

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

HEMISPHERX BIOPHARMA INC  
Form 10-Q  
November 07, 2006

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, 2006

Commission File Number: 0-27072

HEMISPHERx BIOPHARMA, INC.

-----  
(Exact name of registrant as specified in its charter)

Delaware

52-0845822

-----  
(State or other jurisdiction of  
incorporation or organization)

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

1617 JFK Boulevard, Suite 660, Philadelphia, PA 19103

-----  
(Address of principal executive offices) (Zip Code)

(215) 988-0080

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

Not Applicable

-----  
(Former name, former address and former fiscal year, if changed since last  
report)

Indicate by check mark whether the registrant (1) has filed all reports required  
to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during  
the preceding 12 months (or for such shorter period that the registrant was  
required to file such reports), and (2) has been subject to such filing  
requirements for the past 90 days.  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

63,585,329 shares of common stock were issued and outstanding as of November 1,  
2006.

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

### ITEM 1: Financial Statements

#### HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES Consolidated Balance Sheets (in thousands)

	December 31, 2005 -----	September 30, 2006 ----- (unaudited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 3,827	\$ 4,518
Short term investments (Note 4)	12,377	14,505
Inventory, net	1,767	1,092
Accounts and other receivables, net of reserves of \$1 and \$1, respectively	96	279
Prepaid expenses and other current assets	142	87
Total current assets	18,209	20,481
Property and equipment, net	3,364	4,773
Patent and trademark rights, net	795	875
Investment	35	35
Construction in Progress	821	546
Royalty Interest	--	612
Deferred financing costs	113	57
Advance receivable (Note 5)	1,300	1,300
Other assets	17	17
	-----	-----
Total assets	\$ 24,654 =====	\$ 28,696 =====
 <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 991	\$ 2,288
Accrued expenses	865	1,172
Current portion of long-term debt	--	3,756
	-----	-----
Total current liabilities	1,856	7,216
	-----	-----
Long-Term Debt (Note 5)	4,171	--
	-----	-----
 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 56,264,155 and 62,892,847 respectively	56	63
Additional paid-in capital	166,394	183,852
Accumulated other comprehensive (loss) income	(171)	24
Accumulated deficit	(147,652)	(162,459)
	-----	-----

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

Total stockholders' equity	18,627	21,480
	-----	-----
Total liabilities and stockholders' equity	\$ 24,654	\$ 28,696
	=====	=====

See accompanying notes to condensed consolidated financial statements.

2

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

	Three months ended September 30,	
	2005	2006
	-----	-----
Revenues:		
Sales of product net	\$ 216	\$ 189
Clinical treatment programs	55	43
	-----	-----
Total revenues	271	232
Costs and expenses:		
Production/cost of goods sold	93	308
Research and development	987	2,512
General and administrative	1,384	1,276
	-----	-----
Total costs and expenses	2,464	4,096
Interest and other income	250	356
Interest expense	(84)	(164)
Financing costs (Note 5)	(616)	(135)
	-----	-----
Net loss	\$ (2,643)	\$ (3,807)
	=====	=====
Basic and diluted loss per share (Note 2)	\$ (.05)	\$ (.06)
	=====	=====
Weighted average shares outstanding	51,301,946	62,570,061
	=====	=====

See accompanying notes to consolidated financial statements.

3

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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

	Nine months ended September 30,	
	2005	2006
Revenues:		
Sales of product net	\$ 685	\$ 569
Clinical treatment programs	144	146
Total revenues	829	715
Costs and expenses:		
Production/cost of goods sold	294	1,005
Research and development	3,413	7,530
General and administrative	3,933	6,454
Total costs and expenses	7,640	14,989
Interest and other income	543	516
Interest expense	(297)	(574)
Financing costs (Note 5)	(2,403)	(475)
Net loss	\$ (8,968)	\$ (14,807)
Basic and diluted loss per share (Note 2)	\$ (.18)	\$ (.24)
Weighted average shares outstanding	50,401,043	60,953,372

See accompanying notes to consolidated financial statements.

4

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	Accumulat other Comprehens Income (lo
Balance at December 31, 2005	56,264,155	\$ 56	\$ 166,394	\$ (17
Debt conversions	400,642	1	833	-
Interest Payments	43,875	--	101	-
Warrants exercised	255,416	--	672	-
Private placement, net of issuance costs	5,539,366	6	12,587	-

31.2 Certification pursuant to

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

payable and accrued expenses	77,665	--	209	--
Stock issued to purchase patents	61,728	--	150	--
Stock issued to purchase royalty interest	250,000	0	620	--
Stock warrant compensation expense	--	--	2,286	--
Net comprehensive income (loss)	--	--	--	19
Balance at September 30, 2006	62,892,847	\$ 63	\$ 183,852	\$ 2

See accompanying notes to consolidated financial statements.

