HEMISPHERX BIOPHARMA INC
Form 10-Q
May 06, 2011

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, 2011

Commission File Number: 1-13441

HEMISPHERX BIOPHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware	52-0845822
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1617 JFK Boulevard, Suite 660, Philadelphia, PA 19103
(Address of principal executive offices) (Zip Code)

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

Not Applicable

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

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

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

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

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

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

135,335,807 shares of common stock were outstanding as of May 1, 2011.

PART I - FINANCIAL INFORMATION

ITEM 1: Financial Statements

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(in thousands, except for share and per share amounts)

	December 31, 2010	March 31, 2011 (Unaudited)
Current assets:		
Cash and cash equivalents (Note 11)	$ 2,920	$ 2,247
Marketable securities (Note 5)	32,689	29,661
Inventories (Note 4)	787	897
Prepaid expenses and other current assets	278	382
Total current assets	36,674	33,187
Property and equipment, net	4,876	4,826
Patent and trademark rights, net	794	689
Investment	35	35
Marketable securities (Note 5)	8,778	10,920
Construction in progress (Note 8)	485	630
Other assets	38	42
Total assets	$ 51,680	$ 50,329
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,328	$ 1,299
Accrued expenses (Note 6)	1,443	742
Current portion of capital lease (Note 7)	61	61
Total current liabilities	2,832	2,102
Long-term liabilities		
Long-term portion of capital lease (Note 7)	96	108
Redeemable warrants (Note 10)	2,805	2,504
Total liabilities	5,733	4,714
Commitments and contingencies		
Stockholders' equity (Note 9):		
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 135,241,609 and 135,335,807, respectively	135	135
Additional paid-in capital	264,511	264,586
Accumulated other comprehensive loss	(974)	(515)

Accumulated deficit	(217,725)	(218,591)
Total stockholders' equity	45,947	45,615
Total liabilities and stockholders' equity	$ 51,680	$ 50,329

See accompanying notes to consolidated financial statements.

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

	Three months ended March 31,	
	2010	2011
Revenues:		
Clinical treatment programs	$ 32	$ 42
Total revenues	32	42
Costs and expenses:		
Production/cost of goods sold	140	193
Research and development	1,996	1,640
General and administrative	1,969	1,799
Total costs and expenses	4,105	3,632
Operating loss	(4,073)	(3,590)
Interest expense from capital leases	-	(6)
Interest and other income	29	157
Funds received from sale of income tax net operating losses (Note 13)	-	2,272
Redeemable warrants valuation adjustment (Note 10)	(1,336)	301
Net loss	$ (5,380)	$ (866)
Basic and diluted loss per share (Note 2)	$ (.04)	$ (.01)
Weighted average shares outstanding, basic and diluted	132,818,036	135,264,635

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 Compre-hensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2010	135,241,609	$ 135	$ 264,511	$ (974)	$ (217,725)	$ 45,947
Stock issued for settlement of accounts payable	94,198	-	48	-	-	48
Equity based compensation	-	-	27	-	-	27
Net comprehensive loss	-	-	-	459	(866)	(407)
Balance at March 31, 2011	135,335,807	$ 135	$ 264,586	$ (515)	$ (218,591)	$ 45,615

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
For the Three Months Ended March 31, 2010 and 2011
(in thousands)
(Unaudited)

	2010	2011
Cash flows from operating activities:		
Net loss- restated	$(5,380)	$(866)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	94	112
Amortization of patent and trademark rights, and royalty interest	20	106
Redeemable warrants valuation adjustment	1,336	(301)
Equity based compensation	36	27
Change in assets and liabilities:		
Inventories	-	(110)
Prepaid expenses and other current assets	116	(104)
Accounts payable	559	19
Accrued expenses	(706)	(701)
Net cash used in operating activities	$(3,925)	$(1,818)
Cash flows from investing activities:		
Purchase of property and equipment	$(312)	$(36)
Additions to patent and trademark rights	(28)	(147)
Deposits on capital leases	(6)	(4)
Maturities of short-term and long-term investments	-	4,522
Purchase of short-term and long-term investments	(3,073)	(3,176)
Net cash provided by (used in) investing activities	$(3,419)	$1,159

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows (Continued)
For the Nine Months Ended March 31, 2010 and 2011
(in thousands)
(Unaudited)

	2010	2011
Cash flows from financing activities:		
Payments on capital lease	$(5)	$(14)
Net cash used in financing activities	$(5)	$(14)
Net decrease in cash and cash equivalents	(7,349)	(673)
Cash and cash equivalents at beginning of period	58,072	2,920
Cash and cash equivalents at end of period	$50,723	$2,247
Supplemental disclosures of non-cash investing and financing cash flow information:		
Issuance of common stock for accounts payable and accrued expenses	$45	$48
Equipment acquired by capital lease	$70	$26
Unrealized gain (loss) on investments	$(20)	$459
Redeemable warrants valuation adjustment	$1,336	$(301)
Supplemental disclosure of cash flow information:		
Cash paid for interest expense	$-	$6

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 minimal 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 for the year ended December 31, 2010, contained in our Annual Report on Form 10-K for the year ended December 31, 2010.

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 21,236,453 and 52,811,158 shares, are excluded from the calculation of diluted net loss per share for the three months ended March 31, 2010 and 2011, 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-Merton 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,	
	2010	2011
Risk-free interest rate	1.02%	2.24%
Expected dividend yield	-	-
Expected lives	5.0 yrs.	5.0 years
Expected volatility	109.81%	104.47%
Weighted average grant date fair value per options and warrants issued	$0.57 per option for 20,000 options	$0.34 per option for 20,000 options

Stock option activity during the three months ended March 31, 2010 and 2011, respectively, 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, 2009	6,228,752	$2.60	6.95	$-
Options granted	993,728	.80	9.42	-
Options forfeited	-	-	-	-
Outstanding December 31, 2010	7,222,480	$2.35	6.21	$-
Options granted	-	-	-	-
Options forfeited	-	-	-	-
Outstanding March 31, 2011	7,222,480	$2.35	5.96	$-
Exercisable March 31, 2011	7,175,258	$2.35	5.98	$-

No options were granted to employees during the three months ended March 31, 2010 and 2011, 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, 2009	38,333	$1.54	8.00	$-
Options granted	20,000	.66	9.50	-
Options vested	(7,778)	.66	9.50	-
Options forfeited	-	-	-	-
Outstanding December 31, 2010	50,555	$1.33	7.60	$-
Options granted	-	-	-	-
Options vested	(3,333)	.66	9.25	-
Options forfeited	-	-	-	-
Outstanding March 31, 2010	47,222	$1.38	7.22	$-

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, 2009	2,233,432	$2.44	5.73	$-
Options granted	625,000	0.55	9.52	-
Options exercised	-	-	-	-
Options forfeited	(10,000)	2.46	-	-
Outstanding December 31, 2010	2,848,432	$2.03	5.80	$-
Options granted	-	-	-	-
Options exercised	20,000	.55	9.75	-
Options forfeited	-	-	-	-
Outstanding March 31, 2011	2,868,432	$2.02	5.58	$-
Exercisable March 31, 2011	2,766,348	$1.99	5.83	$-

The weighted-average grant-date fair value of non-employee options granted during the three months ended March 31 2010 and 2011 was approximately $11,300 and $6,890, 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, 2009	139,584	$2.68	3.76	$-
Options granted	-	-	-	-
Options vested	(37,500)	2.81	2.50	-
Options forfeited	-	-	-	-
Outstanding December 31, 2010	102,084	$2.63	3.54	$-
Options granted	-	-	-	-
Options vested	(9,375)	2.81	2.25	-
Options forfeited	-	-	-	-
Outstanding March 31, 2011	92,709	$2.61	3.40	$-

The impact on the Company’s results of operations of recording equity based compensation for the three months ended March 31, 2010 and 2011 was to increase general and administrative expenses by approximately $36,000 and $7,000 respectively. The impact on basic and fully diluted earnings per share for the three months ended March 31, 2010 and 2011 was $-0- and $-0-, respectively.

