

HEMISPHERX BIOPHARMA INC  
Form 10-Q  
November 07, 2007

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, 2007

Commission File Number: 0-27072

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

Delaware  
(State or other jurisdiction of  
incorporation or organization)

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

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

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

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

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

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

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

73,620,007 shares of common stock were issued and outstanding as of November 1, 2007.

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**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, 2006	September 30, 2007 (unaudited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 3,646	\$ 6,564
Short term investments (Note 4)	18,375	11,290
Inventory, net	957	627
Accounts and other receivables, net of reserves of \$1 and \$1, respectively	93	132
Asset held for sale (Note 7)	-	610
Prepaid expenses and other current assets	168	73
Total current assets	23,239	19,296
Property and equipment, net	4,720	4,852
Patent and trademark rights, net	857	902
Construction in progress	624	298
Royalty interest	601	557
Deferred financing costs	38	-
Advance receivable (Note 5)	1,300	-
Other assets	52	52
Total assets	\$ 31,431	\$ 25,957
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,548	\$ 1,781
Accrued expenses	1,261	882
Current portion of long-term debt (Note 5)	3,871	-
Total current liabilities	6,680	2,663
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value \$0.01 per share, authorized 5,000,000; issued and outstanding; none	-	-
Common stock, par value \$0.01 per share, authorized 200,000,000 shares; issued and outstanding 66,816,764 and 72,823,139 respectively	67	73
Additional paid-in capital	191,689	204,637
Accumulated other comprehensive income	46	378
Accumulated deficit	(167,051)	(181,794)
Total stockholders' equity	24,751	23,294
Total liabilities and stockholders' equity	\$ 31,431	\$ 25,957

See accompanying notes to condensed 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,	
	2006	2007
<b>Revenues:</b>		
Sales of product net	\$ 189	\$ 251
Clinical treatment programs	43	34
<b>Total revenues</b>	<b>232</b>	<b>285</b>
<b>Costs and expenses:</b>		
Production/cost of goods sold	308	216
Research and development	2,512	2,740
General and administrative	1,276	3,508
<b>Total costs and expenses</b>	<b>4,096</b>	<b>6,464</b>
Reversal of previously accrued interest expense	-	346
Interest and other income and expense	356	119
Interest expense	(164)	-
Financing costs (Note 5)	(135)	(4)
<b>Net loss</b>	<b>\$ (3,807)</b>	<b>\$ (5,718)</b>
<b>Basic and diluted loss per share (Note 2)</b>	<b>\$ (.06)</b>	<b>\$ (.08)</b>
<b>Weighted average shares outstanding, basic and diluted</b>	<b>62,570,061</b>	<b>72,818,720</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,	
	2006	2007
<b>Revenues:</b>		
Sales of product net	\$ 569	\$ 667
Clinical treatment programs	146	107
<b>Total revenues</b>	<b>715</b>	<b>774</b>
<b>Costs and expenses:</b>		
Production/cost of goods sold	1,005	767
Research and development	7,530	8,450
General and administrative	6,454	6,834
<b>Total costs and expenses</b>	<b>14,989</b>	<b>16,051</b>
Reversal of previously accrued interest expense	-	346
Interest and other income and expense	516	584
Interest expense	(574)	(116)
Financing costs (Note 5)	(475)	(280)
<b>Net loss</b>	<b>\$ (14,807)</b>	<b>\$ (14,743)</b>
<b>Basic and diluted loss per share (Note 2)</b>	<b>\$ (.24)</b>	<b>\$ (.21)</b>
<b>Weighted average shares outstanding, basic and diluted</b>	<b>60,935,372</b>	<b>71,293,392</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, 2006	66,816,764	\$ 67	\$ 191,689	\$ 46	\$(167,051)	\$ 24,751
Interest payments	116,745	-	193	-	-	193
Private placement, net of issuance costs	5,750,530	6	10,264	-	-	10,270
Stock issued for settlement of accounts payable	139,100	-	229	-	-	229
Equity based compensation	-	-	2,262	-	-	2,262
Net comprehensive income (loss)	-	-	-	332	(14,743)	(14,411)
Balance at September 30, 2007	72,823,139	\$ 73	\$ 204,637	\$ 378	\$(181,794)	\$ 23,294

See accompanying notes to consolidated financial statements.

