HEMISPHERX BIOPHARMA INC
Form 10-Q
May 11, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q
Quarterly Report Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

For the Quarterly Period Ended March 31, 2009

Commission File Number: 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 No.)

1617 JFK Boulevard, Suite 660, Philadelphia, PA 19103

(Address of principal executive offices) (Zip Code)

(215) 988-0080

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required 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. x Yes ¨ No

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 x No

84,621,416 shares of common stock were issued and outstanding as of May 7, 2009.

PART I - FINANCIAL INFORMATION

ITEM 1: Financial Statements

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2008	March 31, 2009 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,119	$ 3,621
Short term investments (Note 4)	-	1,920
Inventories	864	864
Prepaid expenses and other current assets	330	275
Total current assets	7,313	6,680
Property and equipment, net	4,877	4,794
Patent and trademark rights, net	969	867
Investment	35	35
Other assets	17	16
Total assets	$ 13,211	$ 12,392
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 791	$ 979
Accrued expenses (Note 5)	876	1,468
Total current liabilities	1,667	2,447
Commitments and contingencies		
Stockholders' equity (Note 6):		
Preferred stock, par value $0.01 per share, authorized 5,000,000; issued and outstanding; none	-	-
Common stock, par value $0.001 per share, authorized 200,000,000 shares; issued and outstanding 78,750,995 and 81,842,103 respectively	79	82
Additional paid-in capital	208,874	210,359
Accumulated deficit	(197,409)	(200,496)
Total stockholders' equity	11,544	9,945
Total liabilities and stockholders' equity	$ 13,211	$ 12,392

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations
(in thousands, except share and per share data)
(Unaudited)

	Three months ended March 31,	
	2008	2009
Revenues:		
Sales of product, net	$ 173	$ -
Clinical treatment programs	35	29
Total revenues	208	29
Costs and expenses:		
Production/cost of goods sold	249	121
Research and development	1,307	1,595
General and administrative	1,897	1,166
Total costs and expenses	3,453	2,882
Operating loss	(3,245)	(2,853)
Interest and other income	80	7
Financing costs	-	(241)
Net loss	$ (3,165)	$ (3,087)
Basic and diluted loss per share (Note 2)	$ (.04)	$ (.04)
Weighted average shares outstanding, basic and diluted	73,865,138	79,836,247

See accompanying notes to consolidated financial statements.

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Loss
(in thousands except share data)
(Unaudited)

	Common Stock Shares	Common Stock $.001 Par Value	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2008	78,750,995	$ 79	$ 208,874	$ (197,409)	$ 11,544
Stock issued for settlement of accounts payable	897,258	1	359	-	360
Private placement, net of issuance costs	2,193,850	2	867	-	869
Equity based compensation	-	-	18	-	18
Standby Finance-finance costs	-	-	241	-	241
Net comprehensive loss	-	-	-	(3,087)	(3,087)
Balance at March 31, 2009	81,842,103	$ 82	$ 210,359	$ (200,496)	$ 9,945

See accompanying notes to consolidated financial statements.

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
For the Three Months Ended March 31, 2008 and 2009
(in thousands)
(Unaudited)

	2008	2009
Cash flows from operating activities:		
Net loss	$ (3,165)	$ (3,087)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	84	90
Amortization of patent and trademark rights, and royalty interest	42	119
Financing cost related to Standby Financing	-	241
Equity based compensation	235	18
Increase (decrease) in assets and liabilities:		
Inventories	(272)	-
Accounts and other receivables	26	-
Prepaid expenses and other current assets	(28)	56
Accounts payable	15	547
Accrued expenses	257	592
Net cash used in operating activities	$ (2,806)	$ (1,424)
Cash flows from investing activities:		
Purchase of property plant and equipment	$ -	(6)
Additions to patent and trademark rights	-	(17)
Maturity of short term investments	1,979	-
Purchase of short term investments	$ (1,000)	(1,920)
Net cash provided by (used in) investing activities	$ 979	$ (1,943)

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows (Continued)
For the Three Months Ended March 31, 2008 and 2009
(in thousands)
(Unaudited)

	2008	2009
Cash flows from financing activities:		
Proceeds from sale of stock, net of issuance costs	$ -	$ 869
Net cash provided by financing activities	$ -	869
Net decrease in cash and cash equivalents	(1,827)	(2,498)
Cash and cash equivalents at beginning of period	11,471	6,119
Cash and cash equivalents at end of period	$ 9,644	$ 3,621
Supplemental disclosures of non-cash investing and financing cash flow information:		
Issuance of common stock for accounts payable and accrued expenses	$ 111	$ 360
Unrealized gains on investments	$ 17	$ -

See accompanying notes to consolidated financial statements.

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: BASIS OF PRESENTATION

The consolidated financial statements include the financial statements of Hemispherx Biopharma, Inc. and its wholly-owned subsidiaries. The Company has three domestic subsidiaries BioPro Corp., BioAegean Corp. and Core Biotech Corp., all of which are incorporated in Delaware and are dormant. The Company's foreign subsidiary, Hemispherx Biopharma Europe N.V./S.A., established in Belgium in 1998, has limited or no activity. All significant intercompany balances and transactions have been eliminated in consolidation.

In the opinion of management, all adjustments necessary for a fair presenta−tion of such consolidated financial statements have been included. Such adjust−ments consist of normal recurring items. Interim results are not necessarily indicative of results for a full year.

The interim consolidated financial statements and notes thereto are presented as permitted by the Securities and Exchange Commission ("SEC"), and do not contain certain information which will be included in our annual consolidated financial statements and notes thereto.

These consolidated financial statements should be read in conjunction with our consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2008, as filed with the SEC on March 16, 2009.

NOTE 2: NET LOSS PER SHARE

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Equivalent common shares, consisting of stock options and warrants including the Company's convertible debentures, which amounted to 16,837,947 and 35,737,069 shares, are excluded from the calculation of diluted net loss per share for the three months ended March 31, 2008 and 2009, respectively, since their effect is antidilutive.

NOTE 3: EQUITY BASED COMPENSATION

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model. Expected volatility is based on the historical volatility of the price of the Company's stock. The risk-free interest rate is based on U.S. Treasury issues with a term equal to the expected life of the option. The Company uses historical data to estimate expected dividend yield, expected life and forfeiture rates. The fair values of the options granted, were estimated based on the following weighted average assumptions:

	Three Months Ended March 31,	
	2008	2009
Risk-free interest rate	2.86% – 3.74%	1.76%
Expected dividend yield	-	-
Expected lives	2.5 - 5.0 yrs	5.0 yrs.
Expected volatility	75.69 – 79.18%	86.78%
Weighted average grant date fair value of options and warrants issued	$177,000	$7,800

Stock option activity during the three months ended March 31, 2009, is as follows:

Stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2007	4,626,089	$ 2.66	8.25	-
Options granted	1,655,000	2.42	9.69	-
Options forfeited	(22,481)	2.13	-	-
Outstanding December 31, 2008	6,258,608	2.60	7.92	-
Options forfeited	(17,264)	2.43	7.21	-
Outstanding March 31, 2009	6,241,344	2.59	7.68	-
Exercisable March 31, 2009	6,161,158	$ 2.61	7.70	-

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2008 and 2009 was $0.

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2007	166,763	$ 1.59	7.18	-
Options granted	-	-	-	-
Options vested	(73,420)	1.68	8.58	-
Options forfeited	(16,399)	2.00	6.18	-
Outstanding December 31, 2008	76,944	1.41	3.89	-
Prior unvested	2,882	2.61	7.70	-
Options vested	-	-	-	-
Options forfeited	-	-	-	-
Outstanding March 31, 2009	79,826	$ 1.45	3.79	-

Stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2007	1,935,482	$ 2.43	8.05	-
Options granted	482,000	2.02	6.72	-
Options forfeited	-	-	-	-
Outstanding December 31, 2008	2,417,482	2.35	6.98	-
Options granted	20,000	.72	10.00	-
Options forfeited	(66,300)	3.36	7.08	-
Outstanding March 31, 2009	2,371,182	$ 2.31	6.75	-
Exercisable March 31, 2009	2,344,515	$ 2.32	6.90	-

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2008 and 2009 was approximately $177,000 and $7,800, respectively.