As of March 31, 2010 and 2011, respectively, there was $205,000 and $142,000 of unrecognized equity based compensation cost related to options granted under the Equity Incentive Plan.

Note 4: Inventories

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

Inventories consist of the following:

	(in thousands)	
	December 31, 2010	March 31, 2011
Inventory work-in-process	$ 864	$ 787
Production	373	110
Spoilage	(450)	-
Finished goods, net of reserves of $250,000 at December 31, 2010 and at March 31, 2011, respectively.	-	-
	$ 787	$ 897

The production of Alferon N Injection® from the Work-In-Progress Inventory, which has an approximate expiration date in 2012, had remained on hold for conversion due to the dedication of resources to prepare the New Brunswick facility for the FDA preapproval inspection with respect to Ampligen® NDA. Since adequate financial resources were obtained to commence upgrades to the Ampligen® and Alferon® manufacturing process, the conversion process for the existing Alferon N Injection® Work-In-Progress inventory was started up again in May 2010 towards the manufacture of new Finished Goods.

Note 5: Marketable Securities

Marketable securities consist of fixed income securities with remaining maturities of greater than three months at the date of purchase, debt securities and equity securities. As of March 31, 2011, it was determined that some of the Marketable Securities had other than temporary impairments for a total of approximately $147,000 in loss, which has been included with interest and other income for reporting purposes. At March 31, 2011, all securities were classified as available for sale investments and $21,770,000 were measured as Level 1 instruments and $18,811,000 were measured as level 2 instruments of the fair value measurements standard (see Note 10: Fair Value). Securities classified as available for sale consisted of:

March 31, 2011
(in thousands)

Name Of Security	Cost	Fair Value	Unrealized Gain (Loss)	Maturity Date
Marketable Securities with maturity periods less than one year:				
Bank of America	500	500	-	4/21/2011
Merrick Bank	250	250	-	4/21/2011
Discover Bank	250	250	-	6/23/2011
General Dynamics	753	753	-	7/15/2011
Wells Fargo	1,018	1,018	-	8/1/2011
Bank of America	1,015	1,015	-	8/15/2011
Shell International	755	754	(1)	9/22/2011
Wachovia Bank	264	264	-	9/28/2011
Plainscapital Bank	250	251	1	10/31/2011
Bank One Corp.	1,031	1,031	-	11/15/2011
Merck & Co.	769	769	-	11/15/2011
Morgan Stanley	1,051	1,036	(15)	1/9/2012
PIMCO	22,200	21,770	(430)	NA
Total Marketable Securities with maturity periods less than one year:	$ 30,106	$ 29,661	$ (445)	
Marketable Securities with maturity periods greater than one year:				
Wright Expert Financial Services	250	251	1	4/26/2012
Citibank NA	250	251	1	4/30/2012
GE Capital	104	103	(1)	5/29/2012
Sallie Mae Bank	104	103	(1)	5/29/2012
Bank of Northern Miami	250	251	1	7/30/2012
Merrill Lynch	1,067	1,062	(5)	8/15/2012
Merrill Lynch	810	797	(13)	8/15/2012
Wells Fargo	1,066	1,055	(11)	9/1/2012
Israel Discount Bank	250	250	-	9/11/2012
Allstate	114	111	(3)	9/16/2012
Park Sterling Bank	250	251	1	10/16/2012
Columbus Bank & Trust Company	250	252	2	10/22/2012
JP Morgan Chase	2,153	2,134	(19)	1/2/2013
Barclays Bank	1,023	1,017	(6)	1/23/2013
World's Foremost Bank	103	103	-	1/28/2013
Merrill Lynch	539	529	(10)	2/5/2013
World’s Foremost Bank	104	103	(1)	3/4/2013
Goldman Sachs	250	251	1	6/17/2013
Royal Bank of Scotland	1,031	1,023	(8)	8/23/2013
Royal Bank of Scotland	1,022	1,023	1	8/23/2013

Total Marketable Securities with maturity periods greater than one year:	$ 10,990	$ 10,920	$ (70)
Total Marketable Securities	$ 41,096	$ 40,581	$ (515)

No investment was pledged or restricted at March 31, 2011.

Note 6: Accrued Expenses

Accrued expenses consist of the following:

	(in thousands)	
	December 31, 2010	March 31, 2011
Compensation	$ 995	$ 228
Professional fees	207	113
Other expenses	128	288
Other liability	113	113
	$ 1,443	$ 742

Note 7: Capital Lease

The Company has acquired equipment under capital leases as follows:

	(in thousands)
	Asset Balance at March 31, 2011
Leased Equipment included with property and equipment	$ 227
Less: accumulated depreciation	(29)
	$ 198

The following is a schedule by year of future minimum lease payments under the capital leases as of March 31, 2011:

	(in thousands)
2011	$ 67
2012	57
2013	45
2014	34
2015	22
2016	1
Total lease payments remaining	226
Less: amount representing interest	(57)
Present value of remaining minimum lease payments	169
Less: current obligations under lease obligations	(61)
Long-term capital lease obligations	$ 108

Minimum lease payments under the capital leases range from $576 per month to $2,994 per month and the lease periods range from 24 months to 60 months. Imputed rates are 2% to 24% per annum. Aggregate security deposits of $13,031 were paid and are included in other assets.

Note 8: Construction in Progress

On September 16, 2009, our Board of Directors approved up to $4.4 million for full engineering studies, capital improvements, system upgrades and introduction of building management systems to enhance production of three products: Alferon N Injection®, Alferon® LDO and Ampligen®. Construction in progress consists of accumulated costs for the construction and installation of property and equipment within the Company's New Jersey facility until the assets are placed into service. As of December 31, 2010, construction in progress was $485,000 as compared to $630,000 for the three months ended March 31, 2011. These enhancements to our FDA licensed facility in New Brunswick, NJ are designed to accommodate larger production volumes of Alferon N Injection®.

Note 9: Stockholders' Equity

The Equity Compensation Plan effective May 1, 2004, authorized the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 8,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Plan of 2004. Unless sooner terminated, the Equity Compensation Plan of 2004 will continue in effect for a period of 10 years from its effective date. Prior to March 31, 2011, the Company effectively exhausted this plan by previously issuing an aggregate of 7,989,981 shares, stock options and warrants to vendors, Board Members, Directors and consultants under the 2004 Equity Compensation Plan. The shares had prices ranging from $0.35 to $0.89 based on the NYSE Amex closing price. The stock options had various exercise prices ranging from $1.30 to $6.00, had terms of five to ten years and vesting immediately to three years.

The Equity Incentive Plan of 2007, effective June 20, 2007, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 9,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan of 2007. Unless sooner terminated, the Equity Incentive Plan of 2007 will continue in effect for a period of 10 years from its effective date. The Company issued to vendors, Board Members, Directors and consultants, shares, stock options, warrants and "Incentive Rights" under the Employee Wages or Hours Reduction Program. Prior to March 31, 2011, the Company effectively exhausted this plan by previously issuing an aggregate of 8,980,374 shares and shares issuable upon exercise/conversion of the foregoing securities. The aggregate shares to vendors, Board Members, Directors and consultants had prices ranging from $0.32 to $2.54 based on the NYSE Amex closing price. The stock options had various exercise prices ranging from $0.72 to $3.05, terms of ten years and vesting over varying periods.

The Company utilized the Black-Scholes-Merton Pricing Model to arrive at the fair value of the stock options which had been issued during the three months ended March 31, 2011 and accordingly recorded approximately $7,000 as equity based compensation for these issuances during this period. The stock options generally vested immediately upon grant with the exception of 20,000 options to an executive employee which vest over 18 months, and 150,000 options to another executive employee which vest over 48 months.

