HEMISPHERX BIOPHARMA INC
Form 10-Q
May 12, 2008

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, 2008

Commission File Number: 0-27072

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 o 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):

o Large accelerated filer	x Accelerated filer
o Non-accelerated filer	o Smaller reporting company

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

73,975,265 shares of common stock were issued and outstanding as of May 1, 2008.

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, 2007	March 31, 2008 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,471	$ 9,644
Short term investments (Notes 4)	3,944	2,989
Inventories	511	783
Accounts and other receivables	77	51
Prepaid expenses and other current assets	146	174
Assets held for sale (Note 6)	450	450
Total current assets	16,599	14,091
Property and equipment, net	4,821	5,063
Patent and trademark rights, net	958	926
Investment	35	35
Royalty interest, net	243	233
Construction in progress	469	-
Other assets	17	17
Total assets	$ 23,142	$ 20,365
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,118	$ 952
Accrued expenses	1,069	1,253
Total current liabilities	2,187	2,205
Commitments and contingencies		
Stockholders' equity (Note 5):		
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 73,760,446 and 73,900,945, respectively	74	74
Additional paid-in capital	206,078	206,424
Accumulated other comprehensive income (loss)	(7)	17
Accumulated deficit	(185,190)	(188,355)
Total stockholders' equity	20,955	18,160
Total liabilities and stockholders' equity	$ 23,142	$ 20,365

See accompanying notes to consolidated financial statements.

2

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

	Three months ended March 31,	
	2007	2008
Revenues:		
Sales of product net	$ 220	$ 173
Clinical treatment programs	35	35
Total revenues	255	208
Costs and expenses:		
Production/cost of goods sold	236	249
Research and development	3,716	1,307
General and administrative	1,783	1,897
Total costs and expenses	5,195	3,453
Operating loss	(4,940)	(3,245)
Interest and other income and expense	49	80
Interest expense	(71)	-
Financing costs	(138)	-
Net loss	$ (5,100)	$ (3,165)
Basic and diluted loss per share (Note 2)	$ (.07)	$ (.04)
Weighted average shares outstanding, basic and diluted	68,825,344	73,865,138

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 other comprehensive income	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2007	73,760,446	$ 74	$ 206,078	$ (7)	$ (185,190)	$ 20,955
Stock issued for settlement of accounts payable	140,499	-	111	-	-	111
Equity based compensation	-	-	235	-	-	235
Net comprehensive income (loss)	-	-	-	24	(3,165)	(3,141)
Balance at March 31, 2008	73,900,945	$ 74	$ 206,424	$ 17	$ (188,355)	$ 18,160

See accompanying notes to consolidated financial statements.

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
For the Three Months Ended March 31, 2007 and 2008
(in thousands)
(Unaudited)

	2007	2008
Cash flows from operating activities:		
Net loss	$ (5,100)	$ (3,165)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	61	84
Amortization of patent and trademark rights, and royalty interest	44	42
Financing cost related to debt discounts	138	-
Equity based compensation	145	235
Common stock issued in payment of interest expense	73	-
Increase (decrease) in assets and liabilities:		
Inventories	114	(272)
Accounts and other receivables	(466)	26
Prepaid expenses and other current assets	(27)	(28)
Accounts payable	109	15
Accrued expenses	69	257
Net cash used in operating activities	$ (4,840)	$ (2,806)
Cash flows from investing activities:		
Purchase of property plant and equipment	$ (19)	$ -
Additions to patent and trademark rights	(51)	-
Maturity of short term investments	18,329	1,979
Purchase of short term investments	(20,156)	(1,000)
Net cash (used in) provided by investing activities	$ (1,897)	$ 979

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows (Continued)
For the Three Months Ended March 31, 2007 and 2008
(in thousands)
(Unaudited)

	2007	2008
Cash flows from financing activities:		
Proceeds from sale of stock, net of issuance costs	$ 7,270	$ -
Net cash provided by financing activities	$ 7,270	$ -
Net increase(decrease) in cash and cash equivalents	533	(1,827)
Cash and cash equivalents at beginning of period	3,646	11,471
Cash and cash equivalents at end of period	$ 4,179	$ 9,644
Supplemental disclosures of non-cash investing and financing cash flow information:		
Issuance of common stock for accounts payable and accrued expenses	$ 63	$ 111
Issuance of common stock for patents and royalty interest	$ 770	$ -
Unrealized gains on investments	$ 219	$ 17
Supplemental disclosure of cash flow information:		
Cash paid during the year for interest	$ -	$ -

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 presentation of such consolidated financial statements have been included. Such adjustments 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, 2007, as filed with the SEC on March 17, 2008.

