HEMISPHERX BIOPHARMA INC
Form 10-Q
May 07, 2012

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, 2012

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 (§232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files).

xYes ¨ 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

135,950,160 shares of common stock were outstanding as of May 1, 2012.

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)

	March 31, 2012 (Unaudited)	December 31, 2011 (Audited)
Current assets:		
Cash and cash equivalents	$ 3,650	$ 3,103
Marketable securities – unrestricted	25,466	26,229
Marketable securities – restricted	3,074	1,026
Inventories	1,108	897
Prepaid expenses and other current assets	346	531
Total current assets	33,644	31,786
Property and equipment, net	5,131	5,276
Patent and trademark rights, net	861	863
Marketable securities – unrestricted	0	1,958
Marketable securities – restricted	0	2,075
Construction in progress	3,032	1,484
Other assets	65	71
Total assets	$ 42,733	$ 43,513
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,456	$ 1,681
Accrued expenses	1,200	1,644
Margin Account Loan	2,277	1,695
Current portion of capital lease	49	49
Total current liabilities	5,982	5,069
Long-term liabilities		
Long-term portion of capital lease	86	99
Redeemable warrants	531	380
Total liabilities	6,599	5,548

Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $0.01 per share, authorized 5,000,000; issued and outstanding; none	0	0
Common stock, par value $0.001 per share, authorized 350,000,000 shares; issued and outstanding 135,831,977 and 135,642,303, respectively	136	136
Additional paid-in capital	264,994	264,958
Accumulated other comprehensive gain (loss)	52	(389)
Accumulated deficit	(229,048)	(226,740)
Total stockholders' equity	36,134	37,965
Total liabilities and stockholders' equity	$ 42,733	$ 43,513

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss

(in thousands, except share and per share data)

(Unaudited)

	Three months ended March 31,	
	2012	2011
Revenues:		
Clinical treatment programs	$72	$42
Total revenues	72	42
Costs and expenses:		
Production/cost of goods sold	280	193
Research and development	1,665	1,640
General and administrative	1,874	1,799
Total costs and expenses	3,819	3,632
Operating loss	(3,747)	(3,590)
Interest expense	(11)	(6)
Interest and other income	273	157
Funds received from sale of income tax net operating losses	1,328	2,272
Redeemable warrants valuation adjustment	(151)	301
Net loss	(2,308)	(866)
Other Comprehensive Income (Loss):		
Unrealized gain on Securities	397	446
Realized gain (loss) on securities	(16)	13
Less: Premium amortization	60	0
Net comprehensive loss	$(1,867)	$(407)
Basic and diluted loss per share	$(.02)	$(.01)
Weighted average shares outstanding, basic and diluted	135,787,466	135,264,635

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Income (Loss)

(in thousands except share data)

(Unaudited)

	Common Stock Shares	Common Stock $.001 Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2011	135,642,303	$ 136	$ 264,958	$ (389)	$ (226,740)	$ 37,965
Equity-based compensation	189,674	0	36	0	0	36
Net comprehensive income(loss)	0	0	0	441	(2,308)	(1,867)
Balance at March 31, 2012	135,831,977	$ 136	$ 264,994	$ 52	$ (229,048)	$ 36,134

	Common Stock Shares	Common Stock $.001 Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (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	0	48	0	0	48
Equity based compensation	0	0	27	0	0	27
Net comprehensive income (loss)	0	0	0	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.

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HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

For the Three Months Ended March 31, 2012 and 2011

(in thousands)

(Unaudited)

	2012	2011
Cash flows from operating activities:		
Net loss	$(2,308)	$(866)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	149	112
Amortization of patent and trademark rights, and royalty interest	2	106
Redeemable warrants valuation adjustment	151	(301)
Equity-based compensation	36	27
Change in assets and liabilities:		
Inventories	(211)	(110)
Prepaid expenses and other current assets	185	(104)
Accounts payable	775	19
Accrued expenses	(444)	(701)
Net cash used in operating activities	$(1,665)	$(1,818)
Cash flows from investing activities:		
Purchase of property, equipment and construction in progress	$(1,552)	$(36)
Additions to patent and trademark rights	0	(147)
Deposits on capital leases	6	(4)
Maturities of short-term and long-term investments	3,189	4,522
Purchase of short-term and long-term investments	0	(3,176)
Net cash provided by investing activities	$1,643	$1,159

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows (Continued)

For the Three Months Ended March 31 2012 and 2011

(in thousands)

(Unaudited)

	2012	2011
Cash flows from financing activities:		
Payments on capital leases	$(13)	$(14)
Proceeds from Margin Account Loan	582	0
Net cash provided by (used in) financing activities	$569	$(14)
Net increase (decrease) in cash and cash equivalents	547	(673)
Cash and cash equivalents at beginning of period	3,103	2,920
Cash and cash equivalents at end of period	$3,650	$2,247
Supplemental disclosures of non-cash investing and financing cash flow information:		
Issuance of common stock for accounts payable and accrued expenses	$0	$48
Equipment acquired by capital lease	$0	$26
Unrealized gain on investments	$441	$459
Redeemable warrants valuation adjustment	$151	$(301)
Supplemental disclosure of cash flow information:		
Cash paid for interest expense	$11	$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 the Company's annual consolidated financial statements and notes thereto.

These consolidated financial statements should be read in conjunction with the Company's consolidated financial statements for the year ended December 31, 2011, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2011.

