HEMISPHERX BIOPHARMA INC
Form 10-Q
November 09, 2011

UNITED STATES

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

For the Quarterly Period Ended September 30, 2011

Commission File Number: 1-13441

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

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

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

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

Not Applicable

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§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).
x Yes ¨ No

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

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

135,566,471 shares of common stock were outstanding as of November 1, 2011.

PART I - FINANCIAL INFORMATION

ITEM 1: Financial Statements

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

	December 31, 2010	September 30, 2011 (Unaudited)
Current assets:		
Cash and cash equivalents (Note 13)	$ 2,920	$4,022
Marketable securities – Unrestricted (Note 5)	32,689	27,702
Marketable securities – Restricted (Note 6)	0	1,035
Inventories (Note 4)	787	1,089
Prepaid expenses and other current assets	278	371
Total current assets	36,674	34,219
Property and equipment, net	4,876	4,737
Patent and trademark rights, net	794	725
Investment	35	0
Marketable securities - Unrestricted(Note 5)	8,778	2,457
Marketable securities – Restricted (Note 6)	0	2,107
Construction in progress (Note 9)	485	1,213
Other assets	38	77
Total assets	$ 51,680	$45,535
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,328	$1,576
Accrued expenses (Note 7)	1,443	814
Margin Account Loan (Note 10)	0	1,156
Current portion of capital lease (Note 8)	61	57
Total current liabilities	2,832	3,603
Long-term liabilities		
Long-term portion of capital lease (Note 8)	96	112
Redeemable warrants (Note 12)	2,805	1,247
Total liabilities	5,733	4,962
Commitments and contingencies		
Stockholders' equity (Note 11):		
Preferred stock, par value $0.01 per share, authorized 5,000,000; issued and outstanding; none	0	0
	135	135

Common stock, par value $0.001 per share, authorized 200,000,000 shares; issued and outstanding 135,241,609 and 135,537,970, respectively		
Additional paid-in capital	264,511	264,930
Accumulated other comprehensive loss	(974)	(867)
Accumulated deficit	(217,725)	(223,625)
Total stockholders' equity	45,947	40,573
Total liabilities and stockholders' equity	$ 51,680	$45,535

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,	
	2010	2011
Revenues:		
Clinical treatment programs	$ 35	$ 45
Total revenues	35	45
Costs and expenses:		
Production/cost of goods sold	181	217
Research and development	1,808	1,750
General and administrative	1,738	1,635
Total costs and expenses	3,727	3,602
Operating loss	(3,692)	(3,557)
Interest expense from capital leases	(5)	(9)
Interest and other income	443	212
Redeemable warrants valuation adjustment (Note 12)	(584)	614
Net loss	(3,838)	(2,740)
Unrealized gain (loss) on investments (Note 5, 6 & 14)	719	(529)
Net comprehensive loss (Note 14)	$ (3,119)	$ (3,269)
Basic and diluted loss per share (Note 2)	$ (.02)	$ (.02)
Weighted average shares outstanding, basic and diluted	134,869,730	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,	
	2010	2011
Revenues:		
Clinical treatment programs	$ 108	$ 123
Total revenues	108	123
Costs and expenses:		
Production/cost of goods sold	649	614
Research and development	5,498	5,014
General and administrative	5,495	4,890
Total costs and expenses	11,642	10,518
Operating loss	(11,534)	(10,395)
Interest expense from capital leases	(5)	(21)
Interest and other income	565	686
Funds received from sale of income tax net operating losses (Note 15)	0	2,272
Redeemable warrants valuation adjustment (Note 12)	341	1,558
Net loss	(10,633)	(5,900)
Unrealized gain on investments (Note 5, 6 & 14)	717	107
Net comprehensive loss (Note 14)	$ (9,916)	$ (5,793)
Basic and diluted loss per share (Note 2)	$ (.08)	$ (.04)
Weighted average shares outstanding, basic and diluted	133,605,973	135,379,622

See accompanying notes to consolidated financial statements.

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

	Common Stock Shares	Common Stock $.001 Par Value	Additional Paid-In Capital	Accumulated Other Compre-hensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2010	135,241,609	$135	$264,511	$ (974)	$ (217,725)	$ 45,947
Stock issued for settlement of accounts payable	145,440	0	71	0	0	71
Equity based compensation	150,921	0	348	0	0	348
Net comprehensive loss	0	0	0	107	(5,900)	(5,793)
Balance at September 30, 2011	135,537,970	$135	$264,930	$ (867)	$ (223,625)	$ 40,573

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
For the Nine Months Ended September 30, 2010 and 2011
(in thousands)
(Unaudited)

	2010	2011
Cash flows from operating activities:		
Net loss	$(10,633)	$(5,900)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	295	322
Amortization of patent and trademark rights, and royalty interest	57	161
Redeemable warrants valuation adjustment	(341)	(1,558)
Equity based compensation	659	348
Other than temporary impairment of marketable securities	0	258
Change in assets and liabilities:		
Inventories	(212)	(302)
Prepaid expenses and other current assets	97	(93)
Other assets	(6)	0
Accounts payable	763	319
Accrued expenses	(749)	(629)
Net cash used in operating activities	$(10,070)	$(7,074)
Cash flows from investing activities:		
Purchase of property and equipment	$(514)	$(849)
Additions to patent and trademark rights	(201)	(92)
Deposits on capital leases	(9)	(4)
Maturities of short-term and long-term investments	4,356	11,148
Purchase of short-term and long-term investments	(48,856)	(3,133)
Net cash provided by (used in) investing activities	$(45,224)	$7,070

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows (Continued)
For the Nine Months Ended September 30, 2010 and 2011
(in thousands)
(Unaudited)

	2010	2011
Cash flows from financing activities:		
Payments on capital leases	$(27)	$(50)
Proceeds from Margin Account Loan	0	1,156
Proceeds from sale of stock, net of issuance costs	293	$(0)
Net cash provided by financing activities	$266	$1,106
Net increase (decrease) in cash and cash equivalents	(55,028)	1,102
Cash and cash equivalents at beginning of period	58,072	2,920
Cash and cash equivalents at end of period	$3,044	$4,022
Supplemental disclosures of non-cash investing and financing cash flow information:		
Issuance of common stock for accounts payable and accrued expenses	$328	$71
Equipment acquired by capital lease	$200	$62
Unrealized gain on investments	$717	$107
Redeemable warrants valuation adjustment	$(341)	$(1,558)
Supplemental disclosure of cash flow information:		
Cash paid for interest expense	$5	$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 our annual consolidated financial statements and notes thereto.

These consolidated financial statements should be read in conjunction with our consolidated financial statements for the year ended December 31, 2010, contained in our Annual Report on Form 10-K for the year ended December 31, 2010.

Note 2: Net Loss Per Share

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Equivalent common shares, consisting of stock options and warrants which amounted to 52,686,158 and 53,809,659 shares, are excluded from the calculation of diluted net loss per share for the nine months ended September 30, 2010 and 2011, respectively, since their effect is antidilutive.

Note 3: Equity Based Compensation

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

	Nine Months Ended September 30,	
	2010	2011
Risk-free interest rate	1.02% - 2.03%	0.89% - 2.24%
Expected dividend yield	-	-
Expected lives	5.0 yrs.	5.0 years
Expected volatility	109.57%-110.01%	104.29%-104.88%
Weighted average grant date fair value per options and warrants issued	$0.42 per option for 1,425,000 options	$0.30 per option for 990,000 options

Stock option activity during the nine months ended September 30, 2010 and 2011, respectively, is as follows:

Stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2009	6,228,752	$ 2.60	6.95	$ 0
Options granted	993,728	0.80	9.42	0
Options forfeited	0	0	0	0
Outstanding December 31, 2010	7,222,480	$ 2.35	6.21	$ 0
Options granted	930,000	0.42	9.71	0
Options forfeited	0	0	0	0
Outstanding September 30, 2011	8,152,480	$ 2.13	5.95	$ 0
Exercisable September 30, 2011	8,071,924	$ 2.14	5.95	$ 0

Options to purchase 930,000 shares were granted to employees during the nine months ended September 30, 2011 at a premium value of 110% of the NYSE Amex stock closing price. The options vest immediately to proportionately over 18 months. The weighted average grant-date fair value of the options granted during the nine months ended September 30, 2010 and 2011 was $384,000 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 December 31, 2009	38,333	$1.54	8.00	$0
Options granted	20,000	0.66	9.50	0
Options vested	(7,778)	0.66	9.50	0
Options forfeited	0	0	0	0
Outstanding December 31, 2010	50,555	$1.33	7.60	$0
Options granted	40,000	0.37	10.00	0
Options vested	(9,999)	0.66	8.45	0
Options forfeited	0	0	0	0
Outstanding September 30, 2011	80,556	$0.94	8.20	$0

Stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2009	2,233,432	$ 2.44	5.73	$ 0
Options granted	625,000	0.55	9.52	0
Options exercised	0	0	0	0
Options forfeited	(10,000)	2.46	0	0
Outstanding December 31, 2010	2,848,432	$ 2.03	5.80	$ 0
Options granted	60,000	0.46	9.67	0
Options exercised	0	0	0	0
Options forfeited	0	0	0	0
Outstanding September 30, 2011	2,908,432	$ 2.00	5.15	$ 0
Exercisable September 30, 2011	2,844,473	$ 1.98	5.34	$ 0

The weighted-average grant-date fair value of non-employee options granted during the nine months ended September 30, 2010 and 2011 was approximately $225,000 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 December 31, 2009	139,584	$ 2.68	3.76	$ 0
Options granted	0	0	0	0
Options vested	(37,500)	2.81	2.50	0
Options forfeited	0	0	0	0
Outstanding December 31, 2010	102,084	$ 2.63	3.54	$ 0
Options granted	0	0	0	0
Options vested	(38,125)	2.81	1.75	0
Options forfeited	0	0	0	0
Outstanding September 30, 2011	63,959	$ 2.52	3.41	$ 0

The impact on the Company’s results of operations of recording equity based compensation for the nine months ended September 30, 2010 and 2011 was to increase general and administrative expenses by approximately $659,000 and $348,000, respectively. The impact on basic and fully diluted earnings per share for the nine months ended September 30, 2010 and 2011 was $0.01 and $0.00, respectively.