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 22,294,987 and 16,837,947 shares, are excluded from the calculation of diluted net loss per share for the three months ended March 31, 2007 and 2008, 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,	
	2007	2008
Risk-free interest rate	4.46% - 4.77%	2.86 - 3.74%
Expected dividend yield	-	-
Expected lives	5 yrs	2.5 - 5.0 yrs
Expected volatility	77.06 - 77.57%	75.69 - 79.18%
Weighted average grant date fair value of options and warrants issued	$136,000	$177,000

7

Stock option activity during the three months ended March 31, 2008, 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, 2006	2,001,969	$ 2.51	8.01	
Options granted	2,624,120	2.77	9.05	
Options forfeited	-	-	-	-
Outstanding December 31, 2007	4,626,089	2.66	8.25	-
Options granted	-	-	-	
Options forfeited	-	-	-	
Outstanding March 31, 2008	4,626,089	2.66	8.00	-
Exercisable March 31, 2008	4,459,326	$ 2.70	8.04	-

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2007 and 2008 was approximately $81,000 and $0, respectively.

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2006	113,986	$ 2.26	9.05	
Options granted	130,000	1.34	10.00	
Options vested	(77,223)	(6.86)	8.29	-
Outstanding December 31, 2007	166,763	1.59	7.18	-
Options granted	-	-	-	
Options vested	-	-	-	-
Outstanding March 31, 2008	166,763	$ 1.59	6.93	-

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, 2006	1,326,732	$ 2.63	8.18	
Options granted	608,750	1.99	9.94	

Options forfeited	-		-	-	
Outstanding December 31, 2007	1,935,482		2.43	8.05	-
Options granted	560,000		2.84	8.66	
Options forfeited	-		-	-	-
Outstanding March 31, 2008	2,495,482	$	2.52	8.00	-
Exercisable March 31, 2008	2,455,482	$	2.54	8.02	-

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2007 and 2008 was approximately $42,000 and $177,000, 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, 2006	37,100	$ 2.28	9.81	
Options granted	25,100	1.30	10.00	
Options forfeited	(22,100)	(2.30)	8.23	-
Outstanding December 31, 2007	40,000	1.50	9.30	-
Options granted	-	-	-	
Options forfeited	-	-	-	-
Outstanding March 31, 2008	40,000	$ 1.50	9.05	-

The impact on the Company's results of operations of recording equity based compensation for the three months ended March 31, 2007 and 2008 was to increase general and administrative expenses by approximately $123,000 and $230,000, which had no impact on basic and fully diluted earnings per share.

As of December 31, 2007 and March 31, 2008, respectively, there was $164,000 and $110,000 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:

	December 31, 2007			
Name of security	Cost	Market value	Unrealized loss	Maturity date
Marshall & Isley	$ 1,979,000	$ 1,976,000	$ (3,000)	March 2008
Intesa Funding	1,972,000	1,968,000	(4,000)	April 2008
	$ 3,951,000	$ 3,944,000	$ (7,000)	

	March 31,2008			
Name of Security	Cost	Market Value	Unrealized Gain (Loss)	Maturity Date
Bank of Scotland	$ 1,000,000	$ 999,000	$ (1,000)	April 2008
Intesa Funding	1,972,000	1,990,000	18,000	June 2008
	$ 2,972,000	$ 2,989,000	$ 17,000	

No investment securities were pledged to secure public funds at March 31, 2008 and December 31, 2007, respectively.

The table below indicates the length of time individual securities have been in a continuous unrealized loss position at March 31, 2008 and December 31, 2007.

