HEMISPHERX BIOPHARMA INC
Form 10-Q
November 08, 2010

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, 2010

Commission File Number: 1-13441

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

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

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

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

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

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

135,241,609 shares of common stock were issued and outstanding as of November 03, 2010.

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, 2009	September 30, 2010 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents (Note 11)	$ 58,072	$ 3,044
Marketable securities maturing in less than one year (Note 5)	-	34,202
Inventories (Note 4)	-	1,075
Prepaid expenses and other current assets	332	235
Total current assets	58,404	38,556
Property and equipment, net	4,704	4,794
Marketable securities maturing in one year or greater (Note 5)	-	11,015
Patent and trademark rights, net	830	974
Investment	35	35
Construction in progress (Note 8)	135	464
Other assets (Note 4)	886	38
Total assets	$ 64,994	$ 55,876
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,294	$ 1,729
Accrued expenses (Note 6)	1,321	572
Current portion of capital lease (Note 7)	-	61
Total current liabilities	2,615	2,362
Long-term liabilities		
Long-term portion of capital lease (Note 7)	-	112
Commitments and contingencies		
Stockholders' equity (Note 9):		
Preferred stock, par value $0.01 per share, authorized 5,000,000; issued and outstanding; none	-	-
Common stock, par value $0.001 per share, authorized 200,000,000 shares; issued and outstanding 132,787,447 and 135,241,609, respectively	133	135
Additional paid-in capital	273,093	274,371
Accumulated other comprehensive income	-	717
Accumulated deficit	(210,847)	(221,821)

Total stockholders' equity		62,379		53,402
Total liabilities and stockholders' equity	$	64,994	$	55,876

See accompanying notes to consolidated financial statements.

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

	Three months ended September 30,	
	2009	2010
Revenues:		
Clinical treatment programs	$ 25	$ 35
Total revenues	25	35
Costs and expenses:		
Production/cost of goods sold	146	181
Research and development	1,173	1,808
General and administrative	1,164	1,738
Total costs and expenses	2,483	3,727
Operating loss	(2,458)	(3,692)
Interest expense from capital leases	-	(5)
Interest and other income	23	443
Net loss	$ (2,435)	$ (3,254)
Basic and diluted loss per share (Note 2)	$ (.02)	$ (.02)
Weighted average shares outstanding, basic and diluted	127,788,640	134,869,730

See accompanying notes to consolidated financial statements.

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

	Nine months ended September 30,	
	2009	2010
Revenues:		
Clinical treatment programs	$ 71	$ 108
Total revenues	71	108
Costs and expenses:		
Production/cost of goods sold	419	649
Research and development	4,750	5,498
General and administrative	4,192	5,495
Total costs and expenses	9,361	11,642
Operating loss	(9,290)	(11,534)
Financing costs	(241)	-
Interest expense from capital leases	-	(5)
Interest and other income	139)	565
Net loss	$ (9,392)	$ (10,974)
Basic and diluted loss per share (Note 2)	$ (.09)	$ (.08)
Weighted average shares outstanding, basic and diluted	101,706,216	133,605,973

See accompanying notes to consolidated financial statements.

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

	Common Stock Shares	Common Stock $.001 Par Value	Additional Paid-In Capital	Accumulated Other Compre-hensive Income	Accumulated Deficit	Total Stockholders' Equity	Compre-hensive Loss
Balance at December 31, 2009	132,787,447	$ 133	$ 273,093	$ -	$ (210,847)	$ 62,379	$ -
Stock issued for settlement of accounts payable	498,867	-	328	-	-	328	-
Equity based compensation	1,435,295	1	658	-	-	659	-
Shares sold at the market	520,000	1	292	-	-	293	-
Unrealized gain in investment securities	-	-	-	717	-	717	717
Net loss	-	-	-	-	(10,974)	(10,974)	(10,974)
Balance at September 30, 2010	135,241,609	$ 135	$ 274,371	$ 717	$ (221,821)	$ 53,402	$ (10,257)

See accompanying notes to consolidated financial statements.

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
For the Nine Months Ended September 30, 2009 and 2010
(in thousands)
(Unaudited)

	2009	2010
Cash flows from operating activities:		
Net loss	$ (9,392)	$ (10,974)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	266	295
Amortization of patent and trademark rights, and royalty interest	236	57
Financing cost related to Standby Financing	241	-
Equity based compensation	791	659
Gain on disposal of equipment	(83)	-
Change in assets and liabilities:		
Inventories	-	(212)
Prepaid expenses and other current assets	257	97
Other assets	-	(6)
Accounts payable	1,252	763
Accrued expenses	(233)	(749)
Net cash used in operating activities	$ (6,665)	$ (10,070)
Cash flows from investing activities:		
Purchase of property plant and equipment	$ (51)	$ (514)
Additions to patent and trademark rights	(185)	(201)
Deposits on capital leases	-	(9)
Maturities of short-term and long-term investments	-	4,356
Purchase of short-term and long-term investments	-	(48,856)
Net cash used in investing activities	$ (236)	$ (45,224)

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows (Continued)
For the Nine Months Ended September 30, 2009 and 2010
(in thousands)
(Unaudited)

	2009	2010
Cash flows from financing activities:		
Payments on capital lease	$ -	$ (27)
Warrants and options converted	33,982	-
Proceeds from sale of stock, net of issuance costs	27,842	293
Net cash provided by financing activities	$ 61,824	$ 266
Net increase (decrease) in cash and cash equivalents	54,923	(55,028)
Cash and cash equivalents at beginning of period	6,119	58,072
Cash and cash equivalents at end of period	$ 61,042	$ 3,044
Supplemental disclosures of non-cash investing and financing cash flow information:		
Issuance of common stock for accounts payable and accrued expenses	$ 1,301	$ 328
Equipment acquired by capital lease	$ -	$ 200
Unrealized gain on investments	$ -	$ 717
Supplemental disclosure of cash flow information:		
Cash paid for interest expense	$ -	$ 5

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 included in our annual report on Form 10-K, filed March 12, 2010, and 10-K/A, filed April 30, 2010, for the year ended December 31, 2009.