5

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES  
Consolidated Statements of Cash Flows  
For the Nine Months Ended September 30, 2005 and 2006  
(in thousands)  
(Unaudited)

	2005	2006
Cash flows from operating activities:		
Net loss	\$ (8,968)	\$ (14,807)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	87	131
Amortization of patent and trademark rights, and royalty interest	222	125
Financing cost related to debt discounts	2,403	475
Stock compensation expense	289	2,286
Interest expense	317	101
Changes in assets and liabilities:		
Inventory	314	676
Accounts and other receivables	70	(183)
Prepaid expenses and other current assets	172	54
Accounts payable	263	1,505
Accrued expenses	(452)	309
Net cash used in operating activities	(5,283)	(9,328)
Cash flows from investing activities:		
Purchase of property plant and equipment, net	(289)	(1,266)
Additions to patent and trademark rights	(107)	(47)
Maturity of short term investments	7,934	12,548
Purchase of short term investments	(6,900)	(14,481)
Net cash provided by (used in) investing activities	\$ 638	\$ (3,246)

6

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES  
 Consolidated Statements of Cash Flows (Continued)  
 For the Nine Months Ended September 30, 2005 and 2006  
 (in thousands)  
 (Unaudited)

	2005	2006
	-----	-----
Cash flows from financing activities:		
Proceeds from exercise of stock warrants	8	672
Proceeds from sale of stock, net of issuance costs	790	12,593
	-----	-----
Net cash provided by financing activities	798	13,265
	-----	-----
Net decrease in cash and cash equivalents	(3,847)	691
Cash and cash equivalents at beginning of period	8,813	3,827
	-----	-----
Cash and cash equivalents at end of period	\$ 4,966	\$ 4,518
	=====	=====
Supplemental disclosures of non-cash investing and financing cash flow information:		
Issuance of common stock for Patents and royalty interest	\$ --	\$ 770
	=====	=====
Issuance of common stock for accounts payable and accrued expenses	\$ 314	\$ 209
	=====	=====
Issuance of common stock for debt conversion and debt payments	\$ 1,927	\$ 834
	=====	=====
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 subsidiaries include Hemispherx Biopharma Europe N.V./S.A. established in Belgium in 1998 and Hemispherx Biopharma Europe S.A. incorporated in Luxemburg in 2002, which have limited or no activity. All significant intercompany balances and transactions have been eliminated in consolidation.

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

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/A-2 for the year ended December 31, 2005, as filed with the SEC on July 31, 2006.

### 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 29,319,185 and 29,693,497 shares, are excluded from the calculation of diluted net loss per share for the nine months ended September 30, 2005 and 2006, respectively, since their effect is antidilutive.

### NOTE 3: STOCK BASED COMPENSATION

Prior to the adoption of Statement of Financial Accounting Standard No. 123R, "Share Based Payment", ("FAS 123R") the Company applied the intrinsic value-based method of accounting prescribed by Accounting Principles Board ("APB") Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations including FASB Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation an interpretation of APB Opinion No. 25 issued in March 2000 ("FIN 44"), to account for its fixed plan stock options. Under this method, compensation expense was recorded on the date of grant only if the current market price of the underlying stock exceeded the exercise price. Statement of Financial Accounting Standard No. 123, Accounting for Stock-Based Compensation ("FAS 123"), established accounting and disclosure requirements using a fair value-based method of accounting for stock-based employee compensation plans. In December 2002, the FASB issued Statement of Financial Accounting Standard No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, an amendment of FASB Statement No. 123. This Statement amended FAS 123, to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation.

The Equity Incentive Plan effective May 1, 2004, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 8,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan. Unless sooner terminated, the Equity Incentive Plan will continue in effect for a period of 10 years from its effective date.

8

The Equity Incentive Plan is administered by the Board of Directors. The Equity Incentive Plan provides for awards to be made to such officers, other key employees, non-employee directors, consultants and advisors of the Company and its subsidiaries as the Board may select.

Stock options awarded under the Equity Incentive Plan may be exercisable at such times (not later than 10 years after the date of grant) and at such

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

exercise prices (not less than fair market value at the date of grant) as the Board may determine. The Board may provide for options to become immediately exercisable upon a "change in control," which is defined in the Equity Incentive Plan to occur upon any of the following events: (a) the acquisition by any person or group, as beneficial owner, of 20% or more of the outstanding shares or the voting power of the outstanding securities of the Company; (b) either a majority of the directors of the Company at the annual stockholders meeting has been nominated other than by or at the direction of the incumbent directors of the Board, or the incumbent directors cease to constitute a majority of the Company's Board; (c) the Company's stockholders approve a merger or other business combination pursuant to which the outstanding common stock of the Company no longer represents more than 50% of the combined entity after the transaction; (d) the Company's shareholders approve a plan of complete liquidation or an agreement for the sale or disposition of all or substantially all of the Company's assets; or (e) any other event or circumstance determined by the Company's Board to affect control of the Company and designated by resolution of the Board as a change of control.

Effective January 1, 2006, the Company adopted FAS 123R. Under FAS 123R, share-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the requisite service period. The Company adopted the provisions of FAS 123R using a modified prospective application. Under this method, compensation cost is recognized for all share-based payments granted, modified or settled after the date of adoption, as well as for any unvested awards that were granted prior to the date of adoption. Prior periods are not revised for comparative purposes. Because the Company previously adopted only the pro forma disclosure provisions of FAS 123, it will recognize compensation cost relating to the unvested portion of awards granted prior to the date of adoption, using the same estimate of the grant-date fair value and the same attribution method used to determine the pro forma disclosures under FAS 123, except that forfeitures rates will be estimated for all options, as required by FAS 123R. The cumulative effect of applying the forfeiture rates is not material.