The Equity Incentive Plan of 2009, effective June 24, 2009, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 15,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan of 2009. Unless sooner terminated, the Equity Incentive Plan of 2009 will continue in effect for a period of 10 years from its effective date. As of March 31, 2011 the Company issued 3,496,113 securities to Directors and consultants consisting of an aggregate of 2,880,370 options and 615,743 shares of common stock issuable upon exercise/conversion of the foregoing securities. The shares issued to consultants had prices ranging from $0.40 to $0.68 based on the NYSE Amex closing price.

The aggregate stock options had various exercise prices ranging from $0.51 to $2.81, had terms of ten years and vested immediately upon grant.

Pursuant to a May 28, 2010 Equity Distribution Agreement (the "Agreement") with Maxim Group LLC ("Maxim"), the Company established an At-The-Market ("ATM") Equity Program pursuant to which the Company may sell up to 32,000,000 shares of its Common Stock from time to time through Maxim as its sales agent (the "Agent"). Under the Agreement, the Agent is entitled to a commission at a fixed commission rate of 4.0% of the gross sales price per Share sold, up to aggregate gross proceeds of $10,000,000, and, thereafter, at a fixed commission rate of 3.0% of the gross sales price per Share sold. The Company has no obligation to sell any shares under this program, and may at any time terminate the Agreement. During the fiscal quarter ended March 31, 2011, the Company sold no shares through this program and received no net cash proceeds. As of March 31, 2011, the Company has sold an aggregate of 520,000 shares that resulted in net cash proceeds of approximately $293,000 and commissions paid to Maxim of approximately $12,000.

The proceeds from this financing have been used to fund infrastructure growth including manufacturing, regulatory compliance and market development.

Note 10: Fair Value

The Company is required under U.S. Generally Accepted Accounting Principles ("GAAP") to disclose information about the fair value of all the Company's financial instruments, whether or not these instruments are measured at fair value on the Company's consolidated balance sheet.

The Company estimates that the fair values of cash and cash equivalents, other assets, accounts payable and accrued expenses approximate their carrying values due to the short-term maturities of these items.

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

time between the date of the public announcement of the applicable Fundamental Transaction and the Warrant expiration date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg as of the Trading Day immediately following the public announcement of the applicable Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (D) a remaining option time equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Warrant expiration date.

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

Fair value at March 31, 2011, was estimated using the following assumptions:

Underlying price per share	$0.46
Exercise price per share	$1.31-$1.65
Risk-free interest rate	1.34%-1.58%
Expected holding period	3.13-3.63 yrs.
Expected volatility	118.32%-118.98%
Expected dividend yield	None

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

(i) Risk-Free Interest Rate. The risk-free interest rates for the Warrants are based on U.S Treasury constant maturities for periods commensurate with the remaining expected holding periods of the warrants.
(ii) Expected Holding Period. The expected holding period represents the period of time that the Warrants are expected to be outstanding until they are exercised. The Company utilizes the remaining contractual term of the Warrants at each valuation date as the expected holding period.
(iii) Expected Volatility. Expected stock volatility is based on daily observations of the Company's historical stock values for a period commensurate with the remaining expected holding period on the last day of the period for which the computation is made.
(iv) Expected Dividend Yield. Expected dividend yield is based on the Company's anticipated dividend payments over the remaining expected holding period. As the Company has never issued dividends, the expected dividend yield is $-0- and this assumption will be continued in future calculations unless the Company changes its dividend policy.
(v) Expected Probability of a Fundamental Transaction. The possibility of the occurrence of a Fundamental Transaction triggering a Put right is extremely remote. As discussed above, a Put right would only arise if a Fundamental Transaction 1) is an all cash transaction; (2) results in the Company going private; or (3) is a transaction involving a person or entity not traded on a national securities exchange. The Company believes such an occurrence is highly unlikely because:

a. The Company only has one product that is FDA approved;
b. The Company will have to perform additional clinical trials for FDA approval of its flagship product;
c. Industry and market conditions continue to include a global market recession, adding risk to any transaction;
d. Available capital for a potential buyer in a cash transaction continues to be limited;
e. The nature of a life sciences company is heavily dependent on future funding and high fixed costs, including Research & Development; and
f. The Company's Rights Agreement makes it less attractive to a potential buyer.

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

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

The Monte Carlo Simulation has consistently incorporated a 5.0% probability of a Fundamental Transaction from the initial valuation of May 2009 through March 31, 2011.

(vi) Expected Timing of Announcement of a Fundamental Transaction. As the Company has no specific expectation of a Fundamental Transaction, for reasons elucidated above, the Company utilized a discrete uniform probability distribution over the Expected Holding Period to model in the potential announcement of a Fundamental Transaction occurring during the Expected Holding Period.
(vii) Expected 100 Day Volatility at Announcement of a Fundamental Transaction. An estimate of future volatility is necessary as there is no mechanism for directly measuring future stock price movements. Daily observations of the Company’s historical stock values for the 100 days immediately prior to the Warrants’ grant dates, with a floor of 100%, were utilized as a proxy for the future volatility.
(viii) Expected Risk-Free Interest Rate at Announcement of a Fundamental Transaction. The Company utilized a risk-free interest rate corresponding to the forward U.S. Treasury rate for the period equal to the time between the date forecast for the public announcement of a Fundamental Transaction and the Warrant expiration date for each simulation.
(ix) Expected Time Between Announcement and Consummation of a Fundamental Transaction. The expected time between the announcement and the consummation of a Fundamental Transaction is based on the Company’s experience with the due diligence process performed by acquirers, and is estimated to be six months. The Monte Carlo Simulation approach incorporates this additional period to reflect the delay Warrant Holders would experience in receiving the proceeds of the Put.

While the assumptions remain consistent from period to period (e.g., utilizing historical stock prices), the numbers input change from period to period (e.g., the actual historical prices input for the relevant period). The carrying amount and estimated fair value of the above warrants was approximately $2,504,000 at March 31, 2011. There were no other financial instruments at March 31, 2011.

On January 1, 2008, the Company adopted new accounting guidance (codified at FASB ASC 820 and formerly Statement No. 157 Fair Value Measurements) that defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The guidance does not impose any new requirements around which assets and liabilities are to be measured at fair value, and instead applies to asset and liability balances required or permitted to be measured at fair value under existing accounting pronouncements. The Company measures its warrant liability for those warrants with a cash settlement feature at fair value. As of March 31, 2011, the Company had no derivative assets or liabilities.

FASB ASC 820-10-35-37 (formerly SFAS No. 157) establishes a valuation hierarchy based on the transparency of inputs used in the valuation of an asset or liability. Classification is based on the lowest level of inputs that is significant to the fair value measurement. The valuation hierarchy contains three levels:

- Level 1 – Quoted prices are available in active markets for identical assets or liabilities at the reporting date.
- Level 2 – Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or other valuation techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation. As of March 31, 2011, the Company has classified the Warrants with cash settlement features as Level 3. Management evaluates a variety of inputs and then estimates fair value based on those inputs. As discussed above, the Company utilized the Monte Carlo Simulation Model in valuing these Warrants.

The table below presents the balances of assets and liabilities measured at fair value on a recurring basis by level within the hierarchy as of March 31, 2011:

	Total	Level 1	Level 2	Level 3
Assets				
Marketable Securities	$ 40,581,000	$ 21,770,000	$ 18,811,000	$ -
Liabilities				
Warrants	2,504,000	-	-	2,504,000
Total	$ 43,085,000	$ 21,770,000	$ 18,811,000	$ 2,504,000

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

	Fair Value of Redeemable Warrants (in thousands)	
	2010	2011
Balance at January 1	$ 3,684	$ 2,805
Fair value adjustment at March 31	1,336	(301)
Balance March 31	$ 5,020	$ 2,504

NOTE 11: Cash And Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

NOTE 12: Recent Accounting Pronouncements

The Financial Accounting Standards Board ("FASB") has published FASB Accounting Standards Update 2011-01 and 2011-02 in the three months ended March 31, 2011. The adoption of published FASB Accounting Standards Update 2011-01 and 2011-02 has no material effect on the Company's financial statements for the three months ended March 31, 2011.