Note 2: Net Loss Per Share

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Equivalent common shares, consisting of stock options and warrants including the Company's convertible debentures, which amounted to 21,539,946 and 52,686,158 shares, are excluded from the calculation of diluted net loss per share for the nine months ended September 30, 2009 and 2010, 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,	
	2009	2010
Risk-free interest rate	1.76% - 2.54%	1.02%-2.03%
Expected dividend yield	-	-
Expected lives	2.5 – 5.0 yrs.	5.0 years
Expected volatility	86.78% - 137.47%	109.57%-110.01%
Weighted average grant date fair value of options and warrants issued	$ 528,000	$ 610,069

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Stock option activity for 2009 and during the nine months ended September 30, 2010, 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, 2008	6,258,608	$ 2.60	7.92	$ -
Options granted	-	-	-	-
Options forfeited	(29,856)	2.24	5.75	-
Outstanding December 31, 2009	6,228,752	$ 2.60	6.95	$ -
Options granted	820,000	.66	9.54	-
Options forfeited	-	-	-	-
Outstanding September 30, 2010	7,048,752	$ 2.37	6.37	$ -
Exercisable September 30, 2010	6,993,752	$ 2.38	6.40	$ -

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2009 and 2010 was $252,000 and $384,000, 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, 2008	76,944	$ 1.41	8.89	$ -
Options granted	-	-	-	-
Options vested	(38,611)	1.28	7.92	-
Options forfeited	-	-	-	-
Outstanding December 31, 2009	38,333	$ 1.54	8.00	$ -
Options granted	16,667	.66	9.75	-
Options vested	-	-	-	-
Options forfeited	-	-	-	-
Outstanding September 30, 2010	55,000	$ 1.27	8.01	$ -

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, 2008	2,417,482	$ 2.35	6.98	$ -
Options granted	361,250	2.12	7.00	-
Options exercised	(293,831)	1.56	7.93	-
Options forfeited	(251,469)	2.14	7.43	-
Outstanding December 31, 2009	2,233,432	$ 2.44	5.73	$ -
Options granted	605,000	.55	9.75	-
Options exercised	-	-	-	-
Options forfeited	-	-	-	-
Outstanding September 30, 2010	2,838,432	$ 2.04	6.00	$ -
Exercisable September 30, 2010	2,726,973	$ 2.01	6.26	$ -

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2009 and 2010 was approximately $199,000 and $225,959, 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, 2008	26,667	$ 1.43	9.00	$ -
Options granted	131,250	2.81	3.42	-
Options vested	(18,333)	1.79	7.45	-
Options forfeited	-	-	-	-
Outstanding December 31, 2009	139,584	$ 2.68	3.76	$ -
Options granted	-	-	-	-
Options vested	(28,125)	2.81	2.75	-
Options forfeited	-	-	-	-
Outstanding September 30, 2010	111,459	$ 2.65	3.70	$ -

The impact on the Company’s results of operations of recording equity based compensation for the nine months ended September 30, 2009 and 2010 was to increase general and administrative expenses by approximately $452,000 and $659,000 respectively. The impact on basic and fully diluted earnings per share for the nine months ended September 30, 2009 was $-0- and for September 30, 2010 was to increase loss per share by $0.01.

As of September 30, 2009 and 2010, respectively, there was $255,500 and $180,700 of unrecognized equity based compensation cost related to options granted under the Equity Incentive Plan.

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Note 4: Inventories and Other Assets

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, 2009	September 30, 2010
Inventory work in process	$ -	$ 1,075
Finished goods, net of reserves of $282,000 at December 31, 2009 and $250,000 at September 30, 2010.	-	-
	$ -	$ 1,075

The conversion of existing Alferon N Injection® Work-In-Progress inventory was started up again in May 2010 towards the manufacture of new Finished Goods and is estimated to be available for commercial sales in mid to late 2011. As a result the Work-In-Progress of $864,000, which was included in "Other assets" in 2009, has been reclassified and included with current assets at the September 30, 2010 value of $1,075,000.

Other assets consist of the following:

	(in thousands) December 31, 2009	September 30, 2010
Inventory work in process	$ 864	$ -
Security deposit	15	16
Internet Domain Names	7	7
Deposit on new telephone system	-	6
Security deposit on Capital Lease (see Note 7)	-	9
	$ 886	$ 38

Note 5: Marketable Securities

Marketable securities consist of fixed income securities with remaining maturities of greater than three months at the date of purchase, debt securities and equity securities. At September 30, 2010, all of our fixed income securities were classified as available for sale investments and measured as Level 1 instruments of the fair value measurements standard (see Note 10: Fair Value). Securities classified as available for sale consisted of:

	September 30, 2010 (in thousands)			
Name Of Security	Cost	Market Value	Unrealized Gain (Loss)	Maturity Date
Marketable Securities with maturity periods less than one year:				
GE Money Bank	250	250	-	10/15/2010
Discover Bank	500	500	-	10/29/2010
Beal Bank	250	250	-	12/8/2010
Toyota Motor Credit	1,020	1,009	(11)	12/15/2010
Safra National Bank	250	250	-	1/1/2011

GE Money Bank	250	250	-	1/14/2011
Goldman Sachs	1,063	1,017	(46)	1/15/2011
Oracle Corporation	785	760	(25)	1/15/2011
World Financial Capital	300	300	-	1/28/2011
Cisco Systems	786	765	(21)	2/22/2011
IBM Corporation	783	767	(16)	3/22/2011
Bank of America	500	501	1	4/21/2011
Merrick Bank	250	250	-	4/21/2011
Discover Bank	250	251	1	6/23/2011
General Dynamics	763	758	(5)	7/15/2011
Wells Fargo	1,081	1,049	(32)	8/1/2011
Bank of America	1,066	1,039	(27)	8/15/2011
Shell International	756	756	-	9/22/2011
Wachovia Bank	274	270	(4)	9/28/2011
PIMCO	22,200	23,210	1,010	NA
Total Marketable Securities with maturity periods less than one year:	$ 33,377	$ 34,202	$ 825	

Marketable Securities with maturity periods greater than one year:

Plainscapital Bank	250	251	1	10/31/2011
Bank One Corporation	1,070	1,056	(14)	11/15/2011
Merck & Company	818	790	(28)	11/15/2011
Morgan Stanley	1,077	1,050	(27)	1/9/2012
Wright Expert Financial Services	250	252	2	4/26/2012
Citibank NA	250	251	1	4/30/2012
GE Money Bank	104	103	(1)	5/29/2012
Sallie Mae Bank	104	103	(1)	5/29/2012
Bank of Northern Miami	250	251	1	7/30/2012
Merrill Lynch	1,089	1,074	(15)	8/15/2012
Merrill Lynch	811	806	(5)	8/15/2012
Morgan Stanley	1,071	1,073	2	8/31/2012
Wells Fargo	1,082	1,066	(16)	9/1/2012
Israel Discount Bank	250	250	-	9/11/2012
Allstate	115	112	(3)	9/16/2012
Park Sterling Bank	250	251	1	10/16/2012
Columbus Bank & Trust Company	250	253	3	10/22/2012
World's Foremost Bank	100	104	4	1/28/2013
Merrill Lynch	544	537	(7)	2/5/2013
Merrill Lynch	104	104	-	3/4/2013
Goldman Sachs	250	253	3	6/17/2013
Royal Bank of Scotland	1,034	1,025	(9)	8/23/2013
Total Marketable Securities with maturity periods greater than one year:	$ 11,123	$ 11,015	$ (108)	
Total Marketable Securities	$ 44,500	$ 45,217	$ 717	

No investment was pledged to secure public funds at September 30, 2010.

