HEMISPHERX BIOPHARMA INC
Form 10-Q
May 07, 2010

UNITED STATES

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

For the Quarterly Period Ended March 31, 2010

Commission File Number: 1-13441

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

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

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

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

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

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

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

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

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

132,876,924 shares of common stock were issued and outstanding as of May 05, 2010.

PART I - FINANCIAL INFORMATION

ITEM 1: Financial Statements

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

	December 31, 2009	March 31, 2010 (Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents (Note 11)	$ 58,072	$ 50,723
Inventories (Note 4)	-	-
Marketable securities maturing in less than one year (Note 5)	-	3,053
Prepaid expenses and other current assets	332	216
Total current assets	58,404	53,992
Property and equipment, net	4,704	4,738
Patent and trademark rights, net	830	838
Investment	35	35
Construction in progress (Note 8)	135	389
Other assets (Note 4)	886	892
Total assets	$ 64,994	$ 60,884
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,294	$ 1,808
Accrued expenses (Note 6)	1,321	615
Current portion of capital lease (Note 7)	-	35
Total current liabilities	2,615	2,458
Long-term liabilities		
Long-term portion of capital lease (Note 7)	-	30
Commitments and contingencies		
Stockholders' equity (Note 9):		
Preferred stock, par value $0.01 per share, authorized 5,000,000; issued and outstanding; none	-	-
Common stock, par value $0.001 per share, authorized 200,000,000 shares; issued and outstanding 132,787,447 and 132,860,602, respectively	133	133
Additional paid-in capital	273,093	273,174
Accumulated other comprehensive loss	-	(20)
Accumulated deficit	(210,847)	(214,891)
Total stockholders' equity	62,379	58,396

Total liabilities and stockholders' equity	$ 64,994	$ 60,884

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 March 31,	
	2009	2010
Revenues:		
Clinical treatment programs	$ 29	$ 32
Total revenues	29	32
Costs and expenses:		
Production/cost of goods sold	121	140
Research and development	1,595	1,996
General and administrative	1,166	1,969
Total costs and expenses	2,882	4,105
Operating loss	(2,853)	(4,073)
Financing costs	(241)	-
Interest and other income	7	29
Net loss	$ (3,087)	$ (4,044)
Basic and diluted loss per share (Note 2)	$ (.04)	$ (.03)
Weighted average shares outstanding, basic and diluted	79,836,247	132,818,036

See accompanying notes to consolidated financial statements.

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

	Common Stock Shares	Common Stock $.001 Par Value	Additional Paid-In Capital	Accumulated Other Compre-hensive Loss	Accumulated Deficit	Total Stockholders' Equity	Compre-hensive Loss
Balance at December 31, 2009	132,787,447	$ 133	$ 273,093	$ -	$ (210,847)	$ 62,379	$ -
Stock issued for settlement of accounts payable	73,155	-	45	-	-	45	-
Equity based compensation	-	-	36	-	-	36	-
Unrealized loss in investment securities	-	-	-	(20)	-	-	(20)
Net loss	-	-	-	-	(4,044)	(4,044)	(4,044)
Balance at March 31, 2010	132,860,602	$ 133	$ 273,174	$ (20)	$ (214,891)	$ 58,396	$ (4,064)

See accompanying notes to consolidated financial statements.

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
For the Three Months Ended March 31, 2009 and 2010
(in thousands)
(Unaudited)

	2009	2010
Cash flows from operating activities:		
Net loss	$ (3,087)	$ (4,044)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	90	94
Amortization of patent and trademark rights, and royalty interest	119	20
Financing cost related to Standby Financing	241	-
Equity based compensation	18	36
Change in assets and liabilities:		
Prepaid expenses and other current assets	56	116
Accounts payable	547	559
Accrued expenses	592	(706)
Net cash used in operating activities	$ (1,424)	$ (3,925)
Cash flows from investing activities:		
Purchase of property plant and equipment	$ (6)	$ (312)
Additions to patent and trademark rights	(17)	(28)
Capital lease deposit	-	(6)
Purchase of short-term investments	(1,920)	(3,073)
Net cash used in investing activities	$ (1,943)	$ (3,419)

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows (Continued)
For the Three Months Ended March 31, 2009 and 2010
(in thousands)
(Unaudited)