NOTE 13: Funds Received From Sale Of Income Tax Net Operating Losses

As of December 31, 2010, the Company had approximately $102,000,000 of federal net operating loss carryforwards (expiring in the years 2011 through 2030) available to offset future federal taxable income. The Company also had approximately $37,000,000 of Pennsylvania state net operating loss carryforwards (expiring in the years 2018 through 2030) and approximately $38,000,000 of New Jersey state net operating loss carry forwards (expiring in the years 2011 through 2017) available to offset future state taxable income. In February 2011, the Company effectively sold $28,000,000 of its New Jersey state net operating loss carry forwards (for the years 2003 through 2008) for $2,271,928. The utilization of certain state net operating loss carryforwards may be subject to annual limitations.

NOTE 14: Subsequent Events

The Company evaluated subsequent events through the date on which these financial statements were issued, and other than that disclosure of an April 2011, correspondence received from Biken confirming that the Material Evaluation Agreement ("MEA") had expired without completion of the Evaluation Program along with their intension not to extend or replace the expired MEA with another agreement, we have determined that no other subsequent event constituted a matter that required disclosure or adjustment to the financial statements for the three months ended March 31, 2011. Biken noted in this correspondence that it previously had concluded that "it was possible that Ampligen® would not satisfy the requirements for safety as an adjuvant for influenza vaccines" in Japan and that, after rechecking Hemispherx's basis for disagreement with that finding, it concluded that it could not reconcile the differences between Hemispherx's and its interpretation of experimental results regarding the evaluation of Ampligen® as a candidate adjuvant in influenza vaccines. The Company disputes Biken's findings, and as a result of their intension not to extend or replace the MEA or complete the related Evaluation Program, the Company has concluded that its association with Biken has come to a conclusion with no expected future association.

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

Special Note Regarding Forward-Looking Statements

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

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

Overview

General

We are a specialty pharmaceutical company based in Philadelphia, Pennsylvania and engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. We were founded in the early 1970s doing contract research for the National Institutes of Health. Since that time, we have established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of natural interferon and nucleic acids to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of certain chronic diseases. We have three domestic subsidiaries BioPro Corp., BioAegean Corp., and Core BioTech Corp., all of which are incorporated in Delaware and are dormant. Our foreign subsidiary is Hemispherx Biopharma Europe N.V./S.A. established in Belgium in 1998, which has minimal activity. All significant intercompany balances and transactions have been eliminated in consolidation.

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

We own and operate a 43,000 sq. ft. FDA licensed manufacturing facility in New Brunswick, NJ that was primarily designed to produce Alferon®. On September 16, 2009, our Board of Directors approved up to $4.4 million for full engineering studies, capital improvements, system upgrades and introduction of building management systems to enhance production of three products: Alferon N Injection®, Alferon® LDO and Ampligen®. 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.

Ampligen®

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

On November 25, 2009, we received a Complete Response Letter ("CRL") from the FDA which described specific additional recommendations related to the Ampligen® NDA. In accordance with its 2008 Complete Response procedure, the FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues. Most notably, the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen® and recommended at least one additional clinical study which shows convincing effect and confirms safety in the target population. The FDA indicated that the additional study should be of sufficient size and sufficient duration (six months) and include appropriate monitoring to rule out the generation of autoimmune disease. In addition, patients in the study should be on more than one dose regimen, including at least 300 patients on dose regimens intended for marketing. In designing and implementing these additional trials, we believe that it would be very valuable to first have the capability of utilizing a reliable diagnostic test to better identify potential participants. We are therefore pursuing efforts to identify and validate such a test (see "Progress In Search For CFS Test" below). In the Non-Clinical area, the FDA recommended among other things that we complete rodent carcinogenicity studies in two species.

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

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

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

In December 2010, the FDA granted us a one year extension to file a response to the CRL based on the submission of new data concerning the potential viral etiology of CFS. We are presently enlarging our open label CFS clinical trials in the USA in an attempt obtain more data on possible interrelationships between CFS and XMRV (see below) and the therapeutic response to Ampligen®. The Company is diligently working to address the diagnostic challenges related to CFS.

Progress In Search For CFS Test

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

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

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

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

In May 1997, the FDA approved an open-label treatment protocol, ("AMP 511"), allowing patient access to Ampligen® for treatment. The data collected from the AMP 511 protocol provides safety data on the use of Ampligen® in patients to identify adverse events that occur in a patient to determine if it is related to the drug being tested or other health problems identified in trial participants. In order to facilitate the next phase of collaboration with the WPI, the AMP 511 protocol is in the process of being revised to include monitoring patient samples for XMRV in order to observe a possible relationship between the magnitude of a patient's response to Ampligen® and XMRV viral activity.

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

Alferon N Injection®

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

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

Commercial sales of Alferon N Injection® were halted in March 2008 when our finished goods inventory expired. We are in the process of upgrading our manufacturing capability for Alferon N Injection® at our New Brunswick facility. As a result, we expect to be in a position to resume manufacture of Alferon N Injection®

Alferon® Low Dose Oral (LDO)

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

In October 2009, we submitted a protocol to the FDA proposing to conduct a Phase II, double-blind, adaptive-design, randomized, placebo-controlled, dose-ranging study of Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. Following a teleconference with the FDA in November 2009, the FDA placed the proposed study on "Clinical Hold" because the protocol was deemed by the FDA to be deficient in design, and because of the need for additional information to be submitted in the area of chemistry, manufacturing and controls ("CMC"). On December 22, 2010, the FDA informed us that it had completed its review of our complete response to the Clinical Hold and lifted the Clinical Hold, allowing our Phase II Study to proceed. We are in the early stages of preparation for the Phase II Study with geographic site selection underway.

Other Viral Diseases

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

Ampligen® as a mucosal adjuvant with vaccine has been studied at Japan's National Institute of Infectious Disease ("NIID") and at Biken (the for profit operational arm of the Foundation for Microbial Diseases of Osaka University). Investigators from Japan's NIID have conducted studies in animals that suggested that Ampligen® could stimulate a sufficiently broad immune response to provide cross-protection against a range of virus genetic types, including H5N1 and derivative clades. Japan's Council for Science & Technology Policy ("CSTP"), a cabinet level position, awarded funds from Japan's CSTP to advance research with influenza vaccines utilizing Ampligen®. Dr. Hideki Hasegawa, M.D., Ph.D., Chief of Laboratory of Infectious Disease Pathology for the Department of Pathology for the NIID, undertook studies in 2009 and continued in 2010 that focus on mucosal immunity and the inherent advantages of a vigorous immune response to respiratory pathogens. Dr. Hasegawa has published data that the formulation of pandemic vaccine mixed with Ampligen® increases immuno-genicity and may demonstrate cross protection against mutated strains.

A Material Evaluation Agreement ("MEA") regarding Ampligen® with Biken that was initiated on August 19, 2009, effectively expired on September 1, 2010. Pursuant to the MEA, we supplied Biken with proprietary information related to Ampligen® and Biken purchased Ampligen® from us for use solely in connection with evaluating Ampligen® as a candidate for adjuvant incorporated into potential influenza virus vaccines in the form of intranasal mucosal administration, including conducting further animal studies of intranasal prototype vaccines containing antigens from various influenza sub-types, including H5N1, H1N1, H3N2 and B (the "Evaluation Program"). As previously reported, Hemispherx and Biken had been in correspondence concerning both the possibility of extending or replacing the expired agreement and reconciling the interpretation of experimental results. However, until such time that a new agreement could be established, no collaboration would be undertaken between the respective companies.