		December 31, 2007					
		Less than 12 months		12 months or longer		Total	
Name of security	Number of Securities	Fair value	Unrealized loss	Fair value	Unrealized loss	Fair value	Unrealized loss
Marshall & Isley	1	$ 1,976,000	$ (3,000)	$ -	$ -	$ 1,976,000	$ (3,000)
Intesa Funding	1	1,968,000	(4,000)	-	-	1,968,000	(4,000)
Total temporary impairment securities	2	$ 3,944,000	$ (7,000)	$ -	$ -	$ 3,944,000	$ (7,000)

		March 31,2008					
		Less than 12 months		12 months or longer		Total	
Name of Security	Number of Securities	Fair value	Unrealized Loss	Fair value	Unrealized Loss	Fair value	Unrealized Loss
Bank of Scotland	1	$ 999,000	$ (1,000)	$ -	$ -	$ 999,000	$ (1,000)
Intesa Funding	1	1,990,000	-	-	-	1,990,000	-
		$ 2,989,000	$ (1,000)	$ -	$ -	$ 2,989,000	$ (1,000)

In management's opinion, the unrealized losses reflect changes in interest rates subsequent to the acquisition of specific securities. The Company has the ability to hold these securities until maturity or market price recovery. Management believes that the unrealized losses represent temporary impairment of the securities.

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)	
	2007	2008
Unrealized gains during the period	$ 243	$ 45
Realized gains during the period	(24)	(21)
Other comprehensive income	$ 219	$ 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: STOCKHOLDERS' EQUITY

For the three months ended March 31, 2008, Fusion Capital did not purchase any shares of the Company's common stock pursuant to the April 2006 common stock purchase agreement between the Company and Fusion Capital.

On February 18, 2008, the Company granted 280,000 stock options to two executive officers and two directors of the Company under the 2004 Equity Compensation Plan. The stock options have an exercise price of $4.00 and a term of ten years. The stock options vested immediately upon grant. The Company utilized the Black-Scholes Pricing Model to fair value the stock options and recorded approximately $91,000 as equity based compensation related to this issuance during the three months ended March 31, 2008.

During the three months ended March 31, 2008, the Company issued an aggregate 290,000 stock options and warrants to vendors for services provided under the 2004 Equity Compensation Plan. The stock options had various exercise prices ranging from $0.73 to $.80 and had terms of either five or ten years. The stock options vested immediately upon grant. The Company utilized the Black-Scholes Pricing Model to fair value the stock options and recorded approximately $91,000 as equity based compensation related to this issuance during the three months ended March 31, 2008.

The Company also recorded $53,000 during the three months ended March 31, 2008, in equity based compensation related to the vesting of stock options issued in 2006 and 2007.

NOTE 6: ASSET HELD FOR SALE

Asset held for sale consists of equipment purchases related to the purified water system that was to be installed at the Company's manufacturing facility in New Brunswick, NJ. The Company reevaluated its manufacturing needs and determined the installation of a purified water system would not be cost effective; therefore, the Company, in 2007, reclassed $450,000 to Asset Held for Resale. The Company also recorded an impairment charge of $228,000 in 2007 to bring the cost of the system down to its net realizable value as per SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets".

NOTE 7: RECENT ACCOUNTING PRONOUNCEMENTS

On February 15, 2007, the FASB issued FASB Statement No. 159, The Fair Value Option for Financial Assets and Financial Liabilities - Including an Amendment of FASB Statement No. 115. This standard permits an entity to choose to measure many financial instruments and certain other items at fair value. This option is available to all entities, including not-for-profit organizations. Most of the provisions in Statement 159 are elective; however, the amendment to FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. Some requirements apply differently to entities that do not report net income. The FASB's stated objective in issuing this standard is as follows: "to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions".

The fair value option established by Statement 159 permits all entities to choose to measure eligible items at fair value at specified election dates. A business entity will report unrealized gains and losses on items for which the fair value option has been elected in earnings (or another performance indicator if the business entity does not report earnings) at each subsequent reporting date. A not-for-profit organization will report unrealized gains and losses in its statement of activities or similar statement. The fair value option: (a) may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method; (b) is irrevocable (unless a new election date occurs); and (c) is applied only to entire instruments and not to portions of instruments.

