million for the first quarter 2008 as compared with $22.3 million for the first quarter 2007, an increase of $15.2 million. This increase was due mainly to record results in the Western Pipeline System segment and strong performance in the Terminal Facilities segment, partially offset by a $5.7 million non-cash impairment charge related to a discontinued project.

Net interest expense decreased $0.9 million to $7.7 million for the first quarter 2008 from $8.6 million for the prior year s quarter primarily due to lower interest rates related to the Partnership s revolving credit facility. The balance outstanding on the credit facility decreased $41.0 million from December 31, 2007 to March 31, 2008 as a result of the timing of working capital activity.

Analysis of Segment Operating Income

Eastern Pipeline System

Operating income for the Eastern Pipeline System increased $1.0 million to $10.7 million for the first quarter 2008 from $9.7 million for the first quarter 2007. Sales and other operating revenue increased by $1.9 million to $28.9 million due primarily to higher fees across the Partnership s refined product and crude pipelines. Other income decreased $1.3 million compared to the prior year s quarter due primarily to a decrease in equity income associated with the Partnership s joint venture interests.

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Terminal Facilities

The Terminal Facilities business segment had operating income of $11.2 million for the first quarter 2008, as compared to $12.3 million for the prior year s first quarter. The decrease in operating income was attributable to a $5.7 million non-cash impairment charge related to the Partnership s decision to discontinue efforts to expand liquefied petroleum gas storage capacity at its Inkster, Michigan facility and an increase in costs of products sold and operating expenses largely associated with the purchase of product additives. Partially offsetting this decrease was an increase in revenue. Total revenues for the first quarter of 2008 increased $6.5 million to $39.4 million due primarily to increased throughput and fees at the Nederland crude oil terminal facility, increased volume at the refined product and refinery terminals and higher refined product additive fees.

Western Pipeline System

Operating income for the Western Pipeline System increased $14.3 million to $23.3 million for the first quarter of 2008 compared to the prior year s quarter due to improved asset utilization, higher pipeline volumes, the recognition of income from throughput deficiency arrangements and an improvement in lease acquisition margins. The Partnership s Mid-Valley Pipeline Company equity interest also contributed to increased profitability. Higher crude oil prices were a key driver of the increase in total revenue, cost of products sold and operating expenses from the prior year s quarter which was partially offset by lower crude oil purchase volume. The average price of West Texas Intermediate crude oil at Cushing, Oklahoma increased to $97.96 per barrel for the first quarter of 2008 from $58.23 per barrel for the first quarter of 2007.

Liquidity and Capital Resources

Liquidity

Cash generated from operations and borrowings under the Credit Facility are the Partnership s primary sources of liquidity. At March 31, 2008, the Partnership had available borrowing capacity under the Credit Facility of $350.0 million. The Partnership s working capital position reflects crude oil inventories based on historical costs under the LIFO method of accounting. If the inventories had been valued at their current replacement cost, the Partnership would have had working capital of $68.2 million at March 31, 2008.

On April 28, 2008, Sunoco Pipeline L.P., a subsidiary of the Partnership, entered into a definitive agreement to acquire a refined products pipeline system and certain other real and personal property interests and assets from Mobil Pipe Line Company. In addition to the pipeline system, Sunoco Partners Marketing & Terminals L.P., a subsidiary of the Partnership, entered into definitive agreements with Exxon Mobil Corporation, Mobil Pipe Line Company and ExxonMobil Oil Corporation, to acquire six refined products terminal facilities. Subject to necessary regulatory filings and approvals and the satisfaction of certain other closing conditions, the transactions, with a combined purchase price of approximately $200.0 million, are expected to be completed in the third quarter of 2008. For further information on these transactions see Item 1. Notes to Condensed Consolidated Financial Statements (unaudited) Note 12.

Capital Resources

The Partnership periodically supplements its cash flows from operations with proceeds from debt and equity financing activities.