Note 6: Accrued Expenses

Accrued expenses consist of the following:

	(in thousands)	
	December 31, 2009	September 30, 2010
Compensation	$ 716	$ 170
Professional fees	421	180
Other expenses	71	109
Other liability	113	113
	$ 1,321	$ 572

Note 7: Capital Lease

The Company has acquired equipment under capital leases as follows:

	(in thousands) Asset Balance at September 30, 2010
Leased Equipment included with property and equipment	$ 200
Less: accumulated depreciation	(11)
	$ 189

The following is a schedule by year of future minimum lease payments under the capital leases as of September 30, 2010:

2010	$ 48
2011	59
2012	47
2013	38
2014	27
2015	15
Total lease payments remaining	234
Less: amount representing interest	(61)
Present value of remaining minimum lease payments	173
Less: current obligations under lease obligations	(61)
Long-term capital lease obligations	$ 112

Minimum lease payments under the capital leases range from $1,696 per to $2,994 per month and the lease periods range from 24 months to 60. Imputed rates are 2% to 24% per annum. Aggregate security deposits of $9,380 were paid and are included in other assets.

Note 8: Construction in Progress

On September 16, 2009, our Board of Directors approved up to $4.4 million for full engineering studies, capital improvements, system upgrades and introduction of building management systems to enhance production of three products: Alferon N Injection®, Alferon® LDO and Ampligen®. Construction in progress consists of accumulated costs for the construction and installation of property and equipment within the Company’s New Jersey facility until the assets are placed into service. As of December 31, 2009, construction in progress was $135,000 as compared to $464,000 for the nine months ended September 30, 2010.

Note 9: Stockholders' Equity

The Equity Compensation Plan effective May 1, 2004, authorizes 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. As of September 30, 2010, the Company effectively exhausted this plan and issued an aggregate 7,999,981 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. As of September 30, 2010, the Company effectively exhausted this plan and issued 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, 2010 and accordingly recorded approximately $659,000 as equity based compensation for these issuances during this period. The stock options generally vested immediately upon grant with the exception of 20,000 options to an executive employee which vest over 18 months, and 150,000 options to another executive employee which vest over 48 months.

In an effort to conserve our cash, the Employee Wage Or Hours Reduction Program (the "Program") was ratified by our Board effective January 1, 2009. The Incentive Rights are rights for employees to receive Company shares and had prices ranging from $0.13 to $0.80 based on the average daily closing prices of the Company shares on the NYSE Amex. The Program was suspended as of May 31, 2009 with employees returning back to their rate of pay as of January 1, 2009. At the passage of six months for each of their months of participation, non-affiliate employees executed their right to receive shares for the months ended July 31, August 31, September 30, October 30 and November 30, 2009. As of September 30, 2010, all participants have exercised their rights to receive shares of stock related to this Program.

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, 2010 the Company issued 3,188,187 securities to Directors and consultants consisting of an aggregate of 2,666,642 options and 521,545 shares of common stock issuable upon exercise/conversion of the foregoing securities. The shares issued to consultants had prices ranging from $0.40 to $0.68 based on the NYSE Amex closing price.

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

On May 28, 2010, we entered into an Equity Distribution Agreement (the "Agreement") with Maxim Group LLC ("Maxim") to create an At-The-Market ("ATM") equity program under which we may sell up to 32,000,000 shares of our Common Stock (the "Shares") 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. Sales of the Shares under the Agreement may be made in transactions that are deemed to be "at-the-market" offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers' transactions, including on the NYSE Amex, at market prices or as otherwise agreed with the Agent. We have no obligation to sell any of the Shares, and may at any time suspend offers under the Agreement or terminate the Agreement. The Shares will be issued pursuant to our previously filed and effective Registration Statement on Form S-3 (File No. 333-159856). On June 22, 2009, we filed a base Prospectus and on May 28, 2010, filed a Prospectus Supplement relating to the offering with the Securities and Exchange Commission. During the quarter ended September 30, 2010, we sold no shares through the ATM equity program and received no net cash proceeds. For the life of the ATM equity program through September 30, 2010, we sold 520,000 shares that resulted in net cash proceeds of $292,785 and commissions paid to Maxim of $12,199 with the average daily selling price ranging from $0.53 to $0.61.

Note 10: Fair Value

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

The Company estimates that the fair values of cash and cash equivalents, marketable securities, other assets, accounts payable and accrued expenses approximate their carrying values due to the short-term maturities of these items. Additionally, the Company has certain warrants with a cash settlement feature (in the event of a change in control to a non-public company) that are carried at fair value. Management estimates the fair value using a model which determines the probability that the cash settlement feature conditions will arise. The carrying amount and estimated fair value of the above warrants was zero at September 30, 2010.

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 marketable securities based on quoted prices of active markets and warrant liability, for those warrants with a cash settlement feature, at fair value. As of September 30, 2010, 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 quote 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 December 31, 2009, 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. The primary inputs evaluated by management to determine the likelihood of a change in control to a non-public company (thereby triggering the cash settlement feature) were the Company's FDA approval status including the additional requirements including required cash outflows prior to resubmission to the FDA (observable), the industry and market conditions (unobservable), litigation matters against the Company (observable) and statistics regarding the number of company's going private (observable).

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, 2010:

	Total	Level 1	Level 2	Level 3
Assets:				
Marketable Securities	$ 45,217	$ 23,210	$ 22,007	$ -
Liabilities:				
Warrants	-	-	-	-
Total	$ 45,217	$ 23,210	$ 22,007	$ -

For detailed information regarding the change to the fair value of assets recorded in Level 1 (See Note 5: Marketable Securities). There were no changes in the fair value for the Level 3 Warrants during the three months ended September 30, 2010.

NOTE 11: Cash And Cash Equivalents

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

NOTE 12: Recent Accounting Pronouncements

The Financial Accounting Standards Board ("FASB") has published FASB Accounting Standards Update 2010-01 through 2010-12. The adoption of published FASB Accounting Standards Update 2010-01 through 2010-26 has no material effect on the Company's financial statements for the nine months ended September 30, 2010.

NOTE 13: Subsequent Events

The Company evaluated subsequent events through the date on which these financial statements were issued, and determined that no subsequent event constituted a matter that required disclosure or adjustment to the financial statements for the nine months ended September 30, 2010.

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

Special Note Regarding Forward-Looking Statements

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

Such forward-looking statements involve known and unknown risks, uncertainties and other factors, including but not limited to, the risk factors discussed below, which may cause the actual results, performance or achievements of Hemispherx and its subsidiaries to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements and other factors referenced in this report. We do not undertake and specifically decline any obligation to publicly release the results of any revisions which may be made to any forward-looking statement to reflect events or circumstances after the date of such statements or to reflect the occurrence of anticipated or unanticipated events.

Overview

General

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

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

In May 2010, we announced the formation of a Data Safety Monitoring Board ("DSMB") that consists of two independent regulatory and medical experts along with a Biostatistics expert. The function of the DSMB would be to perform independent safety and efficacy analyses on our clinical trials, including those with Alferon® LDO. However with Alferon® LDO study on FDA Clinical Hold, the DSMB has yet to take action.

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ that was primarily designed to produce Alferon®. On September 16, 2009, our Board of Directors approved up to $4.4 million for full engineering studies, capital improvements, system upgrades and introduction of building management systems to enhance production of three products: Alferon N Injection®, Alferon® LDO and Ampligen®. As of December 31, 2009, construction in progress on this project was $135,000 as compared to $464,000 for the nine months ended September 30, 2010. 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.

