HEMISPHERX BIOPHARMA INC
Form 10-Q
November 02, 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 September 30, 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 ¨ Accelerated filer
¨ Non-accelerated filer x 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

151,010,736 shares of common stock were outstanding as of November 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)

	September 30, 2012 (Unaudited)	December 31, 2011 (Audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,158	$ 3,103
Marketable securities – unrestricted	21,898	26,229
Marketable securities – restricted	10,342	1,026
Inventories	799	897
Prepaid expenses and other current assets	257	531
Total current assets	36,454	31,786
Property and equipment, net	5,327	5,276
Patent and trademark rights, net	947	863
Marketable securities – unrestricted	0	1,958
Marketable securities – restricted	0	2,075
Construction in progress	5,785	1,484
Other assets	65	71
Total assets	$ 48,578	$ 43,513
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,344	$ 1,681
Accrued expenses	1,636	1,644
Margin account loan	5,761	1,695
Current portion of capital lease	49	49
Total current liabilities	9,790	5,069
Long-term liabilities		
Long-term portion of capital lease	64	99
Redeemable warrants	2,112	380

Total liabilities	11,966	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 147,508,498 and 135,642,303, respectively	148	136
Additional paid-in capital	274,671	264,958
Accumulated other comprehensive income (loss)	428	(389)
Accumulated deficit	(238,635)	(226,740)
Total stockholders' equity	36,612	37,965
Total liabilities and stockholders' equity	$ 48,578	$ 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 September 30,	
	2012	2011
Revenues:		
Clinical treatment programs	$ 39	$ 45
Total revenues	39	45
Costs and expenses:		
Production/cost of goods sold	988	217
Research and development	2,357	1,750
General and administrative	1,659	1,635
Total costs and expenses	5,004	3,602
Operating loss	(4,965)	(3,557)
Interest expense	(7)	(9)
Interest and other income	353	212
Redeemable warrants valuation adjustment	(1,968)	614
Net loss	(6,587)	(2,740)
Other Comprehensive Income (Loss):		
Unrealized gain (loss) on marketable securities	306	(543)
Realized gain (loss) on marketable securities	(168)	14
Less: Premium amortization	24	0
Net comprehensive loss	$ (6,425)	$ (3,269)
Basic and diluted loss per share	$ (0.05)	$ (0.02)
Weighted average shares outstanding, basic and diluted	137,012,240	135,496,311

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)

	Nine months ended September 30,	
	2012	2011
Revenues:		
Clinical treatment programs	$ 160	$ 123
Total revenues	160	123
Costs and expenses:		
Production/cost of goods sold	1,476	614
Research and development	5,758	5,014
General and administrative	5,271	4,890
Total costs and expenses	12,505	10,518
Operating loss	(12,345)	(10,395)
Interest expense	(19)	(21)
Interest and other income	873	686
Funds received from sale of income tax net operating losses	1,328	2,272
Redeemable warrants valuation adjustment	(1,732)	1,558
Net loss	(11,895)	(5,900)
Other Comprehensive Income (Loss):		
Unrealized gain (loss)on marketable securities	890	(402)
Realized gain(loss) on securities	(205)	509
Less: Premium amortization	132	0
Net comprehensive loss	$ (11,078)	$ (5,793)
Basic and diluted loss per share	$ (0.09)	$ (0.04)
Weighted average shares outstanding, basic and diluted	136,260,727	135,379,622

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 Compre-hensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2011	135,642,303	$ 136	$ 264,958	$ (389)	$ (226,740)	$ 37,965
Shares sold at the market	10,699,700	11	9,257	0	0	9,268
Stock issued for settlement of accounts payable	926,748	1	261	0	0	262
Equity-based compensation	239,747	0	195	0	0	195
Net comprehensive income (loss)	0	0	0	817	(11,895)	(11,078)
Balance at September 30, 2012	147,508,498	$ 148	$ 274,671	$ 428	$ (238,635)	$ 36,612

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

For the Nine Months Ended September 30, 2012 and 2011

(in thousands)

(Unaudited)

	2012	2011
Cash flows from operating activities:		
Net loss	$(11,895)	$(5,900)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	469	322
Amortization of patent and trademark rights	29	161
Redeemable warrants valuation adjustment	1,732	(1,558)
Equity-based compensation	195	348
Other than temporary impairment of marketable securities	0	258
Inventory reserve	778	0
Change in assets and liabilities:		
Inventories	(680)	(302)
Prepaid expenses and other current assets	274	(93)
Accounts payable	925	319
Accrued expenses	(8)	(629)
Net cash used in operating activities	$(8,181)	$(7,074)
Cash flows from investing activities:		
Purchase of property, equipment and construction in progress	$(4,821)	$(849)
Additions to patent and trademark rights	(113)	(92)
Deposits on capital leases refunded (paid)	6	(4)
Maturities of short-term and long-term marketable securities	13,380	11,148
Purchase of short-term and long-term marketable securities	(13,515)	(3,133)
Net cash (used in) provided by investing activities	$(5,063)	$7,070

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows (Continued)

For the Nine Months Ended September 30, 2012 and 2011

(in thousands)

(Unaudited)

	2012	2011
Cash flows from financing activities:		
Payments on capital leases	$(35)	$(50)
Proceeds from margin account loan	4,066	1,156
Proceeds from sale of stock, net of issuance costs	9,268	0
Net cash provided by financing activities	$13,299	$1,106
Net increase in cash and cash equivalents	55	1,102
Cash and cash equivalents at beginning of period	3,103	2,920
Cash and cash equivalents at end of period	$3,158	$4,022
Supplemental disclosures of non-cash investing and financing cash flow information:		
Issuance of common stock for accounts payable and accrued expenses	$262	$71
Equipment acquired by capital lease	$0	$62
Unrealized gain (loss) on marketable securities	$890	$(402)
Redeemable warrants valuation adjustment	$1,732	$(1,558)
Supplemental disclosure of cash flow information:		
Cash paid for interest expense and capitalized construction interest	$(68)	$(21)

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 9,360,300 and 33,348,458 shares, and 565,411 and 53,809,659 shares for the three months and nine months ended September 30, 2012 and 2011, respectively, are excluded from the calculation of diluted net loss per share since their effect is anti-dilutive.

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. Accordingly, the fair values of the options granted, were estimated based on the following weighted average assumptions:

	Nine Months Ended September 30,	
	2012	2011
Risk-free interest rate	0.68% - 0.86%	0.89% - 2.24%
Expected dividend yield	-	-
Expected lives	5.0 years	5.0 years
Expected volatility	108.76%-111.95%	104.29-104.88%
Weighted average grant date fair value per options and warrants issued	$0.23 per option for 1,499,000 options	$0.30 per option for 990,000 options

Stock option activity during the nine months ended September 30, 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	1,199,000	0.45	9.76	0.35
Forfeited	(10,000)	1.30	1.30	0
Outstanding September 30, 2012	9,441,480	$ 1.90	5.60	$ 0
Vested and expected to vest September 30, 2012	9,441,480	$ 1.90	5.60	$ 0
Exercisable September 30, 2012	8,593,690	$ 2.04	5.21	$ 0

Options to purchase 1,199,000 shares were granted to employees during the nine months ended September 30, 2012. These options were issued at a premium value of 110% of the NYSE MKT stock closing price and vest one year from the issuance date. The weighted average grant-date fair values of the options granted during the nine months ended September 30, 2012 and 2011 were $284,000 and $279,000, 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	809,458	0.44	9.77	0.36
Vested	(100,001)	0.37	8.98	0.43
Forfeited	(10,000)	1.30	5.50	0
Outstanding September 30, 2012	847,790	$ 0.45	9.74	$ 0.35

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	300,000	0.29	9.75	0.51
Exercised	0	0	0	0
Forfeited	0	0	0	0
Outstanding September 30, 2012	3,428,432	$ 1.73	4.96	$ 0
Vested and expected to vest September 30, 2012	3,428,432	$ 1.73	4.96	$ 0
Exercisable September 30, 2012	3,100,303	$ 1.87	4.64	$ 0

Options to purchase 300,000 shares were granted to non-employees during the nine months ended September 30, 2012. These options were issued at a premium value of 110% of the NYSE MKT stock closing price and vest one year from the issuance date. The weighted-average grant-date fair value of non-employee options granted during the nine months ended September 30, 2012 and 2011 was approximately $60,000 and $17,000, respectively.