As of September 30, 2010 and 2011, respectively, there was approximately $181,000 and $120,000 of unrecognized equity based compensation cost related to options granted under the Equity Incentive Plan. The $120,000 unrecognized equity based compensation as of September, 2011 will be fully expensed by June 2013.

Note 4: Inventories

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

Inventories consist of the following:

	(in thousands) December 31, 2010	September 30, 2011
Inventory work-in-process, January 1	$ 864	$ 787
Production	373	302
Spoilage	(450)	0
Finished goods, net of reserves of $250,000 at December 31, 2010 and at September 30, 2011, respectively.	0	0
Inventory work-in-process, end of period	$ 787	$ 1,089

The production of Alferon N Injection® from the Work-In-Progress Inventory continued through January 2011 with its conversion into Active Pharmaceutical Ingredient ("API") and is near completion for the related Final Lot Release Test. To formulate, fill and finish Alferon N Injection® Drug Product, we require a U.S. Food and Drug Administration ("FDA") approved third party Contract Manufacturing Organization ("CMO"). In June 2011, our designated CMO reported to us that they had received an FDA 483 form that identified production issues that needed to be addressed prior to resumption of production. As a result, we continue to evaluate alternative CMOs to undertake the formulation Fill and Finish process. When a new CMO is selected, it will be necessary to conduct production tests to qualify the new CMO. The resulting data must then be submitted to the FDA, with the CMO and finished product lots approved by FDA, prior to our being able to commercially sell Alferon N Injection®. While timing cannot be adequately determined until the selection of a CMO is finalized, we estimate that commercial sales of Alferon N Injection® will not resume until the later part of 2012.

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. For the three and nine months ended September 30, 2011, it was determined that some of the Marketable Securities had other than temporary impairments of approximately $79,000 and $258,000, respectively, which has been included with interest and other income for reporting purposes. At September 30, 2011, all of these securities were classified as available for sale investments and $21,600,000 were measured as Level 1 instruments and $8,560,000 were measured as level 2 instruments of the fair value measurements standard (see Note 12: Fair Value).

Securities classified as available for sale consisted of:

September 30, 2011
(in thousands)

Securities	Cost	Unrealized Gains	Unrealized Losses	Recorded Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 22,210	$ 0	$ (610)	$ 21,600	$ 21,600	$ 0
Certificates of Deposit	2,528	11	(10)	2,529	1,566	963
Corporate Bonds	6,211	0	(181)	6,030	4,536	1,494
Totals	$ 30,949	$ 11	$ (801)	$ 30,159	$ 27,702	$ 2,457

December 31, 2010
(in thousands)

Securities	Cost	Unrealized Gains	Unrealized Losses	Recorded Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 22,200	$ 0	$ (490)	$ 21,710	$ 21,710	$ 0
Certificates of Deposit	4,327	12	(5)	4,334	2,052	2,282
Corporate Bonds	13,092	0	(444)	12,648	8,173	4,475
Foreign Bonds	2,822	0	(47)	2,775	754	2,021
Totals	$ 42,441	$ 12	$ (986)	$ 41,467	$ 32,689	$ 8,778

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, 2011
(in thousands)

	Less Than 12 Months		12 Months or Greater		Totals	
Securities	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	$ 21,600	$ (610)	$ 0	$ 0	$ 21,600	$ (610)
Certificates of Deposit	102	(1)	416	(9)	518	(10)
Corporate Bonds	0	0	3,259	(181)	3,259	(181)
Totals	$ 21,702	$ (611)	$ 3,675	$ (190)	$ 25,377	$ (801)

December 31, 2010
(in thousands)

	Less Than 12 Months		12 Months or Greater		Totals	
Securities	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	$ 21,710	$ (490)	$ 0	$ 0	$ 21,710	$ (490)
Certificates of Deposit	721	(5)	0	0	721	(5)
Corporate Bonds	12,649	(444)	0	0	12,649	(444)
Foreign Bonds	2,775	(47)	0	0	2,775	(47)
Totals	$ 37,855	$ (986)	$ 0	$ 0	$ 37,855	$ (986)

Unrealized losses from fixed-income securities are primarily attributable to changes in interest rates and/or a reduction in their rating of credit worthiness as determined by independent financial rating services. Unrealized losses from domestic and international equities are due to market price movements. Management does not believe any remaining

losses represent other than temporary impairment based on our evaluation of available evidence as of September 30, 2011.

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 two to one to serve as collateral for those funds withdrawn and outstanding (see Note 10: Margin Account Loan).

These restricted 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, 2011, it was determined that none of the Marketable Securities had other than temporary impairments. At September 30, 2011, all restricted securities were classified as restricted from sale investments and $3,142,000 was measured as level 2 instruments of the fair value measurements standard (see Note 12: Fair Value).

Securities classified as restricted from sale consisted of:

September 30, 2011
(in thousands)

Securities	Cost	Unrealized Gains	Unrealized Losses	Recorded Value	Short-Term Investments	Long Term Investments
Corporate Bonds	$ 3,219	$ 0	$ (77)	$ 3,142	$ 1,035	$ 2,107
Totals	$ 3,219	$ 0	$ (77)	$ 3,142	$ 1,035	$ 2,107

There were no restricted marketable securities as of December 31, 2010.

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, 2011
(in thousands)

	Less Than 12 Months		12 Months or Greater		Totals	
Securities	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Corporate Bonds	$ 2,107	$ (46)	$ 1,035	$ (31)	$ 3,142	$ (77)
Totals	$ 2,107	$ (46)	$ 1,035	$ (31)	$ 3,142	$ (77)

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 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 our evaluation of available evidence as of September 30, 2011.

Note 7: Accrued Expenses

Accrued expenses consist of the following:

	(in thousands) December 31, 2010	September 30, 2011
Compensation	$ 995	$ 252
Professional fees	207	165
Other expenses	128	284
Due for returned product	113	113
	$ 1,443	$ 814

Note 8: Capital Lease

The Company has acquired equipment under capital leases as follows:

	(in thousands) Asset Balance at September 30, 2011
Leased Equipment included with property and equipment	$ 263
Less: accumulated depreciation	(51)
	$ 212

The following is a schedule by year of future minimum lease payments under the capital leases as of September 30, 2011:

	(in thousands)
2011	$ 26
2012	72
2013	60
2014	39
2015	23
2016	1
Total lease payments remaining	221
Less: amount representing interest	(52)
Present value of remaining minimum lease payments	169
Less: current obligations under lease obligations	(57)
Long-term capital lease obligations	$ 112

Minimum lease payments under the capital leases range from $576 per month to $2,994 per month and the lease periods range from 24 months to 60 months. Aggregate security deposits of $12,880 were paid and are included in other assets.

Note 9: Construction in Progress

Utilizing our Board of Directors approval of up to $4.4 million for full engineering studies, capital improvements, system upgrades and introduction of building management systems to enhance production of Alferon®, the project has progressed to the construction phase. Construction in progress consists of accumulated costs for the construction and installation of capital improvements and process equipment within the Company's New Brunswick, New Jersey facility until the assets are placed into service. As of December 31, 2010, construction in progress was $485,000 as compared to $1,213,000 as of September 30, 2011. As of September 30, 2011, and including the construction in progress costs, approximately $1,156,000 has been spent on this project of the $4.4 million authorized by the Board. The entire cost of this capital improvement project is currently being financed (see Note 10: Margin Account Loan).

The primary purpose of this upgrade is to significantly increase our production capacity for Alferon® API. As expected in any construction project, we had experienced some delay due to permit issues, demolition concerns and design revisions. Accordingly, we had used this time to pursue cost savings where possible, including locating and acquiring equipment from major U.S. pharmaceutical manufacturers that have recently curtailed or eliminated certain manufacturing activities or plants. As a result, we have estimated a cost savings of approximately $827,000 to date for the project as compared to acquiring the equipment directly from the original manufacturer.