Statement 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. The Company elected not to adopt the fair value option for any eligible instruments.

On December 4, 2007, the FASB issued FASB Statement No. 160, *"Noncontrolling Interests in Consolidated Financial Statements - An Amendment of ARB No. 51."* Statement 160 establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. Specifically, this statement requires the recognition of a noncontrolling interest (minority interest) as equity in the consolidated financial statements and separate from the parent's equity. The amount of net income attributable to the noncontrolling interest will be included in consolidated net income on the face of the income statement. Statement 160 clarifies that changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation are equity transactions if the parent retains its controlling financial interest. In addition, this statement requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. Such gain or loss will be measured using the fair value of the noncontrolling equity investment on the deconsolidation date. Statement 160 also includes expanded disclosure requirements regarding the interests of the parent and its noncontrolling interest.

Statement 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. The Company believes adoption of this standard will not have an impact on the financial condition or the results of the Company’s operations.

On April 21, 2008, the FASB posted a revised FASB Statement No. 133 Implementation guidance for Issues I1, Interaction of the Disclosure Requirements of Statement 133 and Statement 47, and K4, Miscellaneous: Income Statement Classification of Hedge Ineffectiveness and the Component of a Derivative's Gain or Loss Excluded from the Assessment of Hedge Effectiveness. The revisions relate to the issuance of FASB Statement No. 161, Disclosures about Derivative Instruments and Hedging Activities. The Company believes adoption of this standard will not have an impact on the financial condition or the results of the Company’s operations.

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 biopharmaceutical 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. The Company was 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 subsidiaries include Hemispherx Biopharma Europe N.V./S.A. established in Belgium in 1998. Hemispherx Biopharma Europe N.V./S.A. has little or no activity.

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 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 Myalgic Encephalomyelitis/Chronic Fatigue Syndrome ("ME/CFS" or "CFS"), and HIV. In August 2004, we completed a Phase III clinical trial ("AMP 516") treating over 230 ME/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 class of RNA (nucleic acid) molecules to apply for NDA review. For an update on the filing status of our Ampligen New Drug Application filed on October 10, 2007, see "Research and Development Costs" contained within this section below.

The Status of our initiative for Ampligen as an adjuvant for preventative vaccine development includes 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. Our development strategy includes reproduction of preclinical studies outside Japan and completion of the three year program. It is our intent to conduct human studies in the US and other countries and 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 is currently being conducted in Australia through the St. Vincent's Hospital Clinical Trials Centre and is now fully enrolled.

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 1000 patients have participated in Ampligen® clinical trials authorized by the FDA at over twenty clinical trial sites across the U.S., 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 with respect to Multiple Sclerosis and preclinical development (SARS) is being conducted by independent third parties.

We are actively engaged in broad-based ongoing experimental studies assessing the efficacy of our products Ampligen®, Alferon N Injection®, and Alferon LDO® against influenza viruses as an adjuvant and/or single agent antiviral with the Defence R&D Canada, the National Institute of Infectious Diseases in Tokyo, the St. Vincent's Hospital Clinical Trial Centre in Australia and various research affiliates of the National Institutes of Health in the United States.

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ primarily designed to produce Alferon N. 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.

New Accounting Pronouncements

On February 15, 2007, the FASB issued FASB Statement No. 159, The Fair Value Option for Financial Assets and Financial Liabilities - Including an Amendment of FASB Statement No. 115. This standard permits an entity to choose to measure many financial instruments and certain other items at fair value. This option is available to all entities, including not-for-profit organizations. Most of the provisions in Statement 159 are elective; however, the amendment to FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. Some requirements apply differently to entities that do not report net income. The FASB's stated objective in issuing this standard is as follows: "to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions".

The fair value option established by Statement 159 permits all entities to choose to measure eligible items at fair value at specified election dates. A business entity will report unrealized gains and losses on items for which the fair value option has been elected in earnings (or another performance indicator if the business entity does not report earnings) at each subsequent reporting date. A not-for-profit organization will report unrealized gains and losses in its statement of activities or similar statement. The fair value option: (a) may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method; (b) is irrevocable (unless a new election date occurs); and (c) is applied only to entire instruments and not to portions of instruments.