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

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2012	256,250	$ 0.71	8.55	$ 0
Options granted	300,000	0.29	9.75	0.51
Options vested	(228,121)	0.57	7.98	0.23
Options forfeited	0	0	0	0
Outstanding September 30, 2012	328,129	$ 0.43	9.68	$ 0.34

The impact on the Company’s results of operations of recording equity-based compensation for the nine months ended September 30, 2012 and 2011 was to increase general and administrative expenses by approximately $195,000 and $348,000 respectively. The impact on basic and fully diluted earnings per share for the nine months ended September 30, 2012 and 2011 was $0.00 and $0.00, respectively.

As of September 30, 2012 and 2011, respectively, there was $308,000 and $120,000 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)	
	September 30, 2012	December 31, 2011

Inventory work-in-process, January 1	$897	$ 787
Production	680	302
Spoilage	(778)	(192)
Inventory work-in-process, end of period	$799	$ 897

The Technology Transfer process with Althea Technologies, Inc. (“Althea”) of San Diego, CA, for Alferon N Injection® was completed in May 2012 and included the 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. At the completion of each inventory lot in the fill, finish and packaging process, it is projected that Alferon N Injection® will then have an expected shelf life of 42 months. As of September 30, 2012, all but one of our lots of Alferon® Work-In-Process Inventory have completed the fill, finish and packaging process with the final lot converted on October 12, 2012. Of the three lots that had completed the fill, finish and packaging process, the first lot was deemed not suitable for commercial sale due to an issue that occurred in the process and therefore the value was reserved by the Company along with any validation samples and product shrinkage from this final production stage. Upon analysis and revision of the fill and finish process, the second and third lots were completed with the previous issue in the manufacturing step corrected.

While at September 30, 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 it is confirmed by the FDA that the product can be commercially sold as is.

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. As of September 30, 2012, it was determined that none of the marketable securities had other-than-temporary impairments. At September 30, 2012, all securities were classified as available for sale investments and $12,698,000 were measured as Level 1 instruments and $9,200,000 were measured as level 2 instruments of the fair value measurements standard.

Securities classified as available for sale consisted of:

September 30, 2012

(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 12,312	$ 386	$ 0	$ 12,698	$ 12,698	$ 0
US Treasury Bill	9,200	0	0	9,200	9,200	0

Totals	$ 21,512	$ 386	$ 0	$ 21,898	$ 21,898	$ 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:

September 30, 2012

(in thousands)

All unrestricted investments were in a gain position as of September 30, 2012.

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)
Corporate Bonds	4	997	(16)	3,272	(35)	4,269	(51)
Totals	5	$ 997	$ (16)	$ 25,025	$ (369)	$26,022	$ (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.

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 September 30, 2012, it was determined that none of the Marketable Securities had other-than-temporary impairments. At September 30, 2012, all restricted securities were classified as restricted from sale investments and $6,800,000 was measured as level 1 instruments and $3,542,000 were measured as level 2 instruments of the fair value measurements standard (see “Note 11: Fair Value”).

Securities classified as restricted from sale consisted of:

September 30, 2012

(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 6,773	$ 27	$ 0	$6,800	$ 6,800	$ 0
Foreign Bonds	1,004	2	0	1,006	1,006	0
Corporate Bonds	2,523	16	(3)	2,536	2,536	0
Totals	$ 10,300	$ 45	$ (3)	$10,342	$ 10,342	$ 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:

September 30, 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
Corporate Bonds	1	$ 508	$ (3)	$ 0	$ 0	$508	$ (3)
Totals	1	$ 508	$ (3)	$ 0	$ 0	$508	$ (3)

December 31, 2011

(in thousands)

		Less Than 12 Months		12 Months or Greater		Totals	
Securities	Total number in	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair	Total Unrealized

	loss position						Value	Losses
Corporate Bonds	1	$ 2,075	$ (14)	$ 0	$ 0		$2,075	$ (14)
Totals	1	$ 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 September 30, 2012.

Note 7: Accrued Expenses

Accrued expenses consist of the following:

	(in thousands)	
	September 30, 2012	December 31, 2011
Compensation	$256	$ 821
Professional fees	233	215
Other expenses	609	495
Accrued Alferon production cost	425	0
Due for returned product	113	113
	$1,636	$ 1,644

Note 8: Property and Equipment

	(in thousands)	
	September 30, 2012	December 31, 2011
Land, buildings and improvements	$4,209	$ 4,209
Furniture, fixtures, and equipment	4,522	4,002
Leasehold improvements	85	85
Total property and equipment	8,816	8,296
Less: accumulated depreciation and amortization	(3,489)	(3,020)
Property and equipment, net	$5,327	$ 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.

The Board of Directors approved an allocation of up to $7.2 million, which included an increase of $700,000 authorized on June 5, 2012, 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 September 30, 2012, construction in progress was $5,785,000 as compared to $1,484,000 as of December 31, 2011. Due to the necessity to redirect many of our resources to the Ampligen® NDA application process and efforts towards the pre-approval inspection for Ampligen® manufacturing, the validation phase of the Alferon® manufacturing project has been delayed until the Company has completed its focus on the NDA process.

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 September 30, 2012, the principal loan balance of the Margin Account was approximately $5,761,000, for which approximately $10,342,000 in Marketable Securities became restricted as dedicated collateral for the indebtedness. For the nine months ended September 30, 2012, the interest charge was approximately $49,000 which has been capitalized along with the other costs related to the capital improvement project (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 September 30, 2012, the Company issued 7,758,104 securities to Directors and consultants consisting of an aggregate 2,088,734 shares of common stock and options to purchase 5,669,370 shares. The shares issued to consultants had prices ranging from $0.25 to $2.30 based on the NYSE MKT closing price.

The aggregate stock options had various exercise prices ranging from $0.26 to $2.81, had terms of ten years, issued at a premium value of 110% of the NYSE MKT stock closing price and vested over varying periods of time upon grant.

In June 2012, the Equity Distribution Agreement (the "Old EDA") with Maxim Group LLC ("Maxim") expired. Under the Old EDA, the Company could sell up to approximately 32,000,000 shares of its common stock from time to time through Maxim as its sales agent. Under the Old EDA, Maxim was 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 had no obligation to sell any shares under this program, and either party was permitted to terminate the Old EDA at any time without penalty. During the nine months ended September 30, 2012, the Company sold no shares through this program and received no net cash proceeds. The Company sold an aggregate of 520,000 shares over the life of the Old EDA that resulted in net cash proceeds of approximately $293,000 and commissions paid to Maxim of approximately $12,000.