Note 10: Margin Account Loan

A “Margin Account” 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 (see Note 9: Construction in Progress). In order to maintain this Margin Account, established on July 26, 2011 with an estimated maximum dollar value of $4 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% 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%. On September 28, 2011, the principal loan balance of the Margin Account was undertaken for approximately $1,156,000, for which approximately $3,142,000 in Marketable Securities became restricted as dedicated collateral for the indebtedness. As a result of the loan being outstanding for only three days at the end of the quarter, the finance charge was approximately $244 for both three and nine months ended.

Note 11: Stockholders’ Equity

The Equity Compensation Plan effective May 1, 2004, authorized the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 8,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Plan of 2004. Unless sooner terminated, the Equity Compensation Plan of 2004 will continue in effect for a period of 10 years from its effective date. Prior to September 30, 2011, the Company effectively exhausted this plan by previously issuing an aggregate of 7,989,981 shares, stock options and warrants to vendors, Board Members, Directors and consultants under the 2004 Equity Compensation Plan. The shares had prices ranging from $0.35 to $0.89 based on the NYSE Amex closing price. The stock options had various exercise prices ranging from $1.30 to $6.00, had terms of five to ten years and vesting immediately to three years.

The Equity Incentive Plan of 2007, effective June 20, 2007, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 9,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan of 2007. Unless sooner terminated, the Equity Incentive Plan of 2007 will continue in effect for a period of 10 years from its effective date. The Company issued to vendors, Board Members, Directors and consultants, shares, stock options, warrants and "Incentive Rights" under the Employee Wages or Hours Reduction Program. Prior to September 30, 2011, the Company effectively exhausted this plan by previously issuing an aggregate of 8,980,374 shares and shares issuable upon exercise/conversion of the foregoing securities. The aggregate shares to vendors, Board Members, Directors and consultants had prices ranging from $0.32 to $2.54 based on the NYSE Amex closing price. The stock options had various exercise prices ranging from $0.72 to $3.05, terms of ten years and vesting over varying periods.

The Company utilized the Black-Scholes-Merton Pricing Model to arrive at the fair value of the stock options which had been issued during the nine months ended September 30, 2011 and accordingly recorded approximately $296,000 as equity based compensation for these issuances during this period. The stock options are generally priced at a premium of 110% of the stock's NYSE Amex Closing Price on the effective date of issuance or contractual agreement with vesting immediate upon grant.

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, 2011, the Company issued 4,696,777 securities to Directors and consultants consisting of an aggregate 817,906 shares of common stock and options to purchase 3,878,871 shares. The shares issued to consultants had prices ranging from $0.37 to $0.68 based on the NYSE Amex closing price.

The aggregate stock options had various exercise prices ranging from $0.37 to $2.81, had terms of ten years and vested immediately upon grant.

Pursuant to a May 28, 2010 Equity Distribution Agreement (the "Agreement") with Maxim Group LLC ("Maxim"), the Company established an At-The-Market ("ATM") Equity Program pursuant to which the Company may sell up to 32,000,000 shares of its Common Stock from time to time through Maxim as its sales agent (the "Agent"). Under the Agreement, the Agent is entitled to a commission at a fixed commission rate of 4.0% of the gross sales price per Share sold, up to aggregate gross proceeds of $10,000,000, and, thereafter, at a fixed commission rate of 3.0% of the gross sales price per Share sold. The Company has no obligation to sell any shares under this program, and may at any time terminate the Agreement. During the nine months ended September 30, 2011, the Company sold no shares through this program and received no net cash proceeds. As of September 30, 2011, the Company has sold an aggregate of 520,000 shares that resulted in net cash proceeds of approximately $293,000 and commissions paid to Maxim of approximately $12,000.

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

Note 12: Fair Value

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

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

In connection with equity financings on May 11 and 19, 2009, the Company issued warrants (the "Warrants") that are single compound derivatives containing both an embedded right to obtain stock upon exercise (a "Call") and a series of embedded rights to settle the Warrants for cash upon the occurrence of certain events (each, a "Put"). Generally, the Put provisions allow the Warrant Holders liquidity protection; the right to receive cash in certain situations where the Holders would not have a means of readily selling the shares issuable upon exercise of the Warrants (e.g., where there would no longer be a significant public market for our common stock). However because the contractual formula used to determine the cash settlement value of the embedded Put requires use of certain assumptions, the cash settlement value of the embedded Put can differ from the fair value of the unexercised embedded Call option at the time the embedded Put option is exercised. Specifically, the Put rights would be triggered upon the happening of a "Fundamental Transaction" (as defined below) that also is (1) an all cash transaction; (2) a "Rule 13e-3 transaction" under the Exchange Act (where the Company would be taken private); or (3) a transaction involving a person or entity not traded on a national securities exchange. "Fundamental Transactions" include (i) a merger or consolidation of the Company with or into another person or entity; (ii) a sale, lease, license, transfer or other disposition of all or substantially all of the Company's assets; (iii) any purchase offer, tender offer or exchange offer in which holders of Company Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property, which offer has been accepted by the holders of 50% or more of the Company's outstanding Common Stock; (iv) a reclassification, reorganization or recapitalization of the Common Stock pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property; or (v) a stock purchase or other business combination with another person or entity is effected pursuant to which such other person or entity acquires more than 50% of the outstanding shares of Common Stock. Pursuant to the Warrants, the Put rights enable the Warrant Holders to receive cash in the amount of the Black-Scholes value is obtained from the "OV" function on Bloomberg, L.P. ("Bloomberg") determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Warrant expiration date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg as of the Trading Day immediately following the public announcement of the applicable Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (D) a remaining option time equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Warrant expiration date.

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

Fair value at September 30, 2011, was estimated using the following assumptions:

Underlying price per share	$0.31
Exercise price per share	$1.31-$1.65
Risk-free interest rate	0.35%-1.58%
Expected holding period	2.63-3.63 yrs.
Expected volatility	114.9%-120.6%
Expected dividend yield	None

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

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

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

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

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

The Monte Carlo Simulation has consistently incorporated a 5.0% probability of a Fundamental Transaction from the initial valuation of May 2009 through September 30, 2011.

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

While the assumptions remain consistent from period to period (e.g., utilizing historical stock prices), the numbers input change from period to period (e.g., the actual historical prices input for the relevant period). The carrying amount and estimated fair value of the above warrants was approximately $1,247,000 at September 30, 2011. There were no other financial instruments at September 30, 2011.

On January 1, 2008, the Company adopted new accounting guidance (codified at FASB ASC 820 and formerly Statement No. 157 Fair Value Measurements) that defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The guidance does not impose any new requirements around which assets and liabilities are to be measured at fair value, and instead applies to asset and liability balances required or permitted to be measured at fair value under existing accounting pronouncements. The Company measures its warrant liability for those warrants with a cash settlement feature at fair value. As of September 30, 2011, the Company had no derivative assets or liabilities.

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

- Level 1 – Quoted prices are available in active markets for identical assets or liabilities at the reporting date.
- Level 2 – Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or other valuation techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

As of September 30, 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, 2011:

	Total	Level 1	Level 2	Level 3
Assets				
Marketable Securities - unrestricted	$ 30,160,000	$ 21,600,000	$ 8,560,000	$ 0
Marketable Securities-restricted	3,142,000	0	3,142,000	0
Liabilities				
Warrants	1,247,000	0	0	1,247,000
Total	$ 34,549,000	$ 21,600,000	$ 11,702,000	$ 1,247,000

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

	Fair Value of Redeemable Warrants (in thousands)	
	2010	2011
Balance at January 1	$ 3,684	$ 2,805
Fair value adjustment at March 31	1,336	(302)
Balance at March 31	$ 5,020	$ 2,503
Fair value adjustment at June 30	(2,260)	(643)
Balance June 30	$ 2,760	$ 1,860
Fair value adjustment at September 30	583	(613)
Balance September 30	$ 3,343	$ 1,247

Note 13: 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 14: Recent Accounting Pronouncements

In 2011, the Financial Accounting Standards Board ("FASB") had published FASB Accounting Standards Updates 2011-01 through 2011-09. With the exception of Update 2011-05, Management deemed them to have no material effect on the Company's financial statements for the nine months ended September 30, 2011. FASB Accounting Standards Update 2011-05, "Comprehensive Income (Topic 220)", effective for fiscal years beginning after December 15, 2011, is related to the revision of the traditional "Consolidated Statements of Operation" to a "Consolidated Statement of Comprehensive Income". 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. As of September 30, 2011, the new Consolidated Statement of Comprehensive Loss reporting approach was utilized for our presentation of financial results for both the three and nine months periods ended September 30, 2010 and 2011.

Note 15: Funds Received From Sale Of Income Tax Net Operating Losses

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

Note 16: Subsequent Events

The Company evaluated subsequent events through the date on which these financial statements were issued. The Company has determined that no subsequent event constituted a matter that required disclosure or adjustment to the financial statements for the nine months ended September 30, 2011.