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 estimated per share weighted average grant date fair values of stock options granted during the three months ended September 30, 2005 and 2006, were \$.83 and \$0, respectively. The estimated per share weighted average grant date fair values of stock options granted during the nine months ended September 30, 2005 and 2006, were \$.85 and \$1.97, respectively. The fair values of the options granted, were estimated based on the following weighted average assumptions:

9

	Nine months ended September 30,	
	2005	2006
	----	----
Expected volatility	58.78% - 60.67%	72.06% - 79.3%
Risk-free interest rate	4.81%	4.3% - 4.97%
Expected dividend yield	--	--
Expected life	5 years	2.5 - 5 years

Stock option activity during the nine months ended September 30, 2006, is as follows:



Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

	Number of Options -----	Weighted average exercise price -----	Weighted average remaining contracted term (years) -----	Aggregate intrinsic value -----
Outstanding at January 1, 2006	1,985,680	\$ 2.15		
Options granted	1,106,650	3.39		
Options exercised	--	--		
Options forfeited	(1,308)	1.90		
	-----	-----		
Options outstanding at September 30, 2006	3,091,022	\$ 2.59	9.04	-0-
	=====	=====	=====	=====
Options exercisable at September 30, 2006	3,004,322	\$ 2.70	8.56	-0-
	=====	=====	=====	=====

The impact on the Company's results of operations of recording share-based compensation for the three and nine months ended September 30, 2006 was to increase general and administrative expenses by approximately \$23,000 and \$2,286,000, respectively, and reduce earnings per share by \$0 and \$.04 per basic and diluted share, respectively.

As of September 30, 2006, there was no unrecognized stock-based compensation cost related to options granted under the Equity Incentive Plan.

The following table illustrates the effect on the net loss and net loss per share as if the Company had applied the fair value recognition provisions of FAS 123 to stock based compensation prior to January 1, 2006:

	Three months Ended September 30, 2005 (in thousands)
Net loss, as reported	\$ (2,643)
Add stock-based employee compensation expense included in reported net loss	177
Deduct total stock-based employee compensation expense determined under fair value based method for all awards, net of tax	(291)
	-----
Pro forma net loss	\$ (2,757)
	=====
Net loss per common share (Basic and diluted):	
As Reported	\$ (.05)
	=====
Pro Forma	\$ (.05)
	=====

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

Weighted average common shares outstanding:

Basic and diluted

51,301,946

=====

10

Note 4: SHORT TERM INVESTMENTS

Securities classified as available for sale consisted of (in thousands):

Name of security	September 30, 2006			
	Cost	Market value	Unrealized gain	Maturity date
General Electric	\$ 1,199	\$ 1,231	\$ 32	11/21/2006
Natexis Banques Popl	969	967	(2)	5/25/2007
AIG FDG Disc Com Paper	972	971	(1)	4/25/2007
American General Fin Corp	976	974	(2)	3/30/2007
General Electric	965	962	(3)	6/26/2007
Certificate of Deposit	2,000	2,000	--	11/27/2006
Certificate of Deposit	2,000	2,000	--	12/21/2006
Certificate of Deposit	2,000	2,000	--	12/27/2006
Certificate of Deposit	1,400	1,400	--	12/29/2006
Certificate of Deposit	2,000	2,000	--	12/29/2006
	\$14,481	\$14,505	\$ 24	

No investment securities were pledged to secure public funds at September 30, 2006.

Comprehensive Income (loss)

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

	Three months ended September 30		Nine months ended September 30	
	(in thousands)		(in thousands)	
	2005	2006	2005	2006
Unrealized gains (losses) during the period	\$ (149)	\$ 136	\$ (234)	300
Realized loss (gains) during the period	10	(191)	10	(105)
Other comprehensive income(loss)	\$ (139)	\$ (55)	\$ (224)	\$ 195

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

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

The basis on which the Company computes gains and losses is based on the specific identification method of accounting. For the nine months ended September 30, 2006 total gains from sales of securities was \$232,000 and total losses from the sales of securities for the nine months ended September 30, 2006 was \$127,000.

11

### Note 5: DEBENTURE FINANCING

Long term debt consists of the following:

	(in thousands)	
	December 31, 2005	September 30, 2006
	-----	-----
October 2003	\$ 2,071	\$ 2,071
January 2004	1,365	1,031
July 2004	1,500	1,000
	-----	-----
Total	4,936	4,102
Less Discounts	(765)	(346)
	-----	-----
Total	4,171	3,756
	=====	=====
Less current portion	--	3,756
	-----	-----
Long term debt	\$ 4,171	\$ --
	=====	=====

As of December 31, 2005, the Company made installment payments of \$2,389,000 and investors converted an aggregate \$2,818,000 principal amount of debt from the debentures as noted below (in thousands):

Debenture	Original Principal Amount	Debt Conversion to Common Shares	Installment payments in Common Shares	Remaining Principal Amount	Common Shares issued for Conversion	Common Shares issued in installment
	-----	-----	-----	-----	-----	-----
October 2003	\$ 4,142	\$ 2,071	\$ --	\$ 2,071	1,025,336	--
January 2004	4,000	747	1,889	1,365	347,000	1,094,149
July 2004	2,000	--	500	1,500	--	331,669
	-----	-----	-----	-----	-----	-----
Totals	\$ 10,142	\$ 2,818	\$ 2,389	\$ 4,936	1,372,336	1,425,818
	-----	-----	-----	-----	-----	-----

As of September 30, 2006, the Company made aggregate installment payments of \$2,389,000 and the investors converted an aggregate \$3,651,000

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

principal amount of debt from the debentures as noted below (in thousands):

Debenture	Original Principal Amount	Debt Conversion to Common Shares	Installment payments in Common Shares	Remaining Principal Amount	Common Shares issued for Conversion	Common Shares issued in installment
October 2003	\$ 4,142	\$ 2,071	\$ --	\$ 2,071	1,025,336	--
January 2004	4,000	1,080	1,889	1,031	507,257	1,094,149
July 2004	2,000	500	500	1,000	240,385	331,669
Totals	\$ 10,142	\$ 3,651	\$ 2,389	\$ 4,102	1,772,978	1,425,818