On July 23, 2012, the Company entered into a new EDA with Maxim (the "EDA") pursuant to which the Company may sell up to $75,000,000 worth of its shares of Common Stock from time to time through Maxim, as sales agent. Under the EDA, Maxim is entitled to a fixed commission rate of 4.0% of the gross sales price of Shares sold under the EDA, up to aggregate gross proceeds of $10,000,000, and thereafter, at a fixed commission rate of 3.0% of the gross sales price of Shares sold under the EDA. Sales of the Shares, if any, may be made in transactions that are deemed to be "at-the-market" offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers' transactions, including on the NYSE MKT, at market prices or as otherwise agreed with Maxim. The Company has no obligation to sell any of the Shares and may at any time suspend offers under the EDA or terminate the EDA. The Shares are being sold pursuant to the Company's Universal Shelf Registration Statement on Form S-3, declared effective by the Securities and Exchange Commission on July 2, 2012. On September 14, 2012, the Company filed a Prospectus Supplement with the Securities and Exchange Commission related to the offering of 20,000,000 shares under the ATM. On October 5, 2012, the Company filed an updated Prospectus Supplement. As a result, at the date of this report, an aggregate of 40,000,000 shares are allocated for public sale under the Prospectus Supplement pursuant to the ATM. As of September 30, 2012, the Company had sold an aggregate of 10,699,700 shares that resulted in net cash proceeds of approximately $9,268,000. The commissions paid to Maxim were approximately $393,000.

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The proceeds from this financing are intended to be 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 September 30, 2012, was estimated using the following assumptions:

Underlying price per share	$0.28-$0.80
Exercise price per share	$1.31-$1.65
Risk-free interest rate	0.21%-0.44%
Expected holding period	1.63-2.63 yrs.
Expected volatility	69.2%-87.6%
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 $2,112,000 at September 30, 2012. There

were no other financial instruments at September 30, 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 September 30, 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 September 30, 2012 and 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 September 30, 2012:

	(in thousands)			
	Total	Level 1	Level 2	Level 3
Assets:				
Marketable Securities-unrestricted	$21,898	$12,698	$9,200	$0
Marketable Securities-restricted	$10,342	$6,800	$3,542	$0
Liabilities:				
Warrants	$(2,112)	$0	$0	$(2,112)

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
Fair value adjustment at June 30	(387)	(643)
Balance at June 30	144	1,860
Fair value adjustment at September 30	1,968	(613)
Balance at September 30	$ 2,112	$ 1,247

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(loss) on the components of net income(loss) and other comprehensive income(loss). 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. In 2012, the FASB issued Accounting Standards updates 2012-01 through 2012-06. These updates will not have a material 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 carry-forwards 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. On October 5, 2012, the Company filed an updated Prospectus Supplement. As a result, an aggregate of 40,000,000 shares are allocated for public sale under the Prospectus Supplement pursuant to the ATM. Please See “Note 10: Stockholders’ Equity” for information about the ATM with Maxim. Additionally on November 2, 2012, the Company executed an Amended and Restated Rights Agreement amending and restating the November 19, 2002 Rights Agreement between the Company and Continental Stock Transfer & Trust Company. The Amended and Restated Rights Agreement extends the term of the Rights Plan to November 18, 2017 and amends certain other provisions. Other than these events, the Company has determined that no subsequent event constituted a matter that required disclosure or adjustment to the financial statements for the nine months ended September 30, 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, contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements reflect our current views with respect to future events are based on assumptions and are subject to risks, uncertainties and other important factors. We discuss many of these risks, uncertainties and other important factors in greater detail under “Item 1A. Risk Factors” in Part II in this Report. Because the risk factors referred to above and in our Annual Report on Form 10-K for our most recent fiscal year filed with the Securities and Exchange Commission 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, these forward-looking statements represent our estimates and assumptions only as of the date such forward-looking statements are made. You should carefully read this Report completely and with the understanding that our actual future results may be materially different from what we expect. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our business, results of operations and financial condition. 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. 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. Any statements in this Report about our expectations, beliefs, plans, objectives, assumptions or future events or performance that are not historical facts are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as “believe”, “may”, “could”, “will”, “estimate”, “continue”, “anticipate”, “inte “seek”, “plan”, “expect”, “should”, or “would,” and similar expressions intended to identify forward-looking statements.

Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: the potential therapeutic effect of our products, the possibility of obtaining regulatory approval, our ability to manufacture and sell any products, our ability to enter into arrangements with third party vendors, market acceptance of our products, our ability to earn a profit from sales or licenses of any drugs, our ability to discover new drugs in the future, changing market conditions, changes in laws and regulations affecting our industry, and issues related to the improvements and construction at of our New Brunswick, New Jersey facility. Recently we disclosed that we had filed with the FDA our Complete Response in support of the Ampligen® New Drug Application ("NDA") for Chronic Fatigue Syndrome Treatment. Please note that the remaining steps to potentially gain FDA approval of the Ampligen® NDA, the final results of these and other ongoing activities could vary materially from our expectations and could adversely affect the chances for approval of the Ampligen® NDA. These activities and the ultimate outcomes are subject to a variety of risks and uncertainties, including but not limited to risks that (i) the FDA may ask for additional data, information or studies to be completed or provided prior to approval; (ii) the FDA may require additional work related to the commercial manufacturing process to be completed prior to approval or may, in the course of the inspection of manufacturing facilities, identify issues to be resolved; (iii) the FDA may determine that the complete response submitted by us is not "complete," potentially requiring us to conduct additional activities before we can re-file, if at all, the complete response; and (iv) until completion of the FDA review of the Ampligen® NDA, including the Advisory Committee review, and final approval of the product and prescribing information, if any, the specific patient population for which Ampligen® may be indicated will not be known. Any failure to satisfy the FDA's requirements could significantly delay, or preclude outright, approval of the Ampligen® NDA.

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 U.S. 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 upgrading 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, and then again in June 2012 to $7.2 million. The project is in an active construction phase with approximately $5,761,000 spent to date through September 30, 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 upgrades are being undertaken to the Alferon® manufacturing process, this project has not impacted our capability to manufacture the Ampligen® drug substance final intermediates. The production of new Alferon® Active Pharmaceutical Ingredient ("API") inventory will not commence until the capital improvement and validation phases are complete. Due to the necessity to redirect many of our resources to the Ampligen® NDA application process and efforts towards the pre-approval inspection for Ampligen® manufacturing, the validation phase of the Alferon® manufacturing project has been delayed until we have completed our focus on the NDA process. 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 upgrades for Alferon®. Once we begin production of new Alferon® API, we anticipate that it will take approximately nine to twelve months before we will have Alferon® that can be commercially sold.

An element of the June 8, 2012 meeting with the FDA was the FDA's requirement that our New Brunswick manufacturing facility would be ready for GMP pre-approval inspection related to Ampligen® at the time of submission of our complete response submission. In an attempt to accomplish this task, we have redirected many of our resources to the Ampligen® NDA submission and our preparedness for the FDA pre-approval inspections by reassigning personnel, and hiring additional staff, consultants and various independent contractors. We cannot provide any guarantee that the facility will necessarily pass a pre-approval inspection for Ampligen® or Alferon® manufacture, which are conducted in separately dedicated areas within the overall New Brunswick manufacturing complex. See "Ampligen®" below.

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 and the NDA for Ampligen® is the first ever accepted for review by the FDA for systemic use of a toll-like receptor 3 ("TLR-3") 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. Most notably, the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen® and recommended at least one additional clinical study which shows convincing effect and confirms safety in the target population. The FDA indicated that the additional study should be of sufficient size and sufficient duration (six months) and include appropriate monitoring to rule out the generation of autoimmune disease. In addition, patients in the study should be on more than one dose regimen, including at least 300 patients on dose regimens intended for marketing. In 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® in response to certain issues raised in the FDA's CRL.