Statement 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. We elected not to adopt the fair value option for any eligible instruments.

On December 4, 2007, the FASB issued FASB Statement No. 160, *"Noncontrolling Interests in Consolidated Financial Statements - An Amendment of ARB No. 51."* Statement 160 establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. Specifically, this statement requires the recognition of a noncontrolling interest (minority interest) as equity in the consolidated financial statements and separate from the parent's equity. The amount of net income attributable to the noncontrolling interest will be included in consolidated net income on the face of the income statement. Statement 160 clarifies that changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation are equity transactions if the parent retains its controlling financial interest. In addition, this statement requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. Such gain or loss will be measured using the fair value of the noncontrolling equity investment on the deconsolidation date. Statement 160 also includes expanded disclosure requirements regarding the interests of the parent and its noncontrolling interest.

Statement 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. The impact of this statement has not been determined. We believe adoption of this standard will not have an impact on the financial condition or the results of our operations.

On April 21, 2008, the FASB posted a revised FASB Statement No. 133 Implementation guidance for Issues I1, Interaction of the Disclosure Requirements of Statement 133 and Statement 47, and K4, Miscellaneous: Income Statement Classification of Hedge Ineffectiveness and the Component of a Derivative's Gain or Loss Excluded from the Assessment of Hedge Effectiveness. The revisions relate to the issuance of FASB Statement No. 161, Disclosures about Derivative Instruments and Hedging Activities. We believe adoption of this standard will not have an impact on the financial condition or the results of our operations.

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, 2007.

RESULTS OF OPERATIONS

Three months ended March 31, 2007 versus three months ended March 31, 2008

Net loss

Our net loss of approximately $3,165,000 for the three months ended March 31, 2008 was $1,935,000 or 38% lower when compared to the same period in 2007. This decrease in loss was primarily due to:

1) Research and Development costs in 2007 include significant expenses related to the preparation of the Ampligen NDA as well as expenses related to the production of Ampligen for use in stability studies. Expenses related to the Ampligen NDA work in 2008 were down approximately $430,000 as compared to the same period in 2007; Ampligen manufacturing costs were down approximately $1,380,000 in 2008 as well as there was no Ampligen production during the current quarter; and

2) In 2007, we had financing costs and interest expense of $138,000 and $71,000, respectively, related to our convertible debentures. These convertible debentures were paid off in June 2007. No financing costs or interest charges were incurred during the current period related to these debentures.

Net loss per share was $0.04 for the current period versus $0.07 for the same period in 2007.

Revenues

Revenues for the three months ended March 31, 2008 were $208,000 as compared to revenues of $255,000 for the same period in 2007. Ampligen® sold under the cost recovery clinical program was flat while Alferon N Injection® sales were down $47,000 or 21% to $173,000 during the current period. The factors primarily contributing to this decrease in sales: 1) Competition from rival products and 2) a shortage of finished goods inventory available for sale due to product expiration dates. We have petitioned the Drug Shortage Division of the FDA for their assistance in obtaining an extension of the expiration date of our Alferon N Injection finished goods. There is no assurance that the FDA will grant this extension, which if not granted, will adversely affect our sales of Alferon N Injection.

Production costs/cost of goods sold

Production/cost of goods sold was approximately $236,000 and $249,000, respectively, for the three months ended March 31, 2007 and 2008. This represented a slight increase of approximately $13,000 or 6% as compared to the same period in 2007. These costs primarily represent: 1) costs of goods sold of $93,000 and $60,000, respectively, for the three months ended March 31, 2007 and 2008, and 2) Costs to maintain Alferon N Injection Inventory including stability tests and indirect overhead.

We continue to move lot number three of Alferon N Injection work-in-process inventory through to finished goods. This lot should produce approximately 9,800 doses and is scheduled for completion in late 2008.

