

HEMISPHERX BIOPHARMA INC  
Form 10-Q  
November 10, 2008

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

For the Quarterly Period Ended September 30, 2008

Commission File Number: 1-13441

HEMISPHER<sub>x</sub> BIOPHARMA, INC.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

52-0845822  
(I.R.S. Employer  
Identification No.)

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

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

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

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

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

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

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

77,405,709 shares of common stock were issued and outstanding as of November 3, 2008.

**PART I - FINANCIAL INFORMATION****ITEM 1: Financial Statements****HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES****Consolidated Balance Sheets**

(in thousands, except share and per share data)

	December 31, 2007	September 30, 2008 (Unaudited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 11,471	\$ 7,592
Short term investments (Notes 4)	3,944	-
Inventories	511	864
Accounts and other receivables	77	-
Prepaid expenses and other current assets	146	165
Assets held for sale (Note 6)	450	385
Total current assets	16,599	9,006
Property and equipment, net	4,821	4,904
Patent and trademark rights, net	958	981
Investment	35	35
Royalty interest, net	243	-
Construction in progress	469	-
Other assets	17	17
Total assets	\$ 23,142	\$ 14,943
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,118	\$ 1,214
Accrued expenses	1,069	948
Total current liabilities	2,187	2,162
Commitments and contingencies		
Stockholders' equity (Note 5):		
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 73,760,446 and 75,431,119 respectively	74	75
Additional paid-in capital	206,078	207,278
Accumulated other comprehensive income (loss)	(7)	-
Accumulated deficit	(185,190)	(194,572)
Total stockholders' equity	20,955	12,781
Total liabilities and stockholders' equity	\$ 23,142	\$ 14,943

See accompanying notes to consolidated financial statements.



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

	Three months ended September 30,	
	2007	2008
<b>Revenues:</b>		
Sales of product, net	\$ 251	\$ -
Clinical treatment programs	34	17
<b>Total revenues</b>	<b>285</b>	<b>17</b>
<b>Costs and expenses:</b>		
Production/cost of goods sold	216	199
Research and development	2,740	1,594
General and administrative	3,508	1,675
<b>Total costs and expenses</b>	<b>6,464</b>	<b>3,468</b>
<b>Operating loss</b>	<b>(6,179)</b>	<b>(3,451)</b>
Interest and other income	119	36
Reversal of previously accrued interest expense	346	-
<b>Financing costs</b>	<b>(4)</b>	<b>-</b>
<b>Net loss</b>	<b>\$ (5,718)</b>	<b>\$ (3,415)</b>
<b>Basic and diluted loss per share (Note 2)</b>	<b>\$ (.08)</b>	<b>\$ (.05)</b>
<b>Weighted average shares outstanding, basic and diluted</b>	<b>72,818,720</b>	<b>74,914,805</b>

See accompanying notes to consolidated financial statements.

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

	Nine months ended September 30,	
	2007	2008
<b>Revenues:</b>		
Sales of product net	\$ 667	\$ 173
Clinical treatment programs	107	67
<b>Total revenues</b>	<b>774</b>	<b>240</b>
<b>Costs and expenses:</b>		
Production/cost of goods sold	767	643
Research and development	8,450	4,061
General and administrative	6,834	5,362
<b>Total costs and expenses</b>	<b>16,051</b>	<b>10,066</b>
<b>Operating loss</b>	<b>(15,277)</b>	<b>(9,826)</b>
Interest and other income	584	444
Reversal of previously accrued interest expense	346	-
Interest expense	(116)	-
Financing costs	(280)	-
<b>Net loss</b>	<b>\$ (14,743)</b>	<b>\$ (9,382)</b>
<b>Basic and diluted loss per share (Note 2)</b>	<b>\$ (.21)</b>	<b>\$ (.13)</b>
<b>Weighted average shares outstanding, basic and diluted</b>	<b>71,293,392</b>	<b>74,280,332</b>

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 comprehensive income	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2007	73,760,446	\$ 74	\$ 206,078	(\$ 7)	(\$ 185,190)	20,955
Stock issued for settlement of accounts payable	762,151	-	493	-	-	493
Private placement, net of issuance costs	908,522	1	149	-	-	150
Equity based compensation	-	-	558	-	-	558
Net comprehensive income (loss)	-	-	-	7	(9,382)	(9,375)
Balance at September 30, 2008	75,431,119	\$ 75	\$ 207,278	-	(\$ 194,572)	12,781

See accompanying notes to consolidated financial statements.

**HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES****Consolidated Statements of Cash Flows**

For the Nine Months Ended September 30, 2007 and 2008

**(in thousands)**

(Unaudited)

	2007	2008
<b>Cash flows from operating activities:</b>		
Net loss	\$ (14,743)	\$ (9,382)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation of property and equipment	192	255
Amortization of patent and trademark rights, and royalty interest	125	338
Financing cost related to debt discounts	475	-
Equity based compensation	2,286	558
Common stock issued in payment of interest expense	181	-
<b>Increase (decrease) in assets and liabilities:</b>		
Inventories	330	(353)
Accounts and other receivables	(203)	77
Prepaid expenses and other current assets	95	(19)
Assets held for sale	(610)	65
Accounts payable	462	659
Accrued expenses	(379)	(48)
Net cash used in operating activities	\$ (12,007)	\$ (7,850)
<b>Cash flows from investing activities:</b>		
Purchase of property plant and equipment	\$ 2	\$ (12)
Additions to patent and trademark rights	(126)	(118)
Maturity of short term investments	10,220	3,951
Purchase of short term investments	(2,803)	-
Net cash provided by investing activities	\$ 7,293	\$ 3,821

**HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES****Consolidated Statements of Cash Flows (Continued)**

For the Nine Months Ended September 30, 2007 and 2008

**(in thousands)**

(Unaudited)

	2007	2008
Cash flows from financing activities:		
Payment of long-term debt	\$ (4,102)	\$ -
Collection of advance receivable	1,464	-
Proceeds from sale of stock, net of issuance costs	10,270	150
Net cash provided by financing activities	\$ 7,632	\$ 150
Net increase(decrease) in cash and cash equivalents	2,918	(3,879)
Cash and cash equivalents at beginning of period	3,646	11,471
Cash and cash equivalents at end of period	\$ 6,564	\$ 7,592
Supplemental disclosures of non-cash investing and financing cash flow information:		
Issuance of common stock for accounts payable and accrued expenses	\$ 229	\$ 493
Unrealized gains on investments	\$ 332	\$ -

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 for the year ended December 31, 2007, as filed with the SEC on March 17, 2008.

**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 17,456,937 and 29,798,378 shares, are excluded from the calculation of diluted net loss per share for the nine months ended September 30, 2007 and 2008, 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:

	Nine Months Ended September 30,	
	2007	2008
Risk-free interest rate	4.0% - 4.90%	2.52 - 3.74%
Expected dividend yield	-	-
Expected lives	5 yrs	2.5 - 5.0 yrs
Expected volatility	71.64 - 77.57%	74.00 - 79.18%
Weighted average grant date fair value of options and warrants issued	\$ 2,238,000	\$ 474,000

Stock option activity during the nine months ended September 30, 2008, 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, 2006	2,001,969	\$ 2.51	8.01	-
Options granted	2,624,120	2.77	9.05	-
Options forfeited	-	-	-	-
Outstanding December 31, 2007	4,626,089	2.66	8.25	-
Options granted	1,465,000	2.22	10.00	-
Options forfeited	(5,095)	(2.33)	-	-
Outstanding September 30, 2008	6,085,994	\$ 2.55	8.10	-
Exercisable September 30, 2008	5,924,326	\$ 2.58	8.15	-

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2007 and 2008 was approximately \$1,803,000 and \$318,000, respectively.