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. As of September 30, 2012, we had thirty-three patients participating in this open label treatment protocol with twenty-five taking treatment and eight 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. We believe that continued efforts to understand existing data, and to advance the development of new data and information, ultimately supports our re-filing of the Ampligen® NDA.

In November 2010, Hemispherx announced the publication of new analyses of data from the AMP-516 Trial also showed that patients on Ampligen® reduced their use of concomitant medications compared to patients receiving placebo. In particular, Ampligen® patients reduced their use of medications which may prolong the QT interval. Prolongation of the QT interval is a known risk factor for sudden cardiac death and arrhythmias. A greater portion of the placebo patients were found to have a significant prolongation of the QT interval compared to patients who had received Ampligen®, thereby creating a cardiac risk situation in the CFS patients. Cardiac death is one of three major causes of premature death in CFS, which affects predominantly women in their 40s.

In March 2012, a new peer reviewed analysis of data from the AMP-516 Trial was published showing that the proportions of Ampligen® patients with exercise improvements of at least 25% and at least 50% were, respectively, 1.7 and 1.9-fold greater than those patients on placebo. A continuous responder analysis which examined response improvements from 25% to 50% in 5% increments showed a greater improvement in exercise tolerance for patients receiving Ampligen® versus placebo at every 5% increment above 25%.

On June 8, 2012, the Company and its consultants met with the FDA to discuss certain aspects of the CRL relating to its NDA for Ampligen® for the treatment of severely debilitated patients with CFS. Upon our review of the FDA Minutes from this meeting that we received on July 6, 2012, we believe the key points from the meeting to be undertaken by the Company in conjunction with its complete response include the following:

- The FDA agreed to accept, for review, in Hemispherx' complete response new analyses of data from the AMP-516 Trial. Whether these data provide adequate evidence of efficacy will ultimately be a review issue, and there can be no assurance the FDA will conclude the data are adequate to support approval of the Ampligen® NDA;
- As Ampligen® is a new molecular entity, the FDA anticipates that the data submitted in the NDA would be presented at a public FDA Advisory Committee meeting;
- The FDA requires that the Company's complete response include all information necessary for review at the time of filing and that it address all deficiencies identified in the CRL;
- Our New Brunswick manufacturing facility would be expected to be ready for GMP pre-approval inspection at the time of the complete response; and
- We will include in the complete response a request for postponement of rodent carcinogenicity study requirements and a justification for this request.

The FDA also advised that whether the new analyses provide adequate evidence of Ampligen®'s efficacy in treating CFS will ultimately be an Advisory Committee ("AC") review issue. The Company submitted the complete response to the FDA on July 31, 2012 in support of Ampligen®'s NDA for CFS. The FDA acknowledged in writing receipt of the Company's complete response stating, "We consider this a complete, class 2 response to our November 25, 2009, action letter." Based on its designation of our July 31, 2012 submission as a class 2 response, FDA has indicated that its Prescription Drug User Fee Act ("PDUFA") review goal for completing its review is February 2, 2013. The FDA's agreement to review the complete response does not commit the FDA to approve the Ampligen® NDA. Further, no guarantee can be made at this time that the facility will necessarily pass a pre-approval inspection to produce raw materials to manufacture Ampligen®, which is conducted in a separately dedicated area within the overall New Brunswick manufacturing complex. As a result of the FDA meeting, Hemispherx has redirected many of its resources

to the Ampligen® NDA submission and our preparation for the FDA pre-approval inspections by reassigning personnel, hiring additional staff, consultants and various independent contractors.

The FDA has scheduled the AC meeting to discuss the Ampligen® NDA on December 20, 2012. No guarantee can be made at this time that FDA will hold the AC meeting as currently scheduled or that FDA will complete its review of the NDA by the February 2, 2013 review goal.

On July 12, 2012, we filed a new drug application for Ampligen® with the ANMAT (Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica), the agency responsible for the national regulation of drugs, foods and medical technology in Argentina, under the ANMAT's Orphan Drug regulations. We believe that the approval of Ampligen® as an Orphan Drug should allow reimbursement by the Health Services Authority (SSS), the central health authority in Argentina for patients seeking treatment for ME/CFS.

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 intend to 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. However, developments have been paused pending Chronix' implementation of its planned next generation of sequencing equipment and Hemispherx' current need to give priority to Ampligen®'s NDA responsibilities. While we believe that finding an accurate diagnostic for CFS is useful, we do not believe that development of new diagnostic tools is a prerequisite to FDA approval of a CFS treatment, including Ampligen®.

Alferon N Injection®

Alferon N Injection® is the registered trademark for our injectable formulation of natural alpha interferon, which was 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 ANMAT 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. On September 20, 2012, the Company filed with ANMAT an amended NDA for the use of Alferon N Injection® in patients with chronic hepatitis C who have become refractory to recombinant interferon as a result of the appearance of neutralizing antibodies against recombinant interferon.

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 formulate, fill, finish and package ("fill and finish") Alferon N Injection® Drug Product, we require a FDA approved third party Contract Manufacturing Organization ("CMO"). While the Work-In-Process Inventory had expiration dates of September 30, 2012 through March 10, 2013, upon the completion of each inventory lot in the fill, finish and packaging process it is projected that those lots of Alferon N Injection® will then have an expected shelf life of 42 months. In April 2012, FDA reviewers raised certain questions about the status of our existing lots of older Work-In-Process Alferon® materials and API, which would need to be released by FDA before those materials could be used in commercial product. The production of new Alferon® drug product inventory will not commence until the capital improvements and related validation phases at our New Brunswick manufacturing facility are complete.

In January 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea Technologies, Inc. ("Althea") of San Diego, CA, regarding the fill and finish process for Alferon N Injection®. The Technology Transfer process with Althea was completed in May 2012 and included the 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. At the completion of each inventory lot in the fill, finish and packaging process, it is projected that those lots of Alferon N Injection® will then have an expected shelf life of 42 months. As of September 30, 2012, all but one of our four lots of Alferon® Work-In-Process Inventory have completed the fill, finish and packaging process with the final lot to be converted in October 2012. Of the three lots that had completed the fill, finish and packaging process, the first lot was deemed not suitable for commercial sale due to an issue that occurred in the conversion process and therefore its value was reserved by the Company along with any validation samples and product conversion shrinkage from this final production stage for the other lots. Upon analysis and revision of the fill and finish process, the second and third lots were completed with the previous issue in the manufacturing step corrected.

Upon the completion of the fill, finish and packaging protocol, Process Validation of Alferon® Work-In-Process lots need to be completed. A minimum of three months of stability tests is required in a Pre-Approval Supplement ("PAS"). Upon receipt of the PAS, the FDA could take up to six months to render an opinion. When the finished product lots obtain approval from the FDA, we will be able to commercially sell Alferon N Injection® in the United States. If we receive a lot release approval from the FDA as to quality and consistency of these materials, and approval for Althea regarding the fill and finish process, we will then be able to utilize the approved lots for commercial sales of Alferon N Injection®. At the completion of the Company's redirection of many of its resources to the Ampligen® NDA submission and preparedness for the FDA pre-approval inspections, it is projected that an additional six to nine months may be necessary to determine the status of our existing inventory of Alferon N Injection® for commercial sales.

We are unable to provide any assurances that the FDA will approve the finish product lots produced by Althea. In the absence of FDA approvals for commercial sale of product manufactured from existing Work-In-Process inventory, commercial sales of Alferon® in the United States will not resume until new batches of Alferon® Active Pharmaceutical Ingredient can be produced and formulated in order that finished product can be filled, finished, packaged and released by the FDA for commercial sale. While at September 30, 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 it could be confirmed by the FDA that the product can be commercially sold.