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

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

As a result of Biken's intension not to extend or replace the MEA or complete the related Evaluation Program, we have concluded that our association with Biken has come to a conclusion with no expected future association. Accordingly, we intend to seek out potential alternative industrial collaborator(s) in Japan to continue what we believe to be promising preclinical experimental results. Dr. Hasegawa has expressed the desire to continue the preclinical development and a plan to identify other qualified corporate vaccine partners in Japan who have flu vaccines under development along with necessary facilities to test, develop and commercialize the vaccine enhancement approach to achieve cross-protection against pandemic strains.

In April 2010, we began the process to undertake a clinical study with Max Neeman International, a leading and large clinical research organization in India. This collaborative clinical research effort is intended to utilize Alferon N Injection® for treatment of seriously ill patients hospitalized with either seasonal influenza or pandemic influenza. The Indian site selection process was initiated and we obtained approval to begin the study from the Indian Drugs Controller General on July 13, 2010. We began enrolling subjects in September 2010 and continue to enroll subjects through the spring's rainy season, which has a reduced frequency of influenza among the population. As of March 31, 2011, we have five operational Clinical Investigative Sites, with the potential to add additional sites. Our Study has progressed at a rate slower than originally projected with difficulties encountered in the process of screening for subjects who were stricken only with influenza. In an attempt to expedite the process to qualify study subjects, we have added a second "point of care" screening test. We have had seventeen patients complete the testing. It is our objective to qualify and enroll sixty patients for the study.

401(k) Plan

We have a defined contribution plan, entitled the Hemispherx Biopharma Employees 401(k) Plan and Trust Agreement (the "401(k) Plan"). Full time employees of the Company are eligible to participate in the 401(k) Plan following one year of employment. Subject to certain limitations imposed by federal tax laws, participants are eligible to contribute up to 15% of their salary (including bonuses and/or commissions) per annum. Participants' contributions to the 401(k) Plan may be matched by the Company at a rate determined annually by the Board of Directors.

Each participant immediately vests in his or her deferred salary contributions, while Company contributions will vest over one year. The 6% Company matching contribution was terminated as of March 15, 2008 and then was reinstated effective January 1, 2010. For the three months ended March 31, 2011, the Company contributions towards the 401(k) Plan were $48,000.

New Accounting Pronouncements

Refer to “Note 12: Recent Accounting Pronouncements” under Notes To Unaudited Condensed Consolidated Financial Statements.

Disclosure About Off-Balance Sheet Arrangements

None.

Critical Accounting Policies

There have been no material changes in our critical accounting policies and estimates from those disclosed in Part I; Item 2: “Management's Discussion and Analysis of Financial Condition and Results of Operations; Critical Accounting Policies” contained in our amended and restated Annual Report on Form 10-K for the year ended December 31, 2010.

RESULTS OF OPERATIONS

Three months ended March 31, 2011 versus three months ended March 31, 2010

Net Loss

Our net loss was approximately $866,000 for the three months ended March 31, 2011, a decrease of $4,514,000 or 84% when compared to the same period in 2010. This decrease in loss for these three months was primarily due to the following changes in expense elements:

1) a decrease in Research and Development costs of approximately $356,000 or 18%;

2) a decrease in General and Administrative expenses of approximately $170,000 or 9%;

3) an increase in interest income of $128,000 from funds invested in marketable securities;

4) the receipt of funds from the sale of State New Jersey tax net operating losses for years 2003 to 2008 for $2,272,000 (See Note 13); and

5) the revaluation of the Liability related to the Redeemable Warrants resulting in a non-cash gain of $301,000 in 2011 as compared to non-cash net loss of $(1,336,000) for the same period in 2010 (See Note 11); offset by

6) an increase in Production/Cost of Goods Sold expenses of approximately $53,000 or 38%.

Net loss per share was $(0.01) for the current period versus $(0.04) per share for the same period in 2010. The number of shares of our Common Stock outstanding as of March 31, 2011 was 135,335,807.

Revenues

Revenues from our Ampligen® Cost Recovery Program increased $10,000 or 31% for the first quarter of 2011 as compared to the same time period of 2010 due to a 29% increase in the number of patients participating in the program. As previously stated, we have no Alferon N Injection® product to commercially sell at this time and all revenue was generated from the Ampligen® cost recovery clinical treatment programs.

Production/Cost of Goods Sold

Production/Cost of Goods Sold was approximately $193,000 and $140,000, respectively, for the three months ended March 31, 2011 and 2010. This increase of $53,000 or 38% was primarily due to the cost to maintain existing Alferon N Injection® and Ampligen® inventory including storage, stability testing, transport and reporting costs along with our efforts to prepare for production of Alferon N Injection® for potential future commercial sales.

Research and Development Costs

Overall Research and Development ("R&D") costs for the three months ended March 31, 2011 were approximately $1,640,000 as compared to $1,996,000 for the same period a year ago reflecting a decrease of $356,000 or 18%. The primary factors for the decrease in expenses were decreased clinical costs, and research and development costs related to Alferon® LDO.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended March 31, 2011 and 2010 were approximately $1,799,000 and $1,969,000, respectively, reflecting a decrease of $170,000 or 9%. The lower G&A expenses in 2011 consisted primarily of a decrease in legal fees due to settlement in 2010 of various legal proceedings.

Interest and Other Income

Interest and other income for the three months ended March 31, 2011 and 2010 was approximately $157,000 and $29,000, respectively, representing an increase of $128,000 or 441%. The primary cause for the increase of interest income in 2011 was the investment into a diverse portfolio of short and long term investments during 2010. The interest income from these investments is recognized as the investments mature.

Redeemable Warrants

The quarterly fiscal revaluation resulted in non-cash adjustments to the Redeemable Warrants Liability on March 31, 2011 and 2010 of approximately $301,000 and $(1,336,000), respectively, representing an increase of $1,637,000. See "Note 10: Fair Value".

Liquidity and Capital Resources

Cash used in operating activities for the three months ended March 31, 2011 was $1,818,000 compared to $3,925,000 for the same period in 2010, a decrease of $2,107,000 or 54%. As of December 31, 2010, the Company had approximately $38,000,000 of New Jersey state net operating loss carry forwards (expiring in the years 2011 through 2017) available to offset future state taxable income. In February 2011, the Company effectively sold $28,000,000 of its New Jersey state net operating loss carry forwards (for the years 2003 through 2008) for approximately $2,272,000. Excluding the proceeds from this sale of net operating loss carry forwards, cash used in operating

activities for the three months ended March 31, 2011 increased by approximately $165,000 over the prior period. As of March 31, 2011, we had approximately $42,828,000 in Cash, Cash Equivalents and Marketable Securities, or a decrease of approximately $1,559,000 from December 31, 2010.

We have been using the proceeds from our financings with the assistance of Rodman & Renshaw, LLC ("Rodman") as placement agent and from Fusion Capital Fund II, LLC ("Fusion Capital") equity financing to fund operating expense and infrastructure growth including preparation for manufacturing, regulatory compliance and market development costs related to the FDA approval process for Ampligen®. During 2009, we raised in the aggregate approximately $33,712,000 in equity financing pursuant to the two Rodman financings in May 2009 along with an aggregate of approximately $28,112,000 in equity financing pursuant to the Fusion Capital Agreement during 2008 and 2009.

Pursuant to our May 28, 2010 Equity Distribution Agreement (the "Agreement") with Maxim Group LLC ("Maxim"), we established an At-The-Market ("ATM") Equity Program pursuant to which we may sell up to 32,000,000 shares of our Common Stock from time to time through Maxim as our sales agent (the "Agent"). Under the Agreement, the Agent is entitled to a commission at a fixed commission rate of 4.0% of the gross sales price per Share sold, up to aggregate gross proceeds of $10,000,000, and, thereafter, at a fixed commission rate of 3.0% of the gross sales price per Share sold. We have no obligation to sell any shares under this program, and may at any time terminate the Agreement. During the quarter ended March 31, 2011, we sold no shares through this program and received no net cash proceeds. As of March 31, 2011, we sold an aggregate of 520,000 shares through the ATM that resulted in net cash proceeds of approximately $293,000 and commissions paid to Maxim of approximately $12,000.