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 which amounted to 54,057,341 and 51,811,158 shares, are excluded from the calculation of diluted net loss per share for the three months ended March 31, 2012 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. There were no option awards granted during the three months ended March 31, 2012. Accordingly, the fair values of the options granted, were estimated based on the following weighted average assumptions:

	Three Months Ended March 31,	
	2012 2011	
Risk-free interest rate	– 2.24	%
Expected dividend yield	– –	
Expected lives	– 5.0 years	
Expected volatility	– 104.47	%
Weighted average grant date fair value per options and warrants issued	– $0.34 per option for 20,000 options	

Stock option activity during the three months ended March 31, 2012 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 January 1, 2012	8,252,480	$ 2.11	5.75	$ 0
Granted	0	0	0	0
Forfeited	0	0	0	0
Outstanding March 31, 2012	8,252,480	$ 2.11	5.50	$ 0
Vested and expected to vest March 31, 2012	8,252,480	$ 2.11	5.50	$ 0
Exercisable March 31, 2012	8,135,814	$ 2.12	5.43	$ 0

No options were granted to employees during the three months ended March 31, 2012 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 January 1, 2012	148,333	$ 0.49	9.52	$ 0
Granted	0	0	0	0
Vested	(31,667)	0.32	0.80	0
Forfeited	0	0	0	0
Outstanding March 31, 2012	116,666	$ 0.54	11.57	$ 0

Stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2012	3,128,432	$ 1.87	5.25	$ 0
Granted	0	0	0	0
Exercised	0	0	0	0
Forfeited	0	0	0	0
Outstanding March 31, 2012	3,128,432	$ 1.87	5.00	$ 0
Vested and expected to vest March 31, 2012	3,128,432	$ 1.87	5.00	$ 0
Exercisable March 31, 2012	2,914,889	$ 1.95	4.82	$ 0

The weighted-average grant-date fair value of non-employee options granted during the three months ended March 31 2012 and 2011 was approximately $-0- 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 January 1, 2012	256,250	$ 0.71	8.55	$ 0
Options granted	0	0	0	0
Options vested	(42,707)	0.78	1.25	0
Options forfeited	0	0	0	0
Outstanding March 31, 2012	213,543	$ 0.70	9.71	$ 0

The impact on the Company's results of operations of recording equity-based compensation for the three months ended March 31, 2012 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, 2012 and 2011 was $0.00 and $0.00, respectively.

As of March 31, 2012 and 2011, respectively, there was $121,000 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)	
	March 31, 2012	December 31, 2011
Inventory work-in-process, January 1	$897	$ 787
Production	255	302

Spoilage	(44)	(192)
Inventory work-in-process, end of period	$1,108	$ 897

The Work-In-Process Inventory has expiration dates of September 30, 2012 through March 10, 2013. Upon the expected mid-2012 completion of the fill, finish and packaging process by Althea Technologies, Inc. ("Althea"), it is projected that Alferon N Injection® will then have an expected shelf life of 42 months. Provided the Company receives a Release Approval from the FDA as to quality and consistency of its current inventory and final product, as well as Althea is successful in the fill and finish process, the Company estimates that commercial sales of Alferon N Injection® could commence in the later part of 2012. While at March 31, 2012 and December 31, 2011 the Work-In-Process Inventory had no manufacturing steps to be undertaken at the Company's New Brunswick, NJ facility, it will not be classified as Finished Goods until the fill and finish process is completed to create a product that can be commercially sold.

Note 5: Marketable Securities - Unrestricted

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. At March 31, 2012, all securities were classified as available for sale investments and $22,144,000 were measured as Level 1 instruments and $3,322,000 were measured as level 2 instruments of the fair value measurements standard.

Securities classified as available for sale consisted of:

March 31, 2012

(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 22,087	$ 93	$ (36)	$ 22,144	$ 22,144	$ 0
Corporate Bonds	3,355	2	(35)	3,322	3,322	0
Totals	$ 25,442	$ 95	$ (71)	$ 25,466	$ 25,466	$ 0

December 31, 2011

(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 22,087	$ 0	$ (334)	$ 21,753	$ 21,753	$ 0
Certificates of Deposit	2,155	10	0	2,165	1,707	458
Corporate Bonds	4,320	0	(51)	4,269	2,769	1,500
Totals	$ 28,562	$ 10	$ (385)	$ 28,187	$ 26,229	$ 1,958

Unrealized losses on investments

Investments with continuous unrealized losses for less than 12 months and 12 months or greater and their related fair values were as follows:

March 31, 2012

(in thousands)

		Less Than 12 Months		12 Months or Greater		Totals	
Securities	Total Number In Loss Position	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	1	$ 15,026	$ (36)	$ 0	$ 0	$15,026	$ (36)
Corporate Bonds	3	2,557	(35)	0	0	2,557	(35)
Totals	4	$ 17,583	$ (71)	$ 0	$ 0	$17,583	$ (71)

December 31, 2011

(in thousands)

Securities	Total Number In Loss Position	Less Than 12 Months		12 Months or Greater		Totals	
		Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	1	$ 0	$ 0	$ 21,753	$ (334)	$21,753	$ (334)
Certificates of Deposit	0	0	0	0	0	0	0
Corporate Bonds	4	997	(16)	3,272	(35)	4,268	(51)
Totals	5	$ 997	$ (16)	$ 25,025	$ (369)	$26,021	$ (385)

Unrealized losses from fixed-income securities are primarily attributable to changes in interest rates and/or a reduction in their rating of credit worthiness as determined by independent financial rating services. Unrealized losses from domestic and international equities are due to market price movements. Management does not believe any remaining losses represent other-than-temporary impairment based on Management's evaluation of available evidence as of March 31, 2012.

Note 6: Marketable Securities - Restricted

A Margin Account was established on July 26, 2011 for which the Company needs to pledge, restrict from sale and segregate marketable securities at an approximate ratio of approximately two-to-one to serve as collateral for those funds withdrawn and outstanding (see "Note 9 Margin Account Loan").

These restricted marketable securities consist of corporate bonds with remaining maturities of greater than three months at the date of purchase, debt securities and bond funds. As of March 31, 2012, it was determined that none of the Marketable Securities had other-than-temporary impairments. At March 31, 2012, all restricted securities were classified as restricted from sale investments and $3,074,000 was measured as level 2 instruments of the fair value measurements standard (see "Note 11: Fair Value").

Securities classified as restricted from sale consisted of:

March 31, 2012

(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Corporate Bonds	$ 3,045	$ 29	$ 0	$ 3,074	$ 3,074	$ 0
Totals	$ 3,045	$ 29	$ 0	$ 3,074	$ 3,074	$ 0

December 31, 2011

(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Corporate Bonds	$ 3,115	$ 0	$ (14)	$ 3,101	$ 1,026	$ 2,075
Totals	$ 3,115	$ 0	$ (14)	$ 3,101	$ 1,026	$ 2,075

Unrealized losses on investments restricted from sale

Investments restricted from sale with continuous unrealized losses for less than 12 months and 12 months or greater and their related fair values were as follows:

March 31, 2012

(in thousands)

All restricted investments were in a gain position as of March 31, 2012.