### October 2003 Debentures

On October 29, 2003, the Company issued an aggregate of \$4,142,357 in principal amount of 6% Senior Convertible Debentures due October 31, 2005 (the "October 2003 Debentures") and an aggregate of 410,134 Warrants (the "October 2008 Warrants") in a private placement for aggregate gross proceeds of \$3,550,000. Pursuant to the terms of the October 2003 Debentures, \$1,550,000 of the proceeds from the sale of the October 2003 Debentures were held back and were to be released to the Company if, and only if, the Company acquired ISI's facility within 90 days of January 26, 2004 and provided a mortgage on the facility as further security for the October 2003 Debentures. In April 2004, the Company acquired the facility and the Company subsequently provided the mortgage of the facility to the Debenture holders and the above funds were released. The Company recorded an additional debt discount of \$259,000 upon receiving these held back proceeds. The October 2003 Debentures were to mature on October 31, 2005 and bore interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest are to be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Pursuant to the terms and conditions of the October 2003 Debentures, the Company pledged all of the Company's assets, other than the Company's intellectual property, as collateral and was subject to comply with certain financial and negative covenants, which included but were not limited to the repayment of principal balances upon achieving certain revenue milestones (see "Collateral and Financial Covenants" below).

The October 2003 Debentures are convertible at the option of the investors at any time through October 31, 2005 into shares of the Company's common stock. The conversion price under the October 2003 Debentures is fixed at \$2.02 per share, subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect. In addition, in the event that the Company does not pay the redemption price at maturity, the Debenture holders, at their option, may convert the balance due at the lower of (a) the conversion price then in effect and (b) 95% of the lowest closing sale price of the Company's common stock during the three trading days ending on and including the

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

conversion date.

The October 2008 Warrants, as amended, received by the investors were to acquire an aggregate of 410,134 shares of common stock at a price of \$2.32 per share. These Warrants were exercised in July 2004 which produced gross proceeds in the amount of approximately \$952,000.

Pursuant to the Company's agreement with the holders the Company registered the shares issuable upon conversion of the October 2003 Debentures and upon exercise of the October 2008 Warrants for public sale.

The October 2003 Debentures were recorded at a discount on issuance and with an original issue discount of \$2,000,000 and \$333,000, respectively, due to ascribing value to the beneficial conversion feature and fair value of warrants based on the relative fair value of the proceeds.

The conversion option and detachable warrant carry registration rights and a feature that in certain circumstances, deemed in the control of the Company, could require partial settlement of the conversion options to be in cash. In addition, the October 2003 Debentures include other features including mandatory conversion option and optional redemption rights if contingent transactions occur. To determine whether the October 2003 Debentures had embedded derivatives, including the conversion option, that required bifurcation and fair value accounting, the Company analyzed the terms of the debentures in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"), and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock" ("EITF 00-19"). The Company concluded that bifurcation was not required for the conversion option and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") was the appropriate accounting to be applied. The warrants were deemed to be permanent equity. The mandatory conversion option and optional redemption rights were deemed to be derivatives requiring bifurcation and thus the Company obtained a third party valuation for the aggregate fair value of these derivatives that showed the fair value to be immaterial at inception and for each subsequent reporting period.

13

In October 2005, the Company entered into an amendment agreement with the October 2003 Debenture holders to amend the maturity date from October 31, 2005 to June 30, 2007, and increase the interest rate from 6% to 7% (see "Debenture Agreement Amendment" below for more details).

On July 13, 2004, in consideration for the Debenture holders' exercise of all of the July 2003 ("July 2008 Warrants") and October 2003 ("October 2008 Warrants") Warrants amounting to approximately \$2,199,000 in gross proceeds, the Company issued to these holders warrants (the "June 2009 Warrants") to purchase an aggregate of 1,300,000 shares of common stock. The Company recorded charges associated with the issuance of these warrants, as restated, fair valued using the Black-Scholes Method, at \$1,676,000, which has been reflected as a deemed dividend in 2004.

The June 2009 Warrants are to acquire at any time commencing on January 13, 2005 through June 30, 2009 an aggregate of 1,300,000 shares of common stock at a price of \$3.75 per share. On July 13, 2005, the exercise price of these June 2009 Warrants was reset to \$3.33, the lesser of the exercise price then in effect or a price equal to the average of the daily price of the common stock between July 14, 2004 and July 12, 2005. The exercise price (and the reset price) under the June 2009 Warrants also is subject to adjustments for anti-dilution protection similar to those in the other Warrants. Notwithstanding

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

the foregoing, the exercise price as reset or adjusted for anti-dilution, will in no event be less than \$3.33 per share. Upon completion of the August 2004 Private Placement, the exercise price was lowered to \$3.33 per share. The Company agreed to register the shares issuable upon exercise of the June 2009 Warrants pursuant to substantially the same terms as the registration rights agreements between the Company and the holders. Pursuant to this obligation, the Company has registered the shares.

The Company has paid \$1,300,000 into the debenture cash collateral account as required by the terms of the October 2003 Debentures. The amounts paid through September 30, 2006 have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of September 30, 2006. The cash collateral account provides partial security for repayment of the outstanding principal and accrued interest on the Debentures in the event of default.