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

For the Nine Months Ended September 30, 2006 and 2007

**(in thousands)**

(Unaudited)

	2006	2007
<b>Cash flows from operating activities:</b>		
Net loss	\$ (14,807)	\$ (14,743)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation of property and equipment	131	192
Amortization of patent and trademark rights, and royalty interest	125	125
Financing cost related to debt discounts	475	281
Equity based compensation	2,286	2,262
Common stock issued in payment of interest expense	101	181
<b>Increase (decrease) in assets and liabilities:</b>		
Inventory	676	330
Accounts and other receivables	(183)	(203)
Asset held for sale	-	(610)
Prepaid expenses and other current assets	54	95
Accounts payable	1,505	462
Accrued expenses	309	(379)
Net cash used in operating activities	\$ (9,328)	\$ (12,007)
<b>Cash flows from investing activities:</b>		
Purchase of property plant and equipment	\$ (1,266)	\$ 2
Additions to patent and trademark rights	(47)	(126)
Maturity of short term investments	12,548	10,220
Purchase of short term investments	(14,481)	(2,803)
Net cash provided by (used in) investing activities	\$ (3,246)	\$ 7,293

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

For the Nine Months Ended September 30, 2006 and 2007

**(in thousands)**

(Unaudited)

	2006	2007
Cash flows from financing activities:		
Payment of long-term debt	\$ -	\$ (4,102)
Collection of advance receivable	-	1,464
Proceeds from exercise of stock warrants	672	-
Proceeds from sale of stock, net of issuance costs	12,593	10,270
Net cash provided by financing activities	\$ 13,265	\$ 7,632
Net increase in cash and cash equivalents	691	2,918
Cash and cash equivalents at beginning of period	3,827	3,646
Cash and cash equivalents at end of period	\$ 4,518	\$ 6,564
Supplemental disclosures of non-cash investing and financing cash flow information:		
Issuance of common stock for accounts payable and accrued expenses	\$ 209	\$ 229
Issuance of common stock for debt conversion and debt payments	\$ 834	\$ -
Issuance of common stock for patents and royalty interest	\$ 770	\$ -
Unrealized gains on investments	\$ 79	\$ 332
Supplemental disclosure of cash flow information:		
Cash paid during the year for interest	\$ 145	\$ -

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, 2006, as filed with the SEC on March 19, 2007.

**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 26,693,497 and 17,456,937 shares, are excluded from the calculation of diluted net loss per share for the nine months ended September 30, 2006 and 2007, 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,	
	2006	2007
Risk-free interest rate	4.3% - 4.97%	4.0 - 4.90%
Expected dividend yield	-	-
Expected lives	2.5-5 yrs	5 yrs
Expected volatility	72.06%-79.3%	71.64 - 77.57%
Weighted average grant date fair value of options and warrants issued	\$ 2,197,000	\$ 2,238,000

Stock option activity during the nine months ended September 30, 2007, 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	2,504,120		2.84	9.98
Options forfeited	(411)		-	-
Outstanding September 30, 2007	4,505,678		2.69	8.88
Exercisable September 30, 2007	4,376,692		2.71	6.36

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

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	15,000		1.78	10.00
Options forfeited	-		-	-
Outstanding September 30, 2007	128,986	\$ 2.20	8.94	-

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	583,750	\$ 2.02	10.00	
Options forfeited	-		-	-
Outstanding September 30, 2007	1,910,482	\$ 2.44	8.56	-

Exercisable September 30, 2007	1,873,382	\$	2.46	8.66	-
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The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2007 was \$413,000.

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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	-	-	-	
Options forfeited	-	-	-	-
Outstanding September 30, 2007	37,100	\$ 2.28	9.31	-

The impact on the Company's results of operations of recording equity based compensation for the nine months ended September 30, 2007 was to increase general and administrative expenses by approximately \$2,262,000 and reduce earnings per share by \$0.03 per basic and diluted share.

As of September 30, 2007, there was \$80,000 of unrecognized equity based compensation cost related to options granted under the Equity Incentive Plan. Shares issued upon the exercising of stock options are to be issued from previously authorized shares within the Company's Equity Incentive Plan.

#### Note 4: SHORT TERM INVESTMENTS

Securities classified as available for sale consisted of:

Name of Security	September 30, 2007			
	Cost	Market Value	Unrealized Gain	Maturity Date
FHLMC	\$ 1,051,000	\$ 1,093,000	\$ 42,000	November, 2007
FHLMC	960,000	998,000	38,000	October, 2007
FNMA	800,000	828,000	28,000	December, 2007
FNMA	3,000,000	3,110,000	110,000	November, 2007
FHLMC	3,099,000	3,209,000	110,000	December, 2007
HSBC Finance	1,004,000	1,030,000	26,000	December, 2007
General Electric	98,000	1,022,000	24,000	December, 2007
	\$ 10,912,000	\$ 11,290,000	\$ 378,000	

December 31, 2006

Name of security	Cost	Market Value	Unrealized Gain (Loss)	Maturity Date
AIG Discount Commercial	\$ 972,000	\$ 983,000	\$ 11,000	April, 2007
Natexis Banques Popolare	969,000	979,000	10,000	May, 2007
American General Finance	965,000	974,000	9,000	June, 2007
Daimler Chrysler	965,000	974,000	9,000	June, 2007
LaSalle Bank	965,000	974,000	9,000	June, 2007
General Electric	1,240,000	1,242,000	2,000	July, 2007
HSBC Finance	1,000,000	1,000,000	-	August, 2007
American General Finance	976,000	987,000	11,000	September, 2007
General Electric	965,000	974,000	9,000	September, 2007
General Electric	1,202,000	1,200,000	(2,000)	September, 2007
FHLMC	960,000	960,000	-	October, 2007
FHLMC	1,051,000	1,051,000	-	November, 2007
FNMA	3,000,000	2,991,000	(9,000)	November, 2007
FHLMC	3,099,000	3,086,000	(13,000)	December, 2007
	\$ 18,329,000	\$ 18,375,000	\$ 46,000	

No investment securities were pledged to secure public funds at September 30, 2007 and December 31, 2006, respectively.