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2006	113,986	\$ 2.26	9.05	-
Options granted	130,000	1.34	10.00	-
Options vested	(77,223)	(6.86)	8.29	-
Outstanding December 31, 2007	166,763	1.59	7.18	-
Options granted	-	-	-	-
Options forfeited	(5,095)	2.33	-	-
Outstanding September 30, 2008	161,668	\$ 1.57	6.43	-

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, 2006	1,326,732	\$ 2.63	8.18	-
Options granted	608,750	1.99	9.94	-
Options forfeited	-	-	-	-
Outstanding December 31, 2007	1,935,482	2.43	8.05	-
Options granted	672,000	2.57	7.68	-

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Options forfeited	-	-	-	-
Outstanding September 30, 2008	2,607,482	\$ 2.47	7.40	-
Exercisable September 30, 2008	2,567,482	\$ 2.49	7.42	-

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The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2007 and 2008 was approximately \$413,000 and \$147,000, respectively.

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

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2006	37,100	\$ 2.28	9.81	
Options granted	25,100	1.30	10.00	
Options forfeited	(22,100)	(2.30)	8.23	-
Outstanding December 31, 2007	40,000	1.50	9.30	-
Options granted	-	-	-	-
Options forfeited	-	-	-	-
Outstanding September 30, 2008	40,000	\$ 1.50	8.55	-

The impact on the Company's results of operations of recording equity based compensation for the nine months ended September 30, 2007 and 2008 was to increase general and administrative expenses by approximately \$2,262,000 and \$466,000, respectively, and reduce earnings per share by \$.03 and \$.01, respectively.

As of December 31, 2007 and September 30, 2008, respectively, there was \$164,000 and \$47,000 of unrecognized equity based compensation cost related to options granted under the Equity Incentive Plan.

#### Note 4: SHORT TERM INVESTMENTS

Securities classified as available for sale consisted of:

Name of security	December 31, 2007		Unrealized loss	Maturity date
	Cost	Market value		
Marshall & Isley	\$ 1,979,000	\$ 1,976,000	\$ (3,000)	March 2008
Intesa Funding	1,972,000	1,968,000	(4,000)	April 2008
	\$ 3,951,000	\$ 3,944,000	\$ (7,000)	

No investment securities were pledged to secure public funds at December 31, 2007.

The table below indicates the length of time individual securities have been in a continuous unrealized loss position at December 31, 2007.

Name of security	Number of Securities	December 31, 2007				Total Fair value	Total Unrealized loss
		Less than 12 months Fair value	Unrealized loss	12 months or longer Fair value	Unrealized loss		
Marshall & Isley	1	\$ 1,976,000	\$ (3,000)	\$ -	\$ -	\$ 1,976,000	\$ (3,000)
Intesa Funding	1	1,968,000	(4,000)	-	-	1,968,000	(4,000)
Total temporary impairment securities	2	\$ 3,944,000	\$ (7,000)	\$ -	\$ -	\$ 3,944,000	\$ (7,000)

### Comprehensive Income

The Company reports comprehensive income, which includes net loss, as well as certain other items, which result in a charge to equity during the period.

	Three months ended September 30 (in thousands)		Nine months ended September 30 (in thousands)	
	2007	2008	2007	2008
Unrealized gains during the period	\$ 180	\$ -	\$ 671	\$ 7
Realized loss (gains) during the period	(118)	-	(339)	-
Other comprehensive income(loss)	\$ 62	\$ -	\$ 332	\$ 7

There are no income tax effects allocated to comprehensive income as the Company has no tax liabilities due to net operating losses.

### NOTE 5: STOCKHOLDERS' EQUITY

For the nine months ended September 30, 2008, Fusion Capital did not purchase any shares of the Company's common stock pursuant to the April 2006 common stock purchase agreement between the Company and Fusion Capital.

On February 18, 2008, the Company granted 280,000 stock options to two executive officers and two directors of the Company under the 2004 Equity Compensation Plan. The stock options have an exercise price of \$4.00 and a term of ten years. The stock options vested immediately upon grant. The Company utilized the Black-Scholes Pricing Model to fair value the stock options and recorded approximately \$91,000 as equity based compensation related to this issuance during the nine months ended September 30, 2008.

On July 2, 2008, we entered into a \$30 million Common Stock Purchase Agreement (the "Purchase Agreement") with Fusion Capital Fund II, LLC, an Illinois limited liability company. Concurrently with entering into the Purchase Agreement, we entered into a registration rights agreement with Fusion Capital. Under the registration rights agreement, we filed a registration statement related to the transaction with the U.S. Securities & Exchange Commission ("SEC") covering the shares that have been issued or may be issued to Fusion Capital under the common stock purchase agreement. That registration statement was declared effective by the SEC on August 12, 2008. As reported in the registration statement related to the transaction, we have the right over a 25 month period to sell our shares of common stock to Fusion Capital from time to time in amounts between \$120,000 and \$1 million depending on certain conditions as set forth in the agreement, up to a maximum of \$30 million. The purchase price of the shares related to the \$30.0 million of future funding will be based on the prevailing market prices of the Company's shares at the time of sales as computed under the Purchase Agreement without any fixed discount, and the Company will control the timing and amount of any sales of shares to Fusion Capital. Fusion Capital shall not have the right or the obligation to purchase any shares of our common stock on any business day that the price of our common stock is below \$0.40. Recently, the price of the Company's common stock has consistently been below \$0.40 and, accordingly, no additional sales can be made to Fusion Capital unless and until the price rises to \$0.40 per share or better. The Purchase Agreement may be terminated by us at any time at our discretion without any cost to us. There are no negative covenants, restrictions on future funding, penalties or liquidated damages in the agreement. In consideration for entering into the Purchase Agreement, we issued to Fusion Capital 650,000 shares as a commitment fee. Also, we will issue to Fusion Capital up to an additional 650,000 shares as a commitment fee pro rata as we receive up to the \$30.0 million of future funding. During the three months ended September 30, 2008, Fusion has purchased 258,522 shares for \$150,000 under this agreement.

The Company has been using the proceeds from this financing to fund infrastructure growth including manufacturing, regulatory compliance and market development.

During the nine months ended September 30, 2008, the Company issued an aggregate 400,000 stock options and warrants under the 2004 Equity Compensation Plan to vendors for services provided. The stock options had various exercise prices ranging from \$0.35 to \$6.00 and had terms of either five or ten years. The stock options vested immediately upon grant. The Company utilized the Black-Scholes Pricing Model to fair value the stock options and recorded approximately \$126,000 as equity based compensation related to these issuances during the nine months ended September 30, 2008.

On September 17, 2008 the Company issued 1,450,000 stock options under the 2007 Equity Compensation Plan to William A. Carter, CEO for services provided. The stock options have an exercise price of \$2.20, expire in 10 years, vest immediately and recorded as General and Administrative Expenses. The Company utilized the Black-Scholes Pricing Model to fair value the stock options and recorded approximately \$255,000 as equity based compensation in the nine months ended September 30, 2008. These options replaced previously issued options that expired unexercised.

