

HEMISPHERX BIOPHARMA INC
Form 10-K
March 29, 2011

FORM 10-K
SECURITIES AND EXCHANGE COMMISSION
 ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2010

OR

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

For the transition period from _____ to _____

Commission File No. 1-13441

HEMISPHERX BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

52-0845822
(I.R.S. Employer Identification
Number)

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

19103
(Zip Code)

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

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

Common Stock, \$.001 par value

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

(Title of Each Class)

NONE

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

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

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

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

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

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

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE: None.

TABLE OF CONTENTS

	Page
PART I	
Item 1. Business	1
Item 1A. Risk Factors	18
Item 1B. Unresolved Staff Comments	29
Item 2. Properties	29
Item 3. Legal Proceedings	30
PART II	
Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	30
Item 6. Selected Financial Data	32
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	33
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	47
Item 8. Financial Statements and Supplementary Data	47
Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure	47
Item 9A. Controls and Procedures	48
Item 9B. Other Information	50
PART III	
Item 10. Directors and Executive Officers and Corporate Governance	51
Item 11. Executive Compensation	57
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	82
Item 13. Certain Relationships and Related Transactions, and Director Independence	85
Item 14. Principal Accountant Fees and Services	86

PART IV

Item 15. Exhibits and Financial Statement Schedules

87

-2-

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 was primarily designed to produce Alferon®. On September 16, 2009, our Board of Directors approved up to \$4.4 million for full engineering studies, capital improvements, system upgrades and introduction of building management systems to enhance production of three products: Alferon N Injection®, Alferon® LDO and Ampligen®. As of December 31, 2010, construction in progress on this project was \$485,000 as compared to \$135,000 at December 31, 2009. We outsource certain components of our research and development, manufacturing, marketing and distribution while maintaining control over the entire process through our quality assurance group and our clinical monitoring group. Please see “Manufacturing” below for more information.

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

AVAILABLE INFORMATION

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

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

OUR PRODUCTS

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

Ampligen®

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

Nucleic acid compounds represent a potential new class of pharmaceutical products that are designed to act at the molecular level for treatment of human diseases. There are two forms of nucleic acids, DNA and RNA. DNA is a group of naturally occurring molecules found in chromosomes, the cell's genetic machinery. RNA is a group of naturally occurring informational molecules which orchestrate a cell's behavior which, in turn, regulates the action of groups of cells, including the cells which compromise the body's immune system. RNA directs the production of proteins and regulates certain cell activities including the activation of an otherwise dormant cellular defense against viruses and tumors. Our drug technology utilizes specifically-configured RNA. Our double-stranded RNA drug product, trademarked Ampligen®, is an experimental, unapproved drug, that would be administered intravenously. Ampligen® has been assigned the generic name rintatolimod by the United States Adopted Names Council (USAN) and has the chemical designation poly(I) poly(C12,U).

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

On July 7, 2008, the FDA accepted for review our NDA for Ampligen® to treat CFS, originally submitted in October 2007. We are seeking marketing approval for the first-ever treatment for CFS. At present, only supportive, symptom-based care is available for CFS patients. The NDA for Ampligen® is also the first ever accepted for review by the FDA for systemic use of a toll-like receptor therapy to treat any condition. In November 2009, we received a Complete Response Letter ("CRL") from the FDA which described specific additional recommendations related to the Ampligen® NDA. In accordance with its 2008 Complete Response procedure, the FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues.

We have carefully reviewed the CRL and will seek a meeting with the FDA to discuss its recommendations upon the compilation of necessary data to be used in our response. We intend to take the appropriate steps to seek approval and commercialization of Ampligen®. Most notably, the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen® and recommended at least one additional clinical study which shows convincing effect and confirms safety in the target population. The FDA indicated that the additional study should be of sufficient size and sufficient duration (six months) and include appropriate monitoring to rule out the generation of autoimmune disease. In addition, patients in the study should be on more than one dose regimen, including at least 300 patients on dose regimens intended for marketing. In designing and implementing these additional trials, we believe that it would be very valuable to first have the capability of utilizing a reliable diagnostic test to better identify potential participants. We are therefore pursuing efforts to identify and validate such a test (see "Progress In Search For CFS Test" below). In the Non-Clinical area, the FDA recommended among other things that we complete rodent carcinogenicity studies in two species. While as part of the NDA submission we had requested that these studies be waived, this waiver had not been granted by the FDA in their CRL.

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

experimental immunomodulators have been associated with one or more features of aberrant immune activity, including toll-like receptor activators (of which Ampligen® is one), this was specifically not seen with Ampligen® in primates.