There can be no assurances that, if needed, we will be able to raise adequate funds from these or other sources. Our inability to raise such funds, if needed, could have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash. Because of our long-term capital requirements, we may seek to access the public equity market whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. We may also need additional funding earlier than anticipated, and our cash requirements, in general, may vary materially from those now planned, for reasons including, but not limited to, changes in our research and development programs, clinical trials, acquisitions of intellectual property or assets, enhancements to the manufacturing process, competitive and technological advances, the regulatory processes including the commercializing of Ampligen® products or new utilization of Alferon® products.

Our ability to raise additional funds from the sale of equity securities is limited because we only have approximately 32,200,000 shares authorized but unissued and unreserved. We were unable to gather the requisite votes at our annual stockholders' meeting held in June 2009 to amend our Certificate of Incorporation to increase the number of authorized shares of Common Stock from 200,000,000 to 350,000,000. Since we have not been able to obtain approval to increase the number of authorized shares of Common Stock, the amount of proceeds we may receive from the sale of our remaining Common Stock is limited (please see "Part II – OTHER INFORMATION, ITEM 1A. Risk Factors; We may require additional financing which may not be available; The limited number of shares of common stock available for financing or other purposes may hinder our ability to raise additional funding or utilize equity securities for other corporate purposes").

ITEM 3: Quantitative and Qualitative Disclosures About Market Risk

We had approximately $42,828,000 in Cash, Cash Equivalents and Marketable Securities at March 31, 2011. In the past, we had invested the excess cash in minimal risk exposure, three to twelve month interest bearing financial instruments. However with the current state of the market and our funds well in excess of our short-term operational needs, our Board has reassessed our cash investment strategy consistent with the following objectives to:

1. preserve, secure and control capital;
2. maintain liquidity to meet our operating cash flow requirements; and
3. maximize return subject to policies and procedures that manage risks with respect to a conservative to moderate investment exposure at high credit quality institutions.

To accomplish these goals, we entrusted our investible funds through an external investment manager at Wells Fargo Advisors with detailed investment and trading guidelines that are analyzed for compliance on an on-going basis. We have not entered into, and do not expect to enter into, financial instruments for trading or hedging purposes.

Our Cash, Cash Equivalents and Marketable Securities are invested in what Management believes to be high credit quality institutions that primarily consist of:

1. U.S. Treasury and Government Obligations;
2. Federal Agency securities sponsored by enterprises and instrumentalities;
3. Certificates of Deposit;
4. Money market funds with assets of greater than $1 Billion;
5. PIMCO Total Return Fund A;
6. Corporate debt obligations or commercial paper issued by corporations, commercial banks, investment banks and bank holding companies, rated A2/A or better by Moody’s or Standard & Poor’s or P-1 by Moody’s or A-1 or better by Standard & Poor’s; and
7. Asset-backed securities rated AAA/Aaa, P-1 or A-1+ by Moody’s or Standard & Poor’s.

While Management strives to invest our Cash and Cash Equivalents in high credit quality institutions and securities, our financial instruments are exposed to concentrations of credit risk and market change. Additionally, at times our investments may be in excess of the Federal Deposit Insurance Corporation insurance limit or not qualified for such coverage.

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, 2011 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, 2011, 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

(a)Hemispherx Biopharma, Inc. v. Johannesburg Consolidated Investments, et al., U.S. District Court for the Southern District of Florida, Case No. 04-10129-CIV.

The Company filed a Motion for Final Judgment, which was granted by the Court and Hemispherix was awarded $188 million dollars, plus interest against JCI and former JCI officers R.B. Kebble and H.C. Buitendag. The Company is in the process of attempting to domesticate the Final Judgment in South Africa and is being assisted by the South African law firm of Webber Wentzel. No gain has been recorded as to account for this judgment as a gain contingency.

(b)Cato Capital, LLC v. Hemispherx Biopharma, Inc., U.S. District Court for the District of Delaware, Case No. 09-549-GMS.

On July 31, 2009, Cato Capital LLC (“Cato”) filed suit asserting that under a November 2008 agreement, the Company owes Cato a placement fee for certain investment transactions. The Complaint seeks damages in the amount of $5,000,000 plus attorneys’ fees. The Company filed an Answer on August 20, 2009. On October 13, 2009, Cato filed a Motion seeking leave to file an Amended Complaint which proposed that Cato be permitted to add The Sage Group as an additional defendant and to bring additional causes of action against the Company arising from the defenses contained in the Answer, and increase the total amount sought to $9,830,000, plus attorneys’ fees and punitive damages. The Company filed a response objecting to the Motion, and also filed a Motion to Disqualify Cato’s Delaware attorneys on basis of a conflict of interest. On September 14, 2010, the Court granted the Company’s Motion to Disqualify Cato’s Delaware attorneys. Also on September 14, 2010, the Court granted Cato’s Motion for Leave to file an Amended Complaint, but specifically indicated that the Company could file a Motion to Dismiss, raising the arguments that the Company had previously made in response to Cato’s Motion for Leave to file an Amended Complaint. On September 16, 2010, Cato filed its Amended Complaint, and on September 30, 2010, the Company filed a Motion to dismiss all the counts of the Amended Complaint against the Company other than the breach of contract count. The timeframe for the Court's disposition of the Motion to Dismiss cannot be ascertained. In addition pursuant to an indemnification responsibility, the Company has also retained counsel to undertake the defense of the Sage Group, and a motion to dismiss has been filed on behalf of the Sage Group seeking to dismiss all claims against the Sage Group. Both motions to dismiss have been fully briefed and are awaiting disposition by the Court.

The Company believes it has meritorious defenses and is vigorously defending against this claim. There is currently no projection as to the likely outcome of the case.

(c)Hemispherx Biopharma, Inc. v. MidSouth Capital, Inc., Adam Cabibi, And Robert L. Rosenstein v. Hemispherx Biopharma, Inc. and The Sage Group, Inc., Civil Action No. 1:09-CV-03110-CAP.

On June 4, 2009, the Company filed suit in the United States District Court for the Southern District of Florida against MidSouth Capital, Inc. (“Midsouth”) and its principals seeking monetary and injunctive relief against MidSouth's tortious interference with certain financing transactions in which the Company was engaged. The case was transferred to the Northern District of Georgia, and Holland & Knight was engaged as local counsel for the Company on November 13, 2009. On November 19, 2009, MidSouth answered the Company's Complaint and filed a Counterclaim against the Company and The Sage Group, Inc. (“Sage”) seeking to recover between $3,900,000 and $4,800,000 for fees allegedly owed to it as a result of the same financing transactions, plus attorneys' fees and punitive damages, under various contractual, quasi contractual, and tort theories. On January 12, 2010, the Company and Sage filed a Motion for Judgment on the Pleadings as to all parts of MidSouth's Counterclaim. By Order dated March 31, 2010, the Court granted the Motion with respect to MidSouth's contract claim but denied it with respect to MidSouth's other claims.

In April 2011, MidSouth filed a Notice of Appeal from the Order disposing of its claims against the Company and Sage, and the Company filed a Notice of Cross Appeal from the Order granting the Defendants' Motion for Summary Judgment on the original Complaint. The Appeals have been docketed in the Eleventh Circuit Court of Appeals, but no briefs have been filed. Costs have been taxed in the Trial Court in favor of the Company and against MidSouth in the amount of $8,631.82. MidSouth has requested costs against the Company in the amount of $8,876.29, but no action has been taken on that request.

(c) Summation.

We have not recorded any loss contingencies as a result of the above matters for the year ended December 31, 2010 or three months ended March 31, 2011. For greater detail as to legal proceedings, this section should be read in conjunction with Note 14 - Contingencies in our Annual Report on Form 10-K for the year ended December 31, 2010.