December 31, 2011

(in thousands)

	Less Than 12 Months		12 Months or Greater		Totals	
Securities	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Corporate Bonds	$ 2,075	$ (14)	$ 0	$ 0	$2,075	$ (14)
Totals	$ 2,075	$ (14)	$ 0	$ 0	$2,075	$ (14)

Unrealized losses from fixed-income securities (bonds) are primarily attributable to changes in interest rates and/or a reduction in their rating of credit worthiness as deemed by independent financial rating services. Unrealized losses from domestic and international equities are due to market price movements. Management does not believe any remaining losses represent other-than-temporary impairment based on Management’s evaluation of available evidence as of March 31, 2012.

Note 7: Accrued Expenses

Accrued expenses consist of the following:

	(in thousands)	
	March 31, 2012	December 31, 2011
Compensation	$408	$ 921
Professional fees	68	215
Other expenses	611	495
Due for returned product	113	113
	$1,200	$ 1,644

Note 8: Property and Equipment

	March 31, 2012	December 31, 2011
Land, buildings and improvements	$ 4,209	$ 4,209
Furniture, fixtures, and equipment	4,006	4,002
Leasehold improvements	85	85
Total property and equipment	8,300	8,296
Less: accumulated depreciation and amortization	(3,169)	(3,020)
Property and equipment, net	$ 5,131	$ 5,276

Property and equipment are recorded at cost. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the respective assets, ranging from five to thirty-nine years.

Utilizing the Board of Directors approved allocation of up to $6.5 million for full engineering studies, capital improvements, system upgrades and introduction of building management systems to enhance production of Alferon®, the project has progressed to the construction phase. Construction in progress consists of accumulated costs for the construction and installation of capital improvements and process equipment within the Company's New Brunswick, New Jersey facility until the assets are placed into service. As of March 31, 2012, construction in progress was $3,032,000 as compared to $1,484,000 as of December 31, 2011.

Note 9: Margin Account Loan

A "Margin Account" loan was established with Wells Fargo Advisors for which the proceeds of this flexible form of indebtedness effectively serves the Company as a line of credit to finance the capital improvement project underway at the New Brunswick, New Jersey Manufacturing facility. In order to maintain this Margin Account, established on July 26, 2011 with an estimated maximum dollar value of $6.5 million, the Company needs to pledge, restrict from sale and segregate to a dedicated Margin Account its Marketable Securities at an approximate ratio of two to one of security collateral to debt undertaken. With the exception of collateral requirements, the Company maintains all the rights and benefits of ownership including receipt of interest, dividends or proceeds from the securities. While this Margin Account has no material establishment or maintenance fees, it currently carries an effective interest rate of approximately 3.0% per annum applied against the "Margin Debit Balance" (i.e., those funds withdrawn and outstanding), based on the prevailing "Wells Fargo Base Rate" less 2.75%. At March 31, 2012, the principal loan balance of the Margin Account was approximately $2,277,000, for which approximately $3,074,000 in Marketable Securities became restricted as dedicated collateral for the indebtedness. For the three months ended March 31, 2012, the finance charge was approximately $5,000. (see "Note 6: Marketable Securities – Restricted").

Note 10: Stockholders' Equity

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, 2012, the Company issued 5,300,466 securities to Directors and consultants consisting of an aggregate 1,111,913 shares of common stock and options to purchase 4,188,553 shares. The shares issued to consultants had prices ranging from $0.37 to $0.68 based on the NYSE Amex closing price.

The aggregate stock options had various exercise prices ranging from $0.37 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 three months ended March 31, 2012, the Company sold no shares through this program and received no net cash proceeds. As of March 31, 2012, the Company has sold an aggregate of 520,000 shares over the life of the ATM 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 11: 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.

The Company also has certain warrants with a cash settlement feature in the unlikely occurrence of a Fundamental Transaction. The fair value recalculation of the Liability resulting from the issuance of the Warrants ("Call") and existence of the Fundamental Transaction ("Put") related to the May 2009 issuance, are calculated using a Monte Carlo Simulation. While the Monte Carlo Simulation is one of a number of possible pricing models, the Company has determined it to be industry accepted and fairly presented the Fair Value of the Warrants. As an additional factor to determine the Fair Value of the Put's Liability, the occurrence probability of a Fundamental Transaction event was factored into the valuation. 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, 2012, was estimated using the following assumptions:

Underlying price per share	$0.39
Exercise price per share	$1.31-$1.65
Risk-free interest rate	0.35%-0.44 %
Expected holding period	2.13-2.63 yrs.
Expected volatility	69.2%-79.7 %
Expected dividend yield	None

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 $531,000 at March 31, 2012. There were no

other financial instruments at March 31, 2012.

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, 2012, 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. Generally, this includes debt and equity securities that are traded in an active market.
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. Generally, this includes debt and equity securities that are not traded in an active market.
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, 2012, 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, 2012:

	Total	Level 1	Level 2	Level 3
Assets:				
Marketable Securities – unrestricted	$25,466	$22,144	$3,322	$ 0
Marketable Securities – restricted	3,074	0	3,074	0
Liabilities:				
Warrants	531	0	0	531
Total	$29,071	$22,144	$6,396	$ 531

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)	
	2012	2011
Balance at January 1	$ 380	$ 2,805
Fair value adjustment at March 31	151	(302)

Balance at March 31	$ 531	$ 2,503

Note 12: **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 13: Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2011-05, Presentation of Comprehensive Income (ASU 2011-05). This standard eliminated the option to report other Comprehensive Income (Loss) and its components in the Statement of Changes in Stockholders' Equity. Under this standard, an entity can elect to present items of Net Income (Loss) and other comprehensive income (loss) in one continuous statement referred to as the Consolidated Statements of Comprehensive Income (Loss), or in two separate but consecutive, statements. In December 2011, the FASB issued Accounting Standards Update No. 2011-12, Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05 (ASU 2011-12). ASU 2011-12 defers the effective date of the requirement in ASU 2011-05 to disclose on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income on the components of Net Income and other comprehensive income. All other requirements of ASU 2011-05 are not affected by ASU 2011-12. The Company adopted ASU 2011-05 effective September 30, 2011 and indefinitely deferred certain disclosures as allowed under ASU 2011-12. In transitioning to this new presentation prior to the mandatory conversion date of 2012, Management deemed that the only material change is the reflection of our "unrealized gain or (loss) on investments" after our traditional Net Loss reporting. The expiration of deferral allowed by ASU 2011-12 is not expected to have a significant impact on our consolidated financial statements.