Credit Facility

Sunoco Logistics Partners Operations L.P. (the Operating Partnership), a wholly-owned entity of the Partnership, has a five-year $400 million Credit Facility, which is available to fund the Operating Partnership s working capital requirements, to finance future acquisitions, to finance future capital projects and for general partnership purposes. The Credit Facility matures in November 2012. At December 31, 2007, there was $91.0 million outstanding under the credit facility. During the first quarter of 2008, the Partnership had net repayments of $41.0 resulting in an outstanding balance of $50.0 million at March 31, 2008

The Credit Facility bears interest at the Operating Partnership s option, at either (i) LIBOR plus an applicable margin, (ii) the higher of the federal funds rate plus 0.50 percent or the Citibank prime rate (each plus the applicable margin) or (iii) the federal funds rate plus an applicable margin.

The Credit Facility contains various covenants limiting the Operating Partnership s ability to a) incur indebtedness, b) grant certain liens, c) make certain loans, acquisitions and investments, d) make any material change to the nature of its business, e) acquire

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another company, f) or enter into a merger or sale of assets, including the sale or transfer of interests in the Operating Partnership s subsidiaries. The Credit Facility also requires the Operating Partnership to maintain, on a rolling four-quarter basis, a maximum total debt to EBITDA ratio of 4.75 to 1, which can generally be increased to 5.25 to 1 during an acquisition period. The Operating Partnership is in compliance with this requirement as of March 31, 2008. The Partnership s ratio of total debt to EBITDA was 2.8 to 1 at March 31, 2008.

Letters of Credit

In November 2007, the Partnership entered into two standby letters of credit totaling $130.4 million. The letters of credit, which are effective January 1, 2008, are required in connection with certain crude oil exchange contracts in which the Partnership is a party. The letters of credit are subject to commitment fees, which are not material.

Cash Flows and Capital Expenditures

Net cash provided by operating activities for the three months ended March 31, 2008 was $74.6 million compared with $25.6 million of net cash used in operating activities for the first three months of 2007. Net cash provided by operating activities for the first three months of 2008 was primarily the result of net income of $37.5 million, depreciation and amortization of $9.7 million, the $5.7 million impairment charge, and a $24.7 million decrease in working capital. The decrease in working capital was the result of an increase in accounts payable partially offset by increases in accounts receivable and inventory. Net cash used in operating activities for the first three months of 2007 was primarily the result of a $64.0 million increase in working capital partially offset by net income of $22.3 million and depreciation and amortization of $8.9 million. The increase in working capital was primarily attributable to an increase in revenues along with an increase in inventory volumes associated with contango inventory positions.

Net cash used in investing activities for the three months of 2008 was $23.1 million compared with $17.9 million for the first three months of 2007.

Net cash used in financing activities for the first three months of 2008 was $51.4 million compared with $34.1 million net cash provided by financing activities for the first three months of 2007. Net cash used in financing activities for the first three months of 2008 resulted from a $41.0 net repayment of the Partnership s Credit Facility as well as $31.6 million in distributions paid to limited partners and the general partner. These decreases were partially offset by net advances from affiliates in the amount of $21.3 million. Net cash provided by financing activities for the first three months of 2007 was the result of $48.0 million in increased borrowings under the Partnership s Credit Facility to fund the Partnership s organic growth capital program and contango inventory positions, and $15.1 million in advances from affiliates. This increase was partially offset by $28.3 million in distributions paid to limited partners and the general partner .

Under a treasury services agreement with Sunoco, the Partnership participates in Sunoco s centralized cash management program. Advances from affiliates in the Partnership s condensed consolidated balance sheets at March 31, 2008 represent amounts due to Sunoco under this agreement. Advances to affiliates at December 31, 2007 represent amounts due from Sunoco under this agreement.

Capital Requirements

The pipeline, terminalling, and crude oil transport operations are capital intensive, requiring significant investment to maintain, upgrade or enhance existing operations and to meet environmental and operational regulations. The capital requirements have consisted, and are expected to continue to consist, primarily of:

- Maintenance capital expenditures, such as those required to maintain equipment reliability, tankage and pipeline integrity and safety, and to address environmental regulations; and

- Expansion capital expenditures to acquire assets to grow the business and to expand existing and construct new facilities, such as projects that increase storage or throughput volume.