Our manufacturing facility in New Brunswick, New Jersey was inspected by the FDA as part of the Fiscal Year 2010 CDER High Risk Drug Site Workplan on June 21 and June 22, 2010. The inspection was to provide routine current Good Manufacturing Practice ("cGMP") coverage and focused on our approved Alferon N Injection® product. The inspection was conducted in accordance with Agency procedures for Therapeutic Biological Products Inspections. The current inspection covered the Quality and Facilities and Equipment systems. During the current inspection, a complete tour was conducted of the facility. Also, documents were reviewed that related to recent Out of Specification Investigation and Process and Component Deviation Reports. We also discussed with the Inspector our plans for production of Alferon N Injection®, Alferon® LDO and Ampligen® at the New Brunswick facility. No deficiencies were found during the inspection, and no FDA-483, Inspectional Observations were issued.

Ampligen®

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

On November 25, 2009, we received a Complete Response Letter ("CRL") from the FDA which described specific additional recommendations related to the Ampligen® NDA. In accordance with its 2008 Complete Response procedure, the FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues.

We have carefully reviewed the CRL and will seek a meeting with the FDA to discuss its recommendations upon the compilation of necessary data to be used in our response. We intend to take the appropriate steps to seek approval and commercialization of Ampligen®. Most notably, the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen® and recommended at least one additional clinical study which shows convincing effect and confirms safety in the target population. The FDA indicated that the additional study should be of sufficient size and sufficient duration (six months) and include appropriate monitoring to rule out the generation of autoimmune disease. In addition, patients in the study should be on more than one dose regimen, including at least 300 patients on dose regimens intended for marketing. We are presently planning a confirmatory clinical study which will utilize the exercise treadmill duration as the primary endpoint as did our earlier Phase III Study but with an enlarged number of subjects. Lastly, additional data including a well-controlled QT interval study (i.e., a measurement of time between the start of the Q wave and the end of the T wave in the heart's electrical cycle) and pharmacokinetic evaluations of dual dosage regiments were requested. Other items required by the FDA include certain aspects of Non-Clinical safety assessment and Product Quality. In the Non-Clinical area, the FDA recommended among other things that we complete rodent carcinogenicity studies in two species. While as part of the NDA submission we had requested that these studies be waived, this waiver had not been granted by the FDA in their CRL.

In the October 8, 2009 issue of Science Express, a consortium of researchers from the Whittemore Peterson Institute ("WPI"), the National Cancer Institute and the Cleveland Clinic reported a new retrovirus in the blood cells of 67% of Chronic Fatigue Syndrome ("CFS") patients and 3.7% in healthy control subjects. The infectious virus was also greater than 99% identical to that previously detected in prostate cancer. Retrospective analyses of patient samples from the completed Phase III trial of Ampligen® in potential treatment of CFS continues in collaboration with WPI. While an updated agreement is being finalized, we continue to collaborate with WPI under the terms of an "Evaluation Agreement" that had expired on July 23, 2010, to evaluate Hemispherx patient samples for XMRV (xenotropic murine leukemia related virus) using WPI's proprietary flow cytometry assay. We believe that these studies may provide a new perspective on the design of an additional confirmatory Phase III study in this disorder. We presented data at the 1st International Workshop on XMRV held on September 7 and 8, 2010 in Bethesda, Maryland at the U.S. Department of Health & Human Services' National Institutes of Health ("NIH").

In July 2010, we released a report prepared by Hideki Hasegawa, M.D. Ph.D., Director, Laboratory of Infectious Disease Pathology, National Institute of Infectious Disease ("NIID", formerly Japan's National Institute of Health), summarizing the results of a three year Japanese government funded program through the Japanese Minister of Health Labor and Welfare ("MHLW")to develop and test on non-human primates a nasally delivered H5N1 (Avian Flu) vaccine which, when coupled with Ampligen®, produced positive results in a preclinical testing environment showing that the combination provided a more robust and longer lasting immune response as compared to the vaccine used alone. The researchers concluded that their results could be applied to develop intranasally delivered vaccines for influenza virus prophylaxis focused on protection of the mucosal immune system against virus mutations. We expect that the clinical testing phase of Ampligen®, used in conjunction with a H5N1 (Avian Flu) vaccine, in Japan will begin in 2011. However, the timing of clinical testing is dependent upon the successful conclusion of our negotiations with Biken (operational arm of the non-profit Research Foundation for Microbial Disease of Osaka University) along with their timely filing and approval of an Investigatory New Drug ("IND") application for Ampligen® in Japan. A Material Evaluation Agreement (MEA) regarding Ampligen® with Biken that was initiated on August 19, 2009, effectively expired on September 1, 2010 and has yet to be formally extended. Hemispherx and Biken are in correspondence concerning both extending this agreement and the interpretation of experimental results of the two companies, as well as results reported by the NIID.

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 as the current expiration date of our finished goods inventory expired. We continue to undertake a major capital improvement program to upgrade our manufacturing capability for Alferon N Injection® at our New Brunswick facility. As a result, Alferon N Injection® could be available for commercial sales in mid to late 2011.

In April 2010, we began the process to undertake a clinical study with one of the leading and largest clinical research organizations 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 completed and we obtained approval to begin the study from the Indian Drugs Controller General on July 13, 2010. We began enrolling subjects in September 2010 and continue to enroll subjects for this clinical study through the end of monsoon season and into the winter’s flu season. Currently, we have four operational Clinical Investigative Sites with the potential to open up to six more sites, if deemed necessary and upon successful pre-study site visits.

Alferon® Low Dose Oral (LDO)

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

In October 2009, we submitted a protocol to the FDA proposing to conduct a Phase II, well-controlled, clinical study using Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. Following a teleconference with the FDA in November 2009, the FDA placed the proposed study on "Clinical Hold" because the protocol was deemed by the FDA to be deficient in design, and because of the need for additional information to be submitted in the area of chemistry, manufacturing and controls ("CMC"). Thereafter in December 2009, we submitted additional information by Amendment with respect to both the clinical protocol design issues and the CMC items. In January 2010, the FDA acknowledged that our responses to the clinical study design issues were acceptable; however, removal of the Clinical Hold was not warranted because the FDA believed that certain CMC issues had not been satisfactorily resolved. In this regard, the FDA communicated concern regarding the extended storage of Alferon® LDO drug product clinical lots which had been manufactured from an active pharmaceutical ingredient ("API") of Alferon N Injection® manufactured in year 2001. While the biological (antiviral) potency of the product had remained intact, we learned through newly conducted physico-chemical tests (the "new tests" of temperature, pH, oxidation and light on the chemical stability of the active API), that certain changes in the drug over approximately nine storage years (combined storage of Alferon N Injection® plus storage of certain LDO sachets) had introduced changes in the drug which might adversely influence the human safety profile. These "new tests" are part of recent FDA requirements for biological products, such as interferon, which did not exist at the time of the original FDA approval of Alferon N Injection® for commercialization and at the time of FDA approval of the "Product License" and "Establishment License" for the Alferon N Injection® product. Based on the recent FDA request, we have now established and implemented the "new test" procedures. As a result, we have found that certain Alferon N Injection® lots with extended storage (i.e., approximately eight to nine years) do appear to demonstrate some altered physico-chemical properties. However we have also observed that more recent lots, including those manufactured beginning in the year 2006, are superior with respect to the enhanced scrutiny of these tests and, in our view, could be considered appropriate for clinical trials in the Alferon® LDO sachet format. Upon their review, the FDA has been responsive to these new findings and requested additional stability data on the lots proposed for use in this clinical study utilizing the new test methods. The proposed clinical lots were manufactured on June 24, 2010 and placed on stability on June 28, 2010. The FDA has requested three months of stability data on the proposed clinical lots. The three months of product stability data has been compiled and continues to be analyzed with the expectation of submission to the FDA by the end of December 2010. Once the FDA has received and reviewed the additional data, we believe that the Full Clinical Hold could be thereafter lifted assuming that the FDA concurs that the stability data addresses the outstanding CMC issues cited in the January 2010 FDA recommendations.