ITEM 1A. Risk Factors.

The following cautionary statements identify important factors that could cause our actual results to differ materially from those projected in the forward-looking statements made in this Form 10-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 investigational products are in various stages of clinical and pre-clinical development and require further clinical studies and appropriate regulatory approval processes before any such products can be marketed. We do not know when, if ever, Ampligen® or our other products will be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale. Please see the next risk factor.

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

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

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

Our products, including Ampligen®, are subject to extensive regulation by numerous governmental authorities in the United States ("U.S.") and other countries, including, but not limited to, the FDA in the U.S., the Health Protection Branch ("HPB") of Canada, and the Agency for the 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. While Ampligen® is authorized for use in clinical trials in the U.S. and Europe, we cannot assure you that additional clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials. In addition, although Ampligen® has been authorized by the FDA for treatment use under certain conditions, including provision for cost recovery, there can be no assurance that such authorization will continue in effect.

In July 2008, the FDA accepted for review our New Drug Application ("NDA") for Ampligen® to treat CFS, originally submitted in October 2007. On November 25, 2009, we received a Complete Response Letter ("CRL") from the FDA which described specific additional recommendations related to the Ampligen® NDA. In accordance with its 2008 Complete Response procedure, the FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues. In December 2010, the FDA granted us a one year extension to file a response to the CRL. The Company is diligently working to address the diagnostic challenges related to CFS. Please see "Overview; General; Ampligen®" above for more detailed information on the current status of the NDA and CRL.

Alferon® LDO is undergoing pre-clinical testing for possible prophylaxis against influenza. While the studies to date have been encouraging, preliminary testing in the laboratory and in animal models is not necessarily predictive of successful results in clinical testing or human treatment. No assurance can be given that similar results will be observed in clinical trials. Use of Alferon® as a possible treatment of any influenza requires prior regulatory approval. In October 2009, we submitted a protocol to the FDA proposing to conduct a Phase II study for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. As discussed above in "Overview; General; Alferon® Low Dose Oral (LDO)", in November 2009, the FDA placed the proposed study on clinical hold. On December 22, 2010, the FDA informed us that it had completed its review of our complete response to the Clinical Hold and lifted the Clinical Hold, allowing our Phase II Study to proceed.

If we are unable to generate the additional data required by the FDA or if, for that or any other reason, 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.

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, 2011, our accumulated deficit was approximately $(218,591,000). We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

We may require additional financing which may not be available; the limited number of shares of common stock available for financing or other purposes may hinder our ability to raise additional funding or utilize equity securities for other corporate purposes.

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, 2011, we had approximately $42,828,000 in Cash, Cash Equivalents and Marketable Securities. Given the harsh economic conditions, we continue to review every aspect of our operations for cost and spending reductions to assure our long-term financial stability while maintaining the resources necessary to achieve our primary objectives of obtaining NDA approval of Ampligen®, and securing a strategic partner.

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

Our ability to raise additional funds from the sale of equity securities may be limited. In this regard, we only have approximately 32,200,000 shares authorized but unissued and unreserved. We did not gather the requisite votes at our annual stockholders' meeting held in June 2009 to amend our Certificate of Incorporation to increase the number of authorized shares of Common Stock from 200,000,000 to 350,000,000. Since we have not been able to obtain approval to increase the number of authorized shares of Common Stock, the amount of proceeds we may receive from the sale of our remaining Common Stock may be limited.

There can be no assurances that we will raise adequate funds which may have a material adverse effect on our ability to develop our products or continue our operations.

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

Commercial sales of Alferon N Injection® were halted in March 2008 when our finished goods inventory expired. As a result, we have no finished good product to sell at this time. We have undertaken a major capital improvement program that continues in 2011 to enhance our manufacturing capability to produce the purified drug concentrate used in the formulation of Alferon N Injection® at our New Brunswick facility. As a result, we anticipate that new lots of Alferon N Injection® could potentially be available in mid to late 2011. Our agreement with a third party to formulate, package and label Alferon N Injection® has expired and we are seeking to either promptly renew our prior agreement with a third-party vendor or find another vendor that can provide the FDA approved services to be able to complete the manufacture of Alferon N Injection®. Also, certain of the plant and equipment improvements being implemented for production of Alferon N Injection® may require FDA review prior to sale of resulting product, and each production lot of Alferon N Injection® is subject to FDA review and approval prior to releasing the lots to be sold. In light of these contingencies, there can be no assurances that the approved Alferon N Injection® product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

Although we believe that 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 and our former contract partner in Japan has raised questions about certain safety data relating to this use.

Ampligen® has been tested as a vaccine adjuvant for H5N1, a pathogenic avian influenza virus in the laboratories of Dr. Hasegawa at the National Institute of Infectious Diseases in Japan, where the preclinical data has shown activity in preventing lethal challenge with the original N5N1 viral strain used for vaccination as well as the other related, but not identical, isolates of H5N1 virus (i.e., cross-reactivity). We had an agreement regarding Ampligen® with Biken pursuant to which we supplied Biken with proprietary information related to Ampligen® and Biken purchased Ampligen® from us for use solely in connection with evaluating Ampligen® as a candidate for adjuvant incorporated into potential influenza virus vaccines in the form of intranasal mucosal administration. Biken concluded that it was possible that Ampligen® would not satisfy the requirements for safety as an adjuvant for influenza vaccines in Japan. Biken's primary concern was related to a single intravenous high dose study in rats that resulted in an apparent toxicity when doses of Ampligen® were combined with a whole viron influenza vaccine and Carboxyl Vinyl Polymer ("CVP") or CVP alone. Additionally in both cases of Ampligen® being combined with other product(s), the dosage utilized was several hundred times higher than the intended dosage for humans by body weight and delivered intravenously, rather than the prescribed mucosal (nasal) method. We dispute Biken's findings. See "Overview; General; Other Viral Diseases" in Part I above.

No assurance can be given that positive results will be observed in clinical trials. Use of Ampligen® in the treatment of influenza requires prior regulatory approval. Only the FDA or other corresponding regulatory agencies world-wide can determine whether a drug is safe, effective and appropriate for treating a specific application. As discussed above, obtaining regulatory approvals is a rigorous and lengthy process (see "Our drugs and related technologies are investigational and subject to regulatory approval. If we are unable to obtain regulatory approval, our operations will be significantly adversely affected" above).

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

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

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

To date, no consistent policy has emerged regarding the breadth of protection afforded by pharmaceutical and biotechnology patents. There can be no assurance that new patent applications relating to our products 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 all employees and certain consultants to enter into confidentiality agreements with us. There can be no assurance that these agreements will not be breached, that we would have adequate and enforceable remedies for any breach, or that any trade secrets of ours will not otherwise become known or be independently developed by competitors.

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

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

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

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 and services. If we are unable to obtain the required raw materials and/or services, we may not be able to manufacture Alferon N Injection® and/or Ampligen®.

A number of essential materials are used in the production of Alferon N Injection®. We do not have, but are working towards having long-term agreements for the supply 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 organizations in the United States available to provide the final steps in the in manufacturing Alferon N Injection®. At present, we currently do not have an agreement with a third-party vendor to provide needed cGMP formulation, packaging and labeling services related to the final steps to manufacture of Alferon N Injection®. We are currently in negotiations with potential third-party vendors to provide such services necessary to complete the manufacture of Alferon N Injection® as to allow for potential commercial sales by mid to late 2011.

We outsource certain components of our research and development, manufacturing, marketing and distribution while maintaining control over the entire process through our Quality Assurance Group and our Clinical Monitoring Group. We had a Supply Agreement through March 1, 2011 with Hollister-Stier Laboratories LLC of Spokane, Washington (“Hollister-Stier”), pursuant to which Hollister-Stier would formulate and package Ampligen® from the key raw materials that we would supply to Hollister-Stier. We currently are negotiating with Hollister-Stier to renew the supply agreement. If we are unable to renew or extend the Hollister-Stier agreement, we will need to seek out an alternative vendor to formulate and package Ampligen® so that final manufacturing steps can be undertaken.