Note 14: Funds Received From Sale Of Income Tax Net Operating Losses

As of December 31, 2011, the Company has approximately $108,000,000 of federal net operating loss carryforwards (expiring in the years 2012 through 2030) available to offset future federal taxable income. The Company also had approximately $39,000,000 of Pennsylvania state net operating loss carryforwards (expiring in the years 2018 through 2030) and approximately $25,000,000 of New Jersey state net operating loss carryforwards (expiring in the years 2016 through 2018) available to offset future state taxable income.

In January 2012, the Company effectively sold $16,000,000 of its approximately $25,000,000 of New Jersey state Net Operating Loss carryforwards (for the years 2009 and 2010) for approximately $1,328,000. The utilization of certain state net operating loss carryforwards may be subject to annual limitations. With no tax due for the foreseeable future, the Company has determined that the accounting for interest or penalties related to the payment of tax is not necessary

at this time.

Note 15: Subsequent Events

The Company evaluated subsequent events through the date on which these financial statements were issued. The Company has determined that no subsequent event constituted a matter that required disclosure or adjustment to the financial statements for the three months ended March 31, 2012.

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 compar 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 a vaccine enhancer (adjuvant) for therapeutic and/or preventative development related to influenza and cancer treatments. Alferon N Injection® is a Food and Drug Administration (“FDA”) approved product with an indication for refractory or recurring genital warts. Alferon® LDO (Low Dose Oral) is a formulation currently under development targeting influenza.

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ that produces Alferon® and Ampligen®. In December 2011, our Board of Directors (the "Board") reevaluated its facility enhancement project to focus on converting the facility to provide for a high volume, more cost effective manufacturing process for Alferon N Injection®, Alferon® LDO and Ampligen®. In this regard, the Board increased the funding allocated to this project from $4.4 million to $6.5 million. The project is in an active construction phase with approximately $2,277,000 spent to date through March 31, 2012 and financed through a Margin Account with an effective interest rate of approximately 3.0%, as compared to $1,695,000 at December 31, 2011. While facility enhancements are being undertaken, this project has not impacted our capability to manufacture Ampligen®. The production of new Alferon® inventory product will not commence until the capital improvement phase is completed, which is projected for mid-2012. While the facility had been granted approval of its Biological License Application ("BLA") by the FDA for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements. 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.

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

Clinical trials of Ampligen® already conducted by us include studies of the potential treatment of ME/CFS, Hepatitis B, HIV and cancer patients with renal cell carcinoma and malignant melanoma. All of these potential uses will require

additional clinical trials to generate the safety and effectiveness data necessary to support regulatory approval.

In July 2008, the FDA accepted for review our NDA for Ampligen® to treat CFS, originally submitted in October 2007. We are seeking marketing approval for the first-ever treatment for CFS. At present, only supportive, symptom-based care is available for CFS patients. The NDA for Ampligen® is also the first ever accepted for review by the FDA for systemic use of a toll-like receptor therapy to treat any condition. In November 2009, we received a Complete Response Letter ("CRL") from the FDA which described specific additional recommendations related to the Ampligen® NDA. In accordance with its 2008 Complete Response procedure, the FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues. We intend to take the appropriate steps to seek approval and commercialization of Ampligen®. Most notably, the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen® and recommended at least one additional clinical study which shows convincing effect and confirms safety in the target population. The FDA indicated that the additional study should be of sufficient size and sufficient duration (six months) and include appropriate monitoring to rule out the generation of autoimmune disease. In addition, patients in the study should be on more than one dose regimen, including at least 300 patients on dose regimens intended for marketing. We are examining those two major studies for further insight into efficacy and safety. In the Non-Clinical area, the FDA recommended among other things that we complete rodent carcinogenicity studies in two species. While as part of the NDA submission we had requested that these studies be waived, this waiver had not been granted by the FDA in their CRL. Under the Product Quality section of the CRL, the FDA recommended that we submit additional data and complete various analytical procedures. The collection of these data and the completion of these procedures is already part of our ongoing Quality Control, Quality Assurance program for Ampligen® manufacturing under current Good Manufacturing Practice ("cGMP") guidelines and our manufacturing enhancement program. On January 14, 2010, we submitted reports of new preclinical data regarding Ampligen® to the FDA that we believed to be sufficient to address certain preclinical issues in the FDA's CRL. We do not anticipate receiving feedback until we re-file our NDA.

In January 2012, in response to our request for an additional extension, we were informed that, rather than grant additional formal requests for extension, FDA would instead await our complete response to the CRL. Therefore, unless we are informed by the FDA of the need to seek another formal extension, our NDA will remain open while we continue to prepare our response to the CRL. We are currently conducting an open-label treatment protocol in the U.S. and evaluating new diagnostic modalities to provide additional insights into the CFS disorder. It is our plan that the new analyses and other insights will supplement the original study findings. We believe that continued efforts to understand existing data and to advance the development of new data and information, will ultimately support a re-filing of the NDA. Thus, the Company is pursuing the filing of an amended NDA in response to FDA comments in the CRL.

There are multiple reasons for fatigue and the accurate diagnosis of CFS remains one of exclusion and adherence to strict diagnostic guidelines. We had reported at the IACFS/ME Biennial Conference held on September 22-25, 2011, in Ottawa, Ontario, Canada on new data for the potential development of a blood test for CFS that would allow greater accuracy and reduced cost in its diagnosis. This experimental approach utilized by Chronix Biomedical ("Chronix"), tests fragments of DNA released into the bloodstream during the process of apoptosis or programmed cell death reflect alterations in specific regions of the chromosome, which can be detected as distinctive "signatures" in cell-free blood-borne DNA as a function of disease process. Hemispherx and Chronix continue to collaborate in the utilization of this approach towards the development of a diagnostic tool for CFS with extension of the technology to more powerful Massively Parallel Sequencing Platforms in order to increase the statistical power per sample analyzed and explore whether the technology can be used to identify how different persons with CFS will respond to Ampligen® as

compared to placebo. While we believe that finding an accurate diagnostic for CFS is useful, it is not essential for an FDA approval of any CFS treatment including Ampligen®.