As of September 30, 2006, the investors had converted \$2,071,178 principal amount of the October 2003 Debenture into 1,025,336 shares of Common Stock. The remaining balance of \$2,071,178 is convertible into 1,025,336 shares of common stock.

The Company recorded financing costs for the three months ended September 30, 2005 and 2006, with regard to the October 2003 Debentures of \$124,000 and \$0, respectively. Interest expense for the three months ended September 30, 2005 and 2006, with regard to the October 2003 Debentures was approximately \$31,000 and \$37,000, respectively.

The Company recorded financing costs for the nine months ended September 30, 2005 and 2006, with regard to the October 2003 Debentures of \$865,000 and \$0 respectively. Interest expense for the nine months ended September 30, 2005 and 2006, with regard to the October 2003 Debentures was approximately \$93,000 and \$108,000, respectively.

### January 2004 Debentures

On January 26, 2004, the Company issued an aggregate of \$4,000,000 in principal amount of 6% Senior Convertible Debentures due January 31, 2006 (the "January 2004 Debentures"), an aggregate of 790,514 warrants (the "July 2009 Warrants") and 158,104 shares of common stock, and Additional Investment Rights (to purchase up to an additional \$2,000,000 principal amount of January 2004 Debentures commencing in six months) in a private placement for aggregate net proceeds of \$3,695,000. The January 2004 Debentures were to mature on January 31, 2006 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. As discussed below, the maturity date and interest rate were amended. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Pursuant to the terms of the January 2004 Debentures, commencing July 26, 2004, the Company began to repay the then outstanding principal amount under the Debentures in monthly installments amortized over 18 months in cash or, at the Company's option, in shares of common stock. Any shares of common stock issued to the investors as installment payments shall be valued at 95% of the average closing price of the common stock during the 10-day trading period commencing on and including the eleventh trading day immediately preceding the date that the installment is due. Pursuant to the terms and conditions of the January 2004 Debentures, the Company pledged all of the Company's assets, other than the Company's intellectual property, as collateral and was subject to comply with certain financial and negative covenants, which included but were not limited to the repayment of principal balances upon achieving certain revenue milestones (see "Collateral and Financial Covenants" below).

The January 2004 Debentures are convertible at the option of the investors at any time through January 31, 2006 into shares of the Company's common stock. The conversion price under the January 2004 Debentures was fixed at \$2.53 per share, subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect. In addition, in the event that the Company does not pay the redemption price at maturity, the Debenture holders, at their option, may convert the balance due at the lower of (a) the conversion price then in effect and (b) 95% of the lowest closing sale price of the Company's common stock during the three trading days ending on and including the conversion date. Upon completion of the August 2004 Private Placement, the conversion price was lowered to \$2.08 per share. The Company recorded an additional debt discount of approximately \$915,000 due to this conversion price reset.

In October 2005, the Company entered into an amendment agreement with the January 31, 2004 Debenture holders to amend the maturity date from January 2006 to June 30, 2007, and increase the interest rate from 6% to 7% (see "Debenture Agreement Amendment" below for more details).

There are two classes of July 2009 Warrants received by the Investors: Class A and Class B. The Class A warrants are to acquire any time from July 26, 2004 through July 26, 2009 an aggregate of up to 395,257 shares of common stock at a price of \$3.29 per share. The Class B warrants are to acquire any time from July 26, 2004 through July 26, 2009 an aggregate of up to 395,257 shares of common stock at a price of \$5.06 per share. On January 27, 2005, the exercise price of these July 2009 Class A and Class B Warrants were reset to the lesser of their respective exercise price then in effect or a price equal to the average of the daily price of the common stock between January 27, 2004 and January 26, 2005. The exercise price (and the reset price) under the July 2009 Warrants also is subject to similar adjustments for anti-dilution protection. Notwithstanding the foregoing, the exercise prices as reset or adjusted for anti-dilution, will in no event be less than \$2.58 per share. Upon completion of the August 2004 Private Placement the exercise price was lowered to \$2.58 per share.

The January 2004 Debentures were recorded at a discount on issuance and with an original issue discount of \$306,000 and \$465,000, respectively, due to ascribing value to the beneficial conversion feature and fair value of warrants based on the relative fair value of the proceeds.

The conversion option and detachable warrant carry registration rights and a feature that in certain circumstances, deemed in the control of the Company, could require partial settlement of the conversion options to be in cash. In addition, the January 2004 Debentures include other features including mandatory conversion option and optional redemption rights if contingent transactions occur. To determine whether the January 2004 Debentures had embedded derivatives, including the conversion option, that required bifurcation and fair value accounting, the Company analyzed the terms of the debentures in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"), and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock" (EITF "00-19"). The Company concluded that bifurcation was not required for the conversion option and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") was the appropriate accounting to be applied. The warrants were deemed to be permanent equity. The mandatory conversion option and optional redemption rights were deemed to be derivatives requiring bifurcation and thus the Company obtained a third party valuation for

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

the aggregate fair value of these derivatives that showed the fair value to be immaterial at inception and for each subsequent reporting period.