The following table summarizes maintenance and expansion capital expenditures, including net cash paid for acquisitions, for the periods presented (in thousands of dollars):

	Three Months Ended March 31,	
	2008	2007
Maintenance	$ 3,322	$ 2,636
Expansion	19,809	15,245
	$ 23,131	$ 17,881

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Management anticipates maintenance capital expenditures to be approximately $26.0 million for the year ended December 31, 2008, excluding reimbursements from Sunoco in accordance with the terms of certain agreements. Maintenance capital expenditures for both periods presented include recurring expenditures such as pipeline integrity costs, pipeline relocations, repair and upgrade of field instrumentation, including measurement devices, repair and replacement of tank floors and roofs, upgrades of cathodic protection systems, crude trucks and related equipment, and the upgrade of pump stations.

Expansion capital expenditures for the three months ended March 31, 2008 were $19.8 million compared to $15.2 million for the first three months of 2007. Expansion capital for 2008 includes construction in progress in connection with the Partnership s agreement with Motiva Enterprises LLC to construct three crude oil storage tanks at its Nederland Terminal and a crude oil pipeline from Nederland to Motiva s Port Arthur, Texas refinery. Expansion capital also includes construction of three additional new crude oil storage tanks at Nederland, one of which was placed into service at the end of the first quarter of 2008. These three crude oil storage tanks will have a total capacity of approximately 1.8 million shell barrels.

The Partnership expects to fund capital expenditures, including pending and future acquisitions, from both cash provided by operations and, to the extent necessary, from the proceeds of borrowings under the Credit Facility, other borrowings and the issuance of additional common units.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our exposure to interest-rate risk relates primarily to short-term, variable-rate borrowings. Short-term variable-rate debt outstanding at March 31, 2008 was $50.0 million and averaged $85.9 million during the first quarter of 2008. The Partnership issues long-term debt either at fixed rates or use interest rate swaps to limit exposure to changes in interest rates on variable-rate, long-term debt. On January 8, 2008, the Partnership entered into an interest rate swap (the Swap) with a notional amount of $50.0 million maturing January 2010. Under the Swap the Partnership receives interest equivalent to the three-month LIBOR and pays a fixed rate of interest of 3.489 percent with settlements occurring quarterly. To maintain hedge accounting for the Swap, the Partnership is committed to maintaining at least $50.0 million in borrowings on the credit facility at an interest rate based on the three-month LIBOR, plus an applicable margin, through January 2010. As of March 31, 2008, the Partnership had $50.0 million in variable-rate debt outstanding under its revolving credit facility. The interest cost on this debt has been fixed at 3.489 percent as a result of an interest rate swap. Additional variable-rate borrowings under our revolving credit facility will be subject to fluctuations in interest rates.

Commodity Market Risk

The Partnership is exposed to volatility in crude oil commodity prices primarily associated with inventory levels. To manage such exposures, inventory levels and expectations of future commodity prices are monitored when making decisions with respect to risk management. The Partnership has not entered into any derivative transactions with respect to commodity market risk.

Forward-Looking Statements

Some of the information included in this quarterly report on Form 10-Q contains forward-looking statements, as such term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Exchange Act, and information relating to Sunoco Logistics Partners L.P. that is based on the beliefs of its management as well as assumptions made by and information currently available to management.

Forward-looking statements discuss expected future results based on current and pending business operations, and may be identified by words such as anticipates, believes, expects, planned, scheduled or similar expressions. Although management of the Partnership believes these forward-looking statements are reasonable, they are based upon a number of assumptions, any or all of which may ultimately prove to be inaccurate. Statements made regarding future results are subject to numerous assumptions, uncertainties and risks that may cause future results to be materially different from the results stated or implied in this document.

