

HEMISPHERX BIOPHARMA INC
Form 10-Q/A
February 14, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q/A

Quarterly Report Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

For the Quarterly Period Ended June 30, 2010

Commission File Number: 1-13441

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

Delaware
(State or other jurisdiction of
incorporation or organization)

52-0845822
(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.

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 No

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

Large accelerated filer Accelerated filer
 Non-accelerated filer 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 No

134,396,443 shares of common stock were issued and outstanding as of August 03, 2010.

EXPLANATORY NOTE

Hemispherx Biopharma, Inc. (“Hemispherx”, the “Company”, “we”, “our” or “us”) is filing this amendment to its Quarterly Report on Form 10-Q (“Form 10-Q/A”) to restate its Consolidated Condensed Financial Statements as of and for the three and six months ended June 30, 2010 and 2009 as described in Note 11, Restatement, of the Notes to the Consolidated Condensed Financial Statements included herein. As previously disclosed in the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission (the “SEC”) on December 28, 2010, the Company received a comment letter from the SEC concerning its review of the Company’s annual report on Form 10-K, as amended, for the year ended December 31, 2009. During the process of resolving the SEC’s comments, the SEC Staff alerted the Company that they did not agree with the Company’s method of computing the fair value of certain Warrants. As a result, on December 22, 2010, after discussion with the Company’s independent registered public accounting firm, the Company’s Audit Committee determined that the previously issued financial statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2009 and in its Forms 10-Q for the periods ended March 31, 2010, June 30, 2010 and September 30, 2010 and in its Forms 10-Q for the periods ended June 30, 2009 and September 30, 2009, should not be relied upon. The Company simultaneously herewith is filing amendments to its Annual Report on Form 10-K for the year ended December 31, 2009 and Quarterly Reports on Form 10-Q for the quarters ended March 31, 2010 and September 30, 2010 to reflect this restatement.

For the convenience of the reader, this Form 10-Q/A sets forth the Company’s original Form 10-Q for the quarter ended June 30, 2010 (the “Original 10-Q”) in its entirety, as amended by, and to reflect, the restatement. No attempt has been made in this Form 10-Q/A to update other disclosures presented in the Original 10-Q, except as required to reflect the effects of the restatement. This Form 10-Q/A does not reflect events occurring after the filing of the Original 10-Q or modify or update those disclosures, including the exhibits to the Original 10-Q affected by subsequent events.

The following sections of this Form 10-Q/A have been amended to reflect the restatement:

Part I – Item 1 – Financial Statements; and

Part I – Item 2 – Management’s Discussion and Analysis of Financial Condition and Results of Operations.

This Form 10-Q/A has been signed as of a current date and, as required by Rule 12b-15 of the Securities Exchange Act of 1934, all certifications of the Company’s Chief Executive Officer and our Chief Financial and Accounting Officer are given as of a current date. Accordingly, this Form 10-Q/A should be read in conjunction with our filings made with the SEC subsequent to the filing of the Original 10-Q, including any amendments to those filings.

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 (restated)	June 30, 2010 (Unaudited) (restated)
ASSETS		
Current assets:		
Cash and cash equivalents (Note 12)	\$ 58,072	\$ 5,331
Marketable securities maturing in less than one year (Note 5)	-	30,433
Inventories (Note 4)	-	934
Prepaid expenses and other current assets	332	120
Total current assets	58,404	36,818
Property and equipment, net	4,704	4,675
Marketable securities maturing in one year or greater (Note 5)	-	14,783
Patent and trademark rights, net	830	836
Investment	35	35
Construction in progress (Note 8)	135	405
Other assets (Note 4)	886	35
Total assets	\$ 64,994	\$ 57,587
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,294	\$ 1,335
Accrued expenses (Note 6)	1,321	509
Current portion of capital lease (Note 7)	-	35
Total current liabilities	2,615	1,879
Long-term liabilities		
Long-term portion of capital lease (Note 7)	-	21
Redeemable warrants (Note 11)	3,684	2,760
Total liabilities	6,299	4,660
Commitments and contingencies		
Stockholders' equity (Note 9):		
Preferred stock, par value \$0.01 per share, authorized 5,000,000; issued and outstanding; none	-	-
	133	135

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Common stock, par value \$0.001 per share, authorized 200,000,000 shares;
issued and outstanding 132,787,447 and 134,368,677, respectively

Additional paid-in capital	263,151	264,179
Accumulated other comprehensive loss	-	(2)
Accumulated deficit	(204,589)	(211,385)
Total stockholders' equity	58,695	52,927
Total liabilities and stockholders' equity	\$ 64,994	\$ 57,587

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 June 30,	
	2009	2010
	(restated)	(restated)
Revenues:		
Clinical treatment programs	\$ 17	\$ 41
Total revenues	17	41
Costs and expenses:		
Production/cost of goods sold	152	328
Research and development	1,982	1,694
General and administrative	1,862	1,788
Total costs and expenses	3,996	3,810
Operating loss	(3,979)	(3,769)
Interest and other income	109	93
Redeemable warrants valuation adjustment(Note 11)	(10,861)	2,260
Net loss	\$ (14,731)	\$ (1,416)
Basic and diluted loss per share (Note 2)	\$ (.15)	\$ (.01)
Weighted average shares outstanding, basic and diluted	100,077,267	133,107,607

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)

	Six months ended June 30,	
	2009	2010
	(restated)	(restated)
Revenues:		
Clinical treatment programs	\$ 46	\$ 73
Total revenues	46	73
Costs and expenses:		
Production/cost of goods sold	273	468
Research and development	3,577	3,690
General and administrative	3,028	3,757
Total costs and expenses	6,878	7,915
Operating loss	(6,832)	(7,842)
Financing costs	(241)	-
Interest and other income	116	122
Redeemable warrants valuation adjustment (Note 11)	(10,861)	924
Net loss	\$ (17,818)	\$ (6,796)
Basic and diluted loss per share (Note 2)	\$ (.20)	\$ (.05)
Weighted average shares outstanding, basic and diluted	89,110,201	132,963,622