15

### Section 713 of the American Stock Exchange Company Guide

Section 713 of the American Stock Exchange ("AMEX") Company Guide provides that the Company must obtain stockholder approval before issuance, at a price per share below market value, of common stock, or securities convertible into common stock, equal to 20% or more of the Company's outstanding common stock (the "Exchange Cap"). The Debentures and Warrants have provisions that require the Company to pay cash in lieu of issuing shares upon conversion of the Debentures or exercise of the Warrants if the Company is prevented from issuing such shares because of the Exchange Cap. In May 2004, the Debenture holders agreed to amend the provisions of these Debentures and Warrants to limit the maximum amount of funds that the holders could receive in lieu of shares upon conversion of the Debentures and/or exercise of the Warrants in the event that the Exchange Cap was reached to 119.9% of the conversion price of the relevant Debentures and 19.9% of the relevant Warrant exercise price. See below for the accounting effect on this matter.

Taken separately, the March, July, October and January 2004 debenture transactions do not trigger Section 713. However, the AMEX took the position that these transactions should be aggregated and, as such, stockholder approval was required for the issuance of common stock for a portion of the potential exercise of the warrants and conversion of the Debentures in connection with the January 2004 Debentures. The amount of potential shares that the Company could exceed the Exchange Cap amounted to approximately 1,299,000. In accordance with EITF 00-19, Accounting For Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock, the Company recorded on January 26, 2004, a redemption obligation of approximately \$2,160,000 with a corresponding increase to debt discount to be amortized over the life of the debt or until the Company obtains shareholder approval. Any remaining discount would be reclassified to additional paid in capital.

In addition, in accordance with EITF 00-19, the Company revalued this redemption obligation as of March 31, 2004. The Company increased the redemption obligation and recorded additional finance charge of \$1,024,000 as a result of this revaluation. The Company also incurred \$104,000 in financing charges related to the amortization of the related discount during the first quarter of 2004.

Stockholder approval was obtained at the Company's Annual Meeting of Stockholders on June 23, 2004. In accordance with EITF 00-19, the Company revalued this redemption obligation associated with the 1,299,000 shares as of June 23, 2004 (date of shareholder approval). The Company recorded a reduction in the value of the redemption obligation and financing charge of \$839,000 as a result of this revaluation and additional financing charge of \$242,000 related to the amortization of the debt discount in the second quarter 2004. In addition, upon receiving the requisite stockholder approval on June 23, 2004, the redemption obligation of \$2,345,000 and the remaining unamortized debt discount of \$1,815,000 were reclassified as additional paid in capital.

16

As of September 30, 2006, the Company has made aggregate installment payments of \$1,889,000 and the investors have converted an aggregate of \$1,080,000 of principal amount of the January 2004 Debentures into 1,094,149 and 507,257



## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

shares of common stock, respectively. During the quarter ended September 30, 2006, the investors did not convert any of the principal amount of the January 2004 Debentures. The remaining principal on these Debentures was \$1,031,268 as of September 30, 2006.

The Company recorded financing costs for the three months ended September 30, 2005 and 2006 with regard to the January 2004 Debentures of \$236,000 and \$0, respectively. Interest expense for the three months ended September 30, 2005 and 2006, with regard to the January 2004 Debentures was approximately \$25,000 and \$7,000, respectively.

The Company recorded financing costs for the nine months ended September 30, 2005 and 2006 with regard to the January 2004 Debentures of \$746,000 and \$49,000, respectively. Interest expense for the nine months ended September 30, 2005 and 2006, with regard to the January 2004 Debentures was approximately \$117,000 and \$59,000, respectively.

### July 2004 Debentures

Pursuant to the Additional Investment Rights issued in connection with the January 2004 Debentures, the Company issued to the investors an additional \$2,000,000 principal amount of January 2004 Debentures (the "July 2004 Debentures"). The July 2004 Debentures are identical to the January 2004 Debentures except that the conversion price is \$2.58. The investors exercised the Additional Investment Rights on July 13, 2004 and the Company received net proceeds of \$1,860,000. Upon completion of the August 2004 Private Placement, the conversion price of the July 2004 Debentures was lowered to \$2.08 per share. The Company recorded an additional debt discount of approximately \$632,000 upon the conversion price reset to \$2.08 per share, which is being amortized over the remaining life of the debenture in accordance with the effective interest method of accounting.

The July 2004 Debentures were recorded at a discount on issuance of \$628,000 due to ascribing value to the beneficial conversion feature and fair value of warrants based on the relative fair value of the proceeds.

The conversion option and detachable warrant carry registration rights and a feature that in certain circumstances, deemed in the control of the Company, could require partial settlement of the conversion options to be in cash. In addition, the July 2004 Debentures include other features including mandatory conversion option and optional redemption rights if contingent transactions occur. To determine whether the July 2004 Debentures had embedded derivatives, including the conversion option, that required bifurcation and fair value accounting, the Company analyzed the terms of the debentures in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"), and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock" (EITF 00-19"). The Company concluded that bifurcation was not required for the conversion option and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") was the appropriate accounting to be applied. The warrants were deemed to be permanent equity. The mandatory conversion option and optional redemption rights were deemed to be derivatives requiring bifurcation and thus the Company obtained a third party valuation for the aggregate fair value of these derivatives that showed the fair value to be immaterial at inception and for each subsequent reporting period.

In October 2005, the Company entered into an amendment agreement with the July 2004 Debenture holders to amend the maturity date from July 31, 2006 to June 30,

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

2007, and increase the interest rate from 6% to 7% (see "Debenture Agreement Amendment" below for more details).

As of September 30, 2006, the Company has made aggregate installment payments of \$500,000 resulting in the issuance of 331,669 shares of the Company's common stock. During the nine months ended September 30, 2006, the Debenture holders converted \$500,000 principal amount of the July 2004 Debentures into 240,385 shares of common stock. The remaining principal amount on these debentures was \$1,000,000 as of September 30, 2006.