	2009	2010
Cash flows from financing activities:		
Payments on capital lease	$ -	$ (5)
Proceeds from sale of stock, net of issuance costs	869	-
Net cash provided by (used in) financing activities	$ 869	$ (5)
Net decrease in cash and cash equivalents	(2,498)	(7,349)
Cash and cash equivalents at beginning of period	6,119	58,072
Cash and cash equivalents at end of period	$ 3,621	$ 50,723
Supplemental disclosures of non-cash investing and financing cash flow information:		
Issuance of common stock for accounts payable and accrued expenses	$ 360	$ 45
Equipment acquired by capital lease	$ -	$ 70
Unrealized loss on investments	$ -	$ (20)

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 limited or no activity. All significant intercompany balances and transactions have been eliminated in consolidation.

In the opinion of Management, all adjustments necessary for a fair presentation of such consolidated financial statements have been included. Such adjustments consist of normal recurring items. Interim results are not necessarily indicative of results for a full year.

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

These consolidated financial statements should be read in conjunction with our consolidated financial statements included in our annual report on Form 10-K, filed March 12, 2010, and 10-K/A, filed April 30, 2010, for the year ended December 31, 2009.

Note 2: Net Loss Per Share

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Equivalent common shares, consisting of stock options and warrants including the Company's convertible debentures, which amounted to 35,737,069 and 21,236,453 shares, are excluded from the calculation of diluted net loss per share for the three months ended March 31, 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:

	Three Months Ended March 31,	
	2009	2010
Risk-free interest rate	1.76%	1.02%
Expected dividend yield	-	-
Expected lives	5.0 years	5.0 years
Expected volatility	86.78%	109.81%
Weighted average grant date fair value of options and warrants issued	$ 7,800	$ 11,300

7

Stock option activity for 2009 and during the three months ended March 31, 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	-	-	-	-
Options forfeited	-	-	-	-
Outstanding March 31, 2010	6,228,752	$ 2.60	6.70	$ -
Exercisable March 31, 2010	6,190,419	$ 2.60	6.71	$ -

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2009 and 2010 was $-0- and $-0-, 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	-	-	-	-
Options vested	-	-	-	-
Options forfeited	-	-	-	-
Outstanding March 31, 2010	38,333	$ 1.54	7.75	$ -

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	20,000	.89	10.00	-
Options exercised	-	-	-	-
Options forfeited	-	-	-	-
Outstanding March 31, 2010	2,253,432	$ 2.43	5.52	-
Exercisable March 31, 2010	2,123,223	$ 2.39	5.83	-

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2009 and 2010 was approximately $7,800 and $11,300, 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	(9,375)	2.81	4.25	-
Options forfeited	-	-	-	-
Outstanding March 31, 2010	130,209	$ 2.67	3.46	$ -

The impact on the Company’s results of operations of recording equity based compensation for the three months ended March 31, 2009 and 2010 was to increase general and administrative expenses by approximately $18,000 and $36,000 respectively. However, there was no impact on basic and fully diluted earnings per share.

As of March 31, 2009 and 2010, respectively, there was $37,000 and $205,000 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.

9

Inventories consist of the following:

	(in thousands) December 31, 2009	March 31, 2010
Raw materials	$ -	$ -
Finished goods, net of reserves of $282,000 at December 31, 2009 and March 31, 2010.	-	-
	$ -	$ -

The conversion of existing Alferon N Injection® Work-In-Progress inventory is projected to begin in late 2010 or early 2011 to allow for the creation of new Finished Goods available for commercial sales in mid to late 2011. As a result of delaying the conversion of Work-In-Progress, the Company reclassed the $864,000 value of inventory to "Other assets" in 2009.