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 (restated)	Accumulated Other Compre- hensive Loss	Accumulated Deficit (restated)	Total Stockholders' Equity (restated)	Compre- hensive Loss (restated)
Balance at December 31, 2009	132,787,447	\$ 133	\$ 263,151	\$ -	\$ (204,589)	\$ 58,695	\$ -
Stock issued for settlement of accounts payable	446,761	-	302	-	-	302	-
Equity based compensation	614,469	1	434	-	-	435	-
Shares sold at the market	520,000	1	292	-	-	293	-
Unrealized loss in investment securities	-	-	-	(2)	-	(2)	(2)
Net loss - restated	-	-	-	-	(6,796)	(6,796)	(6,796)
Balance at June 30, 2010 - restated	134,368,677	\$ 135	\$ 264,179	\$ (2)	\$ (211,385)	\$ 52,927	\$ (6,798)

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

For the Six Months Ended June 30, 2009 and 2010

(in thousands)

(Unaudited)

	2009 (restated)	2010 (restated)
Cash flows from operating activities:		
Net loss - restated	\$ (17,818)	\$ (6,796)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	177	192
Amortization of patent and trademark rights, and royalty interest	186	39
Financing cost related to Standby Financing	241	-
Redeemable warrants valuation adjustment	10,861	(924)
Equity based compensation	141	435
Gain on disposal of equipment	(83)	(77)
Change in assets and liabilities:		
Accounts and other receivables	(9)	-
Prepaid expenses and other current assets	171	212
Accounts payable	1,017	343
Accrued expenses	987	(812)
Net cash used in operating activities	\$ (4,129)	\$ (7,388)
Cash flows from investing activities:		
Purchase of property plant and equipment	\$ (5)	\$ (362)
Additions to patent and trademark rights	(130)	(45)
Capital lease deposit	-	(6)
Purchase of short-term investments	(1,000)	(45,218)
Net cash used in investing activities	\$ (1,135)	\$ (45,631)

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

	2009 (restated)	2010 (restated)
Cash flows from financing activities:		
Payments on capital lease	\$ -	\$ (15)
Warrants and options converted	5,683	-
Proceeds from sale of stock, net of issuance costs	34,119	293
Net cash provided by financing activities	\$ 39,802	\$ 278
Net increase (decrease) in cash and cash equivalents	34,538	(52,741)
Cash and cash equivalents at beginning of period	6,119	58,072
Cash and cash equivalents at end of period	\$ 40,657	\$ 5,331
Supplemental disclosures of non-cash investing and financing cash flow information:		
Issuance of common stock for accounts payable and accrued expenses	\$ 1,137	\$ 302
Equipment acquired by capital lease	\$ -	\$ 70
Unrealized loss on investments	\$ -	\$ (2)
Redeemable warrants valuation adjustment	\$ 10,861	\$ (924)

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 and the impact of a restatement on the December 31, 2009 Balance Sheet and Income Statement for the year then ended. Interim results are not necessarily indicative of results for a full year.

The interim consolidated financial statements and notes thereto are presented as permitted by the Securities and Exchange Commission ("SEC"), and do not contain certain information which will be included in our annual consolidated financial statements and notes thereto.

These consolidated financial statements should be read in conjunction with our consolidated financial statements for the year ended December 31, 2009 included in our amended and restated annual report on Form 10-K/A-2, filed on February 11, 2011.

Note 2: Net Loss Per Share

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Equivalent common shares, consisting of stock options and warrants including the Company's convertible debentures, which amounted to 35,817,809 and 52,641,984 shares, are excluded from the calculation of diluted net loss per share for the six months ended June 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 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:

	Six Months Ended June 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% - 110.57%	109.72%-110.01%
Weighted average grant date fair value of options and warrants issued	\$113,814	\$402,771

Stock option activity for 2009 and during the six months ended June 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	10.00	-
Options forfeited	-	-	-	-
Outstanding June 30, 2010	7,048,752	\$ 2.37	6.64	\$ -
Exercisable June 30, 2010	6,991,530	\$ 2.38	6.64	\$ -

The weighted-average grant-date fair value of options granted during the six months ended June 30, 2009 and 2010 was \$-0- 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	18,889	.66	10.00	-
Options vested	-	-	-	-
Options forfeited	-	-	-	-
Outstanding June 30, 2010	57,222	\$ 1.25	8.33	\$ -

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	40,000	.71	9.88	-
Options exercised	-	-	-	-
Options forfeited	-	-	-	-
Outstanding June 30, 2010	2,273,432	\$ 2.41	5.31	-
Exercisable June 30, 2010	2,152,598	\$ 2.39	5.61	-

The weighted-average grant-date fair value of options granted during the six months ended June 30, 2009 and 2010 was approximately \$38,000 and \$18,700, 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	(18,750)	2.81	3.00	-
Options forfeited	-	-	-	-
Outstanding June 30, 2010	120,834	\$ 2.66	3.88	\$ -

The impact on the Company's results of operations of recording equity based compensation for the six months ended June 30, 2009 and 2010 was to increase general and administrative expenses by approximately \$141,000 and \$435,000 respectively. The impact on basic and fully diluted earnings per share for the six months ended June 30, 2009 was \$-0- and for June 30, 2010 was to increase loss per share by \$0.03.

As of June 30, 2009 and 2010, respectively, there was \$28,000 and \$19,000 of unrecognized equity based compensation cost related to options granted under the Equity Incentive Plan.