The following are among the important factors that could cause actual results to differ materially from any results projected, forecasted, estimated or budgeted:

Our ability to successfully consummate announced acquisitions or expansions and integrate them into our existing business operations;

Delays related to construction of, or work on, new or existing facilities and the issuance of applicable permits;

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Changes in demand for, or supply of, crude oil, refined petroleum products and natural gas liquids that impact demand for the Partnership s pipeline, terminalling and storage services;

Changes in the demand for crude oil we both buy and sell;

The loss of Sunoco R&M as a customer or a significant reduction in its current level of throughput and storage with the Partnership;

An increase in the competition encountered by the Partnership s petroleum products terminals, pipelines and crude oil acquisition and marketing operations;

Changes in the financial condition or operating results of joint ventures or other holdings in which the Partnership has an equity ownership interest;

Changes in the general economic conditions in the United States;

Changes in laws and regulations to which the Partnership is subject, including federal, state, and local tax, safety, environmental and employment laws;

Changes in regulations concerning required composition of refined petroleum products that result in changes in throughput volumes, pipeline tariffs and/or terminalling and storage fees;

Improvements in energy efficiency and technology resulting in reduced demand for petroleum products;

The Partnership s ability to manage growth and/or control costs;

The effect of changes in accounting principles and tax laws and interpretations of both;

Global and domestic economic repercussions, including disruptions in the crude oil and petroleum products markets, from terrorist activities, international hostilities and other events, and the government s response thereto;

Changes in the level of operating expenses and hazards related to operating facilities (including equipment malfunction, explosions, fires, spills and the effects of severe weather conditions);

The occurrence of operational hazards or unforeseen interruptions for which the Partnership may not be adequately insured;

The age of, and changes in the reliability and efficiency of the Partnership s operating facilities;

Changes in the expected level of capital, operating, or remediation spending related to environmental matters;

Changes in insurance markets resulting in increased costs and reductions in the level and types of coverage available;

Risks related to labor relations and workplace safety;

Non-performance by or disputes with major customers, suppliers or other business partners;

Changes in the Partnership s tariff rates implemented by federal and/or state government regulators;

The amount of the Partnership s indebtedness, which could make the Partnership vulnerable to adverse general economic and industry conditions, limit the Partnership s ability to borrow additional funds, place it at competitive disadvantages compared to competitors that have less debt, or have other adverse consequences;

Restrictive covenants in the Partnership s or Sunoco, Inc. s credit agreements;

Changes in the Partnership s or Sunoco, Inc. s credit ratings, as assigned by ratings agencies;

The condition of the debt capital markets and equity capital markets in the United States, and the Partnership s ability to raise capital in a cost-effective way;

Changes in interest rates on the Partnership s outstanding debt, which could increase the costs of borrowing;

Claims of the Partnership s non-compliance with regulatory and statutory requirements; and

The costs and effects of legal and administrative claims and proceedings against the Partnership or any entity in which it has an ownership interest, and changes in the status of, or the initiation of new litigation, claims or proceedings, to which the Partnership, or any entity in which it has an ownership interest, is a party.

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These factors are not necessarily all of the important factors that could cause actual results to differ materially from those expressed in any of the Partnership s forward-looking statements. Other factors could also have material adverse effects on future results. The Partnership undertakes no obligation to update publicly any forward-looking statement whether as a result of new information or future events.

Item 4. Controls and Procedures

(a) As of March 31, 2008, the Partnership carried out an evaluation, under the supervision and with the participation of the management of the general partner (including the President and Chief Executive Officer and the Vice President and Chief Financial Officer), of the effectiveness of the design and operation of the Partnership s disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon that evaluation, the general partner s President and Chief Executive Officer, and its Vice President and Chief Financial Officer, concluded that the Partnership s disclosure controls and procedures are effective.

(b) No change in the Partnership s internal control over financial reporting has occurred during the fiscal quarter ended March 31, 2008 that has materially affected, or that is reasonably likely to materially affect, the Partnership s internal control over financial reporting.

(c) Disclosure controls and procedures are designed to ensure that information required to be disclosed in the Partnership reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the Partnership reports under the Exchange Act is accumulated and communicated to management, including the President and Chief Executive Officer of Sunoco Partners LLC (the Partnership s general partner) and the Vice President and Chief Financial Officer of the general partner, as appropriate, to allow timely decisions regarding required disclosure.