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. On August 14, 2012, the agreements with Armada and Bio Ridge were extended for one year under the same terms and conditions.

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 have redirected many of our resources to the Ampligen® NDA submission and our preparedness for the FDA pre-approval inspections by reassigning personnel. Upon completion of the Ampligen® NDA effort, we intend to continue our evaluation of 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 better evaluate 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. As of September 30, 2012, eight subjects have participated in this study. As required by the study's protocol, a Data Monitoring Committee (DMC) has reviewed the safety data on these subjects and approved the study to proceed at the next higher dosage level.

In April 2010, we began the process to undertake a clinical placebo-controlled 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. As of June 2012, we had ten operational Clinical Investigative Sites. Thirty patients, of the planned total of sixty, 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 during the past year. Due to the unexpectedly slow enrollment rate for this study, on June 20, 2012, we notified Max Neeman International that this study was suspended, pending an interim analysis of results to date on the thirty completed patients of the planned sixty patient study. Our interim analysis of results has been delayed as we have redirected many of our resources to the Ampligen® NDA submission and our preparedness for the FDA pre-approval inspections by reassigning personnel. Upon completion of the Ampligen® NDA effort, we intend to undertake this analysis.

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 September 30, 2012, three patients have participated in this study. New enrollment into this study is currently suspended pending additional data analyses and non-clinical experimentation by the University of Pennsylvania's School of Medicine in an attempt to modify the immune response elicited by the vaccine adjuvant combination. To date, this treatment has been generally well-tolerated with no tumor regression seen in the first three patients.

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 September 30, 2012, forty 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 September 30, 2012, the Company contributions towards the 401(k) Plan were $107,000.

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 September 30, 2012 versus three months ended September 30, 2011

Net Loss

Our net loss was approximately $6,587,000 for the three months ended September 30, 2012, an increase in loss of approximately $3,847,000 or 140% 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 production costs of approximately $771,000 or 355%;

2) an increase in Research and Development costs of approximately $607,000 or 35%;

3) the revaluation of the Liability related to the Redeemable Warrants resulting in a non-cash loss of $1,968,000 in 2012 as compared to non-cash gain of $614,000 for the same period in 2011, resulting in an increased loss of $2,582,000; offset by

4) an increase in interest income of approximately $141,000 from funds invested in marketable securities.

Net loss per share was $(0.05) for the current three month period versus $(0.02) per share for the same period in 2011. The weighted average number of shares of our common stock outstanding as of September 30, 2012 was 137,012,240 as compared to 135,496,311 as of September 30, 2011.

Revenues

Revenues from our Ampligen® Cost Recovery Program decreased $6,000 or 13% for the third quarter of 2012 as compared to the same time period of 2011. The number of patients increased 14% in the three months ended September 30, 2012, but as there were some shipments to compassionate care patients in this period, the actual amounts collected dropped resulting in lower revenues. As of September 30, 2012, we had no Alferon N Injection® Finished Good product to commercially sell 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 $988,000 and $217,000, respectively, for the three months ended September 30, 2012 and 2011. This increase of $771,000 or 355% was primarily due to quality control testing of Alferon N Injection® Finished Goods inventory utilized in clinical studies and valuation write-down reserve of approximately $733,000 of costs related to three of our four lots of Alferon® Work-In-Process Inventory undertaking the fill, finish and packaging process at Althea. With regard to the costs related to the three lots that had completed this process, the first lot was deemed not suitable for commercial sale due to an issue that occurred in the conversion process, and therefore the value of this inventory was reserved by the Company along with any validation samples and product conversion shrinkage from other lots this final production stage.

Research and Development Costs

Overall Research and Development ("R&D") costs for the three months ended September 30, 2012 were approximately $2,357,000 as compared to $1,750,000 for the same period a year ago reflecting an increase of $607,000 or 35%. The increased R&D efforts during this three month period in 2012 were primarily due to our efforts regarding the Ampligen® NDA, which is currently under review by the FDA and preparedness for the FDA pre-approval inspections of the New Brunswick manufacturing facility.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended September 30, 2012 and 2011 were approximately $1,659,000 and $1,635,000, respectively, reflecting an increase of $24,000 or 1.5%. The G&A expenses in 2012 are essentially flat compared to 2011. The minor increase reflects normal period fluctuations.

Interest and Other Income

Interest and other income for the three months ended September 30, 2012 and 2011 were approximately $353,000 and $212,000, respectively, representing an increase of $141,000 or 67%. The primary cause for the increase in investment income was the increased performance of our investments in 2012 compared to 2011.

Redeemable Warrants

The quarterly fiscal revaluation resulted in non-cash adjustments to the redeemable warrants liability for the three months ended September 30, 2012 and 2011 of approximately ($1,968,000) loss and $614,000 gain, respectively, representing a decrease of ($2,582,000)(see “Note 11: Fair Value”).

Nine months ended September 30, 2012 versus nine months ended September 30, 2011

Net Loss

Our net loss was approximately $11,895,000 for the nine months ended September 30, 2012, an increase in loss of approximately $5,995,000 or 102% when compared to the same period in 2011. This increase in loss for these nine months was primarily due to the following:

1) an increase in Research and Development costs of approximately $744,000 or 15%;

2) an increase in General and Administrative expenses of approximately $381,000 or 8%;

3) an increase in Production/Cost of Goods Sold of approximately $862,000 or 140%;

4) the revaluation of the Liability related to the Redeemable Warrants resulting in a non-cash loss of $1,732,000 in 2012 as compared to non-cash gain of $1,558,000 for the same period in 2011, resulting in an increased loss of $3,290,000; and

5) sale in January 2012 of $16,000,000 of our approximately $25,000,000 of New Jersey state Net Operating Loss carry-forwards (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 carry-forwards (for the years 2003 through 2008) for approximately $2,272,000, representing a decrease in income of $944,000 or 42%; offset by

6) an increase in interest income of $187,000 from funds invested in marketable securities.

Net loss per share was $(0.09) for the current nine month period versus $(0.04) per share for the same period in 2011. The weighted average number of shares of our common stock outstanding as of September 30, 2012 was 136,260,727 as compared to 135,379,622 as of September 30, 2011.

Revenues

Revenues from our Ampligen® Cost Recovery Program increased $37,000 or 30% for the first nine months of 2012 as compared to the same time period of 2011. The number of patients increased 23% in the nine months ended September 30, 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.

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Production/Cost of Goods Sold

Production/Cost of Goods Sold was approximately $1,476,000 and $614,000, respectively, for the nine months ended September 30, 2012 and 2011. This increase of $862,000 or 140% was primarily due to quality control testing of Alferon N Injection® Finished Goods inventory utilized in clinical studies and valuation write-down reserve of approximately $733,000 of costs related to three of our four lots of Alferon® Work-In-Process Inventory undertaking the fill, finish and packaging process at Althea. With regard to the costs related to the three lots that had completed this process, the first lot was deemed not suitable for commercial sale due to an issue that occurred in the process, and therefore the value of this inventory was reserved by the Company along with any product conversion shrinkage from this final production stage.