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

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

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

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

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

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

Progress In Search For CFS Test

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

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

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

In the October 8, 2009 issue of Science Express, a consortium of researchers from the Whittemore Peterson Institute ("WPI"), the National Cancer Institute and the Cleveland Clinic reported a new retrovirus, xenotropic murine leukemia related virus ("XMRV") in the blood cells of 67% of CFS patients and 3.7% in healthy control subjects. The infectious virus was also greater than 99% identical to that previously detected in prostate cancer. Retrospective analyses of patient samples from the completed Phase III trial of Ampligen® in potential treatment of CFS continues in collaboration with WPI. While an updated agreement is being finalized with WPI, we continue to collaborate with WPI under the terms of an "Evaluation Agreement" that expired on July 23, 2010, to evaluate Hemispherx' patient samples for XMRV using WPI's flow cytometry assay. We believe that these studies may provide a new perspective on the design of an additional confirmatory Phase III study in this disorder.

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

Alferon N Injection®

Alferon N Injection® is the registered trademark for our injectable formulation of natural alpha interferon, which is approved by the FDA in 1989 for the treatment of certain categories of genital warts. Alferon® is the only natural-source, multi-species alpha interferon currently approved for sale in the U.S. for the intralesional (within lesions) treatment of refractory (resistant to other treatment) or recurring external genital warts in patients 18 years of age or older.

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

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

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

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

The FDA approved Alferon N Injection® in 1989 for the intralesional (within lesions) treatment of refractory (resistant to other treatment) or recurring external genital warts in patients 18 years of age or older. Certain types of human papilloma viruses (“HPV”) cause genital warts, a sexually transmitted disease (“STD”). The Centers for Disease Control and Prevention (“CDC”) estimates that approximately twenty million Americans are currently infected with HPV with another six million becoming newly infected each year. The CDC states that HPV is so common, that at least 50% of sexually active men and women get it at some point in their lives.

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

Alferon® Low Dose Oral (LDO)

Alferon® LDO [Low Dose Oral Interferon Alfa-n3 (Human Leukocyte Derived)] is an experimental low-dose, oral liquid formulation of Natural Alpha Interferon and like Alferon N Injection® should not cause antibody formation, which is a problem with recombinant interferon. It is an experimental immunotherapeutic believed to work by stimulating an immune cascade response in the cells of the mouth and throat, enabling it to bolster systemic immune response through the entire body by absorption through the oral mucosa. Oral interferon could be economically feasible for patients and logistically manageable in development programs in third-world countries primarily affected

by influenza and other emerging viruses. Oral administration of Alferon® LDO, with its anticipated affordability, low toxicity, no production of antibodies, and broad range of potential bioactivity, could be a breakthrough treatment or prevention for viral diseases.

In October 2009, we submitted a protocol to the FDA proposing to conduct a Phase II, double-blind, adaptive-design, randomized, placebo-controlled, dose-ranging study of Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. Following a teleconference with the FDA in November 2009, the FDA placed the proposed study on “Clinical Hold” because the protocol was deemed by the FDA to be deficient in design, and because of the need for additional information to be submitted in the area of chemistry, manufacturing and controls (“CMC”). Thereafter in December 2009, we submitted additional information by an Amendment with respect to both the clinical protocol design issues and the CMC items. In January 2010, the FDA acknowledged that our responses to the clinical study design issues were acceptable; however, removal of the Clinical Hold was not warranted because the FDA believed that certain CMC issues had not been satisfactorily resolved. In this regard, the FDA communicated concern regarding the extended storage of Alferon® LDO drug product clinical lots which had been manufactured from an active pharmaceutical ingredient (“API”) of Alferon N Injection® manufactured in year 2001. While the biological (antiviral) potency of the product had remained intact, we learned through newly conducted physico-chemical tests (the “new tests” of temperature, pH, oxidation and light on the chemical stability of the active API), that certain changes in the drug over approximately nine storage years (combined storage of Alferon N Injection® plus storage of certain LDO sachets) had introduced changes in the drug which might adversely influence the human safety profile. These “new tests” are part of recent FDA requirements for biological products, such as interferon, which did not exist at the time of the original FDA approval of Alferon N Injection® for commercialization and at the time of FDA approval of the “Product License” and “Establishment License” for the Alferon N Injection® product. Based on the recent FDA request, we have now established and implemented the “new test” procedures. As a result, we have found that certain Alferon N Injection® lots with extended storage (i.e., approximately eight to nine years) do appear to demonstrate some altered physico-chemical properties. However we have also observed that more recent lots, including those manufactured beginning in the year 2006, are superior with respect to the enhanced scrutiny of these tests and, in our view, could be considered appropriate for clinical trials in the Alferon® LDO sachet format. Upon their review, the FDA has been responsive to these new findings and requested additional stability data on the lots proposed for use in this clinical study utilizing the new test methods. The proposed clinical lots were manufactured on June 24, 2010 and placed on stability on June 28, 2010. The FDA had requested three months of stability data on the proposed clinical lots which was compiled, analyzed and submitted to the FDA on November 12, 2010. On December 22, 2010, the FDA informed us that the Agency had completed its review of our complete response to the Clinical Hold and lifted the Clinical Hold, allowing our Phase II Study to proceed.

HISTORICAL COSTS RELATED TO OUR PRODUCTS

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

(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	\$-	\$1,341	\$-	\$-	\$1,341
Research and development	2,787	-	4,658	168	7,613
General and administrative	2,356	1,133	3,937	142	