The table below indicates the length of time individual securities have been in a continuous unrealized loss position at September 30, 2007 and December 31, 2006.

September 30, 2007

Name of Security	Number of Securities	Less Than 12 Months		12 Months Or Longer		Total	
		Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
FHLMC	1	\$1,093,000	\$ -	\$ -	\$ -	\$1,093,000	\$ -
FHLMC	1	998,000	-	-	-	998,000	-
FNMA	1	828,000	-	-	-	828,000	-
FNMA	1	3,110,000	-	-	-	3,110,000	-
FHLMC	1	3,209,000	-	-	-	3,209,000	-
HSBC Finance	1	1,030,000	-	-	-	1,030,000	-
General Electric	1	1,022,000	-	-	-	1,022,000	-
Total Temporary Impairment Securities	-	-	-	-	-	-	-
	7	\$ 11,290,000	\$ -	\$ -	\$ -	\$ 11,290,000	\$ -

December 31, 2006

Less than 12 months      12 months or longer      Total

Name of Security	Number of Securities	Less than 12 months		12 months or longer		Total	
		Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
AIG Discount Commercial	1	\$ 983,000	\$ -	\$ -	\$ -	\$ 983,000	\$ -
Natexis Banques Popolare	1	979,000	-	-	-	979,000	-
American General Finance	1	974,000	-	-	-	974,000	-
Daimler Chrysler	1	974,000	-	-	-	974,000	-
LaSalle Bank	1	974,000	-	-	-	974,000	-
General Electric	1	1,242,000	-	-	-	1,242,000	-
HSBC Finance	1	1,000,000	-	-	-	1,000,000	-
American General Finance	1	987,000	-	-	-	987,000	-
General Electric	1	974,000	-	-	-	974,000	-
General Electric	1	1,200,000	(2,000)	-	-	1,200,000	(2,000)
FHLMC	1	960,000	-	-	-	960,000	-
FHLMC	1	1,051,000	-	-	-	1,051,000	-
FNMA	1	2,991,000	(9,000)	-	-	2,991,000	(9,000)
FHLMC	1	3,086,000	(13,000)	-	-	3,086,000	(13,000)
Total Temporary Impairment Securities	14	\$ 18,375,000	\$ (24,000)	\$ -	\$ -	\$ 18,375,000	\$ (24,000)

In management's opinion, the unrealized losses reflect changes in interest rates subsequent to the acquisition of specific securities. The Company has the ability to hold these securities until maturity or market price recovery. Management believes that the unrealized losses represent temporary impairment of the securities.

#### 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)	
	2006	2007	2006	2007
	Unrealized gains (losses) during the period	\$ 136	\$ 180	\$ 300
Realized loss (gains) during the period	(191)	(118)	(105)	(339)
Other comprehensive income(loss)	\$ (55)	\$ 62	\$ 195	\$ 332

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

**Note 5: DEBENTURE FINANCING**

Long term debt consists of the following:

	(in thousands)	
	December 31, 2006	September 30, 2007
October 2003	\$ 2,071	\$ -
January 2004	1,031	-
July 2004	1,000	-
<b>Total</b>	<b>4,102</b>	<b>-</b>
Less Discounts	(231)	-
<b>Total</b>	<b>3,871</b>	<b>-</b>
Less current portion	3,871	-
<b>Long term debt</b>	<b>\$ -</b>	<b>\$ -</b>

In June 2007, the Company retired all remaining debt related to its convertible debentures issued in October 2003, January 2004 and July 2004. Of the outstanding debt of approximately \$4,102,000, only \$2,638,000 was required to be paid in new funds to retire the debentures, with the balance being covered by the Company's advance receivable held as collateral by one of the debenture holders.

**October 2003 Debentures**

The discount on the October 2003 Debentures was fully amortized; therefore, the Company did not record any financing costs for the three and nine months ended September 30, 2006 and 2007, respectively. Interest expense for the three months ended September 30, 2006 and 2007, with regard to the October 2003 Debentures was approximately \$37,000 and \$0, respectively. For the nine months ended September 30, 2006 and 2007, interest expense related to these debentures was \$108,000 and \$72,000, respectively.

**January 2004 Debentures**

The discount on the January 2004 Debentures was fully amortized; therefore, the Company did not record financing costs for the three months ended September 30, 2006 and 2007, respectively. Financing costs for the nine months ended September 30, 2006 and 2007, was approximately \$49,000 and \$0, respectively. Interest expense for the three months ended September 30, 2006 and 2007, with regard to the January 2004 Debentures was approximately \$7,000 and \$0, respectively. For the nine months ended September 30, 2006 and 2007, interest expense related to these debentures was \$59,000 and \$9,000, respectively.