Unvested stock option activity for non-employees during the year:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2007	40,000	$ 1.50	9.30	-
Options granted	-	-	-	-
Options vested	(13,333)	(1.64)	6.91	-
Options forfeited	-	-	-	-
Outstanding December 31, 2008	26,667	1.43	9.00	-
Options granted	-	-	-	-
Options vested	-	-	-	-
Options forfeited	-	-	-	-
Outstanding March 31, 2009	26,667	$ 1.43	8.75	-

The impact on the Company’s results of operations of recording equity based compensation for the three months ended March 31, 2008 and 2009 was to increase general and administrative expenses by approximately $230,000 and $18,000 respectively. However, there was no impact on basic and fully diluted earnings per share.

As of December 31, 2008 and March 31, 2009, respectively, there was $46,000 and $37,000 of unrecognized equity based compensation cost related to options granted under the Equity Incentive Plan.

Note 4: SHORT TERM INVESTMENTS

Securities classified as available for sale consisted of:

	March 31, 2009			
Name Of Security	Cost	Market Value	Unrealized Loss	Maturity Date
GE Capital-CD	$ 250,000	$ 250,000	-	4/16/2009
American Express –CD	250,000	250,000	-	4/22/2009
American Express – CD	250,000	250,000	-	4/22/2009
Morgan Stanley – CD	250,000	250,000	-	4/23/2009
Goldman Sachs Bank – CD	250,000	250,000	-	4/28/2009
Beal Bank – CD	170,000	170,000	-	5/6/2009
Bank of America – CD	250,000	250,000	-	7/28/2009
Midfirst Bank – CD	250,000	250,000	-	7/28/2009
Total	$ 1,920,000	$ 1,920,000	$ -	

No investment securities were pledged to secure public funds at March 31, 2009.

Comprehensive Income

The Company reports comprehensive income, which includes net loss, as well as certain other items, which result in a charge to equity during the period.

	Three months ended March 31 (in thousands)	
	2008	2009
Unrealized gains during the period	$ 45	$ -
Realized gains during the period	(21)	-
Other comprehensive income	$ 24	$ -

There are no income tax effects allocated to comprehensive income as the Company has no tax liabilities due to net operating losses.

NOTE 5: ACCRUED EXPENSES

Accrued expenses at December 31, 2008 and March 31, 2009 consist of the following:

	(in thousands)	
	December 31, 2008	March 31, 2009
Compensation	$ 192	$ 960
Professional fees	497	288
Royalties	-	30
Other expenses	54	57
Other liabilities	133	133
Total	$ 876	$ 1,468

10

Accrued expense related to Compensation increased approximately $768,000 due to the Company's implementation of the Employee Wages Or Hours Reduction Program on January 1, 2009 (see "ITEM 2: Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; Employee Wage Or Hours Reduction Program" for details on the Employee Wages Or Hours Reduction Program). As a result of this Program, employees are receiving "Incentive Rights" as a form of compensation for their election to reduce wages that accrue monthly and will be awarded as Company stock six months after they have been earned on a rolling basis.

NOTE 6: STOCKHOLDERS' EQUITY

On July 2, 2008, we entered into a $30 million Common Stock Purchase Agreement (the "Purchase Agreement") with Fusion Capital Fund II, LLC ("Fusion Capital", an Illinois limited liability company. Concurrently with entering into the Purchase Agreement, we entered into a registration rights agreement with Fusion Capital. Under the registration rights agreement, we filed a registration statement related to the transaction with the U.S. Securities & Exchange Commission ("SEC") covering the shares that have been issued or may be issued to Fusion Capital under the common stock purchase agreement. That registration statement was declared effective by the SEC on August 12, 2008. As reported in the registration statement related to the transaction, we have the right over a 25 month period from August 2008 to sell our shares of common stock to Fusion Capital from time to time in amounts between $120,000 and $1 million depending on certain conditions as set forth in the agreement, up to a maximum of $30 million. The purchase price of the shares related to the $30.0 million of future funding will be based on the prevailing market prices of the Company's shares at the time of sales as computed under the Purchase Agreement without any fixed discount, and the Company will control the timing and amount of any sales of shares to Fusion Capital. However, Fusion Capital cannot purchase any shares of our common stock pursuant to the Purchase Agreement if the price of our common stock has three trading days with an average value below $0.40 over the prior twelve trading days. For the past three months, the price of our common stock has periodically closed below $0.40, thereby adversely affecting our ability to consistently access the Fusion Capital financing. The Purchase Agreement may be terminated by us at any time at our discretion without any cost to us. There are no negative covenants, restrictions on future funding, penalties or liquidated damages in the agreement. In consideration for entering into the Purchase Agreement, we issued to Fusion Capital 650,000 shares as a commitment fee. Also, we will issue to Fusion Capital up to an additional 650,000 shares as a commitment fee pro rata as we receive up to the $30.0 million of future funding. During the three months ended March 31, 2009, Fusion has purchased 2,193,850 shares for $869,000 under this Purchase Agreement. As of March 31, 2009 Fusion Capital has purchased total shares of 3,404,972 for $1,140,000 under this agreement.

The Company has been using the proceeds from this financing to fund operating expenses and infrastructure growth including manufacturing, regulatory compliance and market development with regards to the FDA approval process of Ampligen®.

The Equity Plan effective May 1, 2004, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 8,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Plan of 2004. Unless sooner terminated, the Equity Plan of 2004 will continue in effect for a period of 10 years from its effective date. As of March 31, 2009, the Company effectively exhausted this plan and issued an aggregate 7,898,355 shares, stock options and warrants to vendors, Board Members, Directors and Consultants under the 2004 Equity Compensation Plan. The shares had prices ranging from $0.35 to $0.89 based on the NYSE Amex closing price. The stock options had various exercise prices ranging from $1.30 to $6.00 and had terms of five to ten years. The stock options vested over varying periods.

The Equity Incentive Plan of 2007, effective June 20, 2007, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 8,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan of 2007. Unless sooner terminated, the Equity Incentive Plan of 2007 will continue in effect for a period of 10 years from its effective date. As of March 31, 2009 the Company issued to vendors, Board Members, Directors and Consultants, shares, stock options, warrants and "Incentive Rights" under the Employee Wages or Hours Reduction Program (see "ITEM 2: Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; Employee Wage Or Hours Reduction Program" for details on the Employee Wages Or Hours Reduction Program). These securities consisted of an aggregate of 6,351,722 shares and shares issuable upon exercise/conversion of the foregoing securities.

The aggregate shares to vendors, Board Members, Directors and Consultants had prices ranging from $0.32 to $0.80 based on the NYSE Amex closing price.

The aggregate stock options had various exercise prices ranging from $0.72 to $2.20 and had terms of ten years. The Company utilized the Black-Scholes Pricing Model to fair value the stock options which had been issued during the three months ended March 31, 2009 and accordingly recorded approximately $7,800 as equity based compensation for these issuances during this period. The stock options vested immediately upon grant.

The aggregate Incentive Rights are rights for employees to receive Company shares and had prices ranging from $0.13 to $0.25 based on the average daily closing prices of the Company shares on the NYSE Amex. These Incentive Rights are issued monthly in a format consistent with the Employee Wages or Hours Reduction Program. An aggregate 1,536,777 of Incentive Rights have been accumulated by employees as of March 31, 2009 with an approximate value of $922,000 as equity based compensation.

The Company also recorded an additional $9,700 during the three months ended March 31, 2009, in equity based compensation which related to the vesting of stock options issued to employees in 2007.