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	June 30, 2010
Inventory work in process	\$ -	\$ 934
Finished goods, net of reserves of \$282,000 at December 31, 2009 and \$250,000 at June 30, 2010.	-	-
	\$ -	\$ 934

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-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 June 30, 2010 value of \$934,000.

Other assets consist of the following:

	(in thousands)	
	December 31, 2009	June 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)	-	6
	\$ 886	\$ 35

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 June 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:

Name Of Security	June 30, 2010 (in thousands)		Unrealized Gain (Loss)	Maturity Date
	Cost	Market Value		
Marketable Securities with maturity periods less than one year:				
Protective Life	523	502	(21)	8/16/2010
GE Money Bank	250	250	-	10/15/2010
Discover Bank	500	500	-	10/29/2010
Toyota Motor Credit	1,020	1.017	(3)	12/15/2010

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GE Money Bank	250	249	(1)	1/14/2011
World Financial Capital	300	299	(1)	1/28/2011
Bank of America	500	499	(1)	4/21/2011
Merrick Bank	250	250	-	4/21/2011
American Express Bank FSB	250	250	-	9/30/2010
Beal Bank	250	250	-	12/8/2010
Safra National Bank	250	250	-	1/1/2011
Goldman Sachs	1,062	1,026	(36)	1/15/2011
Discover Bank	250	249	(1)	6/23/2011
PIMCO	22,200	22,531	331	NA
Cisco Systems	786	771	(15)	2/22/2011
IBM Corp.	784	772	(12)	3/22/2011
Oracle Corp.	785	768	(17)	1/15/2011

Total Marketable Securities with
maturity periods less than one
year:

\$ 30,210 \$ 30,433 \$ 223

Marketable Securities with maturity periods greater than one year:

PlainsCapital Bank	250	249	(1)	10/31/2011
Citibank N.A.	250	250	-	4/30/2012
Wright Express Financial Services	250	250	-	4/26/2012
Bank of Northern Miami	250	250	-	7/30/2012
Park Sterling Bank	250	250	-	10/16/2012
Columbus Bank & Trust Co.	250	251	1	10/22/2012
World's Foremost Bank	100	103	3	1/28/2013
Medallion Bank	242	244	2	4/30/2013
Wells Fargo	1,081	1,052	(29)	8/1/2011
Bank of America	1,066	1,042	(24)	8/15/2011
Wachovia Bank	274	271	(3)	9/28/2011
Bank One Corp.	1,070	1,062	(8)	11/15/2011
Morgan Stanley	1,077	1,045	(32)	1/9/2012
Goldman Sachs	1,035	1,018	(17)	8/1/2012
Merrill Lynch	1,088	1,059	(29)	8/15/2012
Morgan Stanley	1,071	1,053	(18)	8/31/2012
Wells Fargo	1,083	1,066	(17)	9/1/2012
GE Capital	104	102	(2)	5/29/2012
Sallie Mae Bank	104	102	(2)	5/29/2012
Israel Disc Bank	250	249	(1)	9/11/2012
Allstate	115	112	(3)	9/16/2012
World's Foremost Bank	104	103	(1)	3/4/2013
BWW Bank North America	251	252	1	6/4/2013
Goldman Sachs	250	251	1	6/17/2013
General Dynamics	763	758	(5)	7/15/2011
Merck & Co.	817	796	(21)	11/15/2011
Shell International	755	754	(1)	9/22/2011
3M Company	808	789	(19)	11/1/2011
Total Marketable Securities with maturity periods greater than one year:				
	\$ 15,008	\$ 14,783	\$ (225)	
Total Marketable Securities				
	\$ 45,218	\$ 45,216	(2)	

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

Note 6: Accrued Expenses

Accrued expenses consists of the following:

	(in thousands)	
	December 31, 2009	June 30, 2010
Compensation	\$ 716	\$ 205
Professional fees	421	154
Other expenses	71	37
Other liability	113	113
	\$ 1,321	\$ 509

Note 7: Capital Lease

The Company has acquired equipment under a capital lease as follows:

	(in thousands) Asset Balance at June 30, 2010
Leased Equipment included with property and equipment	\$ 70
Less: accumulated depreciation	(4)
	\$ 66

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

	2010 \$	18
	2011	35
	2012	4
Total lease payments remaining		57
Less: amount representing interest		(1)
Present value of remaining minimum lease payments		56
Less: current obligations under lease obligations		(35)
Long-term capital lease obligations	\$	21

Lease payments made under this capital lease are \$3,000 per month for 24 months starting February 2010. Imputed rate is 2% per annum. A security deposit of \$6,000 was paid and is 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 \$405,000 for the six months ended June 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 June 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 over varying periods.

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 June 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 Pricing Model to fair value the stock options which had been issued during the six months ended June 30, 2010 and accordingly recorded approximately \$435,000 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 one officer which vest over 18 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. Dr. William A. Carter, and his spouse, Dr. Katalin Kovari, have yet to exercise their rights to receive their 820,826 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 June 30, 2010 the Company issued 2,571,081 securities to Directors and consultants consisting of an aggregate of 2,101,642 options and 469,439 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 June 30, 2010, we sold 520,000 shares through the ATM equity program that resulted in net cash proceeds of \$292,785 and commissions paid to Maxim of \$12,199. The Shares sold through the ATM equity program had an 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, securities, other assets, accounts payable and accrued expenses approximate their carrying values due to the short-term maturities of these items. The Company also has certain warrants with cash settlement or "Put" rights in the unlikely occurrence of a Fundamental Transaction (the "Warrants"). For a discussion about how the Company values these Warrants, please see Note 11: Restatement, below.