**July 2004 Debentures**

The Company recorded financing costs for the three months ended September 30, 2006 and 2007, with regard to the July 2004 Debentures of \$116,000 and \$0 respectively. For the nine months ended September 30, 2007, the Company recorded financing costs of \$369,000 and \$231,000, respectively. Interest expense for the three months ended September 30, 2006 and 2007, with regard to the July 2004 Debentures was approximately \$16,000 and \$0, respectively. For the nine months ended September 30, 2006 and 2007, interest expense related to these debentures was \$87,000 and \$35,000, respectively.





**NOTE 6: EQUITY FINANCING**

For the nine months ended September 30, 2007, Fusion Capital has purchased from the Company 5,750,530 shares for aggregate gross proceeds of approximately \$10,270,000 pursuant to the April 2006 common stock purchase agreement between the Company and Fusion Capital.

**NOTE 7: 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. The Company reevaluated its manufacturing needs and determined the installation of a purified water system would not be cost effective; therefore, the Company plans to sell this equipment and reclassified this as an asset held for sale. In addition, the Company recorded an impairment charge of \$68,000 to bring the carrying value of the asset to its net realizable value of \$610,000 as of September 30, 2007 as per SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets".

**NOTE 8: RECENT ACCOUNTING PRONOUNCEMENTS**

The Company adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48") effective January 1, 2007. The purpose of FIN 48 is to clarify and set forth consistent rules for accounting for uncertain tax positions in accordance with Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes". The cumulative effect of applying the provisions of this interpretation are required to be reported separately as an adjustment to the opening balance of retained earnings in the year of adoption. The adoption of this standard did not have an impact on the financial condition or the results of our operations.

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 impact of this statement has not been determined.

#### **NOTE 9: SUBSEQUENT EVENT**

On October 10, 2007, we filed a New Drug Application with the FDA for using Ampligen® to treat Chronic Fatigue Syndrome.

#### **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 and marketing of new drug entities based on natural immune system enhancing technologies for the treatment of viral and immune based acute and chronic disorders. We were founded in the early 1970s, as a contract researcher 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 acute and chronic diseases. We own a U.S. Food and Drug Administration ("FDA") approved GMP (good manufacturing practice) manufacturing facility in New Jersey. Our flagship products include Ampligen® and Alferon N Injection®.

Ampligen® is an experimental drug currently undergoing clinical development for the treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (“ME/CFS” or “CFS”), and clinical testing for treatment/prevention of avian and seasonal influenza. We have completed Phase III clinical trials using Ampligen® to treat ME/CFS patients. On October 10, 2007, we filed a New Drug Application with the FDA for using Ampligen to treat CFS.

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 (“WNV”).

### **New Accounting Pronouncements**

We adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48") effective January 1, 2007. The purpose of FIN 48 is to clarify and set forth consistent rules for accounting for uncertain tax positions in accordance with Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes". The cumulative effect of applying the provisions of this interpretation are required to be reported separately as an adjustment to the opening balance of retained earnings in the year of adoption. The adoption of this standard did not have an impact on our financial condition or the results of our operations.

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 impact of this statement has not been determined.

**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, 2006.

**RESULTS OF OPERATIONS**

**Three months ended September 30, 2006 versus three months ended September 30, 2007**

**Net loss**

Our net loss of approximately \$5,718,000 for the three months ended September 30, 2007 was \$1,911,000 higher when compared to the same period in 2006. This increase in loss was primarily due to the combination of:

- 1) Higher General & Administrative expenses of \$2,232,000 principally related to an increase in non-cash equity based compensation;
- 2) Higher Research and Development costs of approximately \$228,000 due to the use of outside consultants related to the filing of our NDA for Ampligen®;
- 3) An increase of \$346,000 in other income due to a reversal of accrued liquidated damages in 2006 with respect to our debentures as a result of our failure to timely file our 2005 Annual 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; and
- 4) Lower interest expense and financing costs of \$295,000 relating to the amortization of debt discounts on our convertible debentures.

Net loss per share was \$0.08 for the current period versus \$0.06 for the same period in 2006.

**Revenues**

Revenues for the three months ended September 30, 2007 were \$285,000 as compared to revenues of \$232,000 for the same period in 2006. Ampligen® sold under the cost recovery clinical program was down \$9,000 or 21% and Alferon N Injection® sales increased \$62,000 or 33% as compared to the prior period. Ampligen® sold under the cost recovery clinical program is a product of physicians and ME/CFS patients applying to us to enroll in the program. This program has been in effect for several years and is offered as a treatment option to patients severely affected by CFS. As the name "cost recovery" implies, we have no gain or profit on these sales. The benefits to us include 1) physicians and patients becoming familiar with Ampligen® and 2) collection of clinical data relating to the patients' treatment and results. We altered our marketing strategy for Alferon N Injection® by relaunching the product via a collaborative marketing initiative between Hemispherx and a national Specialty Pharmacy network encompassing specialty pharmacists, pharmacies and targeted physician specialists. This effort was intended to focus our efforts in the most appropriate and productive market segment for the product. This initiative has had a positive impact on Alferon® revenues in the current quarter.