Other assets consist of the following:

	(in thousands) December 31, 2009	March 31, 2010
Inventory work in process	$ 864	$ 864
Security deposit	15	15
Internet Domain Names	7	7
Security deposit on Capital Lease (see Note 7)	-	6
	$ 886	$ 892

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 March 31, 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:

	March 31, 2010 (in thousands)			
Name Of Security	Cost	Market Value	Unrealized Loss	Maturity Date
Marketable Securities with maturity periods less than one year:				
GE Money Bank	$ 250	$ 250	$ -	4/15/2010
American Express Centurion	500	500	-	4/21/2010
American Express Bank FSB	500	500	-	4/21/2010
Protective Life	523	505	(18)	8/16/2010
GE Money Bank	250	249	(1)	10/15/2010
Discover Bank	500	499	(1)	10/29/2010
GE Money Bank	250	250	-	1/14/2011
World Financial Capital	300	300	-	1/28/2011

Total Marketable Securities with maturity periods less than one year:	$ 3,073	$ 3,053	$ (20)

No investment securities had a maturity of greater than one year nor were pledged to secure public funds at March 31, 2010.

Note 6: Accrued Expenses

Accrued expenses consists of the following:

	(in thousands)	
	December 31, 2009	March 31, 2010
Compensation	$ 716	$ 153
Professional fees	421	186
Other expenses	71	49
Other liability	113	227
	$ 1,321	$ 615

Note 7: Capital Lease

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

	(in thousands)
	Asset Balance at March 31, 2010
Leased Equipment included with property and equipment	$ 70
Less: accumulated depreciation	1
	$ 69

The following is a schedule by year of future minimum lease payments under the capital lease as of March 31, 2010:

2010	$	27
2011		35
2012		4
Total lease payments remaining		66
Less: amount representing interest		1
Present value of remaining minimum lease payments		65
Less: current obligations under lease obligations		35
Long-term capital lease obligations	$	30

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 $389,000 for the three months ended March 31, 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 March 31, 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 March 31, 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 three months ended March 31, 2010 and accordingly recorded approximately $11,300 as equity based compensation for these issuances during this period. The stock options vested immediately upon grant.

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 have been issued shares for the months ended July 31, August 31, September 30, October 30 and November 30, 2009. Individuals defined by Rule 144 in the Securities Act of 1933 as an "affiliate" have yet to receive their distribution of 1,435,295 shares of stock from the 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 March 31, 2010 the Company issued 1,357,475 securities to Directors and consultants consisting of an aggregate of 1,261,642 options and 95,833 shares of common stock issuable upon exercise/conversion of the foregoing securities. The shares issued to consultants had prices ranging from $0.40 to $0.45 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.

Note 10: Fair Value

The Company is required under GAAP to disclose information about the fair value of all the Company's financial instruments, whether or not these instruments are measured at fair value on the Company's consolidated balance sheet.

The Company estimates that the fair values of cash and cash equivalents, marketable securities, other assets, accounts payable and accrued expenses approximate their carrying values due to the short-term maturities of these items. Additionally, the Company has certain warrants with a cash settlement feature (in the event of a change in control to a non-public company) that are carried at fair value. Management estimates the fair value using a model which determines the probability that the cash settlement feature conditions will arise. The carrying amount and estimated fair value of the above warrants was zero at March 31, 2010.

On January 1, 2008, the Company adopted new accounting guidance (codified at FASB ASC 820 and formerly Statement No. 157 Fair Value Measurements) that defines fair value, establishes a framework for measuring fair value in Generally Accepted Accounting Principles, and expands disclosures about fair value measurements. The guidance does not impose any new requirements around which assets and liabilities are to be measured at fair value, and instead applies to asset and liability balances required or permitted to be measured at fair value under existing accounting pronouncements. The Company measures its marketable securities based on quoted prices of active markets and warrant liability, for those warrants with a cash settlement feature, at fair value. As of March 31, 2010, the Company had no derivative assets or liabilities.

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

- Level 1 – Quoted prices are available in active markets for identical assets or liabilities at the reporting date.

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

- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or other valuation techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation. As of December 31, 2009, the Company has classified the warrants with cash settlement features as Level 3. Management evaluates a variety of inputs and then estimates fair value based on those inputs. The primary inputs evaluated by management to determine the likelihood of a change in control to a non-public company (thereby triggering the cash settlement feature) were the Company's FDA approval status including the additional requirements including required cash outflows prior to resubmission to the FDA (observable), the industry and market conditions (unobservable), litigation matters against the Company (observable) and statistics regarding the number of company's going private (observable).