In May 1997, the FDA approved an open-label treatment protocol, ("AMP 511"), allowing patient access to Ampligen® for treatment in an open-label safety study under which severely debilitated CFS patients have the opportunity to be on Ampligen® to treat this very serious and chronic condition. The data collected from the AMP 511 protocol through a consortium group with active clinical sites in New York City, NY, Charlotte, NC, Miami, FL, Incline Village, Nevada, and Salt Lake City, UT, provides safety data on the use of Ampligen® in patients to identify adverse events that occur in a patient to determine if it is related to the drug being tested or other health problems identified in trial participants. We are currently enlisting new sites and continue to enroll patients for this study. As of March 31, 2012, we had thirty-two patients participating in this open label treatment protocol with twenty-eight taking treatment and four on drug holiday. We are establishing an enlarged data base of clinical safety information, which we believe will provide further documentation regarding the absence of autoimmune disease associated with Ampligen® treatment.

Alferon N Injection®

Alferon N Injection® is the registered trademark for our injectable formulation of natural alpha interferon, which is approved by the FDA in 1989 for the treatment of certain categories of genital warts. Alferon® is the only natural-source, multi-species alpha interferon currently approved for sale in the U.S. for the intralesional (within lesions) treatment of refractory (resistant to other treatment) or recurring external genital warts in patients 18 years of age or older. Certain types of human papilloma viruses ("HPV") cause genital warts, a sexually transmitted disease ("STD"). The Centers for Disease Control and Prevention ("CDC") estimates that approximately twenty million Americans are currently infected with HPV with another six million becoming newly infected each year.

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

Commercial sales of Alferon N Injection® were halted in March 2008 when our finished goods inventory expired. The production of Alferon N Injection® from the Work-In-Process Inventory was restarted in May 2010, continued into January 2011 with its conversion into Active Pharmaceutical Ingredient ("API") and is completed for the related Final Lot Release Test. To formulate, fill, finish and package ("fill and finish") Alferon N Injection® Drug Product, we require a FDA approved third party Contract Manufacturing Organization ("CMO"). The Work-In-Process Inventory has expiration dates of September 30, 2012 through March 10, 2013. Upon the expected mid-2012 completion of the fill and finish process, it is projected that the Alferon N Injection® will then have an expected shelf life of 42 months. In January 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea Technologies, Inc. ("Althea") regarding the fill and finish process for Alferon N Injection®. In April 2012, FDA reviewers raised certain questions about the status of some lots of our older in-process Alferon® materials and API, which would need to be released by FDA before those materials could be used in commercial product. If we receive a Release Approval from the FDA as to quality and consistency of these materials, and approval for Althea to perform

the fill and finish process, we estimate that commercial sales of Alferon N Injection® could commence in the later part of 2012. In the absence of FDA approvals for commercial sale of product manufactured from existing inventory, commercial sales of Alferon® in the United States will not resume until new batches of Alferon® inventory and API have been produced, filled and finished, and released by the FDA for sale.

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

The production of new Alferon® inventory product will not commence until the capital improvement phase is completed, at our New Brunswick, NJ facility which is projected for mid-2012.

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 December 2010, the FDA authorized a protocol 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. Our Phase II study has been delayed as we are undertaking a confirmatory study using gene expression measures to identify the systemic gene activation effects in peripheral blood leukocytes following treatment with Alferon® LDO. The outcome of this confirmatory study will allow us to evaluate better the potential effectiveness of this product and to proceed with this study of seasonal and pandemic influenza.

Other Viral Diseases

In July 2011, we received FDA authorization to proceed with the initiation of a new clinical trial of intranasal Ampligen® to be used in conjunction with commercially approved seasonal influenza vaccine. On April 16, 2012, a clinical trial was initiated in which Ampligen® is being nasally administered in conjunction with FluMist® to healthy human volunteers at the University of Alabama at Birmingham under the auspices of Dr. Paul Goepfert, Associate Professor of Medicine in the Division of Infectious Diseases and Director of the Alabama Vaccine Research Clinic. This study is a first use of Ampligen® with a seasonal vaccine in humans to assess the safety of Ampligen® when

nasally delivered as a vaccine adjuvant. Another objective of this study is to determine the extent to which Ampligen® mobilizes potential protections against pandemic influenza by utilization of a seasonal flu vaccine. The study will evaluate the potential immunologic enhancement of Ampligen® by comparing immune parameters in the group receiving Ampligen® plus FluMist® with another group receiving FluMist® plus placebo. We intend to conduct a broad array of immune tests to compare the immune response for both its magnitude and breadth. It is our objective to qualify and enroll 72 patients for this clinical trial.

In April 2010, we began the process to undertake a clinical study with Max Neeman International, a leading and large clinical research organization in India. This collaborative clinical research effort is intended to utilize Alferon N Injection® for treatment of seriously ill patients hospitalized with either seasonal influenza or pandemic influenza. The Indian site selection process was initiated and we obtained approval to begin the study from the Indian Drugs Controller General on July 13, 2010. We continue to enroll subjects with expectation of greater patient participation in the upcoming monsoon season. As of March 31, 2012, we had ten operational Clinical Investigative Sites, with the intention of adding additional sites. Thirty patients have completed the study. Our study has progressed at a rate slower than originally projected due to difficulties encountered in the process of screening for subjects with influenza, rather than other illnesses with symptoms similar to influenza, along with India experiencing an unusually mild flu season. It is our objective to qualify and enroll sixty patients for the study.

In June 2011, we entered into a Material Transfer and Research Agreement with the University of Pennsylvania's School of Medicine to provide Ampligen® for testing as a vaccine adjuvant in a human clinical study in ovarian cancer. This study is a Phase I/II randomized clinical trial for subjects with recurring ovarian, fallopian tube or primary peritoneal cancer to determine the feasibility and safety as well as immunogenicity of a vaccine comprised of autologous oxidized tumor cell lysate ("OC-L") administered by intradermal/subcutaneous injection in combination with intravenous Ampligen®. The OC-L vaccine is an experimental cancer immunotherapy under development by the University of Pennsylvania. This study represents the first use of Ampligen® as a cancer vaccine adjuvant in a randomized clinical study with and without Ampligen®. As of March 31, 2012, three patients have participated in this study.