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 GAAP, and expands disclosures about fair value measurements. The guidance does not impose any new requirements around which assets and liabilities are to be measured at fair value, and instead applies to asset and liability balances required or permitted to be measured at fair value under existing accounting pronouncements. The Company measures its warrant liability at fair value. As of June 30, 2010, except for the Warrants, 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 June 30, 2010, the Company has classified the Warrants (that contain embedded put and call features) as Level 3. Management evaluates a variety of inputs and then estimates fair value based on those inputs. As discussed below in Note 11: Restatement, the Company utilized the Monte Carlo Simulation approach in valuing these Warrants.

The table below presents the balance s of assets and liabilities measured at fair value on a recurring basis by level within the hierarchy as of June 30, 2010 (in thousands):

	Total	Level 1	Level 2	Level 3
Assets:				
Marketable Securities	\$ 45,216	\$ 45,216	\$ -	\$ -
Liabilities:				
Warrants	2,760	-	-	2,760
Total	\$ 47,976	\$ 45,216	\$ -	\$ 2,760

For detailed information regarding the change to the fair value of assets recorded in Level 1 (See Note 5: Marketable Securities).

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

	Fair Value of Redeemable Warrants (in thousands)	
	June 30, 2009	June 30, 2010
Balance at beginning of period	\$ -	\$ 3,684
Value at issuance	17,359	-
Less: value of warrants exercised in May and June 2009	(3,742)	-
Fair value adjustment at June 30	7,186	(924)
Balance at June 30	\$ 20,803	\$ 2,760

Note 11: Restatement

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

Initially, the Company determined that these Warrants created a related Liability in accordance with ASC 480-10-55-29 & 30 due to the fact that the Warrants could be settled for cash as discussed above. In their estimation of the value of this Liability, the Company interpreted and applied the concept of “Fair Value” from ASC 820 (formally SFAS 157). After reviewing current accounting literature and the findings and opinion of an independent appraiser in determining proper accounting treatment, the Company took into account the extreme unlikelihood of the occurrence of a Fundamental Transaction triggering a right to cash settlement as a probability factor in applying a Black-Scholes-Merton valuation of the Warrants. As a result, Management deemed the fair value of the Warrants to be immaterial and, therefore, stated the Warrants’ related Liability from May 31, 2009 through December 31, 2009 at zero.

On September 15, 2010, the Company received a comment letter from the Securities and Exchange Commission (“SEC”) concerning its review of the Company’s annual report on Form 10-K, as amended, for the year ended December 31, 2009. During the process of resolving the SEC’s comments, the SEC Staff alerted Management that they did not agree with their method of computing the fair value of the Warrants as discussed above.

As a result, on December 22, 2010, after discussion with McGladrey & Pullen, LLP, the Company's independent registered public accounting firm, the Company's Audit Committee determined that the previously issued financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2009 and in its Forms 10-Q for the periods ended March 31, 2010, June 30, 2010 and September 30, 2010 and in its Forms 10-Q for the periods ended June 30, 2009 and September 30, 2009, should not be relied upon. Management has restated the financial statements for the year ended December 31, 2009 contained in the Company's Form 10-K and in its Forms 10-Q for the periods ended March 31, 2010, June 30, 2010 and September 30, 2010 (including the comparable periods ended June 30, 2009 and September 30, 2009) to reflect the revised value of this Liability.

The restatements reflect the recalculation of the fair value of the Warrants using a Monte Carlo Simulation approach, applying critical assumptions provided by Management reflecting conditions at the valuation date. The Monte Carlo Simulation approach incorporates the incremental value of the Put rights available to the Warrant Holders. The fair value of Warrants ranged from \$0.37 to \$0.38 at December 31, 2009, ranged from \$2.11 to \$2.14 at June 30, 2009 and was consistent at \$0.28 for June 30, 2010.

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

Fair value at June 30, 2009, was estimated using the following assumptions:

Underlying price per share	\$2.54
Exercise price per share	\$1.31 – \$1.65
Risk-free interest rate	2.50% - 2.67%
Expected holding period	4.88 - 5.38 years
Expected volatility	100.82% – 103.91%
Expected dividend yield	None

Fair value at June 30, 2010, was estimated using the following assumptions:

Underlying price per share	\$0.47
Exercise price per share	\$1.31 – \$1.65
Risk-free interest rate	1.36% - 1.55%
Expected holding period	3.89 – 4.38 years
Expected volatility	112.16% – 115.41%
Expected dividend yield	None

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

- (i) Risk-Free Interest Rate. The risk-free interest rates for the Warrants are based on U.S Treasury constant maturities for periods commensurate with the remaining expected holding periods of the warrants.
- (ii) Expected Holding Period. The expected holding period represents the period of time that the Warrants are expected to be outstanding until they are exercised. The Company utilizes the remaining contractual term of the Warrants at each valuation date as the expected holding period.

(iii) **Expected Volatility.** Expected stock volatility is based on daily observations of the Company's historical stock values for a period commensurate with the remaining expected holding period on the last day of the period for which the computation is made.

(iv) **Expected Dividend Yield.** Expected dividend yield is based on the Company's anticipated dividend payments over the remaining expected holding period. As the Company has never issued dividends, the expected dividend yield is \$-0- and this assumption will be continued in future calculations unless the Company changes its dividend policy.

(v) **Expected Probability of a Fundamental Transaction.** The possibility of the occurrence of a Fundamental Transaction triggering a Put right is extremely remote. As discussed above, a Put right would only arise if a Fundamental Transaction 1) is an all cash transaction; (2) results in the Company going private; or (3) is a transaction involving a person or entity not traded on a national securities exchange. The Company believes such an occurrence is highly unlikely because:

- a. The Company only has one product that is FDA approved;
- b. The Company will have to perform additional clinical trials for FDA approval of its flagship product;
- c. Industry and market conditions continue to include a global market recession, adding risk to any transaction;
- d. Available capital for a potential buyer in a cash transaction continues to be limited;
- e. The nature of a life sciences company is heavily dependent on future funding and high fixed costs, including Research & Development;
- f. According to Forbes.com, of approximately 17,000 public companies, fewer than 30 went private in 2008 and less than 100 were completed in 2007, representing 0.18% and 0.6%, respectively. This would be further reduced based on the nature of a life sciences company and the potential lack of revenues, cash flows and the Company's funding needs; and
- g. The Company's Rights Agreement makes it less attractive to a potential buyer.