The table below presents the balances of assets and liabilities measured at fair value on a recurring basis by level within the hierarchy as of March 31, 2010:

	Total	Level 1	Level 2	Level 3
Assets:				
Marketable Securities	$ 3,053,000	$ 3,053,000	$ -	$ -
Liabilities:				
Warrants	-	-	-	-
Total	$ 3,053,000	$ 3,053,000	$ -	$ -

For detailed information regarding the change to the fair value of assets recorded in Level 1 (See Note 5: Marketable Securities). There were no changes in the fair value for the Level 3 Warrants during the three months ended March 31, 2010.

NOTE 11: Cash And Cash Equivalents

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

NOTE 12: Recent Accounting Pronouncements

The FASB has published FASB Accounting Standards Update 2010-01 through 2010-12. The adoption of published FASB Accounting Standards Update 2010-01 through 2010-12 has no material effect on the Company's financial statements for the three months ended March 31, 2010.

NOTE 13: Subsequent Events

The Company evaluated subsequent events through the date on which the financial statements were issued, and determined that there are no subsequent events that require adjustment or disclosure to the financial statements for the three months ended March 31, 2010.

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

Special Note Regarding Forward-Looking Statements

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

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

Overview

General

We are a specialty pharmaceutical company based in Philadelphia, Pennsylvania and engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. We were founded in the early 1970s doing contract research for the National Institutes of Health. Since that time, we have established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of natural interferon and nucleic acids to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of certain chronic diseases. We have three domestic subsidiaries BioPro Corp., BioAegean Corp., and Core BioTech Corp., all of which are incorporated in Delaware and are dormant. Our foreign subsidiary is Hemispherx Biopharma Europe N.V./S.A. established in Belgium in 1998, which has no 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, absent of serious conflict of interest, 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.

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®. We outsource certain components of our research and development, manufacturing, marketing and distribution while maintaining control over the entire process through our quality assurance group and our clinical monitoring group.

Ampligen®

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

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 are carefully reviewing 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 regiments were requested. Other items required by the FDA include certain aspects of Non-Clinical safety assessment and Product Quality. In the Non-Clinical area, the FDA recommended among other things that we complete rodent carcinogenicity studies in two species. As part of the NDA submission, we had requested that these studies be waived. The waiver has not been granted as of May 5, 2010.

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 with these studies hoping to provide a new perspective on the design of a confirmatory Phase III study in this disorder. The samples are being analyzed for the presence of XMRV, a novel retrovirus reported to be found in approximately two-thirds of CFS patients.

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 acute seriously ill patients hospitalized with either seasonal influenza or pandemic influenza. The Indian site selection process has begun. It is our goal 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 "Establishment License" for Hemispherx' manufacturing facility. Based on the recent FDA request, we have now established and implemented the "new test" procedures. As a result, we have found that certain Alferon N Injection® lots with extended storage (i.e., approximately eight to nine years) do appear to demonstrate some altered physico-chemical properties. However we have also observed that more recent lots, including those manufactured beginning in the year 2006, are superior with respect to the enhanced scrutiny of these tests and, in our view, could be considered appropriate for clinical trials in the Alferon® LDO sachet format. Upon their review, the FDA has been responsive to these new findings and requested additional stability data on the lots proposed for use in this clinical study utilizing the new test methods. These data are expected to be compiled, analyzed and submitted to the FDA in mid to late 2010. Once the FDA has received and reviewed the additional data, we believe that the full Clinical Hold could be thereafter lifted if the FDA concurs that the data address 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 $39,806 for the three months ended March 31, 2010.

New Accounting Pronouncements

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

18

Disclosure About Off-Balance Sheet Arrangements

None.

Critical Accounting Policies

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

RESULTS OF OPERATIONS

Three months ended March 31, 2010 versus three months ended March 31, 2009

Net Loss

Our net loss was approximately $4,044,000 for the three months ended March 31, 2010, which was an increase of $957,000 or 31% when compared to the same period in 2009. This increase in loss for these three months was primarily due to the following expense elements:

1) Research and Development costs increased approximately $401,000 or 25%;

2) General and Administrative expenses increased approximately $803,000 or 69%;

3) A decrease in Production/Cost of Goods Sold of approximately $19,000 or 16%; and

4) A decrease in finance costs of $241,000 from a Standby Finance Agreement executed in February 2009.

Net loss per share was $0.03 for the current period versus $0.04 for the same period in 2009.