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 in the quantities necessary for clinical testing.

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

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

Changes in methods of manufacturing, including commercial scale-up, may affect the chemical structure of Ampligen® and other RNA drugs, as well as their safety and efficacy. The transition from limited production of pre-clinical and clinical research quantities to production of commercial quantities of our products will involve distinct management and technical challenges and 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, or capable of being manufactured under applicable quality standards, economically, and in commercial quantities, or successfully marketed.

We have limited manufacturing experience.

Ampligen® has been produced to date in limited quantities for use in our clinical trials, and we are dependent upon a qualified third party supplier for the manufacturing and packaging process. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a material adverse effect on us. Also, to be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. To the extent we are involved in the production process, our current facilities may not be adequate for the production of our proposed products for large-scale commercialization. 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 cGMP requirements. 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 preclinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, HPB or other regulatory product approvals more rapidly than us. There are no drugs approved for commercial sale with respect to treating ME/CFS in the United States. The dominant competitors with drugs to treat disease indications in which we plan to address include Gilead Sciences, Pfizer, Bristol-Myers Squibb, Abbott Laboratories, GlaxoSmithKline and Merck. 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 AG has FDA approval for a self-administered ointment, Veregen®, which is indicated for the topical treatment of external genital and perianal warts. Alferon N Injection® also competes with surgical, chemical, and other methods of treating genital warts. We cannot assess the impact products developed by our competitors, or advances in other methods of the treatment of genital warts, will have on the commercial viability of Alferon N Injection®. If and when we obtain additional approvals of uses of this product, we expect to compete primarily on the basis of product performance. Our competitors have developed or may develop products (containing either alpha or beta interferon or other therapeutic compounds) or other treatment modalities for those uses. There can be no assurance that, if we are able to obtain regulatory approval of Alferon N Injection® for the treatment of new indications, we will be able to achieve any significant penetration into those markets. In addition, because certain competitive products are not dependent on a source of human blood cells, such products may be able to be produced in greater volume and at a lower cost than Alferon N Injection®. Currently, our wholesale price on a per unit basis of Alferon N Injection® is higher than that of the competitive recombinant alpha and beta interferon products.

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

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

Ampligen®. We believe that Ampligen® has been generally well tolerated with a low incidence of clinical toxicity, particularly given the severely debilitating or life threatening diseases that have been treated. A mild flushing reaction has been observed in approximately 15-20% of patients treated in our various studies. This reaction is occasionally accompanied by a rapid heart beat, a tightness of the chest, urticaria (swelling of the skin), anxiety, shortness of breath, subjective reports of "feeling hot", sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by reducing the rate of infusion. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, transient visual disturbances, slow or irregular heart rate, decreases in platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills, fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months. One or more of the potential side effects might deter usage of Ampligen® in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product. Biken concluded that it was possible that Ampligen® would not satisfy the requirements for safety as an adjuvant for influenza vaccines in Japan. Biken's primary concern was related to a single intravenous high dose study in rats that resulted in an apparent toxicity when doses of Ampligen® were combined with a whole viron influenza vaccine and Carboxyl Vinyl Polymer ("CVP") or CVP alone. Additionally in both cases of Ampligen® being combined with other product(s), the dosage utilized was several hundred times higher than the intended dosage for humans by body weight and delivered intravenously, rather than the prescribed mucosal (nasal) method. We dispute Biken's findings. See "Overview; General; Other Viral Diseases" in Part I above.

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

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

We 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.

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

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

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

Our success is dependent on the continued efforts of our staff, especially certain doctors and researchers along with the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen®, and his knowledge of our overall activities, including patents and clinical trials. The loss of the services of Dr. Carter or other personnel key to our operations, could have a material adverse effect on our operations and chances for success. As a cash conservation measure, we have elected to discontinue the Key Man life insurance on the life of Dr. Carter. An employment agreement continues to exist with Dr. Carter that, as amended, runs until December 31, 2015. However, Dr. Carter has the right to terminate his employment upon not less than 30 days prior written notice. The loss of Dr. Carter or other key personnel or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

Uncertainty of health care reimbursement for our products.

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

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

Our business involves the controlled use of hazardous materials, carcinogenic chemicals, flammable solvents and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such

materials comply in all material respects with the standards prescribed by applicable regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident or the failure to comply with applicable regulations, we could be held liable for any damages that result, and any such liability could be significant. We do not maintain insurance coverage against such liabilities.

Risks Associated With an Investment in Our Common Stock

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

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

- announcements of the results of clinical trials by us or our competitors;
- announcement of legal actions against us and/or settlements or verdicts adverse to us;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency comments regarding the safety or effectiveness of our products, or the adequacy of the procedures, facilities or controls employed in the manufacture of our products;
- changes in U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards;
- overall investment market fluctuation;
- restatement of prior financial results;
- notice of NYSE Amex non-compliance with requirements; and
- occurrence of any of the risks described in these "Risk Factors".

Our common stock is listed for quotation on the NYSE Amex. For the three month period ended March 31, 2011, the closing price of our common stock has ranged from $0.45 to $0.55 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

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

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

Additionally, we registered with the SEC on September 29, 2009, 1,038,527 shares issuable upon exercise of certain other warrants. To the extent the exercise price of our outstanding warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the exercise price of certain of these warrants are adjusted pursuant to anti-dilution protection, the warrants could be exercisable or convertible for even more shares of common stock. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. In this regard we have registered $150,000,000 of securities for public sale pursuant to a universal shelf registration. We have allocated 32,000,000 shares under this registration statement to an At-The-Market equity offering and, as of March 31, 2011, we have sold a total of 520,000 shares pursuant to this offering.

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

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in Management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November 2002, we adopted a Stockholder Rights Plan ("Rights Plan") and, under the Rights Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one-hundredth unit of preferred stock for $30.00. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Dr. Carter, our Chief Executive Officer, who already beneficially owns 5.65% of our common stock, the Rights Plan's threshold will be 20%, instead of 15%. The Rights Plan will expire on November 19, 2012, and may be redeemed prior thereto at $.01 per Right under certain circumstances.

Special Note Regarding Forward Looking Statements

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

ITEM 2: Unregistered Sales of Equity Securities and Use of Proceeds

During the quarter ended March 31, 2011, we issued an aggregate of 94,199 shares to consultants and vendors 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 or pursuant to our Registration Statement on Form S-8.

We did not repurchase any of our securities during the quarter ended March 31, 2011.

ITEM 3: Defaults upon Senior Securities

None.

ITEM 4: Removed and Reserved

ITEM 5: Other Information

An Employee Agreement with Wayne Springate, effective May 1, 2011 and executed May, 3, 2011, superseded that of his January 1, 2007 with following major changes:

1. Promotion to Senior Vice President from Vice President of Operations;
2. A one year term, with an evergreen provision initiated 120 days prior to the initial termination date, utilizing the most current agreement format for Named Executive Officers;
3. The new agreement allows for automatic extension of term for three additional years in the case of a change of control;
4. The opportunity for a performance bonus was increased from 20% to 25% of his base salary, but ultimately remained at the sole discretion of the Compensation Committee; and
5. The granting of non-qualified options was increased from 20,000 to 50,000 shares.

For more detailed information, please see the Springate Employment Agreement filed herewith as Exhibit 10.1.

ITEM 6: Exhibits

(a) Exhibits

10.1 Employee Agreement with Wayne Springate, Senior Vice President of Operations, effective May 1, 2011 and executed May, 3, 2011.

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

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

32.1

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

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

HEMISPHERX BIOPHARMA, INC.

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

/s/ Charles T. Bernhardt
Charles T. Bernhardt, CPA
Chief Financial Officer

Date: May 6, 2011