**Production costs/cost of goods sold**

Production/cost of goods sold decreased approximately \$92,000 or 30% for the three months ended September 30, 2007 compared to the same period in 2006. This decrease was primarily due to: 1) lower production costs of approximately \$40,000 relating to excess production capacity during the prior period as more effort was directed toward Ampligen® research and development and 2) a decrease in costs of goods sold of approximately \$51,000. Cost of goods sold for the three months ended September 30, 2006 and 2007 were \$161,000 and \$121,000, respectively. The primary reason for this decrease in cost of goods sold with a corresponding increase in sales can be attributed to a price increase per vial of Alferon N Injection® coupled with a decrease in the number of vials sold during the current period.

**Research and Development costs**

Overall research and development costs for the three months ended September 30, 2007 were \$2,740,000 as compared to \$2,512,000 for the same period a year ago representing an increase of \$228,000 or 9%. This increase was primarily due to higher outside consulting fees related to the preparation and filing of our NDA for Ampligen®.

Our research and development costs include the direct cost associated with our effort to develop our experimental compound, Ampligen®, as a therapy in treating acute and chronic diseases. In addition to the costs related to the collection and processing of clinical data, our current expenditures include the costs of establishing our in-house polymer production facility and costs related to preparation and completion of our NDA for the use of Ampligen® in treating CFS.

On October 10, 2007, we filed our NDA with the Food and Drug Administration for using Ampligen® in the treatment of CFS. This filing covers some 1,200 enrolled subjects and approximately 90,000 doses of Ampligen®. There is currently no approved treatment for CFS, which affects over one million people in the United States according to the Centers for Disease Control and Prevention (“CDC”). CFS is a debilitating disease with symptoms consisting of extreme fatigue, short term memory impairment, tender lymph nodes, muscle and joint pain and unrefreshed sleep. Symptom severity varies between patients. According to the CDC, there are no specific diagnostic tests available. Over its developmental history Ampligen® has received various designations including Orphan Drug Product Designation and Emergency (compassionate) Cost Recovery Sales Authorization from the FDA. Pursuant to the mutual recognition procedure we plan to proceed with filing New Drug Applications in the European Union.

We are actively engaged in broad-based experimental studies assessing the efficacy of our products, Ampligen®, Alferon N Injection® and Alferon® LDO against influenza viruses as an adjuvant and/or single agent antiviral with the Defence R&D Canada, the National Institute of Infectious Disease in Tokyo and various research affiliates of the National Institutes of Health in the United States. Articles have recently appeared in the peer-reviewed medical and scientific literature.

In September 2007, Japan's National Institute of Infectious Disease ("JNIID") initiated research on the co-administration of JNIID's HIV-1 vaccine with our experimental TLR3 agonist (a substance that binds to a specific receptor and triggers a host defense response in the cell) and immune enhancer, Ampligen®. This research is the result of earlier research suggesting a potential role for Ampligen® in boosting responses to certain vaccines designed to combat avian influenza (Bird Flu) as well as seasonal influenza viruses. The objective of this research is to determine if Ampligen® can overcome the historical problem which has handicapped AIDS vaccine development, namely marginal immune response which undermines the potential of long-lasting protection. Ampligen® will be combined with HIV recombinant protein and administered via an intranasal route.

In October 2007, JNIID published, in two peer reviewed journals, the results of their studies to evaluate the ability of current seasonal influenza vaccine to confer cross-protection against highly pathogenic H5N1 influenza (Bird Flu) virus in mice. These studies indicate that, as a vaccine enhancer co-administered with their seasonal trivalent influenza vaccine, Ampligen® helps induce a protective effect against H5N1 influenza viruses. As such, Ampligen® as a toll-like receptor 3 agonist may aid in overcoming the problems protecting against mutated strains of the H5N1 virus and of limited supplies of H5N1 virus vaccines. Additional studies to support this conclusion are planned.

In April 2007, Japan's Ministry of Health, Labor and Welfare (MHLW) issued authorization to its National Institute of Infectious Diseases (NIID) approving their budget to advance studies indicating that an H5N1 influenza vaccine co-administered intranasally with Hemispherx's experimental therapeutic, Ampligen® protected against mutated strains of the virus and, further that, the seasonal trivalent influenza vaccine co-administered intranasally with Ampligen® maintained efficacy even when challenged with the H5N1 influenza virus.

In June 2007, we initiated a clinical trial in Australia using Ampligen® in combination with seasonal flu vaccine. This trial, expected to continue for several months, is being conducted in Australia's winter season and focuses on populations at risk for virulent cases of influenza, especially those over the age of 60 years who historically may have weakened immune systems. The Australian clinical trial was prompted by the results from the pre-clinical work conducted by the JNIID (see above). Thirty patients are anticipated to be enrolled in this study, which will utilize a two dose Ampligen® regimen of 2 mg per dose. 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. Prospective patients are being screened to be included in the clinical trial.