In August 2011, a study utilizing Ampligen® was initiated by investigators from the Tumor Vaccine Group ("TVG") at the University of Washington in Seattle, WA. As of March 31, 2012, twenty-nine patients have enrolled in this eighty-eight patient Phase I-II Study of HER2 vaccination with Ampligen® as an adjuvant in optimally treated Breast Cancer patients. The goal of this study is to see how well the combination works in treating patients with Stage II-IV human epidermal growth factor receptor 2 ("HER2")-positive breast cancer. Vaccines made from synthetic HER2/neu peptides may help the body build an effective immune response to kill tumor cells that express HER-2/neu. The TVG has developed vaccines against several cancer proteins, and in this study, they are researching a new approach in an attempt to make the immune response to the vaccine even better. Compounds that specifically stimulate TLR receptors are promising immune stimulators, and Ampligen® has the potential to provide a profile of immune stimulation that could be clinically beneficial.

401(k) Plan

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, 2012, the Company contributions towards the 401(k) Plan were $42,000.

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New Accounting Pronouncements

See “Note 13: Recent Accounting Pronouncements”.

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 Annual Report on Form 10-K for the year ended December 31, 2011.

RESULTS OF OPERATIONS

Three months ended March 31, 2012 versus three months ended March 31, 2011

Net Loss

Our net loss was approximately $2,308,000 for the three months ended March 31, 2012, an increase in loss of $1,442,000 or 167% when compared to the same period in 2011. This increase in loss for these three months was primarily due to the following:

1) an increase in Research and Development costs of approximately $25,000 or 2%;

2) an increase in General and Administrative expenses of approximately $75,000 or 4%;

3) an increase in Production/Cost of Goods Sold of approximately $87,000 or 45%;

4) the revaluation of the Liability related to the Redeemable Warrants resulting in a non-cash loss of $151,000 in 2012 as compared to non-cash gain of $301,000 for the same period in 2011, resulting in an increased loss of $452,000; and

5) sale in January 2012 of $16,000,000 of our approximately $25,000,000 of New Jersey state Net Operating Loss carryforwards (for the years 2009 and 2010) for approximately $1,328,000 as compared to February 2011, when the Company effectively sold $28,000,000 of its New Jersey state Net Operating Loss carryforwards (for the years 2003 through 2008) for approximately $2,272,000, representing a decrease in non-cash gain of $944,000 or 42%; offset by

6) an increase in interest income of $116,000 from funds invested in marketable securities.

Net loss per share was $(0.02) for the current three month period versus $(0.01) per share for the same period in 2011. The weighted average number of shares of our Common Stock outstanding as of March 31, 2012 was 135,787,466 as compared to 135,264,635 as of March 31, 2011.

Revenues

Revenues from our Ampligen® Cost Recovery Program increased $30,000 or 71% for the first quarter of 2012 as compared to the same time period of 2011. The number of patients increased 37% in the three months ended March 31, 2012. As previously stated, we have no Alferon N Injection® product to commercially sell at this time and all revenue was generated from the FDA approved open-label treatment protocol, ("AMP 511"), that allows patient access to Ampligen® for treatment in an open-label safety study.

Production/Cost of Goods Sold

Production/Cost of Goods Sold was approximately $280,000 and $193,000, respectively, for the three months ended March 31, 2012 and 2011. This increase of $87,000 or 45% was primarily due to costs related to quality control testing of Alferon N Injection® Finished Goods inventory utilized in clinical studies and an increase in costs associated with the preparation of Alferon N Injection® Work In Process inventory as it is prepared for the fill, finish and packaging stage.

Research and Development Costs

Overall Research and Development ("R&D") costs for the three months ended March 31, 2012 were approximately $1,665,000 as compared to $1,640,000 for the same period a year ago reflecting a slight increase of $25,000 or 2%. The R&D efforts during this three month period in 2012 were essentially consistent compared to the prior year as we continue our efforts regarding the Ampligen® NDA and undertaking of Alferon® LDO preclinical testing.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended March 31, 2012 and 2011 were approximately $1,874,000 and $1,799,000, respectively, reflecting an increase of $75,000 or 4%. The higher G&A expenses in 2012 consisted primarily of an increase of $193,000 in legal fees due to the Cato Capital, LLC litigation and $106,000 of higher Directors' fees offset by $223,000 of lower accounting and other professional fees incurred in 2011 due to the restatement of our 2009 financials and related SEC Reports.

Interest and Other Income

Interest and other income for the three months ended March 31, 2012 and 2011 was approximately $273,000 and $157,000, respectively, representing an increase of $116,000 or 74%. The primary cause for the increase of investment income was a higher rate of return from our portfolio of short and long-term bond and fixed-income type investments during 2012. The interest income from these investments is recognized over the life of the instrument.

Redeemable Warrants

The quarterly fiscal revaluation resulted in non-cash adjustments to the Redeemable Warrants Liability on March 31, 2012 and 2011 of approximately $(151,000) and $301,000, respectively, representing a decrease of $452,000 (see "Note 11: Fair Value").

Sale of New Jersey Tax Net Operating Loss

In January 2012, the Company effectively sold $16,000,000 of its approximately $25,000,000 of New Jersey state Net Operating Loss carryforwards (for the years 2009 and 2010) for approximately $1,328,000 as compared to February 2011, when the Company effectively sold $28,000,000 of its New Jersey state Net Operating Loss carryforwards (for the years 2003 through 2008) for approximately $2,272,000, representing a decrease in gain of $944,000 or 42%. (see "Note 14**:** Funds Received From Sale of Income Tax Net Operating Losses").

Liquidity and Capital Resources

Cash used in operating activities for the three months ended March 31, 2012 was $1,665,000 compared to $1,818,000 for the same period in 2011, a decrease of $153,000 or 8%. Excluding the proceeds from this sale of New Jersey Net Operating Loss carryforwards, Cash used in operating activities for the three months ended March 31, 2012 decreased by approximately $1,097,000 or 27% over the comparable period in 2011.