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

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

The Monte Carlo Simulation incorporated a 5.0% probability of a Fundamental Transaction.

(vi) **Expected Timing of Announcement of a Fundamental Transaction.** As the Company has no specific expectation of a Fundamental Transaction, for reasons elucidated above, the Company utilized a discrete uniform probability distribution over the Expected Holding Period to model in the potential announcement of a Fundamental Transaction occurring during the Expected Holding Period.

(vii) **Expected 100 Day Volatility at Announcement of a Fundamental Transaction.** An estimate of future volatility is necessary as there is no mechanism for directly measuring future stock price movements. Daily observations of the Company's historical stock values for the 100 days immediately prior to the Warrants' grant dates, with a floor of 100%, were utilized as a proxy for the future volatility.

(viii) Expected Risk-Free Interest Rate at Announcement of a Fundamental Transaction. The Company utilized a risk-free interest rate corresponding to the forward U.S. Treasury rate for the period equal to the time between the date forecast for the public announcement of a Fundamental Transaction and the Warrant expiration date for each simulation.

(ix) Expected Time Between Announcement and Consummation of a Fundamental Transaction. The expected time between the announcement and the consummation of a Fundamental Transaction is based on the Company's experience with the due diligence process performed by acquirers, and is estimated to be six months. The Monte Carlo Simulation approach incorporates this additional period to reflect the delay Warrant Holders would experience in receiving the proceeds of the Put.

As a result, the Company restated its financial statements included in its amended and restated annual report on Form 10K/A-2 and the Company has restating its financial statements as and for the periods ended June 30, 2010 and 2009 herein as follows:

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Balance Sheet
June 30,2010

(in thousands)

	June 30,2010 As Previously Reported	Adjustments	June 30, 2010 As restated
ASSETS			
Current Assets:			
Cash and cash equivalents	\$ 5,331		\$ 5,331
Marketable securities maturing in less than one year	30,433		30,433
Inventories	934		934
Prepaid expenses and other current assets	120		120
Total current assets	36,818		36,818
Property and equipment, net	4,675		4,675
Marketable securities maturing in one year or greater	14,783		14,783
Patent and trademark rights, net	836		836
Investment	35		35
Construction in progress	405		405
Other assets	35		35
Total assets	\$ 57,587		\$ 57,587
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts Payable	\$ 1,335		\$ 1,335
Accrued expenses	509		509
Current portion of capital lease	35		35
Total current liabilities	1,879		1,879
Long-term liabilities			
Long-term portion of capital lease	21		21
Redeemable warrants	-	3,684	2,760
		1,336	
		(2,260)	
Total liabilities	1,900	2,760	4,660
Commitment and contingencies			
Stockholders' equity			
Preferred stock	-		-
Common stock	135		135

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Additional paid-in capital	274,121	(7,717)	264,179
		(2,225)	
Accumulated other comprehensive loss	(2)		(2)
Accumulated deficit	(218,567)	4,555	(211,385)
		142	
		(1,061)	
		137	
		3,409	
Total stockholders' equity	\$ 55,687	(2,760)	\$ 52,927
Total liabilities and stockholders' equity	\$ 57,587		\$ 57,587

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statement of Operations

Three months ended June 30, 2009

(in thousands, except per share data)

	June 30, 2009 As Previously Reported	Adjustments	June 30, 2009 As restated
Revenues:			
Sales of product, net	\$		\$
Clinical treatment programs	17		17
Total revenues	17		17
Costs and expenses:			
Production/cost of goods sold	152		152
Research and development	1,982		1,982
General and administrative	1,862		1,862
Total costs and expenses	3,996		3,996
Operating loss	(3,979)		(3,979)
Interest and other income	109		109
Redeemable warrants valuation adjustment		(10,861)	(10,861)
Net loss	\$ (3,870)	(10,861)	\$ (14,731)
Basic and diluted loss per share	\$ (.04)	\$ (.11)	\$ (.15)
Weighted average shares outstanding Basic and Diluted	100,077,267		100,077,267

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statement of Operations
Three months ended June 30,2010

(in thousands, except per share data)

	June 30,2010 As Previously Reported	Adjustments	June 30, 2010 As restated
Revenues:			
Sales of product, net	\$		\$
Clinical treatment programs	41		41
Total revenues	41		41
Costs and expenses:			
Production/cost of goods sold	328		328
Research and development	1,694		1,694
General and administrative	1,788		1,788
Total costs and expenses	3,810		3,810
Operating loss	(3,769)		(3,769)
Interest and other income	93		93
Redeemable warrants valuation adjustment		2,260	2,260
Net loss	\$ (3,676)	2,260	\$ (1,416)
Basic and diluted loss per share	\$ (.03)	\$.02	\$ (.01)
Weighted average shares outstanding Basic and Diluted	133,107,607		133,107,607

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statement of Operations
Six months ended June 30, 2009

(in thousands, except per share data)