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

Special Note Regarding Forward-Looking Statements

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

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

Overview

General

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

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

We own and operate a 43,000 sq. ft. FDA licensed manufacturing facility in New Brunswick, New Jersey that was primarily designed to produce Alferon®. On September 16, 2009, our Board of Directors approved up to $4.4 million for full engineering studies, capital improvements, system upgrades and introduction of building management systems to enhance production of three products: Alferon N Injection®, Alferon® LDO and Ampligen®. As of September 30, 2011, and including the construction in progress costs, approximately $1,156,000 has been spent on this project. 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 Investigational New Drug ("IND") (e.g., treatment investigational new drugs, or "Emergency" or "Compassionate" use authorization) with Cost Recovery Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports ("AHRQ" or Agency for Healthcare Research and Quality). Ampligen® represents the first drug in the class of large (macromolecular) RNA (nucleic acid) molecules to apply for New Drug Application ("NDA") review. Based on the results of published, peer reviewed pre-clinical studies and clinical trials, we believe that Ampligen® may have broad-spectrum anti-viral and anti-cancer properties. Over 1,000 patients have participated in the Ampligen® clinical trials representing the administration of more than 90,000 doses of this drug.

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

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

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

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

In December 2010, the FDA granted us a one year extension to file a response to the CRL based on the submission of new data concerning the potential viral etiology of CFS. We are currently undertaking the process to file a new Request For Extension with the FDA as we diligently work with Chronix Biomedical ("Chronix") to address the diagnostic challenges related to CFS (see below). Because of the diagnostic challenges that CFS poses and our continued work with Chronix for a predictive CFS test, we remain confident that our extension request will meet the FDA's customary regulatory criteria of reasonableness for such an extension request. However, we are unable to provide any assurances that the FDA will ultimately grant an additional extension of time to file a response to the CRL.

Progress In Search For CFS Test

We believe that finding an accurate diagnostic for CFS is very important and would make the study requested in the FDA's CRL more accurate and meaningful.

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

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

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

In the October 8, 2009 issue of Science Express, a consortium of researchers from the Whittemore Peterson Institute for Neuro-Immune Disease, a Nevada non-profit corporation ("WPI"), the National Cancer Institute and the Cleveland Clinic reported their observation of a new retrovirus, xenotropic murine leukemia related virus ("XMRV") in the blood cells of 67% of CFS patients and 3.7% in healthy control subjects. A collaboration with WPI was initiated to undertake a retrospective analyses of patient samples from the completed Phase III trial of Ampligen® for CFS indication. On July 20, 2011, we renewed our agreement with WPI, effective February 1, 2011, whereby they would continue to evaluate Hemispherx' samples for XMRV. On September 22, 2011, Sciencexpress published on their website a study entitled "Failure to Confirm XMRX/MLVs in the Blood of Patients with Chronic Fatigue Syndrome: A Multi-Laboratory Study" in which difficulty in measuring XMRV was reported and the authors concluded that current assays do not reproducibly detect XMRX/MLV in blood samples. As a result of the reproducibility difficulties in detecting XMRV, we no longer plan to focus on a potential diagnostic tool for CFS from XMRV and are pursuing Chronix' CFS testing program. The collaboration with Chronix was initiated in a parallel track as the WPI collaboration.

The NIH's Trans-NIH ME/CFS Working Group's Frequently Asked Questions webpage currently states that "Although it appears that XMRV (xenotropic murine leukemia virus-related virus) is a contaminant and not associated with human disease, the National Institutes of Health (NIH) continues to fund studies to determine whether results of recent studies can be replicated. Additional information will be gained from the completion of two large studies (Lipkin, National Institute of Allergy and Infectious Diseases) and the Blood XMRV Scientific Research Working Group (National Heart Lung and Blood Institute) that were initiated to study any potential connection between XMRV/MLV and human health or risks to the blood supply. In addition, the NIH funds and will continue to fund peer reviewed, investigator-initiated research that seeks to understand the role that viruses, including retroviruses, play in the etiology of a variety of human diseases." These studies may provide further perspective on the design of an additional confirmatory Ampligen® Phase III clinical study related to CFS.

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

At the IACFS/ME Biennial Conference held on September 22-25, 2011 in Ottawa, Ontario, Canada, new data was presented from a recent study on a blood test for CFS based on Chronix' technology. The aim of this study was to find signature DNA sequences from patients with CFS compared to healthy controls with respect to their diagnostic predictive value, as well as, to potentially provide new insight into CFS biology. DNA extracted from serum samples of CFS subjects and normal healthy controls was sequenced and compared to the human genome. A total of about 10,000 high quality sequence reads were generated from each serum sample and four genes were identified by Multivariate Regression that separated CFS patients from the normal control group with a c-value of 0.95. We believe that these results support additional studies with a larger CFS cohort using more powerful Massively Parallel Sequencing platforms with the aim of reduction to validate clinical assays for the diagnosis and evaluation of CFS and to explore whether the technology can be used to identify how different persons with CFS will respond to Ampligen® as compared to placebo.

In May 1997, the FDA approved an open-label treatment protocol, ("AMP 511"), allowing patient access to Ampligen® for treatment in an open-label safety study under which severely debilitated CFS patients have the opportunity to be on Ampligen® to treat this very serious and chronic condition. The data collected from the AMP 511 protocol through a consortium group with active clinical sites in New York City, NY, Charlotte, NC, Miami, FL, Incline Village, Nevada, and Salt Lake City, UT, provides safety data on the use of Ampligen® in patients to identify adverse events that occur in a patient to determine if it is related to the drug being tested or other health problems identified in trial participants. We are currently enlisting new sites and continue to enroll patients for this study. As of September 30, 2011, we had twenty-six patients participating in this open label treatment protocol. We plan to evaluate the DNA signatures of these patients as well as a normal cohort group.

Alferon N Injection®

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

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

Commercial sales of Alferon N Injection® were halted in March 2008 when our finished goods inventory expired. The production of Alferon N Injection® from the Work-In-Progress Inventory continued into January 2011 with its conversion into Active Pharmaceutical Ingredient ("API") and is near completion for the related Final Lot Release Test. To formulate, fill and finish Alferon N Injection® Drug Product, we require a U.S. Food and Drug Administration ("FDA") approved third party Contract Manufacturing Organization ("CMO"). In June 2011, our designated CMO reported to us that they had received an FDA 483 form that identified production issues that needed to be addressed prior to resumption of production. As a result, we are evaluating alternative CMOs to undertake the formulation Fill and Finish process. When a CMO is selected, it will be necessary to conduct production tests to qualify the new CMO. The resulting data must then be submitted to the FDA, with the CMO and finished product lots approved by the FDA prior to our being able to commercially sell Alferon N Injection®. While timing cannot be adequately determined until the selection of a CMO is finalized, we estimate that commercial sales of Alferon N Injection® will not resume until the later part of 2012.

We have 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.

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.

On December 22, 2010, the FDA approved 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 confirmatory Phase II study has been delayed as we work to select a vendor to conduct a confirmatory study using gene expression measures in an attempt to identify on the systemic 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 determine the cost/benefit of proceeding with this study of seasonal and pandemic influenza.

We have recently received notice of a patent issuance regarding Alferon® LDO for the treatment in a number of different human diseases.

Other Viral Diseases

Ampligen® as a mucosal adjuvant with vaccine had been studied at Japan's National Institute of Infectious Disease ("NIID") and at Biken (the for profit operational arm of the Foundation for Microbial Diseases of Osaka University). Investigators from Japan's NIID had conducted studies in animals that suggested that Ampligen® could stimulate a sufficiently broad immune response to provide cross-protection against a range of virus genetic types, including H5N1 and derivative clades. Japan's Council for Science & Technology Policy ("CSTP"), a cabinet level position, awarded funds from Japan's CSTP to advance research with influenza vaccines utilizing Ampligen®.

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

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

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

As a result of Biken's intension not to extend or replace the MEA or complete the related Evaluation Program, we have concluded that our association with Biken has come to a conclusion with no expected future association.

Dr. Hideki Hasegawa, M.D., Ph.D., Chief of Laboratory of Infectious Disease Pathology for the Department of Pathology for the NIID, undertook studies in 2009 and 2010 that focused on mucosal immunity and the inherent advantages of a vigorous immune response to respiratory pathogens. Dr. Hasegawa has published data that the formulation of pandemic vaccine mixed with Ampligen® increases immuno-genicity and may demonstrate cross protection against mutated strains. Dr. Hasegawa has expressed a desire to continue preclinical development of this concept, and as such, he continues to organize and participate in meetings with other qualified corporate vaccine partners in Japan who have intranasal vaccines under development along with necessary facilities to test, develop and commercialize the vaccine enhancement utilizing Ampligen® in an attempt to achieve cross-protection against pandemic strains in a commercial environment.

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. This study is similar to the initial studies of influenza application conducted at Japan's NIID noted above. The primary objective of this study is to evaluate the safety of three cycles of intranasal Ampligen® administered three days following each intranasal dose of seasonal influenza vaccine. Secondary objectives of this study include evaluation of various immune responses to the trivalent seasonal influenza vaccine administered intranasally with and without Ampligen®. We are currently evaluating qualified clinical sites that have the resources to support its implementation.