NOTE 7: RECENT ACCOUNTING PRONOUNCEMENTS

The Emerging Issues Task Force (EITF) issued in 2007 Issue No. 07-5, "Determining Whether an Instrument (or an Embedded Feature) is Indexed to an Entity's Own Stock" provides guidance for determining whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock. Upon review by the Company, it is deemed that the application of this issue has no impact on the financial statements.

The FASB has issued FASB Staff Position FSP FAS 157-4 "Determining Fair Value When the Volume and Level of Activity for Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly." FSP FAS 157-4 is applied prospectively and retrospective application is not permitted. The FSP is effective for interim and annual periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The Company does not expect this FSP to have any material effect on the Company's financial position or results of operations.

NOTE 8: SUBSEQUENT EVENT

On May 8, 2009, the Company entered into a letter agreement (the "Engagement Letter") with Rodman & Renshaw, LLC ("Rodman") as placement agent, relating to a proposed offering of the Company's securities.

On May 10, 2009, the Company entered into Securities Purchase Agreements with two institutional investors. Pursuant to the Securities Purchase Agreements, the Company has agreed to issue to these investors in the aggregate:

(a) 13,636,363 shares of Company common stock; (b) Series I warrants to purchase an additional 6,136,363 shares of Company common stock at an exercise price of $1.65 per share ("Series I Warrants"); and (c) Series II warrants to purchase up to 3,000,000 shares of Company common stock at an exercise price of $1.10 per share ("Series II Warrants," and together with the Series I Warrants, the "Warrants"). The Series I Warrants may be exercised at any time on or after the six month anniversary of the closing date of the offering and for a five year period thereafter. The Series II Warrants may be exercised at any time on or after the date of delivery of the Series II Warrants and for a period of 45 days thereafter.

Rodman, as placement agent, acted on a best efforts basis for the offering and will receive a placement fee equal to $825,000 as well as Series 1 Warrants to purchase 750,000 shares of the Company's common stock equal at an exercise price of $1.38 per share. Rodman also is entitled to a fee equal to 5.5% of any Series II Warrants that are exercised.

ITEM 2: Management's Discussion and Analysis of Financial Condition and Results of Operations.

Special Note Regarding Forward-Looking Statements

Certain statements in this document constitute "forwarding-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange 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 report 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, including but not limited to, the risk factors discussed below, which may cause the actual results, performance or achievements of Hemispherx and its subsidiaries 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 report. 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.

Overview

General

We are a specialty pharmaceutical company engaged in the clinical development, manufacture, marketing and distribution 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 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 limited or no 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 a vaccine enhancer (adjuvant) for both therapeutic and preventative vaccine development. Alferon N Injection® is an FDA approved product with an indication for refractory or recurring genital warts. Alferon® LDO (Low Dose Oral) is an application currently under early stage development targeting influenza and viral diseases both as an adjuvant as well as a single entity anti-viral.

Ampligen® is an experimental drug currently undergoing clinical development for the treatment of CFS. In August 2004, we completed a Phase III clinical trial ("AMP 516") treating over 230 CFS patients with Ampligen® and are presently in the registration process for a new drug application ("NDA") with the Food and Drug Administration ("FDA"). Over its developmental history, Ampligen® has received various designations, including Orphan Drug Product Designation (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports ("AHRQ", Agency Health Research Quality). Ampligen represents the first drug in the class of RNA (nucleic acid) molecules to apply for NDA review.

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®, whose chemical designation is poly I : poly C12U, is also the first ever accepted for review by the FDA for systemic use of a toll-like receptor therapy to treat any condition. On February 18, 2009, we were notified by the FDA that the originally scheduled Prescription Drug User Fee Act date of February 25, 2009 has been extended to May 25, 2009. According to the Pharmaceutical Manufacturing Association, eight (8) completely new molecular entities ("NME") were approved by the FDA in year 2008.

The Status of our initiative for Ampligen® as an adjuvant for preventative vaccine development includes the pre-clinical studies in seasonal and pandemic influenza for intranasal administration being conducted by Japan's National Institute for Infectious Diseases. A three year program targeting regulatory approval for pandemic flu and seasonal flu in Japan has been funded by the Japanese Ministry of Health. Parties to the research grant include Hemispherx, the NIID and BIKEN (operational arm of the non-profit Foundation for Microbial Disease of Osaka University). Our agreement with BIKEN is part of a three party agreement to develop an effective influenza vaccine for Japan and utilizes the resources of the National Institute of Infectious Disease of Japan. We intend to conduct human studies in the US and Australia to seek approval for seasonal and pandemic indications in the US and Europe for intranasal administration. A phase II study for intramuscular administration for seasonal flu was conducted in Australia through St. Vincent's Hospital Clinical Trials Centre. The clinical data from this trial is currently being analyzed and the results are expected by mid-2009.

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.

Alferon N Injection® is the registered trademark for our injectable formulation of natural alpha interferon, which is approved by the FDA for the treatment of genital warts. Alferon N Injection® is also in clinical development for treating West Nile Virus.

Commercial sales of Alferon N Injection® were suspended in April 2008 as the current expiration date of our finished goods inventory expired in March 2008. The FDA has declined to respond to our requests for an extension of the expiration date, therefore we consider the request to be denied. Since our testing of the product indicates that it is not impaired and could be safely utilized, the finished goods inventory of 2,745 Alferon N Injection® 5ml vials may be used to produce approximately 11,000,000 sachets of Low Dose Oral Alferon (LDO) for future clinical trials.

Production of Alferon N injection® from our Work-In-Progress ("WIP") Inventory, which has an approximate expiration date of 2012, has been put on hold at this time due to the resources needed to prepare our New Brunswick facility for the FDA preapproval inspection with respect to our Ampligen® NDA. Our Ampligen® FDA preinspection had noted small discrepancies that have been addressed by us and documented in a response to the regional FDA office in New Jersey on April 28, 2009. Work on the Alferon N Injection® is expected to resume in mid-2009 under the condition that adequate funding is obtained, which means that we may not have any Alferon N Injection® product commercially available until 2010.

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ primarily designed to produce Alferon N Injection®. In 2006, we completed the installation of a polymer production line to produce Ampligen® raw materials on a more reliable and consistent basis.

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.

401(k) Plan

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

Effective March 15, 2008, we ended our 100% matching of up to 6% of the 401(k) contributions provided to the account for each eligible participant. Our 401(k) Plan contribution cost for the twelve months ended December 31, 2008 is $20,421 and it is required for payment prior to the final filing of our 2008 Federal Corporate Tax filing that is projected for September 2009. There have not been any additional matching costs by us since March 15, 2008 and none is projected for calendar year 2009.

New Accounting Pronouncements

Refer to "NOTE 7: RECENT ACCOUNTING PRONOUCEMENTS" under Notes To Unaudited Condensed Consolidated Financial Statements.

Disclosure About Off-Balance Sheet Arrangements

None.

Critical Accounting Policies

There have been no material changes in our critical accounting policies and estimates from those disclosed in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2008.

RESULTS OF OPERATIONS

Three months ended March 31, 2009 versus three months ended March 31, 2008

Net loss

Our net loss of approximately $3,087,000 for the three months ended March 31, 2009 was $78,000 or 2.5% lower when compared to the same period in 2008. This decrease in loss was primarily due to a combination of revenue and expense elements:

1) Production/cost of goods sold was approximately $121,000 and $249,000, respectively, for the three months ended March 31, 2009 and 2008. This represented a decrease of approximately $128,000 or 51% as compared to the same period in 2008. These 2009 expenses primarily represent the costs to maintain Alferon N Injection® and Ampligen® Inventory including storage, stability testing and reporting costs. A secondary reason for the decrease in cost of goods sold can be attributed to the lack of Alferon N Injection® sales since April 1, 2008 and the related impact on expenses.