Revenues

Revenues from our Ampligen® cost recovery program increased $3,000 or 10% for the quarter in 2010 with approximately the same 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 $121,000 and $140,000, respectively, for the three months ended March 31, 2010 and 2009. This is a decrease of $19,000 or 16%. These expenses basically represent the cost to maintain the Alferon N Injection® and Ampligen® inventory including storage, stability testing, transport and reporting costs. The costs are essentially flat and the increase reflects price increases and charges for the movement of inventory between locations.

Research and Development Costs

Overall Research and Development ("R&D") costs for the three months ended March 31, 2010 were approximately $1,996,000 as compared to $1,595,000 for the same period a year ago reflecting a increase of $401,000 or 25%. The primary factor for the increase in expenses was related to our preparation of a response to the November 25, 2009 Complete Response Letter ("CRL") from the FDA which described specific additional recommendations related to the Ampligen® NDA along with R&D costs associated with Alferon® LDO for potential clinical programs and preparations towards a launch of Alferon N Injection® Phase II clinical tests.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended March 31, 2010 and 2009 were approximately $1,969,000 and $1,166,000, respectively, reflecting an increase of $803,000 or 69%. The primary cause of this increase in expense was an additional $769,000 in legal fees associated with our defense in three proceedings (See Part II – OTHER INFORMATION, ITEM 1. Legal Proceedings) plus minor increases in other expenses.

Interest and Other Income

Interest and other income for the three months ended March 31, 2010 and 2009 was approximately $29,000 and $7,000, respectively, representing an increase of $22,000. The primary cause for the increase of interest income in 2010 was increased funds available for secure and highly liquid investments.

Liquidity and Capital Resources

Cash used in operating activities for the three months ended March 31, 2010 was $3,925,000, compared to $1,424,000 for the same period in 2009, an increase of $2,501,000 or 176%. This utilization of cash reflects the increased expenses in operations as explained in Management's Discussion and Analysis section above in conjunction with the impact of 2009's effort to conserve cash through implementation of 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 our common stock issued six months after the shares were earned. As of March 31, 2010, we had approximately $50,723,000 in Cash and Cash Equivalents or a decrease of approximately $7,349,000 from December 31, 2009, of which approximately $3,073,000 was used to purchase short-term investments.

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. While as of September 2009, we had effectively exhausted the Fusion Capital Purchase Agreement through the purchase of the maximum number of shares that were registered under the Registration Statement, this agreement was formally terminated through notification on April 7, 2010.

Because of our long-term capital requirements, we may seek to access the public equity market whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. We may also need additional funding earlier than anticipated, and our cash requirements, in general, may vary materially from those now planned,

for reasons including, but not limited to, changes in our research and development programs, clinical trials, competitive and technological advances, the regulatory processes, including the commercializing of Ampligen® products.

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 $50,723,000 in Cash and Cash Equivalents at March 31, 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:

1. to preserve, secure and control capital;
2. to maintain liquidity to meet our operating cash flow requirements; and
3. to 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, in March 2010 we entrusted our investible funds through external investment managers 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 financial instruments that are exposed to concentrations of credit risk consist primarily of Cash and Cash Equivalents. We place our Cash and Cash Equivalents with what Management believes to be high credit quality institutions. At times such investments may be in excess of the Federal Deposit Insurance Corporation insurance limit.