In April 2010, we began the process to undertake a clinical study with Max Neeman International, a leading and large clinical research organization in India. This collaborative clinical research effort is intended to utilize Alferon N Injection® for treatment of seriously ill patients hospitalized with either seasonal influenza or pandemic influenza. The Indian site selection process was initiated and we obtained approval to begin the study from the Indian Drugs Controller General on July 13, 2010. We continue to enroll subjects with expectation of greater patient participation in the upcoming flu season. As of September 30, 2011, we have eight operational Clinical Investigative Sites, with the intention of adding additional sites. Twenty patients have completed the study with an additional three having completed the treatment phase and undertaking the thirty day follow-up observation process. Our Study has progressed at a rate slower than originally projected due to difficulties encountered in the process of screening for subjects who were stricken only with influenza, rather than Dengue fever which shares some symptoms. In an attempt to expedite the process to qualify study subjects, we added a second "point of care" screening test which has been implemented at the sites as we attempt to qualify subjects for the upcoming flu season. It is our objective to qualify and enroll sixty patients for the study.

In June 2011, we entered into a Material Transfer and Research Agreement with the University of Pennsylvania's School of Medicine to provide Ampligen® for testing as a vaccine adjuvant in a human clinical study in ovarian cancer. This study is a Phase I/II randomized clinical trial for subjects with recurring ovarian, fallopian tube or primary peritoneal cancer to determine the feasibility and safety as well as immunogenicity of a vaccine comprised of autologous oxidized tumor cell lysate ("OC-L") administered by intradermal/subcutaneous injection in combination with intravenous Ampligen®. The OC-L vaccine is an experimental cancer immunotherapy under development by the University of Pennsylvania. This study represents the first use of Ampligen® as a cancer vaccine adjuvant in a randomized clinical study with and without Ampligen®. As of September 30, 2011, three patients are actively participating in this study.

In August 2011, a study utilizing Ampligen® was initiated by investigators from the Tumor Vaccine Group ("TVG") at the University of Washington in Seattle, WA. As of September 30, 2011, seven 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. This study is actively enrolling additional patients.

In July 2011, a new United States Patent was granted for the use of Ampligen® as a vaccine adjuvant for use with seasonal influenza vaccine to induce an enhanced immune response against H5N1 avian influenza. The patent describes a method using intranasal administration of Ampligen® along with a seasonal influenza vaccine to enhance an immune response against a H5N1 avian influenza infection compared to the administration of seasonal influenza vaccine alone.

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 nine months ended September 30, 2011, the Company contributions towards the 401(k) Plan were $118,000.

New Accounting Pronouncements

Refer to “Note 14: Recent Accounting Pronouncements” under Notes To Unaudited Condensed Consolidated Financial Statements.

Disclosure About Off-Balance Sheet Arrangements

None.

Critical Accounting Policies

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

RESULTS OF OPERATIONS

Three months ended September 30, 2011 versus three months ended September 30, 2010

Net Loss

Our net loss was approximately $2,740,000 for the three months ended September 30, 2011, a decrease of $1,098,000 or 29% when compared to the same period in 2010. This decrease in loss for these three months was primarily due to the following:

1) the revaluation of the Liability related to the Redeemable Warrants resulting in a non-cash gain of $614,000 in 2011 as compared to non-cash net loss of $(584,000) for the same period in 2010 (See Note 12: Fair Value); offset by:

2) a decrease in Research and Development costs of approximately $58,000 or 3%; and

3) a decrease in General and Administrative expenses of approximately $103,000 or 6%; offset by

4) a decrease in interest income of $231,000 from funds invested in marketable securities; and

5) an increase in Production/Cost of Goods Sold of approximately $36,000 or 20%.

Net loss per share was $(0.02) for the current three month period versus $(0.02) per share for the same period in 2010. The weighted average number of shares of our Common Stock outstanding as of September 30, 2011 was 135,496,311.

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Revenues

Revenues from our Ampligen® Cost Recovery Program increased $10,000 or 29% for the third quarter of 2011 as compared to the same time period of 2010. The number of patients increased 27% in the three months ended September 30, 2011. As previously stated, we have no Alferon N Injection® product to commercially sell pending identification of a Fill and Finish FDA approved vendor and all revenue was generated from the Ampligen® cost recovery clinical treatment programs. We expect this revenue to increase in coming months based on the screening of patients in the queue and the opening of new clinical sites.

Production/Cost of Goods Sold

Production/Cost of Goods Sold was approximately $217,000 and $181,000, respectively, for the three months ended September 30, 2011 and 2010. This increase of $36,000 or 20% was primarily due to lower facility costs in 2010 resulting from the recognition of insurance proceeds received in 2010 for storm building damages along with an increase in costs related to the transfer existing Alferon N Injection® and Ampligen® inventory to a new vendor (Bio Ridge Pharma, LLC) in coordination with the sales, marketing and education effort to be undertaken by Armada Healthcare, LLC for Alferon N Injection®.

Research and Development Costs

Overall Research and Development ("R&D") costs for the three months ended September 30, 2011 were approximately $1,750,000 as compared to $1,808,000 for the same period a year ago reflecting a slight decrease of $58,000 or 3%. The R&D efforts during this three month period in 2011 were more cost effective as compared to the prior year, the expenses incurred in 2011 included clinical costs along with research and development costs related to Alferon® LDO as we work to select a vendor to conduct a confirmatory study, which will help us to further evaluate the potential effectiveness of this product and determine the cost/benefit of proceeding with this study of seasonal and pandemic influenza.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended September 30, 2011 and 2010 were approximately $1,635,000 and $1,738,000, respectively, reflecting a decrease of $103,000 or 6%. The lower G&A expenses in 2011 consisted primarily of a decrease of $32,000 in legal fees due to settlement in 2010 of various legal proceedings and lower stock compensation expense of $59,000 for stock options issued due to the lower market value of the Company stock in 2011.

Interest and Other Income

Interest and other income for the three months ended September 30, 2011 and 2010 was approximately $212,000 and $443,000, respectively, representing a decrease of $231,000 or 52%. The primary cause for the decrease of interest income in 2011 was the investment into a more diverse and larger portfolio of short and long term investments during 2010. Some of these investments have matured with proceeds utilized in operations, thereby diminishing the amounts available for investments and reducing the interest income earned in the three month ended September 30, 2011. The interest income from these investments is recognized over the life of the instrument.

Redeemable Warrants

The quarterly fiscal revaluation resulted in non-cash adjustments to the Redeemable Warrants Liability on September 30, 2011 and 2010 of approximately $614,000 and $(584,000), respectively, representing a decrease of $1,198,000 (see “Note 12 Fair Value”).

Nine months ended September 30, 2011 versus nine months ended September 30, 2010

Net Loss

Our net loss was approximately $5,900,000 for the nine months ended September 30, 2011, a decrease of $4,733,000 or 45% when compared to the same period in 2010. This decrease in loss for these nine months was primarily due to the following changes:

1) a decrease in Research and Development costs of approximately $484,000 or 9%;

2) a decrease in General and Administrative expenses of approximately $605,000 or 11%;

3) an increase in interest income of $121,000 or 21% from funds invested in marketable securities;

4) the receipt of funds from the sale of State New Jersey tax net operating losses for years 2003 to 2008 for $2,272,000 (See ”Note 15: Funds Received From Sale Of Income Tax Net Operating Losses”);

5) the revaluation of the Liability related to the Redeemable Warrants resulting in a non-cash gain of $1,558,000 in 2011 as compared to non-cash net gain of $341,000 for the same period in 2010 (See “Note 12: Fair Value”); and

6) a decrease in Production/Cost of Goods Sold expenses of approximately $35,000 or 5%.

Net loss per share was $(0.04) for the current nine month period versus $(0.08) per share for the same period in 2010. The weighted number of shares of our Common Stock outstanding as of September 30, 2011 was 135,379,622.

Revenues

Revenues from our Ampligen® Cost Recovery Program increased $15,000 or 14% for the first nine months of 2011 as compared to the same time period of 2010 due to a 55% increase in the number of patients participating in the program offset by a number of shipments being made to patients on compassionate care. As previously stated, we have no Alferon N Injection® product to commercially sell at this time and all revenue was generated from the Ampligen® cost recovery clinical treatment programs. We expect this revenue to increase in coming months based on the screening of patients in the queue and the opening of new clinical sites.

Production/Cost of Goods Sold

Production/Cost of Goods Sold was approximately $614,000 and $649,000, respectively, for the nine months ended September 30, 2011 and 2010. This decrease of $35,000 or 5% was primarily due to the lower cost to maintain existing Alferon N Injection® and Ampligen® inventory including storage, stability testing, transport and reporting costs due to our efforts to reduce the production costs of Alferon N Injection® for potential future commercial sales. These savings achieved in 2011 were somewhat offset by comparison to 2010 due to last year's recognition of insurance proceeds received for storm building damages and September 2011 costs related to the transfer of existing Alferon N Injection® and Ampligen® inventory to a new vendor (Bio Ridge Pharma, LLC) in coordination with the sales, marketing and education effort to be undertaken by Armada Healthcare, LLC for Alferon N Injection®.