2) Research and Development costs in the first three months of 2009 increased approximately $288,000 as compared to the same period in 2008. The first three months of 2009's Research and Development costs include the book value write-off expense as an abandonment expense of $100,000 for 21 patents that Management deemed no longer of value or material to future operations. In addition for the quarter ended March 31, 2009, $388,000 of non-cash labor expenses were attributed to Research and Clinical employees participating in the Employee Wage Or Hour Reduction Program (see "Liquidity and Capital Resources; Employee Wage Or Hours Reduction Program" below for details on the Employee Wages Or Hours Reduction Program). As an offset, Research and development expenses during the first three months of 2009 did not include an expense for $200,000 with the elimination of prior year's NDA related consulting costs.

3) There were no sales of Alferon N Injection® for the three months ended March 31, 2009, as finished goods inventory had reached its current product expiration date of March 31, 2008. Sales of Alferon N Injection® for the three months ended March 31, 2008, amounted to approximately $173,000.

4) General and administrative expenses decreased approximately $731,000 during the current quarter of 2009 as compared to the prior period of 2008 primarily due to reduced legal fees of $362,000, stock compensation of $218,000, accounting consultants and fees of $100,000 along with a saving $43,000 in general. This decrease also reflected 2008 refunds paid to customers for the return of expired Alferon® for $113,000. These cost savings were somewhat offset by an increase of $105,000 of non-cash labor expenses resulting from General and Administrative employees participating in the Employee Wage Or Hour Reduction Program.

5) Interest and other income decreased $73,000 for the three months ended March 31, 2009 as compared to the same period in 2008 due to less Cash available for Short Term Investment in marketable securities in the current period as compared to the prior period in 2008.

6) In the three months ended March 31, 2009 as compared to the same period in 2008, $241,000 non-cash financing costs in the form of Common Stock Commitment Warrants were incurred as a result of the February 2009 implementation of the Standby Financing Agreement (see "Liquidity and Capital Resources; Standby Financing Agreement" below for Agreement details). No agreement of this type existed during the first three months of 2008.

Net loss per share was $0.04 for the current period versus $0.04 for the same period in 2008.

Revenues

Revenues for the three months ended March 31, 2009 were $29,000 compared to revenues of $208,000 for the same period in 2008. There were no revenues related to the sale of Alferon N Injection® for this period in 2009 versus $173,000 in 2008. Revenues from our Ampligen® cost recovery program were down $6,000 for a total of $29,000 in 2009 for the quarter as fewer patients are participating in the program. Commercial sales of Alferon N Injection® were halted in April 2008 as the current expiration date of our Finished Goods Inventory expired in March 2008. As a result, we have no Alferon N Injection® product to commercially sell and all revenue was generated from Ampligen® cost recovery clinical treatment programs.

Major efforts of the New Brunswick manufacturing staff were redirected throughout year 2008 and to date in 2009 to the task of preparing our plant for FDA pre and post approval inspections in connection with the Ampligen® NDA review process.

Work on the Alferon N Injection® is expected to resume in mid-2009, under the condition that adequate funding is obtained, which means that we may not have any Alferon N Injection® product commercially available until 2010.

Production costs/cost of goods sold

Production/cost of goods sold was approximately $121,000 and $249,000, respectively, for the three months ended March 31, 2009 and 2008. This represented a decrease of approximately $128,000 or 51% as compared to the same period in 2008. The 2009 expenses primarily represent the costs to maintain Alferon N Injection® and Ampligen® Inventory including storage, stability testing and reporting costs. A secondary reason for the decrease in cost of goods sold for 2009 can be attributed to the lack of Alferon N Injection® sales since April 1, 2008 and its impact on costs of goods sold for the three months ended March 31, 2008.

Research and development costs

Overall research and development costs for the three months ended March 31, 2009 were $1,595,000 as compared to $1,307,000 for the same period a year ago reflecting an increase of $288,000 or 22%. The first three months of 2009's Research and Development costs include the book value write-off expense of 21 patents that Management deemed no longer of value or material to future operations as an abandonment expense along with non-cash labor expenses which were attributed to Research and Clinical employees participating in the Employee Wage Or Hour Reduction Program (see "Liquidity and Capital Resources; Employee Wage Or Hours Reduction Program" below). As an offset, Research and development expenses during the first three months of 2009 did not include prior year's NDA related consulting costs.

During 2008 and to date in 2009, we spent considerable time and effort preparing for the preapproval inspection by the FDA for manufacturing of Ampligen® product and its raw materials, polynucleotides Poly I and Poly C12U. A satisfactory recommendation from the FDA Office of Compliance based upon an acceptable preapproval inspection is required prior to approval of the product. The preapproval inspection determines compliance with current Good Manufacturing Practices ("cGMPs") as well as a product specific evaluation concerning the manufacturing process of product. The inspection includes many aspects of the cGMP requirements, such as manufacturing process validation, equipment qualification, analytical method validation, facility cleaning, quality systems, documentation system and part 11 compliance.

The New Jersey District Office of the FDA conducted an inspection of the New Brunswick, New Jersey facility in late January and early February 2009. A one-page Form FDA 483 was issued citing a need to reperform four method validations to generate data in the New Brunswick Laboratories. These validations had been performed at another site also owned and operated by us prior to transferring the equipment to New Brunswick. The validations have been completed and the reports were forward to the FDA on April 28, 2009 for review.

The FDA conducted a field inspection at Hollister-Stier Laboratories in Spokane, Washington in mid-2008. The Ampligen® final fill operations are performed under contract with Hollister-Stier. The inspection resulted in a FDA Form 483 with two observations dealing with reviews and validations of process variability. We continue to work with Hollister-Stier to finalize specific actions to address the FDA Form 483 issues and Hollister-Stier has submitted a specific action plan to the Seattle, Washington office of the FDA.

On September 19, 2008, we executed an agreement with Lovelace Respiratory Research Institute in Albuquerque, New Mexico to perform certain animal toxic studies in support of our Ampligen® NDA. These studies were requested by the FDA and will be done in collaboration with the resources of the New Brunswick facility. We expect these studies to be complete in mid- 2009.

We are also engaged in ongoing, experimental studies assessing the efficacy of Ampligen®, Alferon N Injection®, and Alferon® LDO against influenza viruses as a single adjuvant agent antiviral with Japan's National Institute of Infectious disease, Biken (the non-profit operational arm of the Foundation for Microbial Diseases of Osaka University) and St. Vincent's Hospital in Darlinghurst, Australia. As a result of focusing our limited resources on the Australian and Japanese studies, no further experiments have been undertaken by the Defence R&D Canada with respect to their independent study assessing the efficacy of Ampligen® against Influenza viruses as a single agent antiviral.

The Biken arrangement was concluded in December 2007 and basically consists of Biken purchasing Ampligen® for use in conducting further animal studies of intranasal prototype vaccines containing antigens from influenza sub-types H1N1, H3N2 and B progressing to human studies with all programs supported by the Japanese Health Ministry. Under the terms of the non—exclusive licensing arrangement, we will receive royalties as well as income for all Ampligen® used in the ongoing experimental work and any subsequent marketing of Ampligen® as an immuno-enhancer for flu vaccines delivered intranasally in Japan. To date, only two or three pharmaceutical companies worldwide have achieved regulatory authorizations to sell intranasally ("IN") administered influenza vaccines versus many companies receiving approval for intramuscular vaccine delivery routes. Safety has been paramount in developing effective treatments. However, animal studies to date indicate Ampligen®, an experimental drug, may be safely administered intranasally. Clinical studies (in other disorders) have built a database of more than 90,000 injections of Ampligen® when given parenterally (intravenous, or "IV"). In June 2008, Biken notified us they were accelerating their program and were shipped additional Ampligen® supplies for various preclinical vaccine studies and research projects that remain in progress. A secondary goal of the trial is to evaluate whether antibodies stimulated by the vaccine/Ampligen® combination also provide protection against H5N1, the avian influenza virus. Since 2003, the World Health Organization ("WHO") has confirmed 407 cases and attributed 254 human deaths worldwide to H5N1. Investigators from Japan's Institute of Infectious Disease have conducted studies in animals that suggest that Ampligen® can stimulate a sufficiently broad immune response to provide cross-protection against a range of virus genetic types, including H5N1 and derivative clades. Japan's Council for Science & Technology Policy ("CSTP"), a cabinet level position, has recently awarded funds from Japan's CSTP to advance research with influenza vaccines utilizing Ampligen. The Principal Investigator of this advanced study, Dr.Hideki Hasegawa, plans to undertake clinical studies in 2009 and 2010. Dr. Hasegawa's research focuses on mucosal immunity and the inherent advantages of a vigorous immune response to respiratory pathogens.