Research and Development costs

Overall research and development costs for the three months ended March 31, 2008 were $1,307,000 as compared to $3,176,000 for the same period a year ago reflecting a decrease of $1,869,000 or 59%. This decrease was primarily due to reduced outside consulting fees related to the preparation and filing of our NDA for Ampligen. Our Ampligen NDA was finalized and filed on October 10, 2007. On December 5, 2007 we received a Refusal to File (RTF) letter from the FDA as our NDA filing was deemed “not substantially complete”. We responded to the FDA’s concerns on January 8, 2008 addressing their fourteen pre-clinical and clinical questions. A scheduled Guidance Meeting with the FDA on February 8, 2008 resulted in resolving nine of the fourteen concerns. These nine are no longer considered filing issues. The five remaining issues can be grouped into two categories: 1) administrative items which include the submission of additional clinical records, the clarification of some documents previously submitted, additional clinical data reconciliation and additional charts, which summarize specific parts of the clinical data, and 2) the reformatting and enlarged analysis of existing reports to more closely align with current International Committee on Harmonization Guidelines.

These five NDA filing issues have been addressed by our clinical and scientific staff with the filing of 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 ME/CFS. While we are optimistic as to the progress of the NDA filing, there are no assurances the FDA will accept the amended NDA for review, and if accepted, there are no assurances that the NDA will be approved. The April 25, 2008 filing included a full electronic version of the NDA (eNDA) to facilitate efficient FDA review as opposed to a "hybrid" NDA Application filed in October 2007.

We are also engaged in broad based, ongoing, experimental studies assessing the efficacy of Ampligen®, Alferon N Injection®, and Alferon LDO against influenza viruses as an adjuvant single agent antiviral with Defence R&D Canada, 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.

The Biken arrangement was concluded in December 2007 and basically consists of Biken purchasing Ampligen® from us 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 2 or 3 pharma 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 2007, we initiated a clinical trial in Australia using Ampligen® in combination with seasonal flu vaccine. This trial, expected to continue for several months, is being conducted in Australia's winter season and focuses on populations at risk for virulent cases of influenza, especially those over the age of 60 years who historically may have weakened immune systems. The Australian clinical trial was prompted by the results from the pre-clinical work conducted by the JNIID (see above). Approximately, 36 patients are now enrolled in this study, which will utilize a two dose Ampligen® regimen of 2 mg per dose. This study is being monitored by Clinical Network Services Pty. Ltd. located in Brisbane, Australia. The clinical trials center of St. Vincent's Hospital based in DarlingHurst, Australia is conducting the trial. We expect this trial to be fully enrolled by the end of May 2008.

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 Alferson LDO to treat 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 FDA and Japanese health authorities. Also, Tamiflu resistant strains of flu virus are now raising concerns on a world wide basis.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended March 31, 2007 and 2008 were approximately $1,897,000 and $1,783,000, respectively, reflecting an increase of $114,000 or 6%. This increase relates primarily to an increase in legal expenses as compared to the prior period mainly relating to litigation in South Africa and the arbitration proceedings related to Laboratorios del Dr. Esteve. For more information regarding litigation, see "legal Proceedings" contained within Part II. Other Information, Item 1 below.

18

Interest and Other Income and Expense

Interest and other income and expense for the three months ended March 31, 2008 increased approximately $31,000 as compared to the same period a year earlier. The increase in interest and other income during the current period was mainly due to higher interest earned upon the maturity of our marketable securities as compared the same period a year ago. All funds in excess of our immediate needs are invested in short-term securities.

Interest Expense and Financing Costs

We had no interest expense or non-cash financing costs for the three months ended March 31, 2008 as compared to $209,000 for the same period a year ago. The expenses reflected for the three months ended March 31, 2007 reflect financing costs and interest charges related to our convertible debentures which matured in June 2007 when all outstanding loan balances were paid.

Liquidity and Capital Resources

Cash used in operating activities for the three months ended March 31, 2008 was $2,806,000 compared to $4,840,000 for the same period in 2007. This reduction reflects lower costs primarily related to the preparation of our Ampligen NDA which was finalized and filed with the FDA in October 2007. Cash used in operating activities in 2007 included the extensive costs of preparing the NDA. Cash provided by investing activities during the three months ended March 31, 2008 totaled $979,000 primarily due to the maturity and/or purchase of short term investments. We had no proceeds from financing activities during the three months ended March 31, 2008. As of March 31, 2008, we had approximately $12,633,000 in cash and cash equivalents and short-term investments, or a decrease of approximately $2,782,000 from December 31, 2007. Based on our operating plan, we anticipate that these funds should be sufficient to meet our operating cash requirements for approximately 15 months.