	June 30, 2009 As Previously Reported	Adjustments	June 30, 2009 As restated
Revenues:			
Sales of product, net	\$		\$
Clinical treatment programs	46		46
Total revenues	46		46
Costs and expenses:			
Production/cost of goods sold	273		273
Research and development	3,577		3,577
General and administrative	3,028		3,028
Total costs and expenses	6,878		6,878
Operating loss	(6,832)		(6,832)
Financing costs	(241)		(241)
Interest and other income	116		116
Redeemable warrants valuation adjustment		(10,861)	(10,861)
Net loss	\$ (6,957)	(10,861)	\$ (17,818)
Basic and diluted loss per share	\$ (.08)	\$ (.12)	\$ (.20)
Weighted average shares outstanding Basic and Diluted	89,110,201		89,110,201

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statement of Operations
Six months ended June 30, 2010

(in thousands, except per share data)

	June 30, 2010 As Previously Reported	Adjustments	June 30, 2010 As restated
Revenues:			
Sales of product, net	\$		\$
Clinical treatment programs	73		73
Total revenues	73		73
Costs and expenses:			
Production/cost of goods sold	468		468
Research and development	3,690		3,690
General and administrative	3,757		3,757
Total costs and expenses	7,915		7,915
Operating loss	(7,842)		(7,842)
Interest and other income	122		122
Redeemable warrants valuation adjustment		(1,336)	924
		2,260	
Net loss	\$ (7,720)	924	\$ (6,796)
Basic and diluted loss per share	\$ (.06)	\$.01	\$ (.05)
Weighted average shares outstanding Basic and Diluted	132,963,622		132,963,622

Note to above tables: The estimated fair value of the Liability related to the Warrants was revalued at June 30, 2009 and June 30, 2010. Due to the volatile trading value of our stock during the relevant periods, at June 30, 2009, the value of the Liability related to the remaining outstanding Warrants was \$20,803,000, resulting in a related non-cash gain of \$10,861,000, and, at June 30, 2010, the value of the Liability related to the remaining outstanding Warrants was \$2,760,000, resulting in a related non-cash gain of \$924,000.

None of the above issues from this non-cash adjustment affected the Company's revenues, operating expenses, liquidity or cash flows from past, nor should they affect future operations, except in the highly unlikely event that a Put right is triggered under the Warrants.

NOTE 12: Cash And Cash Equivalents

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

NOTE 13: Recent Accounting Pronouncements

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 2010-20 has no material effect on the Company's financial statements for the six months ended June 30, 2010.

NOTE 14: Subsequent Events

The Company evaluated subsequent events through the date on which the financial statements were issued, and determined that three amended employment agreements with Executive Officers and an amended adviser's agreement with The Sage Group, Inc. ("SAGE") constituted subsequent events that required disclosure without adjustment to the financial statements for the six months ended June 30, 2010. In summary:

- The June 11, 2010 employment agreements with William A. Carter, Chairman of the Board and Chief Executive Officer, and Thomas K. Equels, Vice Chairman of the Board, Secretary and General Counsel, were amended to make certain terminology revisions that did not impact or alter the terms of these executives' compensation. These amendments were reviewed and approved by the Compensation Committee on July 14, 2010 with unanimous recommendation to the Board for approval. On July 15, 2010, the Board of Directors unanimously approved the amendments. As a result, these amended employment agreements were signed on July 15, 2010 with an effective date of June 11, 2010.
- The existing employment agreement with Robert Dickey IV, Senior Vice President, was set to expire on September 1, 2010. Upon discussion and review on July 14, 2010, the Compensation Committee unanimously recommendation to the Board that an agreement be authorized for renewal on a month-to-month basis at the same general terms and level of compensation as established in the employment agreement of February 1, 2010. On July 15, 2010, the Board of Directors unanimously authorized the renewal of this extension within the terms recommended by the Compensation Committee. As a result, this agreement renewal was signed on August 3, 2010 with an effective date of September 1, 2010.
- The adviser's agreement with SAGE was scheduled to expire on November 13, 2010. Upon discussion and review on July 15, 2010, the Company entered into an amended adviser's agreement for an initial term of 18 months.

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 "forward-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.

We have formed an independent Data Monitoring Committee (“DMC”) which will oversee our various drug development programs. The principal role of an independent DMC is to perform interim analyses of the clinical outcome data and to insure the safety of patients in clinical trials. The DMC also plays a critical role in studies that may use “Adaptive Design” wherein trial design modifications can be made after patient enrollment has started. Adaptive Design should enable us to respond to data collected during a trial to increase the likelihood of generating statistically and clinically significant results. As of August 3, 2010, there has yet to be any clinical outcome data generated for the DMC to review.

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 \$405,000 for the six months ended June 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 same primary endpoints as our earlier studies but with an enlarged number of subjects to potentially achieve a more representative statistical model. 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 regimens 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, 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 the Whittemore Peterson Institute. We believe that these studies may provide a new perspective on the design of an additional confirmatory Phase III study in this disorder. The samples are being analyzed for the presence of XMRV (xenotropic murine leukemia related virus). Initial results on the XMRV data from the completed Phase III trial are planned for presentation at the 1st International Workshop on XMRV to be 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 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 clinical 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 hope that the clinical testing phase of Ampligen®, used in conjunction with a H5N1 (Avian Flu) vaccine, in Japan will begin in late 2010. However, the timing of clinical testing is dependent upon the successful conclusion of 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. We have proposed extending Biken’s Material Transfer Agreement, contemplated for expiration on September 1, 2010, for three additional months to determine if the parties can agree on various next steps including without limitation the execution of a clinical trial combining Ampligen® with an intranasally delivered influenza vaccine.

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 are undertaking a major capital improvement program to upgrade our manufacturing capability for Alferon N Injection® at our New Brunswick facility that will continue throughout 2010. 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 Max Neeman International, one of the leading and largest clinical research organizations (“CROs”) 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. It is our intension to begin to enroll subjects for the upcoming monsoon season of mid to late 2010.