We received notice of an Annual Report (April 2008-March 2009) prepared by a Director of the National Institute of Infectious Diseases ("NIID") to the governing organization of the Japanese Ministry of Health ("MHLW") reporting a series of successful preclinical studies in new pandemic vaccines which rely critically on Ampligen® (Poly I : Poly C12U) an experimental therapeutic for efficacy. The efficacy was demonstrated both within the airways themselves as well as systemically. As a result, the program is expected to be accelerated into human volunteers promptly under supervision of NIID staff. The project is officially titled "Clinical Application of the Influenza Virus Vaccine in the Intranasal Dosage Form for Mucosal Administration".

Concurrently, our collaborative partner in Japan, Biken Corporation, reported the successful completion of a series of animal/preclinical tests on Ampligen®, an experimental therapeutic, necessary to support a new product registration in Japan. Successful studies in animal models, including the monkey studies conducted to date under auspices of the Japanese NIID, do not necessarily predict human safety and efficacy of any investigational product including Ampligen®.

The recent emergence of a new H1N1 Swine Flu strain with high associated mortality in Mexico provides additional significance to the Japanese studies. The original studies by Dr. Hasegawa and his colleagues that provided the basis for the expanded preclinical trials demonstrated cross-clade protection against H5N1 isolates following vaccination with a seasonal influenza vaccine (J Infect Dis.196:1313-1320, 2007).

The clinical trial in Australia is using Ampligen® in combination with seasonal flu vaccine. This open-label study (Phase IIa) utilizing Ampligen® (Poly I: Poly C12U) as a potential immune-enhancer was conducted in Australia with thirty-eight subjects age 60 or greater with the standard trivalent seasonal influenza vaccines. Ampligen® was administered subcutaneously. Elderly subjects typically have reduced immune responses relative to younger populations. The combinational treatment was generally well-tolerated. Serologic studies to evaluate the magnitude and spectrum of immune response are pending and are expected by mid-2009; however, only certain labs are qualified to conduct these tests and during the course of the clinical testing, one of these testing labs changed ownership.

Collaboration studies in non-human primates conducted by ViroClinics in the Netherlands suggest a potential role for Alferon® LDO as another novel therapeutic approach to viral pandemics. Meetings with prospective partners are underway with respect to conducting clinical trials using Alferon® LDO to treat and/or prevent seasonal influenza in the Pacific Rim countries. Alferon® LDO is now poised for clinical trials against seasonal influenza epidemics; meetings with prospective partners are ongoing to conduct clinical trials in the Pacific Rim countries and elsewhere. The opportunity for Alferon® LDO is reinforced by new reports of severe side effects secondary to Tamiflu®, the present standard of care, by both the FDA and Japanese health authorities. Also, Tamiflu® resistant strains of flu virus are now raising serious concerns on a world-wide basis.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended March 31, 2009 and 2008 were approximately $1,166,000 and $1,897,000, respectively, reflecting a decrease of $731,000 or 39%. This decrease relates primarily to a reduction in all areas of expenses due to the implementation of our cash conservation and cost reduction program implemented in January 2009. Accordingly, savings were obtained in legal and accounting fees, stock compensation expense and controllable expenses for the three months ended March 31, 2009. However, these expense reductions were partially offset by an increase of non-cash labor costs resulting from General and Administrative employees participating in the Employee Wage Or Hour Reduction Program.

Interest and Other Income

Interest and other income for the three months ended March 31, 2009 and 2008 was $7,000 and $80,000, respectively, representing a decrease of $73,000 or 91%. The decrease in interest and other income during the current period was mainly due to $5,541,000 less in cash, cash equivalents and short-term investments were held at the end of the current quarter as compared to that of the prior year's first quarter.

Interest Expense and Financing Costs

We had no interest expense or non-cash financing costs for the three months ended March 31 2008. While there was no interest expense incurred, on February 1, 2009 we entered into a Standby Financing Agreement that produced finance costs of Common Stock Commitment Warrants for the three months ended March 31, 2009. For detailed information on this agreement, refer to "Standby Financing Agreement" below.

Liquidity and Capital Resources

Cash used in operating activities for the three months ended March 31, 2009 was $1,424,000 compared to $2,806,000 for the same period in 2008 a reduction of $1,382,000 or 49%. This reduction reflects lower expenditures primarily related to Management's cash conservation program that included reducing controllable expenses and utilizing our common stock where possible as payment to Board Members, employees, consultants and vendors. Cash provided (used) by investing activities during the three months ended March 31, 2009 and 2008 totaled ($1,943,000) and $979,000, respectively, primarily due to the 2009 purchase and 2008 maturity of short term investments. We had proceeds from financing activities of $869,000 and $-0- during the three months ended March 31, 2009 and 2008, respectively. As of March 31, 2009, we had approximately $5,541,000 in cash, cash equivalents and short-term investments, or a decrease of approximately $578,000 from December 31, 2008.

We have been using the proceeds from Fusion Capital's equity financing to fund operating expense and infrastructure growth including manufacturing, regulatory compliance and market development costs related to the FDA approval process for Ampligen®. During the first quarter of 2009, we were able to raise $869,000 in equity financing (see "Equity Financing" below). We entered into securities purchase agreements to sell stock and warrants for an aggregate of $15,000,000 (the "Placement") and we anticipate that it will close within the next few days (see "Part II, Item 5. "Other Information"). If and when this transaction closes, we do not anticipate needing additional funding within the near future. However, if the Placement does not close, based on our estimate of cash flow demands from the first four months of 2009, along with our receipt of $960,000 of equity funding from Fusion Capital during April 2009, we anticipate that our existing funds should be sufficient to meet our operating cash requirements into the third calendar quarter of 2010.

Equity Financing

For information on the Purchase Agreement with Fusion Capital, please refer to "NOTE 5: STOCKHOLDERS' EQUITY" under Notes To Unaudited Condensed Consolidated Financial Statements in Item 1 above.

Because of our long-term capital requirements, we may seek to access the public equity market whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. In this regard we also have previously registered $50,000,000 worth of our securities in a universal shelf registration statement including the securities to be issued in the Placement. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. We may also need additional funding earlier than anticipated, and our cash requirements, in general, may vary materially from those now planned, for reasons including, but not limited to, changes in our research and development programs, clinical trials, competitive and technological advances, the regulatory processes, including the commercializing of Ampligen® products.

There can be no assurances that we will raise adequate funds from these or other sources should the Placement not close, which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

Standby Financing Agreement

In February 2009, we entered into a Standby Financing Agreement pursuant to which certain individuals ("Individuals"), consisting of Dr. Carter and Thomas Equels, agreed to loan us up to an aggregate of $1,000,000 in funds should we be unable to obtain additional financing, if needed. Under the Standby Financing Agreement, we will use our best efforts in 2009 to obtain one or more additional financing agreements on such terms as our Board deems to be reasonable and appropriate in order to maintain our operations. If at any time after December 1, 2009 and prior to June 30, 2010 a majority of our independent Directors deems that in the event a financing of at least $2.5 Million has not been obtained and additional funds are needed to maintain our operations, we will send a written notice to each of the Individuals informing them of the total amount of additional funds required and the specific amount that will be required from each Individual. Within fifteen calendar days after receipt of the notice, the Individuals will be required to pay us their respective amount. We will then issue to them one year 15% senior secured notes for their respective amounts (the "Notes"). Interest will be paid monthly in our Common Stock. Repayment of the principal and interest under the Notes will be secured by all of our assets. We will not, without the consent of the Individuals, (i) incur any new debt senior or pari passu to the Notes or (ii) encumber or grant a security interest in any assets. Upon 20 business days written notice, we may prepay the Notes in cash at any time at 105% of the then outstanding principal amount of the Notes, plus any accrued but unpaid interest.