The Company also recorded \$84,000 during the nine months ended September 30, 2008, in equity based compensation related to the vesting of stock options issued in 2006 and 2007.

**NOTE 6: ASSET HELD FOR SALE**

Asset held for sale consists of equipment purchases related to the purified water system that was to be installed at the Company's manufacturing facility in New Brunswick, NJ. We are reevaluating our manufacturing needs to determine the cost/benefit for installing the purified water system as compared to selling this asset. As a result of this process, in 2007 the Company reclassified the Equipment of \$678,000 to Asset Held for Sale and then recorded an impairment charge of \$228,000 for this water system to bring the cost down to its net realizable value of \$450,000 as per SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets". For the nine months ended September 30, 2008, the Company recorded an additional \$65,000 impairment charge leaving a balance of \$385,000 in Asset Held for Sale.

**NOTE 7: RECENT ACCOUNTING PRONOUNCEMENTS**

On February 15, 2007, the FASB issued FASB Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities - Including an Amendment of FASB Statement No. 115*. This standard permits an entity to choose to measure many financial instruments and certain other items at fair value. This option is available to all entities, including not-for-profit organizations. Most of the provisions in Statement 159 are elective; however, the amendment to FASB Statement No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, applies to all entities with available-for-sale and trading securities. Some requirements apply differently to entities that do not report net income. The FASB's stated objective in issuing this standard is as follows: "to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions".

The fair value option established by Statement 159 permits all entities to choose to measure eligible items at fair value at specified election dates. A business entity will report unrealized gains and losses on items for which the fair value option has been elected in earnings (or another performance indicator if the business entity does not report earnings) at each subsequent reporting date. A not-for-profit organization will report unrealized gains and losses in its statement of activities or similar statement. The fair value option: (a) may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method; (b) is irrevocable (unless a new election date occurs); and (c) is applied only to entire instruments and not to portions of instruments.

Statement 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. The Company elected not to adopt the fair value option for any eligible instruments.

On December 4, 2007, the FASB issued FASB Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements - An Amendment of ARB No. 51*. Statement 160 establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. Specifically, this statement requires the recognition of a noncontrolling interest (minority interest) as equity in the consolidated financial statements and separate from the parent's equity. The amount of net income attributable to the noncontrolling interest will be included in consolidated net income on the face of the income statement. Statement 160 clarifies that changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation are equity transactions if the parent retains its controlling financial interest. In addition, this statement requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. Such gain or loss will be measured using the fair value of the noncontrolling equity investment on the deconsolidation date. Statement 160 also includes expanded disclosure requirements regarding the interests of the parent and its noncontrolling interest.





Statement 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. The Company believes adoption of this standard will not have an impact on the financial condition or the results of the Company's operations.

On April 21, 2008, the FASB posted a revised FASB Statement No. 133 Implementation guidance for Issues I1, Interaction of the Disclosure Requirements of Statement 133 and Statement 47, and K4, Miscellaneous: Income Statement Classification of Hedge Ineffectiveness and the Component of a Derivative's Gain or Loss Excluded from the Assessment of Hedge Effectiveness. The revisions relate to the issuance of FASB Statement No. 161, Disclosures about Derivative Instruments and Hedging Activities. The Company believes adoption of this standard will not have an impact on the financial condition or the results of the Company's operations.

The FASB has issued FASB Statement No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. Statement 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with U.S. generally accepted accounting principles for nongovernmental entities. The hierarchy under Statement 162 is as follows:

\* FASB Statements of Financial Accounting Standards and Interpretations, FASB Statement 133 Implementation Issues, FASB Staff Positions, AICPA Accounting Research Bulletins and Accounting Principles Board Opinions that are not superseded by actions of the FASB, and Rules and interpretive releases of the SEC for SEC registrants.

\* FASB Technical Bulletins and, if cleared by the FASB, AICPA Industry Audit and Accounting Guides and Statements of Position.

\* AICPA Accounting Standards Executive Committee Practice Bulletins that have been cleared by the FASB, consensus positions of the EITF, and Appendix D EITF topics.

Statement 162 is effective 60 days following the SEC's approval of the PCAOB amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. Since Statement 162 is only effective for nongovernmental entities, the GAAP hierarchy will remain in AICPA Statement on Auditing Standards (SAS) No. 69, *The Meaning of "Present Fairly in Conformity with Generally Accepted Accounting Principles" in the Independent Auditor's Report*, for state and local governmental entities and federal governmental entities. The Company believes the adoption of this standard will not have an impact on the financial condition or the results of the Company's operations.

The FASB issued FASB Statement No. 163, *Accounting for Financial Guarantee Insurance Contracts*. This new standard clarifies how FASB Statement No. 60, *Accounting and Reporting by Insurance Enterprises*, applies to financial guarantee insurance contracts issued by insurance enterprises, including the recognition and measurement of premium revenue and claim liabilities. It also requires expanded disclosures about financial guarantee insurance contracts.

Statement 163 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and all interim periods within those fiscal years, except for disclosures about the insurance enterprise's risk-management activities, which are effective the first period (including interim periods) beginning after May 23, 2008. Except for the required disclosures, earlier application is not permitted. The Company believes the adoption of this standard will not have an impact on the financial condition or the results of the Company's operations.

#### **NOTE 8 - SUBSEQUENT EVENTS**

None.

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

##### **Special Note Regarding Forward-Looking Statements**

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

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

## Overview

### General

We are a biopharmaceutical company engaged in the clinical development, manufacture, marketing and distribution of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. The Company was 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 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 subsidiaries include Hemispherx Biopharma Europe N.V./S.A. established in Belgium in 1998. Hemispherx Biopharma Europe N.V./S.A. has little or no activity.

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

Ampligen® is an experimental drug currently undergoing clinical development for the treatment of Chronic Fatigue Syndrome (“CFS”). In August 2004, we completed a Phase III clinical trial (“AMP 516”) treating over 230 CFS patients with Ampligen® and are presently in the registration process for a new drug application (“NDA”) with the Food and Drug Administration (“FDA”). Over its developmental history, Ampligen® has received various designations, including Orphan Drug Product Designation (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and “promising” clinical outcome recognition based on the evaluation of certain summary clinical reports (AHRQ, Agency Health Research Quality). Ampligen® represents the first drug in the class of RNA (nucleic acid) molecules to apply for NDA review. For an update on the filing status of our Ampligen® New Drug Application filed on October 10, 2007, see “Research and Development Costs” contained within this section below.

On July 7, 2008, the FDA accepted for review our NDA for Ampligen®, an experimental therapeutic, to treat CFS, originally submitted in October 2007. We are seeking marketing approval for the first-ever treatment for CFS. At present, only supportive, symptom-based care is available for CFS patients. The NDA for Ampligen®, whose chemical designation is poly I : poly C12U, is also the first ever accepted for review by the FDA for systemic use of a toll-like receptor therapy to treat any condition.