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 HIV and other emerging viruses (e.g., SARS, Ebola, bird and swine flu). 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 2, 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 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 are expected to be compiled, analyzed and submitted to the FDA by the end of October 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 \$68,364 for the six months ended June 30, 2010.

Restatement

The Management's Discussion and Analysis of Financial Condition and Results of Operations gives effect to the restatement as discussed in Note 11: Restatement of the Notes to Consolidated Condensed Financial Statements.

New Accounting Pronouncements

Refer to "Note 13: Recent Accounting Pronouncements" under Notes To Unaudited Condensed Consolidated Financial Statements.

Disclosure About Off-Balance Sheet Arrangements

None.

Critical Accounting Policies

There have been no material changes in our critical accounting policies and estimates from those disclosed in Part I; Item 2: "Management's Discussion and Analysis of Financial Condition and Results of Operations; Critical Accounting Policies" contained in our amended and restated Annual Report on Form 10-K/A-2 for the year ended December 31, 2009.

RESULTS OF OPERATIONS

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

Net Loss-restated

Our restated net loss was approximately \$1,416,000 for the three months ended June 30, 2010, which was a decrease of \$13,315,000 or 90% when compared to the same period in 2009. This decrease in loss for these three months was primarily due to the following changes in expense elements:

- 1) a decrease in Research and Development costs of approximately \$288,000 or 15%;
- 2) a decrease in General and Administrative expenses of approximately \$74,000 or 4%; offset by
- 3) an increase in Production/Cost of Goods Sold of approximately \$176,000 or 116%;
- 4) an increase in interest income of \$16,000 from invested funds; and
- 5) restatement adjustments of \$(10,861,000) and \$2,260,000 in 2009 and 2010, respectively. See Note 11.

Restated net loss per share was \$0.01 for the current period versus \$0.15 for the same period in 2009.

Revenues

Revenues from our Ampligen® Cost Recovery Program increased \$24,000 or 141% for the second quarter in 2010 as compared to the same time period of 2009 due to a 50% 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 \$328,000 and \$152,000, respectively, for the three months ended June 30, 2010 and 2009. This is an increase of \$176,000 or 116% primarily due to the cost to maintain the Alferon N Injection® and Ampligen® inventory including storage, stability testing, transport and reporting costs.

Research and Development Costs

Overall Research and Development (“R&D”) costs for the three months ended June 30, 2010 were approximately \$1,694,000 as compared to \$1,982,000 for the same period a year ago reflecting a decrease of \$288,000 or 15%. The primary factor for the decrease in expenses was related the Ampligen® NDA and our efforts to respond to the FDA’s Form 483 issues in 2009. However for the three months ended June 30, 2010, our R&D staff continue their efforts in preparation of a response to the CRL from the FDA.

General and Administrative Expenses

General and Administrative (“G&A”) expenses for the three months ended June 30, 2010 and 2009 were approximately \$1,788,000 and \$1,862,000, respectively, reflecting a decrease of \$74,000 or 4%. The lower G&A expenses in 2010 consisted primarily of 1) a reduction of \$383,000 of 2009’s fees related to financing and stock market activities that were not incurred in 2010; 2) an increase of \$113,000 in stock compensation and various compensation related items in 2010; and 3) an increase in 2010 of \$209,000 in legal fees due to class action suits and other legal proceedings.

Interest and Other Income

Interest and other income for the three months ended June 30, 2010 and 2009 was approximately \$93,000 and \$109,000, respectively, representing a decrease of \$16,000. The primary cause for the decrease of interest income in 2010 was the purchase of non-cash equivalent investments with maturity dates of greater than 90 days. The interest income from these securities will be recognized at the investments’ maturity dates.

Redeemable Warrants

Restatement for non-cash valuation adjustments of \$(10,861,000) and \$2,260,000 were made in 2009 and 2010, respectively. See Note 11.

Six months ended June 30, 2010 versus six months ended June 30, 2009

Net Loss-restated

Our restated net loss was approximately \$6,796,000 for the six months ended June 30, 2010, which was a decrease of \$11,022,000 or 62% when compared to the same period in 2009. This decrease in loss for these six months was primarily due to the following expense elements:

- 1) an increase in Production/Cost of Goods Sold of approximately \$195,000 or 71%; and
- 2) an increase in Research and Development costs of approximately \$113,000 or 3%;
- 3) an increase in General and Administrative expenses of approximately \$729,000 or 24%; offset by
- 4) a decrease in finance costs of \$241,000, or 100% from a Standby Finance Agreement executed in February 2009.
- 5) restatement adjustments of \$(10,861,000) and \$924,000 in 2009 and 2010, respectively. See Note 11.

Restated net loss per share was \$0.05 for the current period versus \$0.20 for the same period in 2009.

Revenues

Revenues for the six months ended June 30, 2010 were \$73,000 compared to revenues of \$46,000 for the same period in 2009. There were no revenues related to the sale of Alferon N Injection® for the six month period ended 2010 or 2009. Revenues from our Ampligen® Cost Recovery Program for the six months ended June 30, 2010 were \$73,000 compared to revenues of \$46,000 for the same period in 2009, an increase of \$27,000 or 59% due to a 42% increase in the number of patients participating in the program.

Production/Cost of Goods Sold

Production/Cost of Goods Sold was approximately \$468,000 and \$273,000, respectively, for the six months ended June 30, 2010 and 2009. This is an increase of \$195,000 or 71%. These expenses basically represent the cost to maintain the Alferon N Injection® and Ampligen® inventory including storage, stability testing, transport and reporting costs.

Research and Development Costs

Overall Research and Development (“R&D”) costs for the six months ended June 30, 2010 were approximately \$3,690,000 as compared to \$3,577,000 for the same period a year ago reflecting an increase of \$113,000 or 3%. The primary cause for the increase in expenses was related to our R & D staff’s continued efforts in preparation of a response to the CRL from the FDA, which described specific additional recommendations related to the Ampligen® NDA, along with R&D costs associated with preparations in our attempt to launch Alferon N Injection® and Alferon® clinical tests.