The Center for Disease Control and Prevention reports that the number of mosquito-borne West Nile Virus ("WNV") infections in the United States is "up sharply" over the same period in 2006. This increased infection rate has accelerated the enrollment of patients in our Phase IIb clinical trial using Alferon N™ to treat WNV patients. In lab studies, Alferon N™, a natural cocktail of eight alpha-interferons, shows synergistic effects (up to 100 fold over recombinant interferons) against pathogens such as WNV. The Phase IIb clinical trial is a double-blinded, randomized, multi-center program under the direction of Cornell University and Weill Cornell Medical College/New York Hospital.

### **General and Administrative Expenses**

General and Administrative (“G&A”) expenses for the three months ended September 30, 2006 and 2007 were approximately \$1,276,000 and \$3,508,000, respectively, reflecting an increase of \$2,232,000 or 175%. This rise related primarily to an increase in non-cash equity based compensation of \$2,074,000 compared to the same period in 2006 as stock options were granted to officers and directors in the current period which replaced options that had previously expired.

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

Reversal of previously accrued interest expense was \$346,000 for the three months ended September 30, 2007. This 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 Securities and Exchange Commission (“SEC”) pursuant to the Securities Exchange Act of 1934 (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 and Expense**

Interest and other income and expense for the three months ended September 30, 2006 and 2007 decreased approximately \$237,000 as compared to the same period a year earlier. The decrease in interest and other income during the current period can primarily be attributed to higher interest realized on the maturity of our marketable securities in the prior period. All funds in excess of our immediate need are invested in short-term securities. In addition, we recorded an impairment charge of \$68,000 on an asset that was reclassified as an asset held for sale during the current period. The asset related to equipment purchases for the installation of a purified water system at our manufacturing facility. We re-evaluated our manufacturing needs and determined this installation would not be cost effective; therefore, we classified this equipment as an asset held for sale and adjusted the carrying value of this asset to its net realizable value.

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

Interest expense and non-cash financing costs were approximately \$4,000 for the three months ended September 30, 2007 versus \$299,000 for the same period a year ago. The main reason for the decrease in interest expense and financing costs of \$295,000 can be attributed to the incurring of liquidated damages in 2006 payable to our debenture holders resulting from our failure to timely file our 2005 Annual Report on Form 10-K.

Nine months ended September 30, 2006 versus nine months ended September 30, 2007

### **Net loss**

Our net loss of approximately \$14,743,000 for the nine months ended September 30, 2007 was slightly lower when compared to the same period in 2006. This \$64,000 reduction in loss was primarily due to the combination of:

- 1) Higher Research and Development costs of \$920,000 primarily due to an increase in the use of outside consultants related to the preparation and completion of our NDA for the use of Ampligen® in treating CFS;



- 2) Lower interest expense and financing costs of \$653,000 relating to the amortization of debt discounts on our convertible debentures and the incurring of liquidated damages in 2006 payable to our debenture holders resulting from us failing to timely file our 2005 Annual Report on Form 10-K; and
- 3) An increase of \$346,000 in other income due to a reversal of accrued liquidated damages in 2006 with respect to our debentures holders as a result of our failure to timely file our 2005 Annual 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 \$0.21 for the current period versus \$0.24 for the same period in 2006.

### **Revenues**

Revenues for the nine months ended September 30, 2007 were \$774,000 as compared to revenues of \$715,000 for the same period in 2006. Ampligen® sold under the cost recovery clinical program was down \$39,000 or 27% while Alferon N Injection® sales were up \$98,000 or 17% to \$667,000 during the current period. The increase in Alferon N Injection® sales was due to a price increase instituted this year. Correspondingly, we have experienced a decline in the number of vials sold during the current quarter versus the same period a year ago as we continue to evidence increased competition from rival products.

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

Production/cost of goods sold was approximately \$767,000 during the current period representing a decrease of approximately \$238,000 or 24% as compared to the same period in 2006. This decrease was primarily due to lower production costs of \$117,000 relating to excess production capacity during the prior period as more effort was directed toward Ampligen® research and development and the NDA; and a decrease in costs of goods sold of \$121,000. Costs of goods sold for the nine months ended September 30, 2006 and 2007 was \$394,000 and \$273,000, respectively.

### **Research and Development costs**

Overall research and development costs for the nine months ended September 30, 2007 were \$8,450,000 as compared to \$7,530,000 for the same period a year ago representing an increase of \$920,000 or 12%. These costs are primarily related to the collection and processing of clinical data, including the costs of establishing our in-house polymer production facility and the costs of preparing and completing our NDA for the use of Ampligen® in treating CFS. The increase can be attributed to an increase in the use of consultants related to the above areas.

### **General and Administrative Expenses**

General and Administrative ("G&A") expenses for the nine months ended September 30, 2006 and 2007 were approximately \$6,454,000 and \$6,834,000, respectively, reflecting an increase of \$380,000 or 6%. This increase related primarily to an increase in directors' fees, legal expenses and regulatory filing fees as well as increases in salaries and wages mainly resulting from the hire of our chief operating officer during the 4<sup>th</sup> quarter 2006.