Research and Development Costs

Overall Research and Development ("R&D") costs for the nine months ended September 30, 2012 were approximately $5,758,000 as compared to $5,014,000 for the same period a year ago reflecting an increase of $744,000 or 15%. The increased R&D efforts during this nine month period in 2012 were primarily due to our efforts regarding the Ampligen® NDA, which is currently under review by the FDA and preparedness for the FDA pre-approval inspections of the New Brunswick manufacturing facility.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the nine months ended September 30, 2012 and 2011 were approximately $5,271,000 and $4,890,000, respectively, reflecting an increase of $381,000 or 8%. The higher G&A expenses in 2012 consisted primarily of an increase of $384,000 in legal fees due to the Cato Capital, LLC litigation and efforts to domesticate the judgment against JCI in South Africa along with $252,000 of higher Directors' fees offset by $157,000 of lower stock compensation and $140,000 of 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 nine months ended September 30, 2012 and 2011 was approximately $873,000 and $686,000, respectively, representing an increase of $187,000 or 27%. 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 for the nine months ended September 30, 2012 and 2011 of approximately $(1,732,000) loss and $1,558,000 gain, respectively, representing a decrease of $3,290,000 (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 carry-forwards (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 carry-forwards (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 nine months ended September 30, 2012 was $8,181,000 compared to $7,074,000 for the same period in 2011, an increase of $1,107,000 or 16%. Excluding the proceeds from the sale of New Jersey Net Operating Loss carry-forwards, cash used in operating activities for the nine months ended September 30, 2012 increased by approximately $164,000 or 2% over the comparable period in 2011.

As of September 30, 2012, we had approximately $35,398,000 in cash, cash equivalents and marketable securities (restricted and unrestricted), or an increase of approximately $1,007,000 from December 31, 2011.

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 September 30, 2012, the principal loan balance of the Margin Account was approximately $5,761,000 (see “Note 9: Margin Account Loan” and “Note 6: Marketable Securities – Restricted”).

On July 23, 2012, the Company entered into a new EDA with Maxim (the “EDA”) pursuant to which the Company may sell up to $75,000,000 worth of its shares of common stock from time to time through Maxim, as sales agent. Under the EDA, Maxim is entitled to a fixed commission rate of 4.0% of the gross sales price of Shares sold under the EDA, up to aggregate gross proceeds of $10,000,000, and thereafter, at a fixed commission rate of 3.0% of the gross sales price of Shares sold under the EDA. Sales of the Shares, if any, may be made in transactions that are deemed to be “at-the-market” offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers’ transactions, including on the NYSE MKT, at market prices or as otherwise agreed with Maxim. The Company has no obligation to sell any of the Shares and may at any time suspend offers under the EDA or terminate the EDA. The Shares are being sold pursuant to the Company’s Universal Shelf Registration Statement on Form S-3, declared effective by the Securities and Exchange Commission on July 2, 2012. On September 14, 2012, the Company filed a Prospectus Supplement with the Securities and Exchange Commission related to the offering of 20,000,000 shares under the ATM. On October 5, 2012, the Company filed an updated Prospectus Supplement. As a result, as of the date of this report, an aggregate of 40,000,000 shares are allocated for public sale under the Prospectus Supplement pursuant to the ATM. As of September 30, 2012, the Company had sold an aggregate of 10,699,700 shares that resulted in net cash proceeds of approximately $9,268,000 and commissions paid to Maxim of approximately $393,000. (see “Note 10: Stockholders’ Equity”).

There can be no assurances that, if needed, we will be able to raise adequate funds from the sale of shares under the Maxim ATM or other sources. Our inability to raise such funds, if needed, could have a material adverse effect on our ability to develop our products, commercially produce inventory or continue our operations. 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, upgrades to the manufacturing process, competitive and technological advances, the regulatory processes including the commercializing of Ampligen® products or new utilization of Alferon® products.

ITEM 3: Quantitative and Qualitative Disclosures About Market Risk

We had approximately $35,398,000 in cash, cash equivalents and marketable securities (restricted and non-restricted) at September 30, 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 September 30, 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 September 30, 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 Judges' questions primarily focused on whether it was proper for the District Court to grant Summary Judgment as to MidSouth's claim for quantum meruit. The Judges did not express any opinions as to the merits of the claim, but questioned whether issues of material fact exist that should be determined by a jury as opposed to the District Court. Hemispherx' claim for Tortious Interference was also briefly discussed with very little time spent discussing the other claims. Counsel is unable to express an opinion as to how the Court will ultimately rule regarding this litigation.

In early April 2012, the Company received notice that Robert Rosenstein filed a petition under Chapter 7 of the Bankruptcy Code in the Northern District of Georgia. The Company has elected not to contest the dischargability of its claim against Mr. Rosenstein if the Summary Judgment is reversed on appeal. In the event of a reversal, and if there are any assets in the estate, the Company will file a proof of claim in the Bankruptcy Court as an unsecured creditor.

In April 2011, MidSouth filed a Notice of Appeal from the Order disposing of its claims against the Company and Sage, and the Company filed a Notice of Cross Appeal from the Order granting the Defendants' Motion for Summary Judgment on the original Complaint. MidSouth's appeal has been assigned Case No. 11-11618-E and the Company's Cross-Appeal has been assigned Case No. 11-11650-E. Mediation ordered by the Court of Appeals was unsuccessful.

On August 14, 2012, the panel to which the Appeal and Cross-Appeal had been assigned issued an opinion affirming in part and reversing in part the decisions of the Trial Court. The Court of Appeals affirmed both the Trial Judge's grant of Summary Judgment in favor of the Company and Sage on MidSouth's fraud Counterclaim and the grant of Summary Judgment in favor of MidSouth, Cabibi, and Rosenstein on the Company's tortious interference claims. The Court of Appeals reversed the Trial Court's Order dismissing MidSouth's Counterclaim for breach of contract and the Order granting Summary Judgment in favor of the Company on MidSouth's Counterclaims based on promissory estoppel, quantum meruit, and unjust enrichment.

After remand to the District Court, the parties were directed to submit a proposed Scheduling Order by October 12, 2012. The proposed Scheduling Order was submitted timely by the parties and entered by the Court on October 17, 2012. The Company will vigorously defend the remaining Counterclaims. No date has been set for trial.

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

On July 31, 2009, Cato Capital LLC ("Cato") filed suit asserting that under a November 2008 agreement, the Company owes Cato a placement fee for certain investment transactions. The Complaint sought damages in the amount of $5,000,000 plus attorneys' fees. The Company filed an Answer on August 20, 2009. On October 13, 2009, Cato filed a Motion seeking leave to file an Amended Complaint which proposed that Cato be permitted to add The Sage Group as an additional defendant and to bring additional causes of action against the Company arising from the defenses contained in the Answer, and increase the total amount sought to $9,830,000, plus attorneys' fees and punitive damages. On September 14, 2010, the Court granted Cato's Motion for Leave to file an Amended Complaint, but specifically indicated that the Company could file a Motion to Dismiss, raising the arguments that the Company had previously made in response to Cato's Motion for Leave to file an Amended Complaint. On September 16, 2010, Cato filed its Amended Complaint, and on September 30, 2010, the Company filed a Motion to dismiss all the counts of the Amended Complaint against the Company other than the breach of contract count. In addition, pursuant to an indemnification responsibility, the Company has also retained counsel to undertake the defense of the Sage Group, and a motion to dismiss has been filed on behalf of the Sage Group seeking to dismiss all claims against the Sage Group. On July 28, 2011, the Court denied the Company's motion to dismiss and the motion to dismiss of the Sage Group. On August 11, 2011, the Court entered a Scheduling Order that set Discovery, Motion and other applicable dates, including a trial date of October 1, 2012. The scheduled trial date has since been changed by the Court to October 29, 2012. On August 30, 2011, the Company and the Sage Group filed an Answer with Affirmative Defenses to the Plaintiff's Amended Complaint. On October 24, 2011, Cato filed a Motion for a Partial Summary Judgment, seeking a determination that two of the Company's affirmative defenses to Cato's breach of contract cause of action should be stricken. On November 10, 2011, the Company filed a response controverting Cato's Motion on factual and legal basis. Also on November 10, 2011, the Company filed its own Motion for Partial Summary Judgment, seeking dismissal of Cato's claim for breach of contract. 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 also filed a Motion for Summary Judgment seeking dismissal of all counts asserted against Sage.