401(k) Plan

In December 1995, we established a defined contribution plan, entitled the Hemispherx Biopharma Employees 401(k) Plan and Trust Agreement (the "401(k) Plan"). Full time employees of the Company are eligible to participate in the 401(K) Plan following one year of employment. Subject to certain limitations imposed by federal tax laws, participants are eligible to contribute up to 15% of their salary (including bonuses and/or commissions) per annum. Participants' contributions to the 401(K) Plan may be matched by the Company at a rate determined annually by the Board of Directors.

Each participant immediately vests in his or her deferred salary contributions, while Company contributions will vest over one year. The 6% Company matching contribution was terminated as of March 15, 2008 and was reinstated effective January 1, 2010. The Company provided matching contributions to each employee for up to 6% of annual pay aggregating $95,881 for the nine months ended September 30, 2010.

New Accounting Pronouncements

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

Disclosure About Off-Balance Sheet Arrangements

None.

Critical Accounting Policies

There have been no material changes in our critical accounting policies and estimates from those disclosed in Note 2 of our Annual Report on Form 10-K for the year ended December 31, 2009.

RESULTS OF OPERATIONS

Three months ended September 30, 2010 versus three months ended September 30, 2009

Net Loss

Our net loss was approximately $3,254,000 for the three months ended September 30, 2010, which was an increase of $819,000 or 34% when compared to the same period in 2009. This increase in loss for these three months was primarily due to the following changes in expense elements:

1) an increase in Research and Development costs of approximately $635,000 or 54%;

2) an increase in General and Administrative expenses of approximately $574,000 or 49%; offset by

3) an increase in interest income of $420,000 from funds invested in marketable securities.

Net loss per share was $0.02 for the current period versus $0.02 for the same period in 2009.

Revenues

Revenues from our Ampligen® Cost Recovery Program increased $10,000 or 40% for the third quarter in 2010 as compared to the same time period of 2009 due to a 67% increase in the number of patients participating in the program. As previously stated, we have no Alferon N Injection® product to commercially sell at this time and all revenue was generated from the Ampligen® cost recovery clinical treatment programs.

Production/Cost of Goods Sold

Production/Cost of Goods Sold was approximately $181,000 and $146,000, respectively, for the three months ended September 30, 2010 and 2009. This increase of $35,000 or 24% was primarily due to the cost to maintain existing Alferon N Injection® and Ampligen® inventory including storage, stability testing, transport and reporting costs along with our efforts to prepare for production of Alferon N Injection® for potential future commercial sales.

Research and Development Costs

Overall Research and Development ("R&D") costs for the three months ended September 30, 2010 were approximately $1,808,000 as compared to $1,173,000 for the same period a year ago reflecting an increase of $635,000 or 54%. The primary factors for the increase in expenses were the clinical costs, research and development costs of Alferon® LDO along the initial costs of the Alferon N Injection® Phase IIb clinical trial underway in India.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended September 30, 2010 and 2009 were approximately $1,738,000 and $1,164,000, respectively, reflecting an increase of $574,000 or 49%. The higher G&A expenses in 2010 consisted primarily of 1) an increase of $293,000 that resulted from the 2009 stock compensation expense reduction using the Black-Scholes valuation method prior to dispensation; and 2) an increase in 2010 of $188,000 in legal fees due to various legal proceedings.

Interest and Other Income

Interest and other income for the three months ended September 30, 2010 and 2009 was approximately $443,000 and $23,000, respectively, representing an increase of $420,000. The primary cause for the increase of interest income in 2010 was the purchase of a diverse portfolio of short and long term investments. The interest income from these investments is recognized as the investments mature.

Nine months ended September 30, 2010 versus nine months ended September 30, 2009

Net Loss

Our net loss was approximately $10,974,000 for the nine months ended September 30, 2010, which was an increase of $1,582,000 or 17% when compared to the same period in 2009. This increase in loss was primarily due to the following expense elements:

1) an increase in Production/Cost of Goods Sold of approximately $230,000 or 55%;

2) an increase in Research and Development costs of approximately $748,000 or 16%; and

3) an increase in General and Administrative expenses of approximately $1,303,000 or 31%; offset by

4) a decrease in finance costs of $241,000, or 100% from a Standby Finance Agreement executed in February 2009; and

5) an increase in interest income of $426,000 from invested funds.

Net loss per share was $0.08 for the current period $0.09 for the same period in 2009.

Revenues

Revenues for the nine months ended September 30, 2010 were $108,000 compared to revenues of $71,000 for the same period in 2009. These revenues were from our Ampligen® Cost Recovery Program which increased $37,000 or 52% due to a 46% increase in the number of patients participating in the Program. There were no revenues related to the sale of Alferon N Injection® for the nine month period ended 2010 or 2009.

Production/Cost of Goods Sold

Production/Cost of Goods Sold was approximately $649,000 and $419,000, respectively, for the nine months ended September 30, 2010 and 2009. This is an increase of $230,000 or 55%. This increase in expenses was primarily due to the cost of maintaining existing Alferon N Injection® and Ampligen® inventory including storage, stability testing, transport and reporting costs along with our efforts to prepare for production of Alferon N Injection® for potential future commercial sales.

Research and Development Costs

Overall Research and Development ("R&D") costs for the nine months ended September 30, 2010 were approximately $5,498,000 as compared to $4,750,000 for the same period a year ago, reflecting an increase of $748,000 or 16%. This increase was primarily due to R&D costs associated with preparations related to our effort to launch Alferon N Injection® and Alferon® LDO clinical tests along with our R&D staff's continued efforts to develop a response to the CRL from the FDA.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the nine months ended September 30, 2010 and 2009 were approximately $5,495,000 and $4,192,000, respectively, reflecting an increase of $1,303,000 or 31%. The primary reasons for this increase in expense were an additional $1,137,000 in legal fees associated with our successful Judgment against Johannesburg Consolidated Investments along with our defense efforts in other legal proceedings (See "Part II – OTHER INFORMATION, ITEM 1. Legal Proceedings") and an additional $340,000 in stock compensation to consultants that were offset by a decrease in fees of $213,000 paid to consultants to acquire and maintain an At-The-Market Equity Program.