For agreeing to be obligated to loan us money, each Individual received 10 year warrants (the "Commitment Warrants") to purchase our common stock at the rate of $50,000 worth in warrants per $100,000 committed. The exercise price of these warrants is $0.51 (125% of the market closing price of our Common Stock on the date that Agreement was executed. These warrants vested immediately. If and when we notify the Individuals that we are consummating the Standby Financing, upon each Individual's payment of his committed amount, he will receive additional 10 year warrants to purchase our Common Stock at the rate of $50,000 worth in warrants per $100,000 paid. The exercise price of the warrants will be the closing market price of our Common Stock on the day we receive the funds from the Individuals. These warrants will vest immediately. While any portion of the Notes are outstanding, Individuals will have weighted average anti-dilution rights with regard to the exercise price of all warrants issued pursuant hereto except that these rights will not apply if the securities are issued to employees, Board members, corporate and scientific advisors, select vendors, pursuant to our current agreement with Fusion Capital Fund II, LLC or part of a corporate or strategic alliance.

Employee Wage Or Hours Reduction Program

In an effort to conserve our cash, the Employee Wage Or Hours Reduction Program (the "Program") was ratified by the Board effective January 1, 2009. In a mandatory program that is estimated to be in effect for up to six months, compensation of all active full-time employees as of January 1, 2009 ("Participants") were reduced through a reduction in their wages for which they would be eligible to receive shares of our common stock ("Stock") six months after the shares were earned. While all employees were also offered the option to reduce their work hours with a proportional decease in wages, none elected this alternative.

On a semi-monthly basis, Participants receive rights to Stock ("Incentive Rights") that cannot be traded. Six months after the date the Incentive Rights are awarded, we will undertake a process to have Incentive Rights converted into Stock and issued to each Participant on a monthly basis. We will establish and maintain a record for the number of Incentive Rights awarded to each Participant. At the end of each semi-monthly period, we will determine the number of Incentive Rights by converting the proportionate incentive award to the value of the Stock by utilizing the closing price of the Stock on the NYSE Amex based on the average daily closing price for the period.

The Plan is being administered for full-time employees as follows:

- Employees earning $90,000 or less per year elected a wage reduction of 10% per annum and are receiving an incentive of two times the value in Stock;
- Employees earning $90,001 to $200,000 per year elected a wage reduction of 25% per annum are receiving an incentive of two times the value in Stock;
- Employees earning over $200,000 per year elected a wage reduction of 50% per annum and are receiving an incentive of three times the value in Stock;
- Any employee could elect a 50% per annum wage reduction for which would allow them to be eligible for an incentive award of three times the value of Stock.

Prior to the Stock being issued, we will establish a trading account with an independent brokerage firm for each Participant. Incentive Rights will constitute income to the Participants and be subject to payroll taxes upon Stock issuance. At a brokerage firm selected by us, we will bear all expenses related to selling the Stock (i.e.; broker fees, transaction costs, commissions, etc.) for payroll withholding taxes purposes. Thereafter, for each Participant during the period that they remain an active employee, we will continue to bear such costs from this designated brokerage firm for the maintenance of this account and all expenses related to selling our Stock. Participants leaving us or voluntarily separating from the Plan will receive the Stock earned upon the six month conversion of their Incentive Rights. The Plan benefits for individuals that are no longer Participants will become fixed and we will not continue to bear such costs from the designated brokerage firm for the maintenance of an account nor any expenses related to selling the Stock except for the initial costs associated to the selling of Stock for payroll withholding taxes purposes.

ITEM 3: Quantitative and Qualitative Disclosures About Market Risk

We had approximately $5,541,000 in cash and cash equivalents and short-term investments at March 31, 2009. To the extent that our cash and cash equivalents and short term investments exceed our near term funding needs, we generally invest the excess cash in three to twelve month interest bearing financial instruments. We employ established conservative policies and procedures to manage any risks with respect to investment exposure.

Our financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents. We place our cash and cash equivalents with what management believes to be high credit quality institutions. At times such investments may be in excess of the Federal Deposit Insurance Corporation (“FDIC”) insurance limit.

We have not entered into, and do not expect to enter into, financial instruments for trading or hedging purposes.

Item 4: Controls and Procedures

Our Chairman of the Board (serving as the principal executive officer) and the Chief Financial Officer performed an evaluation of the effectiveness of our disclosure controls and procedures, which have been designed to permit us to effectively identify and timely disclose important information. In designing and evaluating the disclosure controls and procedures, Management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and Management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the controls and procedures were effective as of March 31, 2009 to ensure that material information was accumulated and communicated to our Management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

23

During the quarter ended March 31, 2009, we have made no change in our internal controls over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Part II – OTHER INFORMATION

Item 1. Legal Proceedings

In December 2008, Lovells LP filed a complaint against us in the Federal District Court for the Eastern District of Pennsylvania seeking 151,330 pounds sterling for legal fees allegedly due to Lovells LP by us. We have filed an answer to this complaint and we are defending against this claim as well as considering possible settlement offers. Accordingly, we have recorded a loss contingency of as a result of the matter for the period ended March 31, 2009.

Our litigation in the Court of Common Pleas of the Commonwealth of Pennsylvania against Manuel P. Asensio for defamation and disparagement has been settled and disposed of.

Please see our Annual Report on Form 10-K for the year ended December 31, 2008 for previously reported legal proceedings.

ITEM 1A. Risk Factors.

The following cautionary statements identify important factors that could cause our actual result to differ materially from those projected in the forward-looking statements made in this Form 10-Q. 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 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 general use 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 U.S. and other countries, including, but not limited to, the FDA in the U.S., the Health Protection Branch ("HPB") of Canada, and the Agency for the Evaluation of Medicinal Products ("EMEA") in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen® or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen® will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligen® is authorized for use in clinical trials including a cost recovery program in the United States 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.

We filed an NDA with the FDA for treatment of CFS on October 10, 2007. On December 5, 2007 we received a Refuse To File ("RTF") letter from the FDA as our NDA filing was deemed "not substantially complete". We responded to the FDA's concerns by filing amendments to our NDA on April 25, 2008. These amendments should allow the FDA reviewers to better evaluate independently the statistical efficacy/safety conclusions of our NDA for the use of Ampligen® in treating CFS. On July 7, 2008 the FDA accepted our NDA filing for review. However, there are no assurances that upon review of the NDA that it will be approved by the FDA. On February 18, 2009, we were notified by the FDA that the originally scheduled Prescription Drug User Fee Act date of February 25, 2009 has been extended to May 25, 2009. Additionally, we are in discussions with representatives of the Japanese government regarding potential emergency purchases of Ampligen® for use in a pharmaceutical "stockpile" for a possible influenza pandemic.

If Ampligen® or one of our other products does not receive regulatory approval in the U.S. or elsewhere, such as Japan, our operations most likely will be materially adversely affected.

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

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses, as we pursued our clinical trial effort to get our experimental drug, Ampligen®, approved. As of March 31, 2009, our accumulated deficit was approximately $200,496,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

We may require additional financing which may not be available.

The development of our products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of March 31, 2009, we had approximately $5,541,000 in cash and cash equivalents and short-term investments along with our receipt of $960,000 of equity funding from Fusion Capital Fund II, LLC during April 2009. Given the harsh economic conditions, we have reviewed every aspect of our operations for cost and spending reductions to assure our long term survival while maintaining the resources necessary to achieve our primary objectives of obtaining NDA approval of Ampligen® and securing a strategic partner. Based on these actions, we anticipate, but cannot assure, that these funds will be sufficient to meet our operating cash requirements into the third calendar quarter of 2010.