Research and Development Costs

Overall Research and Development ("R&D") costs for the nine months ended September 30, 2011 were approximately $5,014,000 as compared to $5,498,000 for the same period a year ago reflecting a decrease of $484,000 or 9%. The primary factors for the decrease in expenses were a suspension of some clinical, research and development costs related to Alferon® LDO as we work to select a vendor to conduct a confirmatory study, which will help us to further evaluate the potential effectiveness of this product and determine the cost/benefit of proceeding with the planned study of seasonal and pandemic influenza.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the nine months ended September 30, 2011 and 2010 were approximately $4,890,000 and $5,495,000, respectively, reflecting a decrease of $605,000 or 11%. The lower G&A expenses in 2011 consisted primarily of a decrease in legal fees due to settlement in 2010 of various legal proceedings.

Interest and Other Income

Interest and other income for the nine months ended September 30, 2011 and 2010 was approximately $686,000 and $565,000, respectively, representing an increase of $121,000 or 21%. The primary cause for the increase of interest income in 2011 was that the investment into a more diverse, higher yielding portfolio of short and long term investments did not occur until early 2010. The interest income from these investments is recognized over the life of the instrument. However, the increase in year to date interest income in 2011 was somewhat offset by some proceeds from investments utilized in operations, thereby diminishing the amounts available for investments and proportionately reducing the flow of interest income.

Sale of New Jersey Tax Net Operating Loss

In February 2011, the Company received $2,272,000 from the sale of the State New Jersey tax net operating losses for years 2003 to 2008 (see "Note 15: Funds Received From Sale of Income Tax Net Operating Losses").

Redeemable Warrants

The fiscal revaluation for the nine month period resulted in non-cash adjustments to the Redeemable Warrants Liability on September 30, 2011 and 2010 of approximately $1,558,000 and $341,000, respectively, representing an increase of $1,217,000 (see "Note 12: Fair Value").

Certain Relationships and Related Transactions

During the quarter ended September 30, 2011, our internal controls identified a misstatement in our prior public disclosures, including within the NOTES TO CONSOLIDATED FINANCIAL STATEMENTS of our Annual Report on Form 10-K for the year ended December 31, 2010. A Related Party transaction was accurately reported that we paid Retreat House, LLC $123,200 in 2010 for the use of the property at various times for off-site meetings and lodging. It was determined in September 2011 that the property was owned individually by Dr. William A. Carter, our Chief Executive Officer, through April 28, 2010, at which time it was transferred to Retreat House, LLC, a Virginia limited liability company that is owned by three of the children of William A. Carter and a Senior Primary Revocable Trust in which William A. Carter is the Trustee. Dr. Carter also is the Manager of Retreat House, LLC. It had been previously reported by the Company that Retreat House, LLC was an entity wholly owned by the five children of our CEO, William A. Carter and that Retreat House LLC was owner of the property since 2004; these statements were inaccurate.

Liquidity and Capital Resources

Cash used in operating activities for the nine months ended September 30, 2011 was $7,074,000 compared to $10,070,000 for the same period in 2010, a decrease of $2,996,000 or 30%. This reduction in Cash used was primarily due to lower operating costs and a cash gain from the sale of prior years' New Jersey Net Operating Loss in 2011. As of December 31, 2010, the Company had approximately $38,000,000 of New Jersey state net operating loss carry forwards (expiring in the years 2011 through 2017) available to offset future state taxable income. In February 2011, the Company effectively sold $28,000,000 of its New Jersey state net operating loss carry forwards (for the years 2003 through 2008) for approximately $2,272,000. Excluding the proceeds from this sale of New Jersey net operating loss carry forwards, Cash used in operating activities for the nine months ended September 30, 2011 decreased by approximately $724,000 over the comparable period in 2010. As of September 30, 2011, we had approximately $37,323,000 in Cash, Cash Equivalents and Marketable Securities, or a decrease of approximately $7,064,000 from December 31, 2010.

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

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 9: Construction in Progress"). While this Margin Account has no material establishment or maintenance fees, it currently carries an effective interest rate of approximately 3% 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, 2011, the principal loan balance of the Margin Account was approximately $1,156,000 (see "Note 10: Margin Account Loan").

Pursuant to our May 28, 2010 Equity Distribution Agreement (the "Agreement") with Maxim Group LLC ("Maxim"), we established an At-The-Market ("ATM") Equity Program pursuant to which we may sell up to 32,000,000 shares of our Common Stock from time to time through Maxim as our sales agent (the "Agent"). Under the Agreement, the Agent is entitled to a commission at a fixed commission rate of 4.0% of the gross sales price per Share sold, up to aggregate gross proceeds of $10,000,000, and, thereafter, at a fixed commission rate of 3.0% of the gross sales price per Share sold. We have no obligation to sell any shares under this program, and may at any time terminate the Agreement. During the nine months ended September 30, 2011, we sold no shares through this program and received no net cash proceeds. As of September 30, 2011, we sold an aggregate of 520,000 shares through the ATM that resulted in net cash proceeds of approximately $293,000 and commissions paid to Maxim of approximately $12,000.

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

Our ability to raise additional funds from the sale of equity securities is limited because we only have approximately 31,800,000 shares of common stock authorized but unissued and unreserved. Due to the low vote turn out and the much greater vote required for passage of this proposal, we were unable to gather the requisite votes at the time of our annual stockholders' meeting held on October 13, 2011 to amend our Certificate of Incorporation to increase the number of authorized shares of Common Stock from 200,000,000 to 350,000,000 (the "Share Increase Amendment"). While those shares cast at the time of the meeting represented a 71.4% plurality voting in favor of the proposal, it requires the affirmative vote of the outstanding shares, rather than a majority of the shares present and voting at the meeting (i.e., a positive vote of 67,753,436 rather than 35,132,027 if limited to total votes cast). As a result, Management has left the polls opened for voting on the Share Increase Amendment and adjourned the meeting solely with regard to this proposal until November 10, 2011. Since we have not been able to obtain approval to increase the number of authorized shares of Common Stock, the amount of proceeds we may receive from the sale of our remaining Common Stock is limited (See "Part II – OTHER INFORMATION, ITEM 1A. Risk Factors"; We may require additional financing which may not be available; the limited number of shares of common stock available for financing or other purposes may hinder our ability to raise additional funding or utilize equity securities for other corporate purposes").

ITEM 3: Quantitative and Qualitative Disclosures About Market Risk

We had approximately $37,323,000 in Cash, Cash Equivalents and Marketable Securities at September 30, 2011. In prior years, we had invested the excess cash in minimal risk exposure, three to twelve month interest bearing financial instruments. However with the current state of the market and our funds well in excess of our short-term operational needs, our Board has reassessed our cash investment strategy consistent with the following objectives to:

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

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

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

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

At times our investments may be in excess of the Federal Deposit Insurance Corporation insurance limit or not qualified for such coverage. Additionally, while Management strives to invest our Cash and Cash Equivalents in high credit quality institutions and securities, our financial instruments are exposed to concentrations of credit risk and market change. These type of changes occurred on September 21, 2011, when Moody's Investors Services cut the credit rating of Bank of America from A2 to Baa1, directly impacting its subsidiary, Merrill Lynch & Company. Upon analysis, we concluded that an exemption was merited to our minimum rating standard for asset-backed securities regarding two securities currently held through Merrill Lynch & Company:

- Sr. Unsecured Note (OPN 6.05% due 08/15/12) with maturity value of $1,750,000; and
- Note (OPN 5.45% due 02/05/13) with maturity value of $500,000.

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, 2011 to ensure that material information was accumulated and communicated to our Management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

During the quarter ended September 30, 2011, we have made no change in our internal controls over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Part II – OTHER INFORMATION

ITEM 1. Legal Proceedings

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

In December, 2004, we filed a multi-count complaint in federal court (Southern District of Florida) which was granted by the Court in August 2010 whereby Hemispherx was awarded $188 million dollars, plus interest against JCI and former JCI officers R.B. Kebble and H.C. Buitendag. The Company is attempting to domesticate the Final Judgment in South Africa and is being assisted by the South African law firm of Webber Wentzel. The action to domesticate has been filed in South Africa. No gain has been recorded for this judgment as it is too early in these proceedings to predict an outcome. As required by South African law, on October 11, 2011, Hemispherx has posted a security bond of $66,873 for these proceedings.