The Status of our initiative for Ampligen® as an adjuvant for preventative vaccine development includes the pre-clinical studies in seasonal and pandemic influenza for intranasal administration being conducted by Japan’s National Institute for Infectious Diseases. A three year program targeting regulatory approval for pandemic flu and seasonal flu in Japan has been funded by the Japanese Ministry of Health. Parties to the research grant include Hemispherx, the NIID and BIKEN (operational arm of the non-profit Foundation for Microbial Disease of Osaka University). Our agreement with BIKEN is part of a three party agreement to develop an effective influenza vaccine for Japan and utilizes the resources of the National Institute of Infectious Disease of Japan. Our development strategy includes reproduction of preclinical studies outside Japan and completion of the three year program. It is our intent to conduct human studies in the US and other countries and seek approval for seasonal and pandemic indications in the US and Europe for intranasal administration. A phase II study for intramuscular administration for seasonal flu is currently being conducted in Australia through the St. Vincent’s Hospital Clinical Trials Centre and is now fully enrolled. This clinical study is expected to be completed in December of 2008.



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.

Alferon N Injection® is the registered trademark for our injectable formulation of natural alpha interferon, which is approved by the FDA for the treatment of genital warts. Alferon N Injection® is also in clinical development for treating West Nile Virus.

Commercial sales of Alferon N Injection® were halted in April 2008 as the current expiration date of our finished goods inventory expired in March 2008. The FDA has declined to respond to our requests for an extension of the expiration date, therefore we consider the request to be denied. Since our testing of the product indicates that it is not impaired and could be safely utilized, the finished goods inventory of 2,745 Alferon N Injection® 5ml vials may be used to produce approximately 11,000,000 sachets of Low Dose Oral Alferon (LDO) for future clinical trials.

Production of Alferon N injection® from our work-in-progress inventory, which has an approximate expiration date of 2012, has been put on hold at this time due to the resources needed to prepare our New Brunswick facility for the FDA preapproval inspection with respect to our Ampligen® NDA. Work on the Alferon N Injection® is expected to resume in mid-2009 under the condition that adequate funding is obtained, which means that we may not have any Alferon N Injection® product commercially available until 2010.

We do not believe that our current and planned experimental programs involving Alferon N Injection® and Alferon LDO, including our anticipated clinical trials, will be materially affected by this situation.

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ primarily designed to produce Alferon N Injection®. In 2006, we completed the installation of a polymer production line to produce Ampligen® raw materials on a more reliable and consistent basis.

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.

#### **401(K) Plan**

We have a defined contribution plan, titled Hemispherx Biopharma Employees 401(k) Plan and Trust Agreement (the 401(k) Plan). Full time members are eligible to participate in the 401(k) Plan following one year of employment. Subject to certain limitations imposed by federal laws and contribution limitation on those designated as Highly Compensated Employees by the 401(k) plan, participants are eligible to contribute up to 15% of their salary (including bonuses and/or commissions) per annum. Each participant immediately vests regarding his or her deferred salary contributions while our contributions vest over one year.

Effective March 15, 2008, we ended our 100% matching of up to 6% of the 401(k) contributions provided to the account for each eligible participant. Our 401(k) Plan contribution cost for the nine months ended September 30, 2008 is \$20,421 with no company matching costs projected regarding the plan for the remaining of calendar year 2008.

### **New Accounting Pronouncements**

Refer to “NOTE 7: RECENT ACCOUNTING PRONOUNCEMENTS” under Notes To Unaudited Condensed Consolidated Financial Statements.

### **Disclosure About Off-Balance Sheet Arrangements**

None.

### **Critical Accounting Policies**

There have been no material changes in our critical accounting policies and estimates from those disclosed in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2007.

## **RESULTS OF OPERATIONS**

### **Three months ended September 30, 2007 versus three months ended September 30, 2008**

#### **Net loss**

Our net loss of approximately \$3,415,000 for the three months ended September 30, 2008 was \$2,303,000 or 40% lower when compared to the same period in 2007. This decrease in loss was primarily due to:

- 1) Research and Development costs in 2007 include significant expenses related to the preparation of the Ampligen® NDA as well as expenses related to the production of Ampligen® for use in stability studies. Research and development expenses in 2008 were down approximately \$1,146,000 as compared to the same period in 2007.
- 2) There were no sales of Alferon N Injection® for the three months ended September 30, 2008, as finished goods inventory has reached its current product expiration date of March 31, 2008. Sales of Alferon N Injection® for the three months ended September 30, 2007, amounted to approximately \$251,000.
- 3) General and administrative expenses decreased approximately \$1,833,000 during the current quarter as compared to the prior period primarily due to the reduction of Stock Compensation Expense for approximately \$1,814,000 for the three months ended September 30, 2008.
- 4) Interest and other income decreased \$83,000 for the three months ended September 30, 2008 as compared to the same period in 2007 due to a reduction in Short Term Investments for marketable securities in the current period as compared to the prior period.

5) In September 2007, an increase of \$346,000 in other income occurred due to the reversal of accrued liquidated damages in 2006 with respect to our debentures holders as a result of our failure to timely file our 2005 Audit Report on Form 10-K. These damages related to certain debenture covenants were settled without charge in the maturation and pay down of the debenture holder's outstanding loan balances in 2007.

Net loss per share was \$0.05 for the current period versus \$0.08 for the same period in 2007.

### **Revenues**

Revenues for the three months ended September 30, 2008 were \$17,000 compared to revenues of \$285,000 for the same period in 2007. There were no revenues related to the sale of Alferon N Injection® for this period in 2008 versus \$251,000 in 2007. Revenues from our Ampligen® cost recovery program were down \$17,000 as fewer patients are participating in the program. Commercial sales of Alferon N Injection® were halted in April 2008 as the current expiration date of our finished goods inventory expired in March 2008. As a result, we have no product to sell and all \$17,000 of Revenue was generated from clinical treatment programs.

Major efforts of the New Brunswick manufacturing staff were redirected throughout year 2008 to the upcoming preapproval FDA inspection of the Ampligen® program.

Work on the Alferon N Injection® is expected to resume in mid-2009 under the condition that adequate funding is obtained, which means that we may not have any Alferon N Injection® product commercially available until 2010.

### **Production costs/cost of goods sold**

Production/cost of goods sold was approximately \$216,000 and \$199,000, respectively, for the three months ended September 30, 2007 and 2008. This represented a decrease of approximately \$17,000 or 7% as compared to the same period in 2007. These costs primarily represent: 1) costs of goods sold of approximately \$95,000 and \$0, respectively, for the three months ended September 30, 2007 and 2008, 2) testing and reporting costs incurred in our attempt to have the FDA extend the commercial sales life of our Alferon Finished Goods and 3) costs to maintain Alferon N Injection® work-in-process Inventory including stability tests and indirect overhead.

Our Alferon N Injection® work-in-process ("WIP"), with an approximate expiration of 2012, should produce approximately 7,500 doses when completed. At this time we have put further work on the WIP on hold as we are applying our New Brunswick resources to the task of preparing our plant for an FDA Pre-approval Inspection in connection with the Ampligen® NDA review process.

### **Research and development costs**

Overall research and development costs for the three months ended September 30, 2008 were \$1,594,000 as compared to \$2,740,000 for the same period a year ago reflecting a decrease of \$1,146,000 or 42%. This decrease was primarily due to reduced outside consulting fees and other costs related to the preparation and filing of our NDA for Ampligen®.