ITEM 4: Controls and Procedures

Our Chairman of the Board (serving as the principal executive officer) and the Chief Financial Officer performed an evaluation of the effectiveness of our disclosure controls and procedures, which have been designed to permit us to effectively identify and timely disclose important information. In designing and evaluating the disclosure controls and procedures, Management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and Management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the controls and procedures were effective as of March 31, 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 March 31, 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 federal court (Southern District of Florida) for fraud and injunctive relief against Bioclones, Dr. Donniger, Bart Goemare, 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 Donninger 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. In February of 2010, the Court began considering the remaining Defendants'(JCI, estate of Kebble, and Buidentag) motion to dismiss the complaint. On April 7, 2010, the Court denied the motion to dismiss and we are awaiting Defendants' Answer. 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 tortuous interference with certain financing transactions in which we were engaged. The case was transferred to the Northern District of Georgia, and we engaged Holland & Knight LLP on November 13, 2009 to serve as 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. Additionally, the Court denied the Motion to dismiss insofar as it pertained to MidSouth's claims based upon promissory estoppel, quantum meruit, unjust enrichment, fraud, and MidSouth's request for attorney's fees and punitive damages. The Court's ruling merely held that MidSouth's pleadings were sufficient to state those claims; it does not constitute a ruling on the merits. We are vigorously defending the remaining counterclaim and prosecuting our own claims against MidSouth. Discovery is in a very preliminary stage. Accordingly, 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 as (b), (c) and (d), 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 three months ended March 31, 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 (“EMEA”) in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen® or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen® will ultimately be demonstrated to be safe or efficacious. While Ampligen® is authorized for use in clinical trials in the U.S. and Europe, we cannot assure you that additional clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials. In addition, although Ampligen® has been authorized by the FDA for treatment use under certain conditions, including provision for cost recovery, there can be no assurance that such authorization will continue in effect.

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

On November 25, 2009, we received a Complete Response Letter ("CRL") from the FDA which described specific additional recommendations related to the Ampligen® NDA. In accordance with its 2008 Complete Response procedure, the FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues. We are carefully reviewing the CRL and will seek a meeting with the FDA to discuss its recommendations. We intend to take the appropriate steps to seek approval and commercialization of Ampligen®. Most notably, the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen® and recommended at least one additional clinical study which shows convincing effect and confirms safety in the target population. The FDA indicated that the additional study should be of sufficient size and sufficient duration (6 months) and include appropriate monitoring to rule out the generation of autoimmune disease. In addition, patients in the study should be on more than one dose regimen, including at least 300 patients on dose regimens intended for marketing. Finally, additional data including a well-controlled QT interval study of the heart's electrical cycle and pharmacokinetic evaluations of dual dosage regiments was requested. Other items required by the FDA include certain aspects of Non-Clinical safety assessment and product Quality. In the Non-Clinical area, the FDA recommended among other things that we complete rodent carcinogenicity studies in two species. As part of the NDA submission, we had requested that these studies be waived, but the waiver has not been granted.

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

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 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, the FDA communicated the additional requirement of testing 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. 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 for use 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 March 31, 2010, our accumulated deficit was approximately $(214,891,000). 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 development of our products will require the commitment of substantial resources to conduct the time consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of March 31, 2010, we had approximately $50,723,000 in Cash and Cash Equivalents. 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 32,200,000 shares authorized but unissued and unreserved. At our annual stockholders' meeting held on June 24, 2009, we sought 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. At this meeting, there was an insufficient number of votes in favor of the proposal and voting on this proposal had been left open until September 3, 2009. We announced on September 2, 2009 that insufficient votes were obtained for passage of Proposal No. 3 contained in the proxy for the 2009 Annual Meeting of Stockholders. With voting on this proposal as the sole purpose of the adjourned Stockholders' Meeting scheduled for September 4, 2009, this meeting was cancelled. Since the approval was not obtained to increase the number of authorized shares of Common Stock, the amount of proceeds we may receive from the sale of our Common Stock is limited.

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

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

Commercial sales of Alferon N Injection® were halted in March 2008 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 in vitro testing indicates that Ampligen® enhances the effectiveness of different drug combinations on avian influenza, preliminary testing in the laboratory is not necessarily predictive of successful results in clinical testing or human treatment.

Ampligen® is currently being tested as a vaccine adjuvant for H5N1, a pathogenic avian influenza virus ("HPAIV") in Japan, where the preclinical data has shown activity in preventing lethal challenge with the original virus used for vaccination as well as the other related, but not identical, isolates of H5N1 virus (i.e., cross-reactivity). The clinical testing phase of Ampligen® in Japan is expected to begin in 2010. 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.

27

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

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

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

To protect our rights, we require 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.

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

We have limited manufacturing experience.

Ampligen® has been produced to date in limited quantities for use in our clinical trials, and we are dependent upon a qualified third party supplier for the manufacturing and packaging process. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a material adverse 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® or other products in commercial quantities at costs acceptable to us.