Interest and Other Income

Interest and other income for the nine months ended September 30, 2010 and 2009 was $565,000 and $139,000, respectively, representing an increase of $426,000 or 306%. The primary cause for the increase of interest income in 2010 was the purchase of a diverse portfolio of short and long term investments. The interest income from these investments is recognized as the investments mature.

Interest Expense and Financing Costs

We had interest expense of $5,000 and $-0- from capital leases for the nine months ended September 30, 2010 or 2009, respectively. On February 1, 2009, we entered into a Standby Financing Agreement that produced finance costs of $241,000 in Common Stock Commitment Warrants for the nine months ended September 30, 2009, for which no agreement nor related expenses of this type existed during the first nine months ended in 2010. For detailed information on this agreement, refer to "Standby Financing Agreement" as disclosed in our annual report on Form 10-K/A for the year ended December 31, 2009, filed April 30, 2010.

Liquidity and Capital Resources

Cash used in operating activities for the nine months ended September 30, 2010 was $10,070,000 compared to $6,665,000 for the same period in 2009, an increase of $3,405,000 or 51%. This utilization of cash reflects the increased expenses in operations as explained above in the "Production/Cost of Goods Sold" disclosure in conjunction with the impact of our effort in 2009 to conserve cash through the Employee Wage Or Hours Reduction Program (the "Program") implemented January 1 through May 31, 2009 in which all active full-time employees reduced their base salary from 10% to 50% in return for "Incentive Rights" to our common stock. As of September 30, 2010, we had approximately $48,261,000 in Cash, Cash Equivalents and Marketable Securities, or a decrease of approximately $9,811,000 from December 31, 2009.

We have been using the proceeds from 2009's equity 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 expenses and infrastructure growth including preparation for manufacturing, regulatory compliance and market development costs related to the FDA approval process for Ampligen®, Alferon N Injection® and Alferon® LDO development.

Pursuant to our May 28, 2010 Equity Distribution Agreement (the "Agreement") with Maxim Group LLC ("Maxim") we established an At-The-Market ("ATM") Equity Program pursuant to which we may sell up to 32,000,000 shares of our Common Stock from time to time through Maxim as our sales agent (the "Agent"). Under the Agreement, the Agent is entitled to a commission at a fixed commission rate of 4.0% of the gross sales price per Share sold, up to aggregate gross proceeds of $10,000,000, and, thereafter, at a fixed commission rate of 3.0% of the gross sales price per Share sold. We have no obligation to sell any shares under this program, and may at any time terminate the Agreement. During the quarter ended September 30, 2010, we sold no shares through this program and received no net cash proceeds. For the nine months ended September 30, 2010, we sold 520,000 shares that resulted in net cash proceeds of $292,785 and commissions paid to Maxim of $12,199.

Because of our long-term capital requirements, we may seek to access the public equity market through the above ATM equity program or otherwise 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, competitive and technological advances, the regulatory processes, including the commercializing of Ampligen® and new utilization of Alferon® products. Our ability to raise funds from the sale of equity is limited due to the limited number of shares of common stock authorized but not issued or reserved (please see "Part II – OTHER INFORMATION, ITEM 1A. Risk Factors; We may require additional financing which may not be available; The limited number of shares of common stock available for financing or other purposes may hinder our ability to raise additional funding or utilize equity securities for other corporate purposes").

There can be no assurances that, if needed, we will raise adequate funds from these or other sources, which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

ITEM 3: Quantitative and Qualitative Disclosures About Market Risk

We had approximately $48,261,000 in Cash, Cash Equivalents and Marketable Securities at September 30, 2010. In the past, we had invested the excess cash in minimal risk exposure, three to twelve month interest bearing financial instruments. However with the current state of the market and our funds well in excess of our short-term operational needs, our Board has reassessed our cash investment strategy consistent with the following objectives to:

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

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

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

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

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

ITEM 4: Controls and Procedures

Our Chairman of the Board (serving as the principal executive officer) and the Chief Financial Officer performed an evaluation of the effectiveness of our disclosure controls and procedures, which have been designed to permit us to effectively identify and timely disclose important information. In designing and evaluating the disclosure controls and procedures, Management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and Management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the controls and procedures were effective as of September 30, 2010 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, 2010, 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.

On August 11, 2010, Hemispherx won a $188 million judgment in U.S. Federal Court (Southern District of Florida) ending a six-year litigation battle against JCI and former JCI officers R.B. Kebble and H.C. Buitendag. Kebble and Buitendag were found to have engaged in fraud that included an illegal attempt to devalue, take over and pillage Hemispherx. We intend to pursue collection of the judgment in Florida and South Africa.

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

On June 4, 2009, we 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 tortuous interference with certain financing transactions in which we were engaged. The case was transferred to the Northern District of Georgia, and we engaged Holland & Knight LLP on November 13, 2009 to serve as trial counsel. On November 19, 2009, MidSouth answered our Complaint and filed a Counterclaim against us and The Sage Group, Inc., 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.

On January 12, 2010, we filed a Motion for Judgment on the Pleadings with the Court. By Order dated March 31, 2010, the Court granted that Motion in part and denied it in part. The Court held that MidSouth's claim based upon an alleged breach of contract could not be sustained. The case proceeded on our claims against the Defendants and MidSouth's claims based upon promissory estoppel, quantum meruit, unjust enrichment, fraud, and MidSouth's request for attorney's fees and punitive damages. Discovery closed in mid-May. The Defendants have filed a Motion for Summary Judgment on our claims against them, and we have filed a Motion for Summary Judgment on all the remaining counterclaims. The Briefing has been completed and Motions have been submitted to the Court to await a decision. We will vigorously defend any of the counterclaims which survive our Motion for Summary Judgment, and will continue to prosecute our claims against the Defendants if we prevail on their Motion. We have no projection as to the likely outcome of the case.

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

On July 31, 2009, Cato Capital LLC ("Cato") filed suit asserting that under a November 2008 agreement, we owe Cato a placement fee for certain investment transactions. The Complaint seeks damages in the amount of $5,000,000 plus attorneys fees. We filed our 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 us arising from the defenses contained in our Answer, and increase the total amount sought to $9,830,000, plus attorneys' fees and punitive damages. We 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 our 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 we could file a Motion to Dismiss, raising the arguments we 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, we filed a Motion to dismiss all the counts of the Amended Complaint against us other than the breach of contract count. Cato's response to the Motion to Dismiss is due on November 30, 2010. The timeframe for the Court's disposition of our Motion to Dismiss cannot be ascertained.

We believe we have meritorious defenses and are vigorously defending against this claim.

(d) In re Hemispherx Biopharma, Inc. Litigation, U. S. District Court for the Eastern District of Pennsylvania, Civil Action No. 09-5262.

Between November 10, 2009 and December 29, 2009, five putative class actions were filed against us and our Chief Executive Officer generally asserting that Defendants misrepresented the status of our New Drug Application ("NDA") for Ampligen®. Each action was purportedly brought on behalf of investors who purchased our publicly traded securities. On February 12, 2010, the Court consolidated the five actions ("Securities Class Action Lawsuit") and on February 26, 2010, a consolidated amended complaint was filed, adding our Medical Director as a Defendant. On March 12, 2010, we filed a motion to dismiss the amended complaint, which the Court denied on April 20, 2010. On April 27, 2010, the Court entered a Case Management Order directing the parties to undertake the Discovery process.