On July 7, 2008 we were notified that the FDA accepted for review our amended NDA filing for using Ampligen® to treat CFS. FDA approval of this application would provide the first-ever treatment for CFS. At present, only supportive symptom-based care is available for CFS patients. While we are optimistic, there are no assurances that the NDA will be approved. Over the summer of 2008, our clinical monitors visited our sites associated with our AMP-511 cost recovery treatment program for the collection and audit of additional data to be submitted to the FDA in support of our NDA for CFS currently under review. FDA inspections of several clinical sites did not result in the issuance of any “483” reports indicating lack of compliance with various regulations governing clinical trials.

We are preparing for the preapproval inspection by the U.S. FDA for manufacturing of Ampligen® product and its starting materials, polynucleotides Poly I and Poly C<sub>12</sub>U. A satisfactory recommendation from the FDA Office of Compliance based upon an acceptable preapproval inspection is required prior to approval of the product. The preapproval inspection determines compliance with current Good Manufacturing Practices (cGMPs) as well as a product specific evaluation concerning the manufacturing process of product. Currently, Hemispherx’s personnel are working diligently towards a successful preapproval inspection. The activities include many aspects of the cGMP requirements, such as manufacturing process validation, equipment qualification, analytical method validation, facility cleaning, quality systems, documentation system and part 11 compliance. On September 19, 2008, we executed an agreement with Lovelace Respiratory Research Institute in Albuquerque, New Mexico to perform certain animal toxic studies in support of our Ampligen® NDA. These studies were requested by the FDA and will be done in collaboration with the resources of the New Brunswick facility. We expect these studies to be complete in January 2009.

We are also engaged in ongoing, experimental studies assessing the efficacy of Ampligen®, Alferon N Injection®, and Alferon LDO against influenza viruses as a single adjuvant agent antiviral with Japan’s National Institute of Infectious disease, Biken (the non-profit operational arm of the Foundation for Microbial Diseases of Osaka University) and St. Vincent’s Hospital in Darlinghurst, Australia. No further results have been reported by Defence R&D Canada with respect to their independent study assessing the efficacy of Ampligen® against Influenza viruses as a single agent antiviral.

The Biken arrangement was concluded in December 2007 and basically consists of Biken purchasing Ampligen® from us for use in conducting further animal studies of intranasal prototype vaccines containing antigens from influenza sub-types H1N1, H3N2 and B progressing to human studies with all programs supported by the Japanese Health Ministry. Under the terms of the non—exclusive licensing arrangement, we will receive royalties as well as income for all Ampligen® used in the ongoing experimental work and any subsequent marketing of Ampligen® as an immuno-enhancer for flu vaccines delivered intranasally in Japan. To date, only two or three pharma companies worldwide have achieved regulatory authorizations to sell intranasally (IN) administered influenza vaccines versus many companies receiving approval for intramuscular vaccine delivery routes. Safety has been paramount in developing effective treatments. However, animal studies to date indicate Ampligen®, an experimental drug, may be safely administered intranasally. Clinical studies (in other disorders) have built a database of more than 90,000 injections of Ampligen® when given parenterally (intravenous, or “IV”). In June 2008, Biken notified us they were accelerating their program and requested additional Ampligen® supplies for various preclinical vaccine studies. A secondary goal of the trial is to evaluate whether antibodies stimulated by the vaccine/Ampligen® combination also provide protection against H5N1, the avian influenza virus. Since 2003, the World Health Organization has attributed 241 human deaths worldwide to H5N1. Investigators from Japan’s Institute of Infectious Disease have conducted studies in animals that suggest that Ampligen® can stimulate a sufficiently broad immune response to provide cross-protection against a range of virus strains, including H5N1.



We completed enrollment in our Phase II clinical trial to evaluate the safety and efficacy of Ampligen® as an enhancer for seasonal influenza vaccine. This study is being monitored by Clinical Network Services Pty. Ltd. located in Brisbane, Australia. The clinical trials center of St. Vincent's Hospital based in DarlingHurst, Australia is conducting the trial. This clinical study is expected to be completed in the Fall of 2008. The data is being analyzed from the single-center study in Australia in which 38 healthy volunteers between 60 and 80 years of age who have not received this year's seasonal flu vaccine. Study subjects were randomized into groups receiving vaccine plus Ampligen® or vaccine plus a placebo. Under the double-blinded structure of the trial, neither study subjects nor clinicians conducting the trial know which subjects are receiving Ampligen® or placebo until final results are recorded. Efforts will be made to determine whether cross-protection, seen in monkey studies, is also observed in human studies with Ampligen®.

As reported in the Journal of American Medical Association in 2003 by Thompson, Shay, Weintraub, Brammer, Cox, Anderson, et al. seasonal influenza kills approximately 36,000 Americans annually, most over the age of 70. In 2004 in JAMA, the same authors attributed 200,000 U.S. hospital admissions annually to seasonal flu.

Collaboration studies in non-human primates conducted by ViroClinics in the Netherlands suggest a potential role for Alferon LDO as another novel therapeutic approach to viral pandemics. Meetings with prospective partners are underway with respect to conducting clinical trials using Alferon LDO to treat and/or prevent seasonal influenza in the Pacific Rim countries. Alferon LDO is now poised for clinical trials against seasonal influenza epidemics; meetings with prospective partners are ongoing to conduct clinical trials in the Pacific Rim countries and elsewhere. The opportunity for Alferon LDO is reinforced by new reports of severe side effects secondary to Tamiflu, the present standard of care, by both the FDA and Japanese health authorities. Also, Tamiflu resistant strains of flu virus are now raising serious concerns on a world-wide basis.

### **General and Administrative Expenses**

General and Administrative ("G&A") expenses for the three months ended September 30, 2007 and 2008 were approximately \$3,508,000 and \$1,675,000, respectively, reflecting a decrease of \$1,833,000 or 52%. This decrease relates primarily to the reduction of Stock Compensation Expense for approximately \$1,814,000 for the three months ended September 30, 2008.

### **Reversal of Previously Accrued Interest Expense**

We had no reversal of previously accrued interest expense for the three months ended September 30, 2008 as compared to the \$346,000 for the same period in 2007. This September 2007 item, classified as other income, resulted from the reversal of accrued liquidated damages in 2006 related to a certain covenant in our debenture agreements. These charges were incurred as a result of our failure to timely file our 2005 Annual Report on Form 10-K and our report on Form 10-Q for the quarterly period ended March 31, 2006 with the SEC pursuant to the 1934 Act. These liquidated damages were not included as part of the maturation and pay down of the debenture holder's outstanding loan balances.

### **Interest and Other Income**

Interest and other income for the three months ended September 30, 2007 and 2008 was \$119,000 and \$36,000, respectively, representing a decrease of \$83,000 or 70%. The decrease in interest and other income during the current period was mainly due to a reduction in the holding of Short Term Investments for \$3,944,000 as marketable securities in the current period as compared to the prior period.

### **Interest Expense and Financing Costs**

We had no interest expense or non-cash financing costs for the three months ended September 30, 2007 and 2008.