We have never produced Ampligen® or any other products in large commercial quantities. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen® or 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. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, transient visual disturbances, slow or irregular heart rate, decreases in platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills, fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months. One or more of the potential side effects might deter usage of Ampligen® in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

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

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

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

On November 28, 2008, we suspended product liability insurance for Alferon N Injection® and Ampligen®. In the case of an international emergency basis sale of Ampligen® or Alferon® LDO, we would require the third-party to indemnify us. We concluded that years of successfully addressing the limited number of product liability claims filed against Ampligen® and Alferon® LDO, combined with the informed consent and other patient waivers completed as an element of clinical trials, and the lack of any commercial sales since April 2008, that temporarily discontinuing the liability insurance was an acceptable risk until we receive regulatory clearance for Ampligen® or Alferon® LDO or until Alferon N Injection® again becomes available.

Currently, without product liability coverage for Ampligen®, Alferon N Injection® and Alferon® LDO, a claim against the products could have a materially adverse effect on our business and financial condition.

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

Our success is dependent on the continued efforts of our staff, especially certain doctors and researchers along with the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen®, and his knowledge of our overall activities, including patents and clinical trials. The loss of the services of Dr. Carter or other personnel key to our operations, could have a material adverse effect on our operations and chances for success. As a cash conservation measure, we have elected to discontinue the Key Man life insurance on the life of Dr. Carter. An employment agreement continues to exist with Dr. Carter that, as amended, runs until December 31, 2010. However, Dr. Carter has the right to terminate his employment upon not less than 30 days prior written notice. The loss of Dr. Carter or other key personnel or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

Uncertainty of health care reimbursement for our products.

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

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

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

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

A number of purported class action lawsuits have been filed against us alleging securities fraud (see “Part II – Other Information; Item 1. Legal Proceedings”). The complaints seek monetary damages, costs, attorneys’ fees, and other equitable and injunctive relief. Securities class action suits and derivative suits are often brought against companies following periods of volatility in the market price of their securities. Defending against these suits, even if meritless, can result in substantial costs to us and could divert the attention of our management.

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

Risks Associated With an Investment in Our Common Stock

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

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

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

Our common stock is listed for quotation on the NYSE Amex. For the 12 month period ended March 31, 2010, the closing price of our common stock has ranged from $0.45 to $3.75 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

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

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

In May 2009 we issued an aggregate of 25,543,339 shares and warrants to purchase an additional 14,708,687 shares under a universal shelf registration statement. 4,895,000 of these warrants have been exercised as of March 31, 2010. Depending upon market conditions, we anticipate selling 9,813,687 shares pursuant to the conversion of remaining warrants.

33

In addition to the foregoing, we registered with the SEC on September 29, 2009, 1,038,527 shares issuable upon exercise of certain other warrants. To the extent the exercise price of our outstanding warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the exercise price of certain of these warrants are adjusted pursuant to anti-dilution protection, the warrants could be exercisable or convertible for even more shares of common stock. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. In this regard we have registered $150,000,000 of securities for public sale pursuant to a universal shelf registration, none of which has been designated or issued. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock.

Sales of substantial amounts of our common stock in the public market, including our sale of securities pursuant to the universal shelf registration statement, could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in Management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November 2002, we adopted a Stockholder Rights Plan (“Rights Plan”) and, under the Rights Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one-hundredth unit of preferred stock for $30.00. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Dr. Carter, our Chief Executive Officer, who already beneficially owns 5.4% of our common stock, the Rights Plan’s threshold will be 20%, instead of 15%. The Rights Plan will expire on November 19, 2012, and may be redeemed prior thereto at $.01 per Right under certain circumstances.

Special Note Regarding Forward Looking Statements

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

incurred in the development of Ampligen® for commercial application. Possible losses may fluctuate from quarter to quarter as a result of differences in the timing of significant expenses incurred and receipt of licensing fees and/or cost recovery treatment revenue.

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

During the quarter ended March 31, 2010, we issued an aggregate of 73,155 shares to consultants and vendors for services performed.

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

We did not repurchase any of our securities during the quarter ended March 31, 2010.

ITEM 3: Defaults upon Senior Securities

None.

ITEM 4: Removed and Reserved

ITEM 5: Other Information

None.

ITEM 6: Exhibits

(a) Exhibits

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

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

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

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

SIGNATURES

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

HEMISPHERx BIOPHARMA, INC.

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

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

Date: May 7, 2010