We have entered into securities purchase agreements to sell stock and warrants for an aggregate of $15,000,000 (the “Placement”) and we anticipate that it will close within the next few days (see “Part II, Item 5. “Other Information”). If and when this transaction closes, we do not anticipate needing additional funding within the near future. However, if it does not close, we have in place two potential sources of financing: 1) a Common Stock Purchase Agreement (the "Purchase Agreement") with Fusion Capital Fund II, LLC (“Fusion Capital”) pursuant to which we have the right to sell shares of our Common Stock to Fusion Capital (see “Part I - Financial Information”, “Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; Equity Financing”); and 2) a Standby Financing Agreement with certain of our executives, directors and strategic consultants (see “Part I - Financial Information”, “Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; Standby Financing Agreement”). However, Fusion Capital cannot purchase any shares of our common stock pursuant to the Purchase Agreement if the price of our common stock has three trading days with an average value below $0.40 over the prior twelve trading days. While the current market price is in excess of $0.40 per share, during the past few months, the price of our common stock periodically has been below $0.40, thereby adversely affecting our ability to utilize the Fusion Capital equity financing.

Assuming no material financing from the sale of securities to Fusion Capital, financing under the Standby Financing Agreement is not sufficient and if we are unable to commercialize and sell Ampligen® and/or recommence and increase sales of Alferon N Injection® or our other products, we will 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 including the commercializing of Ampligen® products. In this regard we previously registered $50,000,000 worth of our securities in a universal shelf registration statement, including the securities to be issued in the Placement. 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. Should the Placement not close, there can be no assurances that we will raise adequate funds which may have a material adverse effect on our ability to develop our products or continue our operations.

26

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

Our finished goods inventory of Alferon N Injection® reached it's expiration date in March 2008. As a result, we have no product to commercially sell at this time. The FDA has declined to respond to our requests for an extension of the expiration date, therefore we consider the request to be denied. Since our testing of the product indicates that it is not impaired and could be safely utilized, the finished goods inventory of 2,745 Alferon N Injection® 5ml vials may be used to produce approximately 11,000,000 sachets of Low Dose Oral Alferon (LDO) for future clinical trials.

Production of Alferon N Injection® from our work-in-progress inventory, which has an approximate expiration date of 2012, has been put on hold at this time due to the resources needed to prepare our New Brunswick facility for the FDA preapproval inspection with respect to our Ampligen® NDA. Work on the Alferon N Injection® is expected to resume in mid-2009, under the condition that adequate funding is obtained, which means that we may not have any Alferon N Injection® product commercially available until 2010. However, if there is a significant absence of the product from the market place, no assurance can be given that sales will return to prior 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® continues to undergo pre-clinical testing for possible treatment of avian flu. Although preliminary in vitro testing indicates that Ampligen® enhances the effectiveness of different drug combinations on avian flu, preliminary testing in the laboratory 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 Ampligen® in the treatment of avian flu requires prior regulatory approval. Only the FDA can determine whether a drug is safe, effective or promising for treating a specific application. As discussed in the prior risk factor, obtaining regulatory approvals is a rigorous and lengthy process.

In addition, Ampligen® is currently being tested on strains of influenza virus. There are a number of strains and strains mutate. No assurance can be given that Ampligen® will be effective on any strains that might infect humans.

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®, which is carried out according to standard operating procedure manuals. We also have been issued patents on the use of Ampligen® in combination with certain other drugs for the treatment of chronic Hepatitis B virus, chronic Hepatitis C virus, and a patent which affords protection on the use of Ampligen® in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of Ampligen® as a sole treatment for any of the cancers, which we have sought to target. With regard to Alferon N Injection®, we have acquired from ISI its patents for natural alpha interferon produced from human peripheral blood leukocytes and its production process and we have filed a patent application for the use of Alferon® LDO in treating viral diseases including avian influenza. We cannot assure that our competitors will not seek and obtain patents regarding the use of similar products in combination with various other agents, for a particular target indication prior to our doing such. If we cannot protect our patents covering the use of our products for a particular disease, or obtain additional patents, we may not be able to successfully market our products.

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

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

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

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

28

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

To protect our rights, we require certain employees and 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®-CFS may include licensing/co-marketing agreements utilizing the resources and capacities of a strategic partner(s). We are currently seeking worldwide 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.

We cannot assure that our US or foreign marketing strategy will be successful or that we will be able to establish future marketing or third party distribution agreements on terms acceptable to us, or that the cost of establishing these arrangements will not exceed any product revenues. Our inability to establish viable marketing and sales capabilities would most likely have a materially adverse effect on us.

There are no long-term agreements with suppliers of required materials. If we are unable to obtain the required raw materials, we may be required to scale back our operations or stop manufacturing Alferon N Injection® and/or Ampligen®.

A number of essential materials are used in the production of Alferon N Injection®, including human white blood cells. We do not have long-term agreements for the supply of any of such materials. There can be no assurance we can enter into long-term supply agreements covering essential materials on commercially reasonable terms, if at all.

There are a limited number of manufacturers in the United States available to provide the polymers for use in manufacturing Ampligen®. At present, we do not have any agreements with third parties for the supply of any of these polymers. We have established relevant manufacturing operations within our New Brunswick, New Jersey facility for the production of Ampligen® polymers from raw materials in order to obtain polymers on a more consistent manufacturing basis.

If we are unable to obtain or manufacture the required polymers, we may be required to scale back our operations or stop manufacturing. 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.

Small 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, and can, among other things, require new clinical studies and affect orphan drug status, particularly, market exclusivity rights, if any, under the Orphan Drug Act. The transition from limited production of pre-clinical and clinical research quantities to production of commercial quantities of our products will involve distinct management and technical challenges and will require additional management and technical personnel and capital to the extent such manufacturing is not handled by third parties. There can be no assurance that our manufacturing will be successful or that any given product will be determined to be safe and effective, capable of being manufactured economically in commercial quantities or successfully marketed.

We have limited manufacturing experience.

Ampligen® has been only produced to date in limited quantities for use in our clinical trials and we are dependent upon a third party supplier for substantially all of the production process. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a material adverse affect on us. Also to be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. To the extent we are involved in the production process, our current facilities are not adequate for the production of our proposed products for large-scale commercialization, and we currently do not have adequate personnel to conduct commercial-scale manufacturing. We intend to utilize third-party facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. We will need to comply with regulatory requirements for such facilities, including those of the FDA pertaining to current Good Manufacturing Practices (“cGMP”) regulations. There can be no assurance that such facilities can be used, built, or acquired on commercially acceptable terms, or that such facilities, if used, built, or acquired, will be adequate for our long-term needs. Please refer to the Risk Factor “Our Alferon N Injection® commercial sales have halted due to lack of finished goods inventory”.

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

We have never produced Ampligen® or any other products in large commercial quantities. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen® or enter into third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Also, each production lot of Alferon N Injection® is subject to FDA review and approval prior to releasing the lots to be sold. This review and approval process could take considerable time, which would delay our having product in inventory to sell.

30

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 pre-clinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, HPB or other regulatory product approvals more rapidly than us. There are no drugs approved for commercial sale with respect to treating ME/CFS in the United States. The dominant competitors with drugs to treat disease indications in which we plan to address include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs, GlaxoSmithKline, Merck and Schering-Plough Corp. These potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Although we believe our principal advantage is the unique mechanism of action of Ampligen® on the immune system, we cannot assure that we will be able to compete.