Equity Financing

On April 12, 2006, we entered into a common stock purchase agreement (the “2006 Purchase Agreement”) with Fusion Capital Fund II, LLC (“Fusion Capital”), pursuant to which Fusion Capital has agreed, under certain conditions, to purchase on each trading day $100,000 of our common stock up to an aggregate of $50.0 million over a period of approximately 25 months. Pursuant to the terms of the Registration Rights Agreement, dated as of April 12, 2006, we registered 12,386,723 shares issuable to or issued to Fusion Capital under the Purchase Agreement. Through May 1, 2008, we have sold to Fusion Capital an aggregate of 10,682,032 shares under the common stock purchase agreement for aggregate gross proceeds of approximately $19,739,000 and issued 448,816 Commitment Shares. Pursuant to the 2006 Purchase Agreement, Fusion Capital cannot purchase shares if our stock price is under $1.00. Our current stock price is below $1.00. Unless and until the market price increases to at least $1.00, no additional shares will be sold to Fusion Capital under the existing agreement.

We are using the proceeds from this financing for general corporate purposes.

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. 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, 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.

ITEM 3: Quantitative and Qualitative Disclosures About Market Risk

We had approximately $12,633,000 in cash and cash equivalents and short-term investments at March 31, 2008. 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 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, 2008 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.

During the quarter ended March 31, 2008, 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

See our Form 10-K for the period ending December 31, 2007 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 Refusal to File (RTF) letter from the FDA as our NDA filing was deemed "not substantially complete". We responded to the FDA's concerns on January 8, 2008 addressing their fourteen pre-clinical and clinical questions. A scheduled Guidance Meeting with the FDA on February 8, 2008 resulted in resolving nine of the fourteen concerns. These nine are no longer considered filing issues. The five remaining issues can be grouped into two categories: 1) administrative items which include the submission of additional clinical records, the clarification of some documents previously submitted, additional clinical data reconciliation and additional charts, which summarize specific parts of the clinical data, and 2) the reformatting and enlarged analysis of the existing reports to more closely align with current International Committee on Harmonization Guidelines.

These five NDA filing issues have been addressed by our clinical and scientific staff with the filing of 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 ME/CFS. However, there are no assurances the FDA will accept the amended NDA for review, and if accepted, there are no assurances that the NDA will be approved.

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

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® is undergoing 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 being tested on two strains of avian 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 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, 2008, our accumulated deficit was approximately $188,355,000. 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, 2008, we had approximately $12,633,000 in cash and cash equivalents and short-term investments. We anticipate, but cannot assure, that these funds will be sufficient to meet our operating cash requirements for the next 15 months.

In April 2006, we entered into a common stock purchase agreement with Fusion Capital pursuant to which Fusion Capital has agreed, under certain conditions and with certain limitations, to purchase on each trading day $100,000 of our common stock up to an aggregate of $50,000,000 until August 1, 2008 (see “The Fusion Transaction” in Selling Stockholders” below).

We only have the right to receive up to $100,000 per trading day under the agreement with Fusion Capital unless our stock price exceeds $1.90 by at least $0.10, in which case the daily amount may be increased under certain conditions as the price of our common stock increases. Fusion Capital does not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than $1.00. We have registered an aggregate of 13,201,840 shares purchasable by Fusion Capital pursuant to the common stock purchase agreement (inclusive of up to 643,502 additional Commitment Shares) and, through May 1, 2008, we have sold to Fusion Capital an aggregate of 10,682,032 shares under the common stock purchase agreement for aggregate gross proceeds of approximately $19,739,000. Assuming a purchase price of $1.00 per share, the lowest price at which Fusion is obligated to purchase shares from us (the closing sale price of the common stock on May 1, 2008 was $0.71) and the purchase by Fusion Capital of the remaining 1,061,189 shares (not including the remaining 194,688 Commitment Shares), total gross proceeds to us from the remaining shares would only be approximately $1,061,000 ($20,800,000 in the aggregate under the common stock purchase agreement).