The Company recorded financing costs for the three months ended September 30, 2005 and 2006 with regard to the July 2004 Debentures of \$114,000 and \$116,000, respectively. Interest expense for the three months ended September 30, 2005 and 2006, with regard to the July 2004 Debentures was approximately \$28,000 and \$16,000, respectively.

The Company recorded financing costs for the nine months ended September 30, 2005 and 2006 with regard to the July 2004 Debentures of \$361,000 and \$369,000, respectively. Interest expense for the nine months ended September 30, 2005 and 2006, with regard to the July 2004 Debentures was approximately \$61,000 and \$87,000, respectively.

### Debenture Agreement Amendment

On October 6, 2005, the Company entered into a material definitive agreement with the October 2003, January 2004 and July 2004 debenture holders to 1) amend the remaining outstanding Debentures that were to mature on October 31, 2005 (as amended, the "October 2003 Debenture") and the two tranches of outstanding debentures due to mature on January 31, 2006 (as amended, respectively, the "January 2004 and July 2004 Debentures"), to a maturity date of June 30, 2007, 2) to increase the interest rate from 6% per annum to 7% per annum. In consideration for extending the maturity date of the outstanding debentures, the Company issued an aggregate of 225,000 Warrants (the "October 2009 Warrants") to the debenture holders to acquire common stock at a price of \$2.50 per share at any time from October 31, 2005 through October 31, 2009. The October 2009 Warrants contain provisions for adjustment of the exercised price in the event of certain anti-dilution events. The Company agreed to register 135% of the shares issuable as interest shares that might result due to the amendments to the Debentures and issuable upon exercise of the October 2009 Warrants.

In accordance with EITF 96-19, "Debtor's Accounting for a Modification or Exchange of Debt Instruments", the Company has treated the change in terms to the original debentures as non-substantial in nature and have not accounted for such modification as an extinguishment of debt, but rather a debt modification. In addition, the 225,000 warrants issued to the debenture holders as consideration for extending the maturity date were valued using the Black-Scholes method and \$189,000 of additional debt discount on the July 2004 Debenture was recorded. The discount will be amortized as interest expense over the new term of the debt instrument in accordance with the effective interest method of accounting. Any costs incurred by third parties were expensed as incurred.

### Conversion of Convertible Debt

The maximum number of shares issuable upon debt conversion, including interest as well as 135% of the shares issuable upon conversion and interest payments were 3,667,662 and 2,851,331 shares at December 31, 2005 and September 30, 2006, respectively.

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

### Collateral and Financial Covenants

The Company paid \$1,300,000 in 2003 into the debenture cash collateral account held by the debenture holders as required by the terms of the October 2003 Debentures. The amounts paid have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of September 30, 2006. The cash collateral account provides partial security for repayment of the outstanding Debentures in the event of default.

Pursuant to the terms and conditions of all of the outstanding Debentures, the Company has pledged all of the Company's assets, other than the Company's intellectual property, as collateral, and the Company is subject to comply with certain financial covenants. As of September 30, 2006, the Company was fully compliant with its financial covenants.

The Company failed to timely file its 2005 Annual Report on Form 10-K and Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2006 with the Securities and Exchange Commission ("SEC") pursuant to the 1934 Act, and therefore, was in violation of its covenant to timely file within its debenture agreements. The Company obtained a waiver letter from its debenture holders regarding the failure to meet this covenant. In addition, due to the Company's inability to timely file its annual report on Form 10-K for the year ended December 31, 2005, the Company's registration statement, and the prospectus contained therein, registering the shares issuable upon conversion of and interest under the debentures and upon exercise of related warrants was no longer current. As a result, the Company was subject to payment of liquidated damages until such time as the foregoing shares were again registered for public resale or eligible for resale pursuant to Rule 144(k) under the Securities Act. Liquidated damages are based on the outstanding debt balance times the rate of 0.00067 per day or approximately \$2,748 per day. On July 31, 2006, the Company filed with the SEC its Form 10-K/A-2 for the year ended December 31, 2005, its Forms 10-Q/A for the quarterly periods ended June 30, 2005 and September 30, 2005, and, its registration statement on Form S-1 to, among other things, update its stale registration statements previously filed on Form S-3. The Form S-1 was declared effective on August 7, 2006, which included the shares issuable upon conversion and interest under the debenture securities and upon exercise of certain warrants. Through September 30, 2006, liquidated damages due to the debenture holders were calculated to be approximately \$350,000.

### Note 6: EQUITY FINANCING

On July 8, 2005, the Company entered into a common stock 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 \$40,000 of the Company's common stock up to an aggregate of \$20.0 million over approximately a 25 month period, subject to earlier termination at the Company's discretion. In the Company's discretion, it could elect to sell less common stock to Fusion Capital than the daily amount and it could increase the daily amount as the market price of the Company's stock increases. The purchase price of the shares of common stock was equal to a price based upon the future market price of the common stock without any fixed discount to the market price. Fusion Capital did not have the right or the obligation to purchase shares of the Company's common stock in the event that the price of the common stock is less than \$1.00.

Pursuant to the Company's agreement with Fusion Capital, the Company registered for public sale by Fusion Capital up to 10,795,597 shares of our common stock. However, in the event that the Company decides to issue more than 10,113,278, i.e. greater than 19.99% of the outstanding shares of common stock as of the date of the agreement, the Company would first seek stockholder approval in order to be in compliance with American Stock Exchange rules. As of

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

April 3, 2006, Fusion Capital had purchased an aggregate of 8,791,838 (4,678,382 in 2006) shares amounting to approximately \$20,000,000, in gross proceeds to the Company which completed the terms of the July 8, 2005, Fusion Capital agreement. Pursuant to the agreement, the Company also issued 785,597 (235,287 in 2006) commitment fee shares and 10,000 shares as reimbursement for expenses.