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

On July 31, 2009, Cato Capital LLC (“Cato”) filed suit asserting that under a November 2008 agreement, the Company owes Cato a placement fee for certain investment transactions. The Complaint seeks damages in the amount of $5,000,000 plus attorneys’ fees. The Company filed an Answer on August 20, 2009. On October 13, 2009, Cato filed a Motion seeking leave to file an Amended Complaint which proposed that Cato be permitted to add The Sage Group as an additional defendant and to bring additional causes of action against the Company arising from the defenses contained in the Answer, and increase the total amount sought to $9,830,000, plus attorneys’ fees and punitive damages. The Company filed a response objecting to the Motion, and also filed a Motion to Disqualify Cato’s Delaware attorneys on basis of a conflict of interest. On September 14, 2010, the Court granted the Company’s Motion to Disqualify Cato’s Delaware attorneys. Also on September 14, 2010, the Court granted Cato’s Motion for Leave to file an Amended Complaint, but specifically indicated that the Company could file a Motion to Dismiss, raising the arguments that the Company had previously made in response to Cato’s Motion for Leave to file an Amended Complaint. On September 16, 2010, Cato filed its Amended Complaint, and on September 30, 2010, the Company filed a Motion to dismiss all the counts of the Amended Complaint against the Company other than the breach of contract count. 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. On August 30, 2011, the Company and the Sage Group filed an Answer with Affirmative Defenses to the Plaintiff's Amended Complaint. The Company and other parties to the litigation are now in the discovery phase of the litigation. 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. The Company's response date is November 10, 2011, and the Company intends to respond, controverting Cato's Motion on factual and legal basis. The Company also intends to file its own motion for summary judgment at an appropriate time. The time frame for the Court's determination of Cato's Motion for Partial Summary Judgment cannot be ascertained.

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

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

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

The parties conducted discovery and subsequently, all parties filed Motions for Summary Judgment. By Order dated March 9, 2011, the Court granted the Company's Motion on all the remaining counts of MidSouth's counterclaim, granted Sage's Motion with respect to MidSouth's claims against Sage, and granted MidSouth's Motion with respect to the Company's original Complaint against MidSouth. Costs have been taxed in the Trial Court in favor of the Company and against MidSouth in the amount of $8,631.82, and in favor of MidSouth and against the Company in the amount of $7,916.90.

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. Mediation ordered by the Court of Appeals was unsuccessful. The appeal and cross appeal have been fully briefed. The case is set for oral argument at the end of January, 2012.

The Company believes it has meritorious defenses and is vigorously defending against this claim. There is currently no projection as to the likely outcome of the case or timing for the Court of Appeals will issue an opinion.

(c) Summation.

We have not recorded any loss contingencies as a result of the above matters for the year ended December 31, 2010 or nine months ended September 30, 2011. For greater detail as to legal proceedings, this section should be read in conjunction with NOTE 14 - Contingencies in our Annual Report on Form 10-K for the year ended December 31, 2010.

ITEM 1A. Risk Factors.

The following cautionary statements identify important factors that could cause our actual results to differ materially from those projected in the forward-looking statements made in this Form 10-Q. Among the key factors that have a direct bearing on our results of operations are:

Risks Associated With Our Business

No assurance of successful product development.

Ampligen® and related products. The development of Ampligen® and our other related products is subject to a number of significant risks. Ampligen® may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale, be uneconomical to market or be precluded from commercialization by proprietary right of third parties. Our investigational products are in various stages of clinical and pre-clinical development and require further clinical studies and appropriate regulatory approval processes before any such products can be marketed. We do not know when, if ever, Ampligen® or our other products will be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale. Please see the next risk factor.

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

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

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

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

In July 2008, the FDA accepted for review our NDA for Ampligen® to treat CFS, originally submitted in October 2007. On November 25, 2009, we received a Complete Response Letter ("CRL") from the FDA which described specific additional recommendations related to the Ampligen® NDA. In accordance with its 2008 Complete Response procedure, the FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues. In December 2010, the FDA granted us a one year extension to file a response to the CRL. The Company is diligently working to file a new Request For Extension with the FDA as well as address the diagnostic challenges related to CFS. Please see "Overview; General; Ampligen®" and "Progress in Search of CFS Test" of Part 1, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations" above for more detailed information on the current status of the NDA and CRL. We are unable to provide assurances that the FDA will ultimately grant the one year extension to file a response to the CRL. If this extension is not granted by the FDA, our operations most likely will be materially adversely affected.

The production of Alferon N Injection® from the Work-In-Progress Inventory continued into January 2011 with its conversion into Active Pharmaceutical Ingredient and is near completion for the related Final Lot Release Test. To formulate, fill and finish Alferon N Injection® Drug Product, we require a FDA approved third party Contract Manufacturing Organization ("CMO"). In June 2011, our designated CMO reported to us that they had received an FDA 483 form that identified production issues that needed to be addressed prior to resumption of production. As a result, we continue to evaluate alternative CMOs to undertake the formulation Fill and Finish process. When a CMO is selected, it will be necessary to conduct production tests to qualify the new CMO. The resulting data must then be submitted to the FDA, with the CMO and finished product lots approved by the FDA prior to our being able to commercially sell Alferon N Injection®. While timing cannot be adequately determined until the selection of a CMO is finalized, we estimate that commercial sales of Alferon N Injection® will not resume until the later part of 2012. Please see "Overview; General; Alferon N Injection®" of Part 1, Item 2 above for more detailed information. We are unable to provide any assurances that the FDA will approve the final inventory lots produced by the CMO. If this finish goods inventory is not granted approval by the FDA for clinical sales, our operations most likely will be materially adversely affected.

Alferon® LDO is undergoing pre-clinical testing for possible use as prophylaxis against influenza. While the studies to date have been encouraging, preliminary testing in the laboratory and in animal models is not necessarily predictive of successful results in clinical testing or human treatment. No assurance can be given that similar results will be observed in clinical trials. Use of Alferon® as a possible treatment of any influenza requires prior regulatory approval. In October 2009, we submitted a protocol to the FDA proposing to conduct a Phase II study for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. In November 2009, the FDA placed the proposed study on clinical hold. On December 22, 2010, the FDA informed us that it had completed its review of our complete response to the Clinical Hold and lifted the Clinical Hold, allowing our Phase II Study to proceed. Our confirmatory Phase II study has been delayed as we work to select a vendor to conduct a confirmatory study using gene expression measures in an attempt to identify the systemic effects in peripheral blood leukocytes following the treatment with Alferon® LDO. We believe that such a study will help us to further evaluate the potential effectiveness of this product and determine the cost/benefit of proceeding with this study of seasonal and pandemic influenza. Please see “Overview; General; Alferon® LDO” of Part 1, Item 2. “Management's Discussion and Analysis of Financial Condition and Results of Operations” above for more detailed information. We are unable to provide any assurances that Phase II Alferon® LDO study for the prophylaxis and treatment of seasonal and pandemic influenza will be undertaken.

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

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

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses, as we pursued our clinical trial effort to get our experimental drug, Ampligen®, approved. As of September 30, 2011, our accumulated deficit was approximately $(223,625,000). We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

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

The development of our products will require the commitment of substantial resources to conduct the time consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of September 30, 2011, we had approximately $37,323,000 in Cash, Cash Equivalents and Marketable Securities, of which $3,142,000 in Marketable Securities are restricted from sale as dedicated collateral for our indebtedness. Given the harsh economic conditions, we continue to review every aspect of our operations for cost and spending reductions to assure our long-term financial stability while maintaining the resources necessary to achieve our primary objectives of obtaining NDA approval of Ampligen®, and securing a strategic partner.

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

Our ability to raise additional funds from the sale of equity securities may be limited. In this regard, we only have approximately 31,800,000 shares authorized but unissued and unreserved. We did not gather the requisite votes at our annual stockholders' meeting held on October 13, 2011 to amend our Certificate of Incorporation to increase the number of authorized shares of Common Stock from 200,000,000 to 350,000,000 (the "Share Increase Amendment"). While we have held the poles open in the Share Increase Amendment proposal until November 10, 2011, we cannot assure that the Share Increase Amendment will be approved by stockholders. Unless and until we are able to obtain approval to increase the number of authorized shares of Common Stock, the amount of proceeds we may receive from the sale of our remaining Common Stock may be limited.

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

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

Commercial sales of Alferon N Injection® were halted in March 2008 when our finished goods inventory expired. The production of Alferon N Injection® from the Work-In-Progress Inventory continued into January 2011 with its conversion into Active Pharmaceutical Ingredient and is near completion of the Final Lot Release Test. To formulate, fill and finish Alferon N Injection® Drug Product, we require an FDA approved third party CMO. In June 2011, our designated CMO reported to us that they had received an FDA 483 form that identified production issues that needed to be addressed prior to resumption of production. As a result, we are evaluating alternative CMOs. When a CMO is selected, it will be necessary to conduct production tests to qualify the new CMO and the quality of the finished good inventory lots. The resulting data must then be submitted to the FDA, with the CMO and finished product lots approved by the FDA, prior to our being able to commercially sell Alferon N Injection®. While timing cannot be adequately determined until the selection of a CMO is finalized, we estimate that commercial sales of Alferon N Injection® will not resume until the later part of 2012. We are unable to provide any assurances that the FDA will approve the final inventory lots produced by the CMO. If this finished goods inventory is not granted approval by the FDA for clinical sales, our operations most likely will be materially adversely affected.