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. On September 10, September 12, and September 13 2012 the Court entered Orders denying all pending Motions by all parties.

The Parties are scheduled to commence a Non-Jury trial on January 2, 2013 before the United States District Court for the District of Delaware.

As of October 24, 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 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 nine months ended September 30, 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 in a timely manner, or at all, our operations will be materially harmed and our stock 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 and efficacious. While Ampligen® is authorized for use in clinical trials in the U.S., 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.

On June 8, 2012, the Company and its consultants met with the FDA to discuss certain aspects of the CRL. Upon our review of the FDA Minutes from this meeting, we believe the key points from the meeting to be undertaken by the Company in conjunction with its complete response included the following:

- The FDA agreed to accept, for review, in Hemispherx' complete response new analyses of data from the AMP-516 Trial. Whether these data provide adequate evidence of efficacy will ultimately be a review issue, and there can be no assurance the FDA will conclude the data are adequate to support approval of the Ampligen® NDA;
- As Ampligen® is a new molecular entity, the FDA anticipates that the data submitted in the NDA would be presented at a public FDA Advisory Committee meeting;
- The FDA requires that the Company's complete response include all information necessary for review at the time of filing and that it address all deficiencies identified in the CRL;
- Our New Brunswick manufacturing facility would be expected to be ready for GMP pre-approval inspection at the time of the complete response; and
- We will include in the complete response a request for postponement of rodent carcinogenicity study requirements and a justification for this request.

The FDA also advised that whether the new analyses provide adequate evidence of Ampligen®'s efficacy in treating CFS will ultimately be an Advisory Committee review issue. We submitted the complete response to the FDA on July 31, 2012. The FDA acknowledged in writing receipt of the response stating, "We consider this a complete, class 2 response to our November 25, 2009, action letter." Based on its designation of the submission as a class 2 response, FDA indicated that the Prescription Drug User Fee Act ("PDUFA") goal for completion of the FDA review will be February 2, 2013. The FDA's agreement to review the complete response does not commit the FDA to approve the Ampligen® NDA. Further, no guarantee can be made at this time that the facility will necessarily pass a pre-approval inspection to produce raw materials to manufacture Ampligen®, which is conducted in a separately dedicated area within the overall New Brunswick manufacturing complex. As a result of the FDA meeting, we have redirected many of our resources to the Ampligen® NDA submission and our preparation for the FDA pre-approval inspections by reassigning personnel, hiring additional staff, consultants and various independent contractors.

The FDA has scheduled the Advisory Committee meeting to discuss the Ampligen® NDA on December 20, 2012. The FDA is not bound by, and has in the past missed, its PDUFA goals, and it is unknown whether the AC meeting will be held as scheduled or the review of our NDA filing for Ampligen® will be completed by the FDA review goal or will be delayed. The FDA's regulatory review and approval process is extensive, lengthy, expensive and inherently uncertain. To receive approval for a product candidate, we must, among other things, demonstrate to the FDA's satisfaction with substantial evidence from well-controlled pre-clinical and clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. We cannot predict if or when we might receive regulatory approval for Ampligen® for Chronic Fatigue Syndrome. Even if Ampligen® regulatory approval from the FDA for CFS is received, any approvals that we obtain could contain significant limitations in the form of narrow indications, patient populations, warnings, precautions or contra-indications or other conditions of use, or the requirement that we implement a risk evaluation and mitigation strategy. In such an event, our ability to generate revenues from such products could be greatly reduced and our business could be harmed.

Even if we believe that data collected from our preclinical studies and clinical trials of our product candidate are promising, our data may not be sufficient to support marketing approval by the FDA, or regulatory interpretation of these data and procedures may be unfavorable. If the FDA does not approve the Ampligen® NDA that we have submitted, it may require that we conduct additional clinical, pre-clinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be successful or considered sufficient by the FDA for approval or even to make our applications approvable. If any of these outcomes occur, we may be forced to abandon one or more of our future applications for approval, which might significantly harm our business and prospects. As a result, we cannot predict when or whether regulatory approval will be obtained for any product candidate we develop.

Obtaining approval of a NDA by the FDA, or a comparable foreign regulatory authority, is inherently uncertain. Even after completing clinical trials and other studies, a product candidate could fail to receive regulatory approval for many reasons, including the following:

- not be able to demonstrate to the satisfaction of the FDA that our product candidate is safe and effective for any indication;
- the FDA may disagree with the design or implementation of our clinical trials or other studies;
- the results of the clinical trials or other studies may not demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from clinical trials or other studies;
- the data collected from clinical trials and other studies of a product candidate may not be sufficient to support the submission of a NDA;
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical and other study data insufficient for approval; and
- the FDA may not approve the proposed manufacturing processes and facilities for a product candidate.

In April 2012, FDA reviewers raised certain questions about the status of our existing lots of older Work-In-Process Alferon® materials and API, which would need to be released by FDA before those materials could be used in commercial product. We are unable to provide any assurances that the FDA will approve the final inventory lots produced by Althea. 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 can be produced, filled and finished, and released by the FDA for commercial sale.

If we are unable to gain necessary FDA approvals related to Ampligen® and Alferon® on a timely basis, our operations most likely will be materially and/or adversely affected. For more information on the Ampligen® NDA and its current status with the FDA, and the status of regulatory approval for Alferon N Injection®, please see "Ampligen®" and "Alferon N Injection®", respectively, in Item 2: "Management's Discussion and Analysis of Financial Condition and Results of Operations; Overview; General".

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 have redirected many of our resources to the Ampligen® NDA submission and our preparedness for the FDA pre-approval inspections by reassigning personnel. Upon completion of the NDA effort, we intend to continue our evaluation of 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 better evaluate 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 the 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 on a timely manner, or at all, 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 ability to generate revenues to sustain our operations will be substantially impaired, which would increase the likelihood that we would need to obtain additional financing for our other development efforts;
- Our reputation among investors might be harmed, which might make it more difficult for us to obtain equity capital on attractive terms or at all; and
- Our profitability would be delayed, our business will be materially harmed and our stock price may be adversely affected.

Biotechnology stock prices, including our stock price, have declined significantly in certain instances where companies have failed to meet expectations with respect to FDA approval or the timing for FDA approval.

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 September 30, 2012, our accumulated deficit was approximately $(238,635,000). 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 most likely will require additional financing which may not be available. The limitation on the number of shares of common stock available for financing without prior stockholder approval eventually may hinder our ability to raise additional funding.

The development of our products requires 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 September 30, 2012, we had approximately $35,398,000 in cash, cash equivalents and marketable securities (inclusive of $10,342,000 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® along with the manufacturing, marketing and distribution of our products. We may also need additional funds to eventually commercialize and sell Ampligen® or Alferon® LDO and/or recommence and increase sales of Alferon N Injection® or our other products. We anticipate securing other sources of funding, if and when needed, through additional equity, debt financing or other sources.

In this regard, on July 23, 2012, we entered into an Equity Distribution Agreement with Maxim pursuant to which we may sell up to $75,000,000 worth of our shares of Common Stock from time to time through Maxim, as sales agent (See Part I; Item 2: “Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources” above). We cannot assure how much funding will be obtained from the Maxim EDA or whether it will be sufficient in conjunction with current financial resources to permit us to take all actions needed to obtain FDA approval for Ampligen® and manufacturing, commercialization, marketing and distribution of our products.