### **Nine months ended September 30, 2007 versus nine months ended September 30, 2008**

### **Net loss**

Our net loss of approximately \$9,382,000 for the nine months ended September 30, 2008 was \$5,361,000 or 36% lower when compared to the same period in 2007. This decrease in loss was primarily due to:

- 1) Research and Development costs in 2007 include significant expenses related to the preparation of the Ampligen® NDA as well as expenses related to the production of Ampligen® for use in stability studies and preparation of pre commercial lots for regulatory review purposes. Research and development expenses in 2008 were down approximately \$4,389,000 as compared to the same period in 2007.
- 2) There were no sales of Alferon N Injection® for the last six months as finished goods inventory has reached its current product expiration date of March 31, 2008. Sales of Alferon N Injection® for the nine months ended September 30, 2008 and 2007 amounted to approximately \$173,000 and \$667,000, respectively for a reduction of \$494,000.
- 3) General and administrative expenses decreased approximately \$1,472,000 during the nine months ended September 30, 2008 versus the same period a year ago primarily due to reductions in the cost of Stock Compensation of \$1,704,000, Director Fees for \$125,000 and Accounting Fees of \$73,000 that were offset with an increase of Legal Fees for \$506,000 resulting from litigation.
- 4) Interest and other income decreased \$140,000 for the nine months ended September 30, 2008 as compared to the same period in 2007 due to a reduction in the holding of Short Term Investments for \$3,944,000 as marketable securities in the current period as compared to the prior period.
- 5) In 2007, we had financing costs and interest expense of \$280,000 and \$116,000, respectively, related to our convertible debentures. These convertible debentures were paid off in June 2007. No financing costs or interest charges were incurred during the current period related to these debentures.

6) In September 2007, an increase of \$346,000 in other income occurred due to the reversal of accrued liquidated damages in 2006 with respect to our debentures holders as a result of our failure to timely file our 2005 Audit Report on Form 10-K. These damages related to certain debenture covenants were settled without charge in the maturation and pay down of the debenture holder's outstanding loan balances in 2007.

Net loss per share was \$0.13 for the current period versus \$0.21 for the same period in 2007.

### **Revenues**

Revenues for the nine months ended September 30, 2008 were \$240,000 compared to revenues of \$774,000 for the same period in 2007. Revenues related to the sale of Alferon N Injection® for the nine months ended September 30, 2008 were \$173,000 versus \$667,000 in 2007. The primary reason for the 74% drop in sales for the nine months ended September 30, 2008 is that commercial sales of Alferon N Injection® were halted in April 2008 as the current expiration date of our finished good inventory expired in March 2008. As a result, we had no product to sell for the last six months. Revenues from our Ampligen® cost recovery program were down \$40,000 or 37% as fewer patients are participating in the program. Our clinical staff discouraged cost recovery clinical enrollments in order that resources could address the NDA and related documents preparatory to filing for a full commercial license.

### **Production costs/cost of goods sold**

Production/cost of goods sold was approximately \$767,000 and \$643,000, respectively, for the nine months ended September 30, 2007 and 2008. This represented a decrease of approximately \$124,000 or 16% as compared to the same period in 2007. These costs primarily represent: 1) costs of goods sold of approximately \$273,000 and \$60,000, respectively, for the nine months ended September 30, 2007 and 2008, and 2) Costs to maintain Alferon N Injection Inventory including storage, stability testing and reporting costs incurred in our attempt to have the FDA extend the commercial sales life of our Alferon N Injection® Finished Goods. The primary reason for the decrease in costs can be attributed to the lack of Alferon N Injection® sales since April 1, 2008 and its impact on costs of goods sold.

### **Research and development costs**

Overall research and development costs for the nine months ended September 30, 2008 were \$4,061,000 as compared to \$8,450,000 for the same period a year ago reflecting a decrease of \$4,389,000 or 52%. This decrease was primarily due to reduced outside consulting fees related to the preparation and filing of our NDA for Ampligen®. For more detail on Research and Development costs, please see above discussion on "Research and Development Costs" contained within the discussion on results of Operations for the three months ended September 30, 2007 versus three months ended September 30, 2008.

### **General and Administrative Expenses**

General and Administrative ("G&A") expenses for the nine months ended September 30, 2007 and 2008 were approximately \$6,834,000 and \$5,362,000, respectively, reflecting a decrease of \$1,472,000 or 22% primarily due to reductions in the cost of Stock Compensation of \$1,704,000, Director Fees for \$125,000 and Accounting Fees of \$73,000 that were offset with an increase of Legal Fees for \$506,000 resulting from litigation.

### **Reversal of Previously Accrued Interest Expense**

We had no reversal of previously accrued interest expense for the nine months ended September 30, 2008 as compared to the \$346,000 for the same period in 2007. This September 2007 item, classified as other income, resulted from the reversal of accrued liquidated damages in 2006 related to a certain covenant in our debenture agreements. These charges were incurred as a result of our failure to timely file our 2005 Annual Report on Form 10-K and our report on Form 10-Q for the quarterly period ended March 31, 2006 with the SEC pursuant to the 1934 Act. These liquidated damages were not included as part of the maturation and pay down of the debenture holder's outstanding loan balances.

### **Interest and Other Income**

Interest and other income for the nine months ended September 30, 2007 and 2008 was \$584,000 and \$444,000, respectively, representing a decrease of \$140,000 or 24%. The decrease in interest and other income during the current period was mainly due to a reduction in the holding of Short Term Investments for \$3,944,000 as marketable securities in the current period as compared to the prior period.

### **Interest Expense and Financing Costs**

We had no interest expense or non-cash financing costs for the nine months ended September 30, 2008 as compared to \$396,000 for the same period a year ago. The expenses reflected for the nine months ended September 30, 2007 reflect financing costs and interest charges related to our convertible debentures which matured in June 2007 when all outstanding loan balances were paid.

### **Liquidity and Capital Resources**

Cash used in operating activities for the nine months ended September 30, 2008 was \$7,850,000 compared to \$12,007,000 for the same period in 2007. This reduction reflects lower expenditures primarily related to the preparation of our Ampligen® NDA which was finalized and filed with the FDA in October 2007. Cash used in operating activities in 2007 included the extensive costs of preparing the NDA. Cash provided by investing activities during the nine months ended September 30, 2007 and 2008 totaled \$7,293,000 and \$3,821,000, respectively, primarily due to the maturity of short term investments. We had proceeds from financing activities of \$150,000 during the nine months ended September 30, 2008. As of September 30, 2008, we had approximately \$7,592,000 in cash and cash equivalents and short-term investments, or a decrease of approximately \$7,823,000 from December 31, 2007.

We have been using the proceeds from financing to fund infrastructure growth including manufacturing, regulatory compliance and market development. Due to the current market conditions, we are unable to raise funds pursuant to the terms of the Fusion Capital Stock Purchase Agreement (see Equity Financing below). Based on our estimate, we anticipate that our existing funds should be sufficient to meet our operating cash requirements for approximately 10 months.

## **Equity Financing**

On July 2, 2008, we entered into a \$30 million Common Stock Purchase Agreement (the "Purchase Agreement") with Fusion Capital Fund II, LLC, an Illinois limited liability company. Concurrently with entering into the Purchase Agreement, we entered into a registration rights agreement with Fusion Capital. Under the registration rights agreement, we agreed to file a registration statement related to the transaction with the U.S. Securities & Exchange Commission ("SEC") covering the shares that have been issued or may be issued to Fusion Capital under the common stock purchase agreement. The SEC declared effective the registration statement on August 12, 2008. We have the right over a 25 month period to sell our shares of common stock to Fusion Capital from time to time in amounts between \$120,000 and \$1 million depending on certain conditions as set forth in the agreement, up to a maximum of \$30 million. The purchase price of the shares related to the \$30.0 million of future funding will be based on the prevailing market prices of our shares at the time of sales as computed under the Purchase Agreement without any fixed discount, and we will control the timing and amount of any sales of shares to Fusion Capital. Fusion Capital shall not have the right or the obligation to purchase any shares of our common stock on any business day that the price of our common stock is below \$0.40. Recently, the price of our common stock has consistently been below \$0.40 and, accordingly, no additional sales can be made to Fusion Capital unless and until the price rises to \$0.40 per share or better. The Purchase Agreement may be terminated by us at any time at our discretion without any cost to us. There are no negative covenants, restrictions on future funding, penalties or liquidated damages in the agreement. In consideration for entering into the Purchase Agreement, upon execution of the Purchase Agreement we issued to Fusion Capital 650,000 shares as a commitment fee. Also, we will issue to Fusion Capital up to an additional 650,000 shares as a commitment fee pro rata as we receive up to the \$30.0 million of future funding.