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

Reversal of previously accrued interest expense was \$346,000 for the nine months ended September 30, 2007. This 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 and Expense**

Interest and other income and expense for the nine months ended September 30, 2006 and 2007 increased approximately \$68,000 as compared to the same period a year earlier. The increase in interest and other income during the current period was mainly due to higher interest earned upon the maturity of our marketable securities as compared the same period a year ago. This was offset by an impairment charge of \$68,000 recorded in the current period upon the reclassification of equipment to an asset held for sale. We wrote down the carrying value of the equipment to our net realizable value as of September 30, 2007.

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

Interest expense and non-cash financing costs were approximately \$396,000 for the nine months ended September 30, 2007 versus \$1,049,000 for the same period a year ago. The main reason for the decrease in interest expense and financing costs of \$653,000 or 62% can be attributed to decreased amortization charges on debt discounts and the incurring of liquidated damages in 2006 payable to our debenture holders resulting from our failure to timely file our 2005 Annual Report on Form 10-K as we were in violation of provisions within our debenture agreements.

### **Liquidity and Capital Resources**

Cash used in operating activities for the nine months ended September 30, 2007 was \$12,007,000. Cash provided by investing activities for the nine months ending September 30, 2007, amounted to \$7,293,000, primarily from the maturity and purchase of short-term investments. Cash provided by financing activities for the nine months ended September 30, 2007 amounted to \$7,632,000. This was primarily due to proceeds received from the sale of our common stock of approximately \$10,270,000. This was offset by the net repayment of our outstanding debt of \$2,638,000 in June 2007. As of October 31, 2007, we had approximately \$17,400,000 in cash and cash equivalents and short-term investments, or a decrease of approximately \$4,621,000 from December 31, 2006. We anticipate that these funds should be sufficient to meet our operating cash requirements for the next 14 months.

In June 2007, we retired all remaining debt related to our convertible debentures issued in October 2003, January 2004 and July 2004. Of the outstanding debt of approximately \$4,102,000, only \$2,638,000 was required to be paid in new funds to retire the debentures, with the balance being covered by other cash and securities already held as collateral for the debentures.

### **Equity Financing**

On April 12, 2006, we entered into a common stock purchase agreement (the “2006 Purchase Agreement”) with Fusion Capital Fund II, LLC (“Fusion Capital”), pursuant to which Fusion Capital has agreed, under certain conditions, to purchase on each trading day \$100,000 of our common stock up to an aggregate of \$50.0 million over a period of approximately 25 months. Pursuant to the terms of the Registration Rights Agreement, dated as of April 12, 2006, we registered 12,386,723 shares issuable to or issued to Fusion Capital under the Purchase Agreement. Through November 1, 2007, we have sold to Fusion Capital an aggregate of 10,539,112 shares under the common stock purchase agreement for aggregate gross proceeds of \$19,529,128 and issued 447,465 Commitment Shares.

Under the rules of the American Stock Exchange, in the event that we elect to sell more than 12,386,723 shares to Fusion Capital, we were required to seek stockholder approval. This approval was obtained on September 20, 2006. We also will be required to file a new registration statement and have

it declared effective by the SEC in the event we elect to sell to Fusion Capital more than the 12,386,723 shares previously registered.

We are using the proceeds from this financing for general corporate purposes.

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. 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 \$17,854,000 in cash and cash equivalents and short-term investments at September 30, 2007. 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, 2007 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, 2007, 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 October 2007, in order to protect our minority shareholder position in Ribotech (Pty) Ltd., we filed an Application in the High Court of South Africa naming as respondents Ribotech (Pty) Ltd, Bioclones (Pty) Ltd, the Trustees of the Biopad Trust and the Directors of Ribotech (Pty) Ltd. The Application asks the court to declare that certain minority shareholder protection provisions bound and still bind Ribotech (Pty) Ltd, that the appointment of certain Directors of Ribotech (Pty) Ltd is and was invalid, and that the allotment of certain shares of stock of Ribotech (Pty) Ltd is and was invalid. This Application is currently pending.

See our Form 10-Q for the period ending June 30, 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.



On October 10, 2007 we filed an NDA with the FDA for approval to use Ampligen® in the treatment of Chronic Fatigue Syndrome. We can provide no guidance as to the tentative date at which the filing of the NDA will be accepted or, if accepted, when or if the NDA will be approved. The timing of the FDA review process of the NDA is subject to the control of the FDA and could result in one of the following events; 1) approval to market Ampligen® for use in treating ME/CFS patients 2) require more research, development, and clinical work, 3) approval to market as well as conduct more testing, or 4) reject our NDA application. Given these variables, we are unable to project when material net cash inflows are expected to commence from the sale of Ampligen®.

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 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. 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, 2007, our accumulated deficit was approximately \$181,794,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

***We may require additional financing which may not be available.***

The development of our products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of September 30, 2007, we had approximately \$17,850,000 in cash and cash equivalents and short-term investments. We anticipate, but cannot assure, that these funds will be sufficient to meet our operating cash requirements for the next 14 months.