On August 24, 2010, we announced that, as result of court mediation proceedings, we had entered into a written agreement in principle with the Court-appointed lead plaintiffs to settle all of the currently pending securities class actions consolidated in the U.S. District Court for the Eastern District of Pennsylvania. On October 20, 2010, an "Order Preliminarily Approving The Settlement, Directing The Issuance Of Notice, And Scheduling A Settlement Fairness Hearing" ("Order") was entered by the U.S. District Court overseeing the Securities Class Action Lawsuit. As described in the Order, we entered into a Stipulation and Agreement of Settlement dated September 24, 2010 in full and final settlement of each and every Released Claim against Hemispherx. If it receives final approval by the Court, the settlement will be paid from our insurance coverage and will not result in the payment of any funds by us. Furthermore, the settlement expressly is not an admission of any culpability by Hemispherx nor its Officers.

The related Settlement Fairness Hearing is scheduled to be held on January 20, 2011 at the United States District Court for the Eastern District of Pennsylvania to determine whether:

- the Action should be finally certified as a class action suit;
- the proposed Settlement is fair, reasonable, adequate and should be approved;
- the Released Claims against Hemispherx should be dismissed;
- the proposed Plan of Allocation for the proceeds of the Settlement should be approved by the Court;
- the application of the Lead Counsel for an award of attorney fess and reimbursement of litigation expenses should be approved;
- to determine the amount of reimbursement of cost and expenses for representation of the suit;
- any other matters as the Court deem appropriate.

The Claims Administrator for the litigation is Heffler, Radetich & Saitta LLP, P.O. Box 58578, Philadelphia, PA 19102-8578.

In December 2009 and January 2010, three Shareholder Derivative Complaints were filed against us and some of our Officers and Directors ("Shareholder Derivative Lawsuits"). These suits also allege that the named Defendants caused us to misrepresent the status of our NDA for Ampligen®. On February 12, 2010, the Court consolidated the Securities Class Action Lawsuit with the Shareholder Derivative Lawsuits for purposes of Discovery and transferred the Shareholder Derivative Lawsuits to the civil suspense docket.

We continue to vigorously defend the Shareholder Derivative Complaints. Due to the preliminary state of the proceedings, the potential impact of these actions, which seek unspecified damages, attorneys' fees and expenses, are uncertain.

(e) Jeffrey Bastedo v. Hemispherx Biopharma, Inc., Delaware Chancery Court, Case No. 5748-VCP.

On August 24, 2010, Jeffrey Bastedo filed a complaint to gain access to our books and records for the purpose of inspection pursuant to Section 220 if the Delaware General Corporate Law. This suit asserts that its purpose is to investigate Hemispherx regarding alleged efforts of Hemispherx to mislead the investing public regarding its New Drug Application for Ampligen® and concealed carcinogenicity studies.

We believe that this claim is without merit and is duplicative of Derivative Litigation pending in the United States District Court for the Eastern District of Pennsylvania described above in (d). We have moved timely to dismiss the Complaint asserting that it was filed for no proper purpose, violates the First Filed Legal Doctrine, and is not in our best interests to comply. We subsequently filed our Opening Brief in support of our Motion to Dismiss. The Opening Brief of Plaintiff in opposition to the Motion to Dismiss has not yet been filed. The date of final disposition of this Motion cannot yet be determined.

We plan on vigorously defending against this Complaint. Due to the preliminary state of this Complaint and our Motion to Dismiss the Complaint, the potential impact of this action, which seeks access to information, unspecified attorneys' fees and expenses, is uncertain.

(f) Summation.

In reference to Contingencies identified above, there can be no assurance that an adverse result in these proceedings would not have a potentially material adverse effect on our business, results of operations, and financial condition. With regards to Contingency (d), we maintain a Directors and Officers Insurance Policy that provides coverage for claims and retention of legal counsel. Given the anticipated settlement of the Securities Class Action Lawsuit, it is uncertain if sufficient amounts of coverage will remain from the November 2009-2010 policy to cover the Shareholder Derivative Lawsuits fees and potential liability.

We have not recorded any loss contingencies as a result of the above matters for the year ended December 31, 2009 or nine months ended September 30, 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.

On July 7, 2008, the FDA accepted for review our New Drug Application ("NDA") for Ampligen® to treat CFS, originally submitted in October 2007.

On November 25, 2009, we received a Complete Response Letter ("CRL") from the FDA which described specific additional recommendations related to the Ampligen® NDA. In accordance with its 2008 Complete Response procedure, the FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues. We have carefully reviewed the CRL and will seek a meeting with the FDA to discuss its recommendations. We intend to take the appropriate steps to seek approval and commercialization of Ampligen®. Most notably, the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen® and recommended at least one additional clinical study which shows convincing effect and confirms safety in the target population. The FDA indicated that the additional study should be of sufficient size and sufficient duration (6 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. Finally, additional data including a well-controlled QT interval study of the heart's electrical cycle and pharmacokinetic evaluations of dual dosage regiments was requested. Other items required by the FDA include certain aspects of Non-Clinical safety assessment and product Quality. In the Non-Clinical area, the FDA recommended among other things that we complete rodent carcinogenicity studies in two species. As part of the NDA submission, we had requested that these studies be waived, but the waiver has not been granted.

If we are unable to generate the additional data required by the FDA or if, for that or any other reason, Ampligen® or one of our other products does not receive regulatory approval in the U.S. or elsewhere, our operations most likely will be materially adversely affected.

The Alferon® LDO clinical study for possible prophylaxis and treatment against influenza is currently suspended due the FDA Clinical Hold. 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 flu requires prior regulatory approval. In October 2009, we submitted a protocol to the FDA proposing to conduct a Phase II, well-controlled, clinical study using Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. Following a teleconference with the FDA in November 2009, the FDA placed the proposed study on "Clinical Hold" because the protocol was deemed by the FDA to be deficient in design and because additional information was required to be submitted in the area of chemistry, manufacturing and controls ("CMC"). Thereafter in December 2009, we submitted additional information by Amendment with respect to both the clinical protocol design issues and the CMC items. While the FDA has acknowledged that our responses to the

clinical issues were acceptable, in January 2010 they requested additional stability data on the lots proposed for use in clinical studies utilizing new test methods and the Clinical Hold remains in effect because the FDA believed that certain CMC issues had not yet been satisfactorily resolved. In this regard, new clinical lots were manufactured on June 24, 2010 and placed on stability on June 28, 2010. Only the FDA can determine whether a drug is safe, effective or appropriate for clinical testing or treating a specific application. Therefore, no assurance can be given that the use of our existing inventory will be permitted in future clinical trials. The three months of product stability data has been compiled and continues to be analyzed with the expectation of submission to the FDA by the end of December 2010. Only the FDA can determine whether a drug is safe, effective or appropriate for clinical testing or treating a specific application. Therefore, no assurance can be given that the use of our existing inventory will be permitted in future clinical trials.