We have undertaken at our New Brunswick facility a major capital improvement program that continues in 2011 to enhance our manufacturing capability to produce bulk quantities of API, a purified drug concentrate used in the formulation of Alferon N Injection® at the CMO,. As with all major changes to a FDA approved pharmaceutical manufacturing process, certain of the plant and equipment improvements being implemented for production of Alferon N Injection® may require FDA review prior to commercial sale of the resulting new product, and each production lot of Alferon N Injection® using this new process is subject to FDA review and approval prior to releasing the lots to be sold.

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

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

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. See "Overview; General; Other Viral Diseases" in Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations" above.

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, unable to generate the data of successfully completion of clinical studies, 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 adversely affected.

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

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

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

To date, no consistent policy has emerged regarding the breadth of protection afforded by pharmaceutical and biotechnology patents. There can be no assurance that new patent applications relating to our products, 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® may include licensing/co-marketing agreements utilizing the resources and capacities of one or more strategic partners. 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 Health Care to undertake the marketing, education and sales of Alferon N Injection® throughout the United States.

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

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

There are a limited number of organizations in the United States available to provide the final steps in the manufacturing Alferon N Injection®. At present, we do not have and are evaluating third party Contract Manufacturing Organizations to undertake the formulation Fill and Finish process related to the final steps in the manufacturing of Alferon N Injection®. When a CMO is selected, it will be necessary to conduct tests to qualify the new CMO and the quality of the finished good inventory lots. The supporting data must then be submitted to the FDA, and the CMO and finished product lots approved by the FDA, prior to our being able to commercially sell Alferon N Injection®. While timing cannot be adequately determined until the selection of a CMO is finalized, we estimate that commercial sales of Alferon N Injection® will not resume until the later part of 2012. We are unable to provide any assurances that the FDA will approve the final inventory lots produced by the CMO. If this finish goods inventory is not granted approval by the FDA for clinical sales, our operations most likely will be materially adversely affected.

If we were unable to obtain this necessary service, it could adversely impact our ability to timely relaunch Alferon N Injection® for commercial sales. In light of this contingency, there can be no assurances that the approved Alferon N Injection® product will be returned to commercial sales on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

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. On October 2, 2011, we finalized our Fourth Amendment to our Supply Agreement, effective through March 11, 2014, with Jubilant Hollister-Stier Laboratories LLC of Spokane, Washington (“Hollister-Stier”), pursuant to which Hollister-Stier will formulate and package Ampligen® from the key raw materials that we would supply to them.

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

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

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

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

We have limited manufacturing experience.

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

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

We have never produced Ampligen® or any other products in large commercial quantities. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen® or continue to maintain third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. 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 approved Alferon N Injection® product will be returned to commercial sales on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

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

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

Our products may be subject to substantial competition.

Ampligen®. Competitors may be developing technologies that are, or in the future may be, the basis for competitive products. Some of these potential products may have an entirely different approach or means of accomplishing similar therapeutic effects to products being developed by us. These competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments may offer competition to our products. Furthermore, many of our competitors have significantly greater experience than us in preclinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, HPB or other regulatory product approvals more rapidly than us. There are no drugs approved for commercial sale with respect to treating ME/CFS in the United States. The dominant competitors with drugs to treat disease indications in which we plan to address include Gilead Sciences, Pfizer, Bristol-Myers Squibb, Abbott Laboratories, GlaxoSmithKline and Merck. These potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Although we believe our principal advantage is the unique mechanism of action of Ampligen® on the immune system, we cannot assure that we will be able to compete.

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

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

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

Ampligen®. We believe that Ampligen® has been generally well tolerated with a low incidence of clinical toxicity, particularly given the severely debilitating or life threatening diseases that have been treated. A mild flushing reaction has been observed in approximately 15-20% of patients treated in our various studies. This reaction is occasionally accompanied by a rapid heart beat, a tightness of the chest, urticaria (swelling of the skin), anxiety, shortness of breath, subjective reports of “feeling hot”, sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by reducing the rate of infusion. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, transient visual disturbances, slow or irregular heart rate, decreases in platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills, fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months. One or more of the potential side effects might deter usage of Ampligen® in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product. Biken concluded that it was possible that Ampligen® would not satisfy the requirements for safety as an adjuvant for influenza vaccines in Japan. Biken’s primary concern was related to a single intravenous high dose study in rats that resulted in an apparent toxicity when doses of Ampligen® were combined with a whole viron influenza vaccine and Carboxyl Vinyl Polymer (“CVP”) or CVP alone. Additionally in both cases of Ampligen® being combined with other product(s), the dosage utilized was several hundred times higher than the intended dosage for humans by body weight and delivered intravenously, rather than the prescribed mucosal (nasal) method. We dispute Biken’s findings. See “Overview; General; Other Viral Diseases” in Part I, Item 2. “Management's Discussion and Analysis of Financial Condition and Results of Operations” above.

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

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

We face an inherent business risk of exposure to product liability claims in the event that the use of Ampligen®, 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.

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

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

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

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

Uncertainty of health care reimbursement for our products.

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

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

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

Risks Associated With an Investment in Our Common Stock

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

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

- announcements of the results of clinical trials by us or our competitors;
- announcement of legal actions against us and/or settlements or verdicts adverse to us;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency comments regarding the safety or effectiveness of our products, or the adequacy of the procedures, facilities or controls employed in the manufacture of our products;
- changes in U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;

- conditions and trends in the pharmaceutical and other industries;
- new accounting standards;
- overall investment market fluctuation;
- restatement of prior financial results;
- notice of NYSE Amex non-compliance with requirements; and
- occurrence of any of the risks described in these "Risk Factors".

Our common stock is listed for quotation on the NYSE Amex. For the nine months ended September 30, 2011, the closing price of our common stock has ranged from $0.27 to $0.55 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

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

In May 2009 we issued an aggregate of 25,543,339 shares and warrants to purchase an additional 14,708,687 shares under a universal shelf registration statement. 4,895,000 of these warrants have been exercised as of September 30, 2011. Depending upon market conditions, we anticipate selling 9,813,687 shares pursuant to the conversion of remaining warrants.

Additionally, we registered with the SEC on September 29, 2009, 1,038,527 shares issuable upon exercise of certain other warrants. To the extent the exercise price of our outstanding warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the exercise price of certain of these warrants are adjusted pursuant to anti-dilution protection, the warrants could be exercisable or convertible for even more shares of common stock. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. In this regard we have registered $150,000,000 of securities for public sale pursuant to a universal shelf registration. We have allocated 32,000,000 shares under this registration statement to an At-The-Market equity offering and, as of September 30, 2011, we have sold a total of 520,000 shares pursuant to this offering.

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

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in Management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November 2002, we adopted a Stockholder Rights Plan ("Rights Plan") and, under the Rights Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one-hundredth unit of preferred stock for $30.00. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Dr. Carter, our Chief Executive Officer, who already beneficially owns 6% of our common stock, the Rights Plan's threshold will be 20%, instead of 15%. The Rights Plan will expire on November 19, 2012, and may be redeemed prior thereto at $.01 per Right under certain circumstances.

Special Note Regarding Forward Looking Statements

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

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

During the nine months ended September 30, 2011, we issued an aggregate of 145,440 shares to consultants and vendors for services performed.

All of the foregoing transactions were conducted pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933 or pursuant to our Registration Statement on Form S-8.

We did not repurchase any of our securities during the nine months ended September 30, 2011.

ITEM 3: Defaults upon Senior Securities

None.

ITEM 4: Removed and Reserved

ITEM 5: Other Information

In September 2011, the Audit Committee of our Board of Directors engaged the services of a consultant who meets the criteria of a “Financial Expert” as defined by the SEC to enhance the current structure and expertise of the Committee. After an extensive search, the Audit Committee selected Stewart L. Appelrouth, a Florida and North Carolina licensed Certified Public Accountant to directly support the efforts of the Audit Committee. Mr. Appelrough is a Certified Valuation Analyst, Accredited in Business Valuation and a Diplomate of the American Board of Forensic Accounting. Mr. Appelrouth has a Masters Degree in Finance from Florida International University and an undergraduate degree in Business Administration from Florida State University. He is one of the founding partners of Appelrouth Farah & Co., with approximately thirty employees dispersed in three offices, which serves Southern Florida as a full service accounting and international business advisory firm specializing in auditing, domestic and international taxation, litigation support, forensic accounting, fraud examination and business valuation. The Firm is affiliated with MGI, a worldwide association of independent auditing and accounting firms.

ITEM 6: Exhibits

(a) Exhibits

10.1 Vendor Agreement with Bio Ridge Pharma, LLC, effective on August 15, 2011 and executed on September 6, 2011. Confidential portions of this exhibit have been redacted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

10.2 Vendor Agreement with Armada Healthcare, LLC, effective and executed on September 6, 2011. Confidential portions of this exhibit have been redacted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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, 2011, formatted in eXtensible Business Reporting Language ("XBRL"): (i) the Condensed Consolidated Statements of Income; (ii) the Condensed Consolidated Balance Sheets; (iii) the Condensed Consolidated Statements of Cash Flows; and (iv) Notes to Condensed Consolidated Financial Statements.

SIGNATURES

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

HEMISPHERX BIOPHARMA, INC.

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

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

Date: November 9, 2011