In August, 2008 we registered 21,300,000 shares pursuant to the terms of this agreement. Under the rules of the NYSE Alternext US (formerly, the American Stock Exchange), we may issue no more than 14,823,651 shares (19.99% of our outstanding shares as of July 2, 2008, the date of the purchase agreement) without first obtaining the approval of stockholders. We are currently seeking stockholder approval to issue the additional 6,476,349 shares. As of September 30, 2008, we have executed transactions pursuant the Fusion Capital Stock Purchase Agreement valued at \$150,000 and 258,522 shares.

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

In April 2006 we entered into a prior common stock purchase agreement with Fusion Capital, pursuant to which we sold an aggregate of 10,682,032 shares for total gross proceeds of approximately \$19,739,000 through November, 2007. This agreement expired on July 31, 2008.

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. In this regard we also have previously registered \$50,000,000 worth of our securities in a universal shelf registration statement, 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. 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 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 \$7,592,000 in cash and cash equivalents and short-term investments at September 30, 2008. To the extent that our cash and cash equivalents and short term investments exceed our near term funding needs, we generally invest the excess cash in three to twelve month interest bearing financial instruments. We employ established conservative policies and procedures to manage any risks with respect to investment exposure.

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 FDIC insurance limit.

We have not entered into, and do not expect to enter into, financial instruments for trading or hedging purposes.

### **Item 4: Controls and Procedures**

Our Chairman of the Board (serving as the principal executive officer) and the Chief Financial Officer performed an evaluation of the effectiveness of our disclosure controls and procedures, which have been designed to permit us to effectively identify and timely disclose important information. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the controls and procedures were effective as of September 30, 2008 to ensure that material information was accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

During the quarter ended September 30, 2008, 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**

In July 2008, we settled all outstanding legal issues with Bioclones (Proprietary), Ltd. and Ribotech (Pty), with no damages being paid by any of the parties, the termination of the 1994 agreement between us and Bioclones (Proprietary) Ltd. being confirmed and our retention of our equity position in Ribotech (Pty) Ltd. As a result of the settlement, we are in the process of dismissing Bioclones (Proprietary) Ltd. and Cyril Donniger from the multi-count complaint we filed in December 2004 in the Federal District Court in the Southern District of Florida which is now on appeal to the 11<sup>th</sup> Federal Circuit Court of Appeals. Also, as a result of the settlement, Bioclones (Proprietary) Ltd. is in the process of dismissing the arbitration proceeding it initiated against us in January 2007 in South Africa and we are in the process of dismissing the application we filed in January 2007 in South Africa for the dissolution of Ribotech (PTY), Ltd.

In June 2008, we settled the arbitration proceeding initiated in December 2007 by Laboratorios del Dr. Esteve, with both parties waiving all claims to damages and it being agreed that the March 2002 agreement between us and Laboratorios del Dr. Esteve has been terminated.

In July 2008, the arbitration proceeding initiated in March 2007 against us by Cedric Philipp (“Philipp”) was concluded with all claims against us by Philipp being denied.

See our Form 10-K for the period ending December 31, 2007 for previously reported legal proceedings.

#### **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 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 general use 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 U.S. and other countries, including, but not limited to, the FDA in the U.S., the Health Protection Branch (“HPB”) of Canada, and the Agency for the Evaluation of Medicinal Products (“EMA”) in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen® or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen® will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligen® is authorized for use in clinical trials including a cost recovery program in the United States 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.

We filed an NDA with the FDA for treatment of CFS on October 10, 2007. On December 5, 2007 we received an RTF letter from the FDA as our NDA filing was deemed “not substantially complete”. We responded to the FDA’s concerns by filing amendments to our NDA on April 25, 2008. These amendments should allow the FDA reviewers to better evaluate independently the statistical efficacy/safety conclusions of our NDA for the use of Ampligen® in treating CFS. On July 7, 2008 the FDA accepted our NDA filing for review. However, there are no assurances that upon review of the NDA that it will be approved by the FDA.

If 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.

***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 undergoing pre-clinical testing for possible treatment of avian flu. Although preliminary in vitro testing indicates that Ampligen® enhances the effectiveness of different drug combinations on avian flu, preliminary testing in the laboratory 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 Ampligen® in the treatment of avian flu requires prior regulatory approval. Only the FDA can determine whether a drug is safe, effective or promising for treating a specific application. As discussed in the prior risk factor, obtaining regulatory approvals is a rigorous and lengthy process.



In addition, Ampligen® is being tested on two strains of avian influenza virus. There are a number of strains and strains mutate. No assurance can be given that Ampligen® will be effective on any strains that might infect humans.

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

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses, as we pursued our clinical trial effort to get our experimental drug, Ampligen®, approved. As of September 30, 2008, our accumulated deficit was approximately \$194,572,000. 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.

***Our Alferon N Injection Commercial Sales have halted due to lack of finished goods inventory.***

Our finished goods inventory of Alferon N Injection® reached its current expiration date in March 2008. As a result, we have no product to sell at this time. The FDA has declined to respond to our requests for an extension of the expiration date, therefore we consider the request to be denied. Since our testing of the product indicates that it is not impaired and could be safely utilized, the finished goods inventory of 2,745 Alferon N Injection® 5ml vials may be used to produce approximately 11,000,000 sachets of Low Dose Oral Alferon (LDO) for future clinical trials.

Production of Alferon N injection® from our work-in-progress inventory, which has an approximate expiration date of 2012, has been put on hold at this time due to the resources needed to prepare our New Brunswick facility for the FDA preapproval inspection with respect to our Ampligen® NDA. Work on the Alferon N Injection® is expected to resume in mid-2009 under the condition that adequate funding is obtained, which means that we may not have any Alferon N Injection® product commercially available until 2010.

In 2007, we averaged Alferon N Injection® sales of approximately \$77,000 per month. With no FDA approval to extend the expiration date of our finished good inventory, we will not receive these monthly revenues. In addition, if there is a significant absence of the product from the market place, no assurance can be given that sales will return to prior levels.

***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 September 30, 2008, we had approximately \$7,592,000 in cash and cash equivalents and short-term investments. We anticipate based on our estimate, but cannot assure, that these funds will be sufficient to meet our operating cash requirements for the next 10 months.

We hope, but cannot assure, that we will be able to raise additional capital from the sale of shares under the Purchase Agreement. However, our ability to raise funds from sales under the Purchase Agreement is hampered by current adverse market conditions and our reduced stock price that has, for the most part, been under the \$0.40 minimum share price required by the Purchase Agreement. In addition, shares sold pursuant to the Purchase Agreement cannot exceed 19,99% of our shares outstanding as of July 2, 2008 without stockholder approval, which we are seeking to obtain at our November 11, 2008 Stockholder Meeting.