As of March 31, 2012, we had approximately $32,190,000 in Cash, Cash Equivalents and Marketable Securities (restricted and unrestricted), or a decrease of approximately $2,201,000 from December 31, 2012.

A Margin Account was established on July 26, 2011, with Wells Fargo Advisors for which the proceeds of this flexible form of indebtedness effectively serves the Company as a line of credit to finance the capital improvement project underway at the New Brunswick, New Jersey Manufacturing facility (see “Note 8: Property and Equipment”). While this Margin Account has no material establishment or maintenance fees, it currently carries an effective interest rate of approximately 3.0% per annum applied against the “Margin Debit Balance” (i.e., those funds withdrawn and outstanding), based on the prevailing “Wells Fargo Base Rate” less 2.75%. As of March 31, 2012, the principal loan balance of the Margin Account was approximately $2,277,000 (see “Note 9: Margin Account Loan” and “Note 6: Marketable Securities – Restricted”).

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. In this regard, we only have approximately 31,862,000 shares authorized but unissued and unreserved and available for fund raising purposes without getting additional stockholder approval. While we recently increased the number of authorized shares of Common Stock from 200,000,000 to 350,000,000, the additional 150,000,000 shares cannot be issued for fundraising purposes without prior stockholder approval.

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ITEM 3: Quantitative and Qualitative Disclosures About Market Risk

We had approximately $32,190,000 in cash, cash equivalents and Marketable Securities (restricted and non-restricted) at March 31, 2012 as compared to $34,391,000 at December 31, 2011. To the extent that our cash and cash equivalents exceed our near term funding needs, we intend to invest the excess cash in money market accounts, high-grade corporate bonds or fixed-income type bond funds. We employ established conservative policies and procedures to manage any risks with respect to investment exposure.

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, 2012 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, 2012, 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

Except as set forth below, there have been no material developments in litigation from that disclosed in our Annual Report Form 10-K for the fiscal year ended December 31, 2011, Note 16 - Contingencies:

***(b) 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.**

Oral arguments on consolidated appeals took place before the Eleventh Circuit Court of Appeals on February 1, 2012. The Court has not yet ruled. Counsel is unable to express an opinion as to how the Court will ultimately rule regarding this litigation.

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

In accordance with a Scheduling Order set by the Court, the parties concluded Fact and Expert Discovery on April 16, 2012. On April 30, 2012 the Company filed Motions for Summary Judgment seeking dismissal of all counts. The Sage Group (“Sage”) also filed a Motion for Summary Judgment seeking dismissal of all counts asserted against Sage.

The time frame for the Court's determination of the respective Motions for Partial Summary Judgment and for Summary Judgment cannot be ascertained. As of May 1, 2012, no informed judgment can be made as to the likely outcome and Counsel is unable to provide a precise estimate of the merits or probability of success of the Cato Capital, LLC claims or a range of potential recovery or loss.

(d) Summation.

In reference to Contingencies identified, there can be no assurance that an adverse result in these proceedings would not have a potentially material adverse effect on our business, results of operations, and financial condition. The Company believes it has meritorious defenses and is vigorously defending against the claims identified. There is currently no projection as to the likely outcome of the cases and the Company has not recorded any gain or loss contingencies as a result of the above matters for the three months ended March 31, 2012 or year ended December 31, 2011.

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

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

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

On January 26, 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea regarding the fill and finish process for Alferon N Injection®. We are diligently working with Althea in the Technology Transfer phase of the process that includes evaluation of manufacturing and technology transfer feasibility, equipment and/or equipment modification requirements, engineering runs, process definition along with development and approval of the Master Batch Record. When the Technology Transfer process is complete, it will be necessary to conduct production tests with the resulting data to be submitted to the FDA. Only upon the finished product lots obtaining approval from the FDA will we be able to commercially sell Alferon N Injection®. In April 2012, FDA reviewers raised certain questions about the status of some lots of our older in-process Alferon® materials and API, which would need to be released by FDA before those materials could be used in commercial product. If we receive a Release Approval from the FDA as to quality and consistency of these materials, and approval for Althea to perform the fill and finish process, we estimate that commercial sales of Alferon N Injection® could commence in the later part of 2012. In the absence of FDA approvals for commercial sale of product manufactured from existing inventory, commercial sales of Alferon® in the United States will not resume until new batches of Alferon® inventory and API have been produced, filled and finished, and released by the FDA for sale. We are unable to provide any assurances that the FDA will approve the final inventory lots produced by the CMO. If this finish goods inventory is not granted approval by the FDA for commercial sales, our operations most likely will be materially adversely affected.

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

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

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

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, with a major emphasis on new drug diagnostic and development, we have incurred substantial operating losses, as we pursued our clinical trial effort to get our experimental drug, Ampligen®, approved. As of March 31, 2012, our accumulated deficit was approximately $(229,048,000). We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

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

The development of our products will require the commitment of substantial resources to conduct the time consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of March 31, 2012, we had approximately $32,190,000 in Cash, Cash Equivalents and Marketable Securities (inclusive of $3,074,000 in Marketable Securities collateralizing certain debts). Given the challenging economic conditions, we continue to review every aspect of our operations for cost and spending reductions to assure our long-term financial stability while maintaining the resources necessary to achieve our primary objectives of obtaining NDA approval of Ampligen®, and securing a strategic partner.

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

Our ability to raise additional funds from the sale of equity securities is limited. In this regard, we only have approximately 31,862,000 shares authorized but unissued and unreserved. While we recently increased the number of authorized shares of Common Stock from 200,000,000 to 350,000,000, the additional 150,000,000 shares cannot be issued for fundraising purposes without prior stockholder approval.