On April 12, 2006, we entered into a common stock purchase agreement with Fusion Capital pursuant to which Fusion Capital has agreed, under certain conditions and with certain limitations, to purchase on each trading day \$100,000 of our common stock up to an aggregate of \$50,000,000 over a 25 month period (see Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources").

We only have the right to receive up to \$100,000 per trading day under the agreement with Fusion Capital unless our stock price exceeds \$1.90 by at least \$0.10, in which case the daily amount may be increased under certain conditions as the price of our common stock increases. Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than \$1.00. We have registered an aggregate of 13,201,840 shares purchasable by Fusion Capital pursuant to the common stock purchase agreement (inclusive of up to 643,502 additional Commitment Shares) and, through November 1, 2007, we have sold to Fusion Capital an aggregate of 10,539,112 shares under the common stock purchase agreement for aggregate gross proceeds of approximately \$19,529,128. Assuming a purchase price of \$1.59 per share (the closing sale price of the common stock on November 1, 2007) and the purchase by Fusion Capital of the remaining 1,204,109 shares (after issuing the remaining 196,037 Commitment Shares), total gross proceeds to us from the remaining shares would only be \$1,914,533 (\$21,443,661 in the aggregate under the common stock purchase agreement).

In the event we elect to issue additional shares to Fusion Capital, we will be required to file a new registration statement and have it declared effective by the Securities and Exchange Commission. In addition, Fusion Capital cannot purchase more than 27,386,723 shares, inclusive of Commitment Shares under the common stock purchase agreement.

Accordingly, depending upon the future market price of our common stock, even if we register the balance of the shares issuable to Fusion Capital under the Purchase Agreement, we most likely will realize less than the maximum \$50,000,000 proceeds from the sale of stock under the Purchase Agreement.

The extent to which we rely on Fusion Capital as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources.

If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive 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 another source of funding in order to satisfy our working capital needs. Even if we are able to access the full \$50,000,000 under the common stock purchase agreement with Fusion Capital, we may need to raise additional funds through additional equity or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes including the commercializing of Ampligen® products. 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. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.



***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® and 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.

***If our 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 on the efforts of third parties, and there is no assurance that these efforts will be successful. Our agreement with Accredo offers the potential to provide some marketing and distribution capacity in the United States while agreements with Biovail Corporation and Laboratorios Del Dr. Esteve S.A. may provide a sales force in Canada, Spain and Portugal.

We cannot assure that our U.S. or foreign marketing partners will be able to successfully distribute our products, 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-. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could 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 third party suppliers 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.

***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 ME/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, Glaxo Smith Kline, 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®. Many 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. 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; and
- the occurrence of any of the risks described in these "Risk Factors."

Our common stock is listed for quotation on the American Stock Exchange. For the 12-month period ended October 31, 2007, the price of our common stock has ranged from \$1.06 to \$2.49 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.

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

We have registered 13,201,840 for sale by Fusion Capital and 143,658 shares by others, and may, in the future, register an additional 15,000,000 shares for sale by Fusion Capital under the common stock purchase agreement. As of November 1, 2007, approximately 208,855 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act. Also, we have registered 6,571,072 shares issuable upon exercise of 135% of certain Warrants and upon exercise of certain other warrants. Registration of the shares permits the sale of the shares in the open market or in privately negotiated transactions without compliance with the requirements of Rule 144. 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. We are unable to estimate the amount, timing or nature of future sales of outstanding 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.

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***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 and other shares registered for selling stockholders could cause the price of our common stock to decline.***

The sale by Fusion Capital and other selling stockholders of our common stock will increase the number of our publicly traded shares, which could depress the market price of our common stock. Moreover, the mere prospect of sales by Fusion Capital and other selling stockholders could depress the market price for our common stock. The issuance of shares to Fusion Capital under the common stock purchase agreement will dilute the equity interest of existing stockholders and could have an adverse effect on the market price of our common stock.

The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement will fluctuate based on the price of our common stock. All shares sold to Fusion Capital are to be freely tradable. Fusion Capital may sell none, some or all of the shares of common stock purchased from us at any time. We expect that the shares offered by Fusion Capital will be sold over a period of in excess of two years. Depending upon market liquidity at the time, a sale of shares by Fusion at any given time could cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock to Fusion Capital pursuant to the purchase agreement, 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.

***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 8.9% 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 revenues in Europe, Canada and in the United States.

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

During the quarter ended September 30, 2007, we issued an aggregate of 47,350 shares for services performed and an aggregate of 51,976 shares for the payment of interest.

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, 2007.

**ITEM 3: Defaults upon Senior Securities**

None.

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

None

**ITEM 5: Other Information**

None.

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**ITEM 6: Exhibits**

(a) Exhibits

- 31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer
- 31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer
- 32.1 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer
- 32.2 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer

SIGNATURES

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

HEMISPHERx BIOPHARMA, INC.

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

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

Date: November 7, 2007

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