General and Administrative Expenses

General and Administrative (“G&A”) expenses for the six months ended June 30, 2010 and 2009 were approximately \$3,757,000 and \$3,028,000, respectively, reflecting an increase of \$729,000 or 24%. The primary cause of this increase in expense was an additional \$971,000 in legal fees associated with our defense in three proceedings (See “Part II – OTHER INFORMATION, ITEM 1. Legal Proceedings”) that were offset by a decrease in fees of \$213,000 paid to consultants to acquire equity financing along with a minor decrease of \$29,000 in other expenses.

Interest and Other Income

Interest and other income for the six months ended June 30, 2010 and 2009 was \$122,000 and \$116,000, respectively, representing a increase of \$6,000 or 5%. The primary cause for the increase of interest income in 2010 was increased funds available for secure investments.

Interest Expense and Financing Costs

We had no interest expense for the six months ended June 30, 2010 or 2009. 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 six months ended June 30, 2009, for which no agreement or related expenses of this type existed during the first six 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.

Redeemable Warrants

Restatement for non-cash valuation adjustments of \$(10,861,000) and \$924,000 were made in 2009 and 2010, respectively. See Note 11.

Liquidity and Capital Resources

Cash used in operating activities for the six months ended June 30, 2010 was \$7,388,000, compared to \$4,129,000 for the same period in 2009, an increase of \$3,259,000 or 79%. 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 June 30, 2010, we had approximately \$50,547,000 in Cash, Cash Equivalents and Marketable Securities, or a decrease of approximately \$7,525,000 from December 31, 2009.

We have been using the proceeds from 2009’s 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 June 30, 2010, we sold 520,000 shares through this program and received net cash proceeds of \$292,785 and paid commissions to Maxim of \$12,199.

Because of our long-term capital requirements, we may seek to access the public equity market through the above 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 \$50,547,000 in Cash, Cash Equivalents and Marketable Securities at June 30, 2010. In the past, we had invested the excess cash in 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 June 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 June 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.

In December, 2004, we filed a multi-count complaint in U.S. Federal Court (Southern District of Florida) for fraud and injunctive relief against Bioclones, Dr. Donniger, Bart Goemare, Johannesburg Consolidated Investments (“JCI”), Brett Kebble and H.C. Buidentag. However, a Motion to dismiss the Complaint, in part on grounds that the matter must be arbitrated in South Africa, was granted by the Court. We appealed this decision to the 11th Circuit Court of Appeals. In July 2008, while the appeal was pending, we settled our disputes with both Bioclones and Cyril Donniger and dismissed them from the lawsuit. In 2005 Buitendag and Kebble were indicted for using JCI to perpetrate the largest financial fraud in South African history. The Appeals Court allowed the fraud action to go forward. In 2008, we filed a second Amended Complaint for fraud against JCI, Goemare, the Estate of Kebble and Buidentag, the only remaining defendants. In 2009, we settled our disputes with Goemare and dismissed him from the lawsuit. On April 7, 2010, the Court denied the remaining Defendants’ (JCI, estate of Kebble, and Buidentag) motion to dismiss the Complaint. Following that ruling, the Defendants’ counsel withdrew from the case. The Court gave the Defendants until June 17, 2010 to retain new counsel and until June 28, 2010 to answer our Complaint. The Defendants failed to meet either deadline, and have not filed anything with the Court since their former counsel withdrew from their representation. On June 30, 2010, the Court ordered entry of default against the Defendants, and on July 23, 2010, we filed our Motion for entry of final default judgment against the Defendants. The Court held an evidentiary hearing on our Motion on August 4, 2010 and we are awaiting the Court’s ruling. We continue to vigorously prosecute this case and the law firm of Colson Hicks Eidson is serving as our co-counsel.

(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 tortious 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 local 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. Briefing is expected to be completed in August 2010, and then the motions will be submitted to the Court for 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 proposes 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 with disposition of this Motion pending before the Court. The law firm of Black and Gerngross is serving as our local counsel. 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 begin the Discovery process.

Also 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 intend to vigorously defend the Securities Class Action Lawsuit and the Shareholder Derivative Lawsuits. 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)

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.

We have not recorded any loss contingencies as a result of the above matters for the year ended December 31, 2009 or six months ended June 30, 2010.

ITEM 1A. Risk Factors.

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

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 regimens 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.

Alferon® LDO is undergoing pre-clinical testing for possible prophylaxis against influenza. While the studies to date have been encouraging, preliminary testing in the laboratory and in animal models is not necessarily predictive of successful results in clinical testing or human treatment. No assurance can be given that similar results will be observed in clinical trials. Use of Alferon® as a possible treatment of any flu requires prior regulatory approval. In October 2009, we submitted a protocol to the FDA proposing to conduct a Phase 2, 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, they have 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. The three months of stability data are expected to be compiled, analyzed and submitted to the FDA by the end of October 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 June 30, 2010, our accumulated deficit was approximately \$(211,385,000). 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 June 30, 2010, we had approximately \$50,547,000 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 are undertaking a major capital improvement program, that will continue throughout 2010, 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.

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

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

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

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

Ampligen®. We believe that Ampligen® has been generally well tolerated with a low incidence of clinical toxicity, particularly given the severely debilitating or life threatening diseases that have been treated. A mild flushing reaction has been observed in approximately 15-20% of patients treated in our various studies. This reaction is occasionally accompanied by a rapid heart beat, a tightness of the chest, urticaria (swelling of the skin), anxiety, shortness of breath, subjective reports of "feeling hot", sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by reducing the rate of infusion. ¶16