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, 2010, our accumulated deficit was approximately $(221,821,000). 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, 2010, we had approximately $48,261,000 in Cash, Cash Equivalents and Marketable Securities. Given the harsh economic conditions, we continue to review every aspect of our operations for cost and spending reductions to assure our long-term financial stability while maintaining the resources necessary to achieve our primary objectives of obtaining NDA approval of Ampligen® and securing a strategic partner.

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

Our ability to raise additional funds from the sale of equity securities is limited. In this regard, we only have approximately 32,000,000 shares authorized but unissued and unreserved for any purpose, other than for sale under the ATM Equity Program. At our 2009 annual stockholders' meeting, we sought, but did not receive, approval of an amendment to our Certificate of Incorporation to increase the number of authorized shares of Common Stock from 200,000,000 to 350,000,000. 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 including, but not limited to, acquisitions or joint ventures with potential strategic partners.

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 as the current expiration date of our finished goods inventory expired in March 2008. As a result, we have no product to sell at this time. We continue to undertake a major capital improvement program to enhance our manufacturing capability to produce the purified drug concentrate used in the formulation of Alferon N Injection® at our New Brunswick facility. As a result, Alferon N Injection® could be available for commercial sales in mid to late 2011. However our agreement with a third party to formulate, package and label Alferon N Injection® has expired and we are seeking new vendors to supply this service. Also, each production lot of Alferon N Injection® is subject to FDA review and approval prior to releasing the lots to be sold. In light of these contingencies, there can be no assurances that the approved Alferon N Injection® product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

Although preliminary 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.

A three year Japanese government funded program to develop and test on non-human primates a nasally delivered H5N1 (Avian Flu) vaccine coupled with Ampligen® has been completed (see “PART I; ITEM 2: Management's Discussion and Analysis of Financial Condition and Results of Operations; Overview; Ampligen®“). No assurance can be given that similar results will be observed in clinical trials. Use of Ampligen® in the treatment of flu requires prior regulatory approval. Only the FDA or other corresponding regulatory agencies world-wide can determine whether a drug is safe, effective and appropriate for treating a specific application. As discussed above, obtaining regulatory approvals is a rigorous and lengthy process (see “Our drugs and related technologies are investigational and subject to regulatory approval. If we are unable to obtain regulatory approval, our operations will be significantly adversely affected” above).

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

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

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

To date, no consistent policy has emerged regarding the breadth of protection afforded by pharmaceutical and biotechnology patents. There can be no assurance that new patent applications relating to our products or technology will result in patents being issued or that, if issued, such patents will afford meaningful protection against competitors with similar technology. It is generally anticipated that there may be significant litigation in the industry regarding patent and intellectual property rights. Such litigation could require substantial resources from us and we may not have the financial resources necessary to enforce the patent rights that we hold. No assurance can be made that our patents will provide competitive advantages for our products or will not be successfully challenged by competitors. No assurance can be given that patents do not exist or could not be filed which would have a materially adverse effect on our ability to develop or market our products or to obtain or maintain any competitive position that we may achieve with respect to our products. Our patents also may not prevent others from developing competitive products using related technology.

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.

We currently license certain proprietary information from third parties, some of which may have been developed with government grants under circumstances where the government maintained certain rights with respect to the proprietary information developed. No assurances can be given that such third parties will adequately enforce any rights they may have or that the rights, if any, retained by the government will not adversely affect the value of our license.

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

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

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

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

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

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

There are no long-term agreements with suppliers of required materials and services. If we are unable to obtain the required raw materials and/or services, we may not be able to manufacture Alferon N Injection® and/or Ampligen®.

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

There are a limited number of 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, 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®, Alferon® 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 certain aspects of 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 affect on us. Also, to be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. To the extent we are involved in the production process, our current facilities 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 current Good Manufacturing Practice (“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® or other products in commercial quantities at costs acceptable to us.

We have never produced Ampligen®, Alferon® or any other products in large commercial quantities. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen® or enter into third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Also, each production lot of Alferon N Injection® is subject to FDA review and approval prior to releasing the lots to be sold. This review and approval process could take considerable time, which would delay our having product in inventory to sell.

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

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

Our products may be subject to substantial competition.

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

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

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

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

On November 28, 2008, we suspended product liability insurance for Alferon N Injection® and Ampligen®. We concluded that years of successfully addressing the limited number of product liability claims filed against Ampligen® and Alferon® LDO, combined with the informed consent and other safeguards employed as an element of clinical trials and the lack of any commercial sales since April 2008, that temporarily discontinuing the liability insurance was an acceptable risk as a measure of cash conservation. As of September 17, 2010, we reinstated our Products Liability and Clinical Trial insurance coverage for Ampligen® and Alferon®. However even with maintaining product 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.

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.

A Number of Lawsuits Have Been Filed Against Us and We May Be Subject to Civil Liabilities.

A number of lawsuits have been filed against us, some alleging securities fraud (see "Part II – Other Information; Item 1. Legal Proceedings"). The complaints seek monetary damages, costs, attorneys' fees, and other equitable and injunctive relief. Securities class action suits and derivative suits are often brought against companies following periods of volatility in the market price of their securities. Defending against these suits, even if meritless, can result in substantial costs to us and could divert the attention of our management. Given the anticipated settlement of the Securities Class Action Lawsuit, it is uncertain if sufficient amounts of coverage will remain from the November 2009-2010 policy to cover the Shareholder Derivative Lawsuits fees and potential liability.

The existence of these proceedings could have a material adverse effect on our ability to access the capital markets to raise additional funds. While Management believes that the lawsuits are without merit, we cannot predict or determine the timing or final outcomes of the lawsuits and are unable to estimate the amount or range of loss that could result from unfavorable outcomes. Adverse results in some or all of these legal proceedings could be material to our results of operations, financial condition or cash flows.

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;

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- overall investment market fluctuation; 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 12 month period ended September 30, 2010, the closing price of our common stock has ranged from $0.44 to $1.95 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action and derivative litigation have often been instituted against companies. In this regard, please see “A Number of Lawsuits Have Been Filed Against Us and We May Be Subject to Civil Liabilities” above.

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, 2010. 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, 2010, we have sold 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, could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in Management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November 2002, we adopted a Stockholder Rights Plan (“Rights Plan”) and, under the Rights Plan, our Board of Directors declared a dividend distribution of one

Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one-hundredth unit of preferred stock for $30.00. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Dr. Carter, our Chief Executive Officer, who already beneficially owns 5.0% of our common stock, the Rights Plan's threshold will be 20%, instead of 15%. The Rights Plan will expire on November 19, 2012, and may be redeemed prior thereto at $.01 per Right under certain circumstances.

Special Note Regarding Forward Looking Statements

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

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

During the quarter ended September 30, 2010, we issued an aggregate of 52,106 shares to consultants and vendors for services performed.

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

We did not repurchase any of our securities during the quarter ended September 30, 2010.

ITEM 3: Defaults upon Senior Securities

None.

ITEM 4: Removed and Reserved

ITEM 5: Other Information

None.

ITEM 6: Exhibits

(a) Exhibits

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

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

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

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

SIGNATURES

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

HEMISPHERx BIOPHARMA, INC.

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

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

Date: November 8, 2010