PART II

OTHER INFORMATION

Item 1. Legal Proceedings

Sunoco Partners Marketing & Terminals L.P. (SPMT), which is wholly owned by the Partnership, has received a proposed penalty assessment from the Internal Revenue Service (IRS) in the aggregate amount of $5.1 million based on a failure to timely file excise tax information returns relating to its terminal operations during the calendar years 2004 and 2005. SPMT became current on its information return filings with the IRS in July of 2006. SPMT believes it had reasonable cause for the failure to not file the information returns on a timely basis, and provided this information to the IRS on October 19, 2007 in a formal filing. SPMT is currently awaiting a response from the IRS. The proposed penalties are for the failure to file information returns rather than any failure to pay taxes due, as no taxes were owed by SPMT in connection with such information. The timing or outcome of this claim, and the total costs to be incurred by SPMT in connection therewith, cannot be reasonably estimated at this time.

Additionally, we have received notices for violations and potential fines under various federal, state or local provisions relating to the discharge of materials into the environment or protection of the environment. While we believe that even if any one or more of the environmental proceedings listed below were decided against us, it would not be material to the Partnership s financial position, we are required to report environmental proceedings if we reasonably believe that such proceedings will result in monetary sanctions in excess of $0.1 million.

In January 2007, the Pipeline Hazardous Materials Safety Administration proposed penalties totaling $0.2 million based on alleged violations of various pipeline safety requirements relating to our meter facilities in the Western Pipeline System. In November 2007 and February 2008, we received notices of administrative fines from the Delaware County Regional Water Control Authority totaling approximately $0.6 million relating to alleged non-compliance with monthly average arsenic limits at our Darby Creek, Pennsylvania tank farm. We are currently in discussions with the government agencies to resolve these matters.

There are certain legal and administrative proceedings arising prior to the February 2002 IPO pending against the Partnership s Sunoco-affiliated predecessors and the Partnership (as successor to certain liabilities of those predecessors). Although the ultimate outcome of these proceedings cannot be ascertained at this time, it is reasonably possible that some of them may be resolved unfavorably. Sunoco has agreed to indemnify the Partnership for 100 percent of all losses from environmental liabilities related to the transferred assets arising prior to, and asserted within 21 years of February 8, 2002. There is no monetary cap on this indemnification from Sunoco. Sunoco s share of liability for claims asserted thereafter will decrease by 10 percent each year through the thirtieth year following the February 8, 2002 date. Any remediation liabilities not

covered by this indemnity will be the Partnership s responsibility. In addition Sunoco is obligated to indemnify the Partnership under certain other agreements executed after the February 2002 IPO.

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There are certain other pending legal proceedings related to matters arising after the February 2002 IPO that are not indemnified by Sunoco. Management believes that any liabilities that may arise from these legal proceedings will not be material to the Partnership s financial position at March 31, 2008.

Item 1A. Risk Factors

There have been no material changes from the risk factors described previously in Part I, Item 1A of the Partnership s Annual Report on Form 10-K for the year ended December 31, 2007, filed on February 26, 2008.

Item 2. Unregistered Sales of Equity Securities and Uses of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

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

None.

Item 5. Other Information

None.

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Item 6. Exhibits

Exhibits

12.1 :	Statement of Computation of Ratio of Earnings to Fixed Charges
31.1 :	Chief Executive Officer Certification of Periodic Report Pursuant to Exchange Act Rule 13a-14(a)
31.2 :	Chief Financial Officer Certification of Periodic Report Pursuant to Exchange Act Rule 13a-14(a)
32.1 :	Chief Executive Officer Certification of Periodic Report Pursuant to Exchange Act Rule 13a-14(b) and U.S.C. §1350
32.2 :	Chief Financial Officer Certification of Periodic Report Pursuant to Exchange Act Rule 13a-14(b) and U.S.C. §1350

We are pleased to furnish this Form 10-Q to unitholders who request it by writing to:

Sunoco Logistics Partners L.P.

Investor Relations

Mellon Bank Center

1735 Market Street

Philadelphia, PA 19103-7583

or through our website at www.sunocologistics.com.

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SIGNATURE

Pursuant to the requirements 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.

Sunoco Logistics Partners L.P.

By: /s/ NEAL E. MURPHY
Neal E. Murphy
Vice President and Chief Financial Officer
Date: April 30, 2008