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

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

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

Commercial sales of Alferon N Injection® were halted in March 2008 when our finished goods inventory expired. The production of Alferon N Injection® from the Work-In-Process Inventory was restarted in May 2010, continued into January 2011 with its conversion into API and is completed for the related Final Lot Release Test. To fill and finish Alferon N Injection® Drug Product, we require a FDA approved third party CMO. In January 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea regarding the fill and finish process for Alferon N Injection®. Our Work-In-Process Inventory has expiration dates of September 30, 2012 through March 10, 2013. Upon the expected mid-2012 completion of the fill and finish process, it is projected that Alferon N Injection® will have an expected shelf life of 42 months. In April 2012, FDA reviewers raised certain questions about the status of some lots of our older in-process Alferon® materials and API, which would need to be released by FDA before those materials could be used in commercial product. If we receive a Release Approval from the FDA as to quality and consistency of these materials, and approval for Althea to perform the fill and finish process, we estimate that commercial sales of Alferon N Injection® could commence in the later part of 2012. In the absence of FDA approvals for commercial sale of product manufactured from existing inventory, commercial sales of Alferon® in the United States will not resume until new batches of Alferon® inventory and API have been produced, filled and finished, and released by the FDA for sale. We are unable to provide any assurance that the Work-In-Process Inventory will be converted into Finished Goods prior to the product’s expiration nor that the FDA will approve the final inventory lots manufactured by us or produced by Althea. If this Finished Goods inventory does not complete the fill and finish steps prior to their expiration or the inventory is not granted approval by the FDA for clinical sales, our operations most likely will be materially adversely affected.

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

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

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

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

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

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

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

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

To date, no consistent policy has emerged regarding the breadth of protection afforded by pharmaceutical and biotechnology patents. There can be no assurance that new patent applications relating to our products, process or technology will result in patents being issued or that, if issued, such patents will afford meaningful protection against competitors with similar technology. It is generally anticipated that there may be significant litigation in the industry regarding patent and intellectual property rights. Such litigation could require substantial resources from us and we may not have the financial resources necessary to enforce the patent rights that we hold. No assurance can be made that our patents will provide competitive advantages for our products, process and technology or will not be successfully challenged by competitors. No assurance can be given that patents do not exist or could not be filed

which would have a materially adverse effect on our ability to develop or market our products or to obtain or maintain any competitive position that we may achieve with respect to our products. Our patents also may not prevent others from developing competitive products or process using related technology.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The production of Alferon N Injection® from the Work-In-Process Inventory was restarted in May 2010, continued into January 2011 with its conversion into API and is completed for the related Final Lot Release Test. To formulate, fill and finish Alferon N Injection® drug product, we require a FDA approved third-party CMO. In January 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea regarding the formulation, fill, finish and packaging process for Alferon N Injection®. The Work-In-Process Inventory has expiration dates of September 30, 2012 through March 10, 2013. Upon the expected mid-2012 completion of the fill and finish process, it is projected that the Alferon N Injection® will have an expected shelf life of 42 months. In April 2012, FDA reviewers raised certain questions about the status of some lots of our older in-process Alferon® materials and API, which would need to be released by FDA before those materials could be used in commercial product. If we receive a Release Approval from the FDA as to quality and consistency of these materials, and approval for Althea to

perform the fill and finish process, we estimate that commercial sales of Alferon N Injection® could commence in the later part of 2012. In the absence of FDA approvals for commercial sale of product manufactured from existing inventory, commercial sales of Alferon® in the United States will not resume until new batches of Alferon® inventory and API have been produced, filled and finished, and released by the FDA for sale. There can be no assurance that some or all of our existing Alferon® API will be successfully converted into finished product prior to their expiration, that our inventory will obtain FDA approval from their Final Lot Release Test, nor that the final drug product will obtain FDA approval upon completion of the fill and finish stage. Without FDA approval, our existing Alferon N Injection® will not be considered suitable for commercial sales. Additionally, there can be no assurance that the final manufacturing steps will be timely or successful, that any given product will be determined to be safe and effective, or capable of being manufactured under applicable quality standards.

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

There can be no assurance that the FDA will determine that our existing inventory and final product to be safe and effective, will meet the short-term patient demand for Alferon N Injection® or will be permitted to be sold as commercial product.

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

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

There are a limited number of organizations in the United States available to provide the final steps in the manufacturing for Alferon N Injection® and Ampligen®. To formulate, fill, finish and package our products (“fill and finish”), we require a FDA approved third party CMO.

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

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

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

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

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

We have limited manufacturing experience for Ampligen®.

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

or that such facilities, if used, built, or acquired, will be adequate for the production of our proposed products for large-scale commercialization or our long-term needs.

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

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

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

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

Our products may be subject to substantial competition.

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

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

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

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

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

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

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

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

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

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

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

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

Uncertainty of health care reimbursement for our products.

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

realize an appropriate return on our investment in product development.

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

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

Risks Associated With an Investment in Our Common Stock:

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

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

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

Our common stock is listed for quotation on the NYSE Amex. For the three month period ended March 31, 2012, the closing price of our common stock has ranged from $0.19 to $0.47 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

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

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

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

Additionally, we registered with the SEC on September 29, 2009, 1,038,527 shares issuable upon exercise of certain other warrants. To the extent the exercise price of our outstanding warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the exercise price of certain of these warrants are adjusted pursuant to anti-dilution protection, the warrants could be exercisable or convertible for even more shares of common stock. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. In this regard we have registered $150,000,000 of securities for public sale pursuant to a universal shelf registration. We have allocated 32,000,000 shares under this registration statement to an At-The-Market equity offering and, as of March 31, 2012, 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 5.6% of our common stock, the Rights Plan’s threshold will be 20%, instead of 15%. The Rights Plan will expire on November 19, 2012, and may be redeemed prior thereto at $0.01 per Right under certain circumstances.

Special Note Regarding Forward Looking Statements

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

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

We did not have any unregistered sales nor repurchase any of our securities during the three months ended March 31, 2012.

ITEM 3: Defaults upon Senior Securities

None.

ITEM 4: Mine Safety Disclosures

Not Applicable.

ITEM 5: Other Information

None.

ITEM 6: Exhibits

(a) Exhibits

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

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

32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer.
32.2	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer.
101	The following materials from Hemispherx' Quarterly Report on Form 10-Q for the period ended March 31, 2012, formatted in eXtensible Business Reporting Language ("XBRL"): (i) the Condensed Consolidated Statements of Income; (ii) the Condensed Consolidated Balance Sheets; (iii) the Condensed Consolidated Statements of Cash Flows; and (iv) Notes to Condensed Consolidated Financial Statements.

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 7, 2012