Unless and until the market price for our common stock increases to at least $1.00, no additional shares will be sold to Fusion Capital under the agreement. We will realize much less than the maximum $50,000,000 proceeds from the sale of stock under the Purchase Agreement.

Assuming no material additional financing from Fusion Capital and if we are unable to commercialize and sell Ampligen® and/or 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 from other sources in order to satisfy our working capital needs and to complete the necessary clinical trials and the regulatory approval processes including the commercializing of Ampligen® products. 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.

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 have been issued certain patents including those on the use of Ampligen® and Ampligen® in combination with certain other drugs for the treatment of HIV. We also have been issued patents on the use of Ampligen® in combination with certain other drugs for the treatment of chronic Hepatitis B virus, chronic Hepatitis C virus, and a patent which affords protection on the use of Ampligen® in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of AmpligenÒ as a sole treatment for any of the cancers, which we have sought to target. With regard to Alferon N Injection®, we have acquired from 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.

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 worldwide basis.

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

There 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 and capacity.

Ampligen® has been only produced 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.

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.

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, Glaxo Smith Kline, 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'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 recently received 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% 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 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. Although we currently maintain product liability insurance coverage, there can be no assurance that this insurance will provide adequate coverage against Ampligen® and/or Alferon N Injection® product liability claims. A successful product liability claim against us in excess of Ampligen's® $1,000,000 in insurance coverage; $3,000,000 in aggregate, or in excess of Alferon N Injection's® $5,000,000 in insurance coverage; $5,000,000 in aggregate; or for which coverage is not provided could have a negative 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 Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen®, and his knowledge of our overall activities, including patents and clinical trials. The loss of Dr. Carter's services could have a material adverse effect on our operations and chances for success. We have secured key man life insurance in the amount of $2,000,000 on the life of Dr. Carter and we have an employment agreement 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. 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; and
- the occurrence of any of the risks described in these "Risk Factors."

Our common stock is listed for quotation on the American Stock Exchange. For the 12-month period ended March 31, 2008, the closing price of our common stock has ranged from $0.61 to $2.00 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 have registered 1,704,691 shares of our common stock for public resale consisting of shares currently owned by Fusion Capital and shares issuable under the common stock purchase agreement. Also, we have registered 135% of 3,615,514 shares issuable upon exercise of Warrants related to our former convertible debentures and 5,594,104 shares issuable upon exercise of certain other warrants. Registration of the shares permits the sale of the shares in the open market or in privately negotiated transactions without compliance with the requirements of Rule 144. 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. We are unable to estimate the amount, timing or nature of future sales of outstanding 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.

The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by Fusion Capital and other shares registered for selling stockholders could cause the price of our common stock to decline.

The sale by Fusion Capital and other selling stockholders of our common stock will increase the number of our publicly traded shares, which could depress the market price of our common stock. Moreover, the mere prospect of sales by Fusion Capital and other selling stockholders could depress the market price for our common stock. The issuance of shares to Fusion Capital under the common stock purchase agreement will dilute the equity interest of existing stockholders and could have an adverse effect on the market price of our common stock.

The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement will fluctuate based on the price of our common stock. All shares sold to Fusion Capital are to be freely tradable. Fusion Capital may sell none, some or all of the shares of common stock purchased from us at any time. We expect that the shares offered by Fusion Capital and other selling stockholders will be sold over a period of six to twelve months. Depending upon market liquidity at the time, a sale of shares by Fusion or other selling stockholders at any given time could cause the trading price of our common stock to decline. Given the current market price of our common stock which is below the $1.00 threshold for Fusion to purchase shares, we do not anticipate sales by Fusion to materially affect the market price. Nevertheless, should the market price rise, the sale of a substantial number of shares of our common stock to Fusion Capital pursuant to the purchase agreement, 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.

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 7.8% 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, 2008, we issued an aggregate of 140,499 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, 2008.

ITEM 3: Defaults upon Senior Securities

None.

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

None

ITEM 5: Other Information

None.

ITEM 6: Exhibits

(a) Exhibits

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/ Robert E. Peterson
Robert E. Peterson
Chief Financial Officer

Date: May 9, 2008