Our ability to raise additional funds from the sale of equity securities may be limited due to limitations on our ability to sell stock for funding purposes. Pursuant to our Amended and Restated Certificate of Incorporation, the purposes for which 150,000,000 of our authorized shares (the “Restricted Shares”) may be utilized is limited. Specifically,

without stockholder approval, the Restricted Shares can only be issued where such issuance would be primarily in connection with strategic transactions or other non-fundraising purpose that met certain significant criteria. In this regard, approximately 21,000,000 shares are authorized but unissued and unreserved at September 30, 2012 with an additional 75,000,000 of the Restricted Shares approved by Stockholders for certain generally defined business purposes.

There can be no assurances that we can obtain the requisite stockholder approval to use any additional Restricted Shares for funding purposes or raise adequate funds from other sources. If we are unable to obtain additional funding, through the Maxim EDA or otherwise, our ability to develop our products, commercially produce inventory 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 required a FDA approved third party CMO in Althea.

In April 2012, FDA reviewers raised certain questions about the status of our existing lots of older Work-In-Process Alferon® materials and API, which would need to be released by FDA before those materials could be used in commercial product. We are unable to provide any assurances that the FDA will approve the final inventory lots of Alferon® produced by Althea. 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 can be produced, filled and finished, and released by the FDA for commercial sale.

If we are unable to gain the necessary FDA approvals related to Alferon®, our operations most likely will be materially and/or adversely affected. For more information on Alferon N Injection® regarding potential commercial sales, please see “Alferon N Injection®” in Item 2: “Management's Discussion and Analysis of Financial Condition and Results of Operations; Overview; General”.

We continue to undertake at our New Brunswick, NJ facility a major capital improvement program to upgrade our manufacturing capability to produce bulk quantities of Alferon N Injection® API. The production of new API inventory will not commence until the capital improvement and validation phases are complete. Due to the necessity to redirected many of our resources to the Ampligen® NDA application process and efforts towards the pre-approval inspection for Ampligen® manufacturing, the validation phase of the Alferon® manufacturing project has been delayed until we have completed our focus on the NDA process. Once we begin production of new Alferon® API, we anticipate that it will take approximately nine to twelve months before we will have Alferon® that can be commercially sold. While the facility had been granted approval of its Biological License Application by the FDA for Alferon®, this status will need to be reaffirmed upon the completion of the facility’s upgrades for Alferon®. We cannot provide any guarantee that the facility will necessarily pass a pre-approval inspection for Ampligen® or Alferon® manufacture, which are conducted in separately dedicated areas within the overall New Brunswick manufacturing complex.

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 both Ampligen® and Alferon® in Argentina 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. For more information on Ampligen®, please see the “Ampligen®” section in Item 2: Management's Discussion and Analysis of Financial Condition and Results of Operations; Overview; General.

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 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.

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®. The Technology Transfer process with Althea was completed in May 2012 and included the 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. As of September 30, 2012, all but one of our four lots of Alferon® Work-In-Process Inventory have completed the fill, finish and packaging process with the final lot converted on October 12, 2012. Of the three lots that had completed the fill, finish and packaging process, the first lot was deemed not suitable for commercial sale due to an issue that occurred in the conversion process and therefore its value was reserved by the Company along with any product conversion shrinkage from this final production stage for the other lots. Upon analysis and revision of the fill and finish process, the second and third lots were completed with the previous issue in the manufacturing step corrected.

Pursuant our Supply Agreement with Hollister-Stier, 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. This Supply Agreement, as amended extends through March 11, 2014.

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. For more information on Ampligen® and Alferon N Injection®, please see “Ampligen®” and “Alferon N Injection®” in Item 2: “Management's Discussion and Analysis of Financial Condition and Results of Operations; Overview; General”.

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 upgrade our 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.

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We have limited manufacturing experience for Ampligen® and Alferon®. We may not be profitable unless we can produce Ampligen®, Alferon® or other products in commercial quantities at costs acceptable to us.

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.

We continue to undertake at our New Brunswick, NJ facility a major capital improvement program to upgrade our manufacturing capability to produce bulk quantities of Alferon N Injection® API. The production of new API inventory will not commence until the capital improvement and validation phases are complete. Due to the necessity to redirected many of our resources to the Ampligen® NDA application process and efforts towards the pre-approval inspection for Ampligen® manufacturing, the validation phase of the Alferon® manufacturing project has been delayed until we have completed our focus on the NDA process. 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 upgrades for Alferon®. We cannot provide any guarantee that the facility will necessarily pass a pre-approval inspection for Ampligen® or Alferon® manufacture, which are conducted in separately dedicated areas within the overall New Brunswick manufacturing complex. 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.

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 have never produced Ampligen®, Alferon® 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® and/or Alferon®, or continue to maintain third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Should the Ampligen® 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® and/or Alferon® 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 MKT 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 MKT. For the nine month period ended September 30, 2012, the closing price of our common stock has ranged from $0.19 to $1.00 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

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 September 30, 2012. 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 statement and we have been selling shares under this shelf registration statement and the Maxim EDA. Through

September 30, 2012, the Company had sold an aggregate of 10,699,700 shares under the EDA.

Pursuant to the July 23, 2012 EDA with Maxim, the Company may sell up to $75,000,000 worth of its shares of Common Stock from time to time through Maxim, as sales agent. The Company has no obligation to sell any of the Shares and may at any time suspend offers under the EDA or terminate the EDA. While the Company has no obligation to sell any of the Shares and may at any time suspend offers under the EDA or terminate the EDA, the sale of substantial numbers of Shares under the EDA may have an adverse impact on the trading value of the stock.

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 Maxim EDA or otherwise under 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, on November 2, 2012, we amended and restated our 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 and may be redeemed prior to November 19,2017, the expiration date, at $0.001 per Right under certain circumstances. 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 6.0% of our common stock, the Rights Plan’s threshold will be 20%, instead of 15%. For more information, see Part II; Item 5: “Other Information”.

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 nine months ended September 30, 2012.

ITEM 3: Defaults upon Senior Securities

None.

ITEM 4: Mine Safety Disclosures

Not Applicable.

ITEM 5: Other Information

On November 2, 2012, the Company executed an Amended and Restated Rights Agreement amending and restating the November 19, 2002 Rights Agreement between the Company and Continental Stock Transfer & Trust Company, as Rights Agent (as amended, the "Rights Agreement"). The Rights Agreement extends the term of the Rights Plan to November 18, 2017 and amends certain other provisions, as described in the Company's Amended Registration Statement on Form 8-A/A, filed on November 2, 2012 (the "Amended Form 8-A").

The foregoing description of the Rights Agreement is qualified in its entirety by reference to the full text of the Rights Agreement, attached to the Amended Form 8-A as Exhibit 1.0 and incorporated herein by reference.

ITEM 6: Exhibits

	(a)	Exhibits
4.1	Amended and Restated Rights Agreement, dated as of November 2, 2012, between Hemispherx Biopharma, Inc. and Continental Stock Transfer & Trust Company. The Rights Agreement includes the Form of Amended and Restated Certificate of Designation, Preferences and Rights of the Series A Junior Participating Preferred Stock, the Form of Rights Certificate and the Summary of the Right to Purchase Preferred Stock.(1)	

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 September 30, 2012, formatted in eXtensible Business Reporting Language ("XBRL"): (i) Condensed Balance Sheets ; (ii) Condensed Consolidated Statements of Comprehensive Loss; (iii) Condensed Consolidated Statements of Cash Flows; and (iv) Notes to Condensed Consolidated Financial Statements.

(1) Filed with the Securities and Exchange Commission as an exhibit to the Company's Amended Registration Statement on Form 8-A/A on November 2, 2012 and is hereby incorporated by reference.

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: November 2, 2012