ALFERON N Injection®. Our competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Alferon N Injection® currently competes with Schering-Plough's injectable recombinant alpha interferon product (INTRON® A) for the treatment of genital warts. 3M Pharmaceuticals also offer competition from its immune-response modifier, Aldara®, a self-administered topical cream, for the treatment of external genital and perianal warts. In addition, Medigene® has FDA approval for a self-administered ointment, VeregenTM, which is indicated for the topical treatment of external genital and perianal warts. Alferon N Injection® also competes with surgical, chemical, and other methods of treating genital warts. We cannot assess the impact products developed by our competitors, or advances in other methods of the treatment of genital warts, will have on the commercial viability of Alferon N Injection®. If and when we obtain additional approvals of uses of this product, we expect to compete primarily on the basis of product performance. Our competitors have developed or may develop products (containing either alpha or beta interferon or other therapeutic compounds) or other treatment modalities for those uses. There can be no assurance that, if we are able to obtain regulatory approval of Alferon N Injection® for the treatment of new indications, we will be able to achieve any significant penetration into those markets. In addition, because certain competitive products are not dependent on a source of human blood cells, such products may be able to be produced in greater volume and at a lower cost than Alferon N Injection®. Currently, our wholesale price on a per unit basis of Alferon N Injection® is higher than that of the competitive recombinant alpha and beta interferon products.

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

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

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

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

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

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

On November 28, 2008, we suspended product liability insurance for Alferon® N and Ampligen® until we receive regulatory clearance for Ampligen®. We now require third parties to indemnify us in conjunction with all overseas emergency sales of Ampligen® and Alferon® LDO. We concluded that years of successfully addressing the limited number of product liability claims filed against Ampligen® and Alferon® LDO, combined with the mandatory patient waivers completed as an element of clinical trials and lack of any commercial sales since April 2008, that discontinuing the liability insurance was an acceptable risk given our financial condition and need to conserve cash.

Currently, without product liability 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.

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. As a result of our implementation of the Employee Wage Or Hours Reduction Program, our staff has agreed to take a portion of their compensation in shares of our Common Stock. While we believe that our employees are dedicated to us and while we have incentivised them to remain with us through the establishment of a Goal Achievement Incentive Program for the implementation of a Strategic Partnering Agreement and Bonus Pool that would award them money in the event that the FDA approves our NDA for Ampligen®, we cannot assure that they will remain with us. For information on the Goal Achievement Incentive Program and the Bonus Pool, please see our Form 10-K for the year ended December 31, 2008; “Item 11. Executive Compensation; Compensation Discussion and Analysis; Elements of Executive Compensation; Other Compensation.” The loss of the services of personnel key to our operations or Dr. Carter 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 in the amount of $2,000,000 on the life of Dr. Carter until we receive regulatory clearance for Ampligen®. An employment agreement continues to exist with Dr. Carter that, as amended, runs until December 31, 2010. 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 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;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness 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; 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 15-month period ended March 31, 2009, the price of our common stock has ranged from $0.25 to $1.20 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

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. If we face securities litigation in the future, even if without merit or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

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

We anticipate selling 13,636,363 shares pursuant to the Placement along with warrants to purchase an additional 9,136,363 shares. In connection with entering into the Purchase Agreement with Fusion in August 2008, we registered 21,300,000 shares in the aggregate, consisting of 20,000,000 shares which we may sell to Fusion and 1,300,000 shares we have issued or may issue to Fusion as a commitment fee. As of March 31, 2009, we have sold an aggregate of 3,404,972 shares to Fusion under the Purchase Agreement for gross proceeds of approximately $1,140,000, leaving 17,895,029 shares. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the agreement. The purchase price for the common stock to be sold to Fusion Capital pursuant to the Purchase Agreement will fluctuate based on the price of our common stock. Under the rules of the NYSE Amex, we may not issue more than 14,823,651 shares (19.99% of our outstanding shares as of July 2, 2008, the date of the purchase agreement) without first obtaining the approval of stockholders. In November 2008, we received stockholder approval to issue the additional 6,476,349 shares. It is anticipated that shares registered could be sold over a period of up to 16 months after the date hereof. Depending upon market conditions at the time, a sale of shares by Fusion at any given time could cause the trading price of our common stock to decline. Fusion Capital may ultimately purchase all, some or none of the remaining 17,895,029 shares available but not yet issued. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Fusion Capital by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Fusion Capital, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Fusion Capital and the agreement may be terminated by us at any time at our discretion without any cost to us.

In addition to shares and warrant shares to be issued in the Placement and the shares registered for Fusion Capital, we have previously registered 135% of 1,920,256 shares issuable upon exercise of warrants related to our former convertible debentures and 14,442,294 shares issuable upon exercise of certain other warrants. To the extent the exercise price of the 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 conversion price and exercise price of these securities are adjusted pursuant to anti-dilution protection, the securities 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 previously registered $50,000,000 worth of our securities in a universal shelf registration statement, none of which has been designated or issued. 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 could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November 2002, we adopted a stockholder rights plan and, under the 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 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 8.1% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at $.01 per Right under certain circumstances.

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 2: Unregistered Sales of Equity Securities and Use of Proceeds

During the quarter ended March 31, 2009, we issued an aggregate of 709,758 shares for services performed.

All of the foregoing transactions were conducted pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933.

We did not repurchase any of our securities during the quarter ended March 31, 2009.

See also, Item 5 below

ITEM 3: Defaults upon Senior Securities

None.

ITEM 4: Submission of Matters to a Vote of Security Holders

None.

ITEM 5: Other Information

On May 8, 2009, we entered into a letter agreement (the "Engagement Letter") with Rodman & Renshaw, LLC ("Rodman") as placement agent, relating to a proposed offering of our securities. A copy of the Engagement Letter is attached hereto as Exhibit 1.1.

On May 10, 2009, we entered into Securities Purchase Agreements with two institutional investors. Pursuant to the Securities Purchase Agreements, we have agreed to issue to these investors in the aggregate: (a) 13,636,363 shares of our common stock; (b) Series I warrants to purchase an additional 6,136,363 shares of our common stock at an exercise price of $1.65 per share ("Series I Warrants"); and (c) Series II warrants to purchase up to 3,000,000 shares of our common stock at an exercise price of $1.10 per share ("Series II Warrants," and together with the Series I Warrants, the "Warrants"). The Series I Warrants may be exercised at any time on or after the six month anniversary of the closing date of the offering and for a five year period thereafter. The Series II Warrants may be exercised at any time on or after the date of delivery of the Series II Warrants and for a period of 45 days thereafter.

Rodman, as placement agent, acted on a best efforts basis for the offering and will receive a placement fee equal to $825,000 as well as Series 1 Warrants to purchase 750,000 shares of our common stock equal at an exercise price of $1.38 per share. Rodman also is entitled to a fee equal to 5.5% of any Series II Warrants that are exercised.

We are making the offering and sale of the above shares and Warrants pursuant to a shelf registration statement on Form S-3 (Registration No. 333-151696) declared effective by the Securities and Exchange Commission on June 27, 2008, and a base prospectus dated as of the same date, as supplemented by a prospectus supplement to be filed with the Securities and Exchange Commission on May 12, 2009.

The descriptions of terms and conditions of the Engagement Letter, Securities Purchase Agreements and Warrants set forth herein do not purport to be complete and are qualified in their entirety by the full text of the Engagement Letter, which is attached hereto as Exhibit 1.1 and incorporated herein by reference, the form of Securities Purchase Agreement, which is attached hereto as Exhibit 10.1 and incorporated herein by reference, and the forms of the Warrants, which are attached hereto as Exhibit 4.1 and Exhibit 4.2 and incorporated by reference herein.

A copy of the press release making the announcement of the offering is filed herewith as Exhibit 99.1 and are incorporated by reference herein.

ITEM 6: Exhibits

(a) Exhibits

1.1 Engagement Letter between the Company and Rodman & Renshaw, LLC.

4.1 Form of Series I common stock purchase warrant.
4.1 Form of Series II common stock purchase warrant.

10.1 Form of Securities Purchase Agreement entered into on May 10, 2009.

31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer

31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer

32.1 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer

32.2 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer

SIGNATURES

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.

HEMISPHERx
BIOPHARMA,
INC.

/S/ William A.
Carter
William A. Carter,
M.D.
Chief Executive
Officer
& President

/S/ Charles T.
Bernhardt
Charles T.
Bernhardt
Chief Financial
Officer

Date: May 11, 2009