Assuming no material financing from the sale of securities to Fusion Capital and if we are unable to commercialize and sell Ampligen® and/or increase sales of Alferon N Injection® or our other products, we will need to secure other sources of funding through additional equity or debt financing or from other sources in order to satisfy our working capital needs and to complete the necessary clinical trials and the regulatory approval processes including the commercializing of Ampligen® products. In this regard we previously registered \$50,000,000 worth of our securities in a universal shelf registration statement, 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. 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.

***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®, which is carried out according to standard operating procedure manuals. We have been issued certain patents including those on the use of Ampligen® in combination with certain other drugs for the treatment of HIV. 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 such. 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.

***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-CFS includes licensing/co-marketing agreements utilizing the resources and capacities of a strategic partner(s). We are currently seeking worldwide marketing partner(s), with the goal of having a relationship in place before approval is obtained. In parallel to partnering discussions, appropriate pre-marketing activities will be undertaken. We intend to control manufacturing of Ampligen® on a worldwide 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. If we are unable to obtain the required raw materials, we may be required to scale back our operations or stop manufacturing 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 long-term agreements for the supply of any 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 polymers, we may be required to scale back our operations or stop manufacturing. 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.***

Small 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, and can, among other things, require new clinical studies and affect orphan drug status, particularly, market exclusivity rights, if any, under the Orphan Drug Act. 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, capable of being manufactured economically in commercial quantities or successfully marketed.

***We have limited manufacturing experience and capacity.***

Ampligen® has been only produced in limited quantities for use in our clinical trials and we are dependent upon a third party supplier for substantially all of the production 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 are not adequate for the production of our proposed products for large-scale commercialization, and we currently do not have adequate personnel to conduct commercial-scale manufacturing. 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 Practices (“cGMP”) regulations. 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. Please refer to Risk Factor “Our Alferon N Injection® sales have been halted due to lack of finished goods inventory”.

***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 pre-clinical 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 CFS in the United States. The dominant competitors with drugs to treat disease indications in which we plan to address include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs, GlaxoSmithKline, Merck and Schering-Plough Corp. 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 recently received 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% of patients treated in our various studies. This reaction is occasionally accompanied by a rapid heart beat, a tightness of the chest, urticaria (swelling of the skin), anxiety, shortness of breath, subjective reports of "feeling hot", sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by reducing the rate of infusion. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, transient visual disturbances, slow or irregular heart rate, decreases in platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills, fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months. One or more of the potential side effects might deter usage of Ampligen® in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

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

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

We face an inherent business risk of exposure to product liability claims in the event that the use of Ampligen® or other of our products results in adverse effects. This liability might result from claims made directly by patients, hospitals, clinics or other consumers, or by pharmaceutical companies or others manufacturing these products on our behalf. Our future operations may be negatively affected from the litigation costs, settlement expenses and lost product sales inherent to these claims. While we will continue to attempt to take appropriate precautions, we cannot assure that we will avoid significant product liability exposure. Although we currently maintain product liability insurance coverage, there can be no assurance that this insurance will provide adequate coverage against Ampligen® and/or Alferon N Injection® product liability claims. A successful product liability claim against us in excess of Ampligen's® \$1,000,000 in insurance coverage; \$3,000,000 in aggregate, or in excess of Alferon N Injection's® \$5,000,000 in insurance coverage; \$5,000,000 in aggregate; or for which coverage is not provided could have a negative 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 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 Dr. Carter's services could have a material adverse effect on our operations and chances for success. We have secured key man life insurance in the amount of \$2,000,000 on the life of Dr. Carter and we have an employment agreement 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 personnel or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

***Uncertainty of health care reimbursement for our products.***

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

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

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

**Risks Associated With an Investment in Our Common Stock**

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

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

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness 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 Alternext US (formerly, the American Stock Exchange). For the 12-month period ended September 30, 2008, the closing price of our common stock has ranged from \$0.33 to \$2.00 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

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. If we face securities litigation in the future, even if without merit or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

***The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by Fusion Capital could cause the price of our common stock to decline.***

In connection with entering into the Purchase Agreement with Fusion Capital in August 2008, we registered 21,300,000 shares in the aggregate, consisting of 20,000,000 shares which we may sell to Fusion Capital and 1,300,000 shares we have issued or may issue to Fusion Capital as Commitment Shares. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the agreement. The purchase price for the common stock to be sold to Fusion Capital pursuant to the Purchase Agreement will fluctuate based on the price of our common stock. Under the rules of the NYSE Alternext US (formerly, the American Stock Exchange), we may issue more than 14,823,651 shares (19.99% of our outstanding shares as of July 2, 2008, the date of the purchase agreement) without first obtaining the approval of stockholders. We are currently seeking stockholder approval to issue the additional 6,476,349 shares. It is anticipated that shares registered will be sold over a period of up to 25 months after the registration statement is declared effective. Depending upon market liquidity at the time, a sale of shares by Fusion Capital at any given time could cause the trading price of our common stock to decline. Fusion Capital may ultimately purchase all, some or none of the 20,000,000 shares of common stock to be registered but not yet issued. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Fusion Capital by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock By Fusion Capital, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Fusion Capital and the agreement may be terminated by us at any time at our discretion without any cost to us.

In addition to the 21,300,000 shares registered for Fusion Capital, we have previously registered 135% of 3,615,514 shares issuable upon exercise of Warrants related to our former convertible debentures and 14,442,294 shares issuable upon exercise of certain other warrants. To the extent the exercise price of the 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 conversion price and exercise price of these securities are adjusted pursuant to anti-dilution protection, the securities 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 previously registered \$50,000,000 worth of our securities in a universal shelf registration statement, 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 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 and, under the 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 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 7.7% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at \$.01 per Right under certain circumstances.

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

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

During the quarter ended September 30, 2008, we issued an aggregate of 363,951 shares 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.

We did not repurchase any of our securities during the quarter ended September 30, 2008.

## **ITEM 3: Defaults upon Senior Securities**

None.

## **ITEM 4: Submission of Matters to a Vote of Security Holders**

As a result of not attaining the required quorum of stockholders eligible to vote at our Annual Meeting of Stockholders initially held on September 17, 2008, and at the initial adjournment of that meeting on October 17, 2008, the meeting has been adjourned to November 11, 2008 at the Crowne Plaza Hotel in Philadelphia. Stockholders' will be voting on various matters at this meeting. At the October 17, 2008 meeting, shares representing approximately 48.5% of eligible votes were present, however a quorum required in excess of 50%. A significant number of stockholders are domiciled in Europe and less readily accessible for notification purposes. To assure that the meeting can be held, our Board of Directors has amended our By-Laws to reduce the quorum for the meeting from a majority to 44% in voting power of the outstanding shares of stock entitled to vote at the meeting. The reduced quorum relates solely to the 2008 Annual Stockholders' Meeting of November 11, 2008. The Company will continue to solicit proxies in an attempt to receive votes from a majority of the shares eligible to vote at the meeting.

**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

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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/ Robert E.  
Peterson  
Robert E. Peterson  
Chief Financial  
Officer

Date: November 10, 2008

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