19

On April 12, 2006, the Company entered into another Common Stock Purchase Agreement ("Purchase Agreement") with Fusion Capital. Pursuant to the terms of the Purchase Agreement, Fusion Capital has agreed to purchase from the Company up to \$50,000,000 of common stock over a period of approximately twenty-five (25) months. Pursuant to the terms of the Registration Rights Agreement, dated as of April 12, 2006, the Company registered 12,386,723 shares issuable to or issued to Fusion Capital under the Purchase Agreement. Once the Registration Statement was declared effective, each trading day during the term of the Purchase Agreement the Company has the right to sell to Fusion Capital up to \$100,000 of the Company's common stock on such date or the arithmetic average of the three lowest closing trade prices of the common stock during the immediately preceding 12 trading day period. At the Company's option under certain conditions, Fusion Capital can be required to purchase greater amounts of common stock during a given period. In connection with entering into the Purchase Agreement, the Company issued to Fusion Capital as commitment shares 321,751 shares of our common stock and the Company is obligated to issue an additional 321,751 commitment shares. These additional commitment shares will be issued in an amount equal to the product of (x) 321,751 and (y) the Purchase Amount Fraction. The "Purchase Amount Fraction" means a fraction, the numerator of which is the purchase price at which the shares are being purchased by Fusion Capital and the denominator of which is \$50,000,000.

The purchase price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction. Fusion Capital may not purchase shares of the Company's common stock under the common stock purchase agreement if it, together with its affiliates, would beneficially own more than 9.9% of our common stock outstanding at the time of the purchase by Fusion Capital. Fusion Capital has the right at any time to sell any shares purchased under the 2006 Purchase Agreement which would allow it to avoid the 9.9% limitation. Due to AMEX guidelines, without prior stockholder approval, we do not have the right or the obligation under the Agreement to sell shares to Fusion Capital in excess of 12,386,723 shares (i.e. 19.99% of the 61,964,598 outstanding shares of our common stock on April 12, 2006, the date of the 2006 Purchase Agreement) inclusive of commitment shares issued to Fusion Capital under the Agreement. In addition, Fusion Capital cannot purchase more than 27,386,723 shares, inclusive of the commitment shares under the Agreement. On September 20, 2006 our stockholders voted to allow us to sell up to 27,386,723 shares pursuant to the terms of the Fusion agreement.

As of September 30, 2006, Fusion Capital has purchased from the Company 300,000 shares for aggregate gross proceeds of approximately 613,000. In addition, the Company issued to Fusion Capital 3,946 shares towards the remaining commitment fee.

### NOTE 7 - INTANGIBLE ASSETS

On July 3, 2006, and July 20, 2006, the Company entered into an agreement with Paul Griffin and The Asclepius Trust ("Asclepius") whereby the Company acquired the right, title and interest in certain awarded patents and pending patent applications ("patents"). Consideration given by the Company for the acquisition of these patents amounted to \$150,000 paid with shares of the Company's common stock to Paul Griffin valued at the closing price on the date

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

of the agreement or July 3, 2006. The value of the Company's common stock was \$2.43 on this date and equated to consideration of 61,728 shares of HEB common stock. The Company registered these shares on behalf of Mr. Griffin for public resale. Asclepius will receive in consideration a 2% royalty of the gross sums received from all sales utilizing or relying upon the patents. The Company recorded the acquisition of these patents under guidance set forth in SFAS No. 2 Accounting for Research and Development Costs ("FAS 2") and refers to SFAS No. 142 - Goodwill and Other Intangible Assets ("FAS 142") as an intangible asset to be amortized over the remaining life of the patent.

20

On July 26, 2006, the Company executed an agreement with Stem Cell Innovations, Inc. (formerly Interferon Sciences, Inc.) whereby it acquired the royalty interest previously granted Interferon Sciences with respect to the Company's sale of products containing alpha interferon in exchange for 250,000 shares of common stock. The Company registered these shares on behalf of Stem Cell Innovations for public resale. The Company recorded this transaction on its balance sheet as an intangible asset under guidance provided by FAS 142 -. The total consideration paid to Stem Cell under the agreement amounted to \$620,000 and was derived by multiplying the number of shares issued by the fair market value of the Company's common stock on the date of the agreement or \$2.48 per share. The intangible asset will be amortized over the period which the asset is expected to contribute directly or indirectly to the Company's cash flow. The balance of this intangible asset as of September 30, 2006, was \$612,000.

### Note 8 - SUBSEQUENT EVENTS

To facilitate a financing undertaken by Chronix Biomedical, Inc. ("Chronix") on October 5, 2006 the Company terminated a Shareholders Agreement, Investor Rights Agreement and a Co-Sale Agreement between the Company, Chronix and certain Chronix investors, each dated as of August 25, 2000 (the "Chronix Agreements"). As consideration for terminating the Chronix Agreements the Company received 250,000 shares of restricted Chronix common stock and entered into a Voting Agreement, Investor Rights Agreement and Co-Sale and Right of First Refusal Agreement with Chronix and Certain Chronix investors. The Company does not believe that this transaction will have a material financial impact on its financial statements.

### NOTE 9: RECENT ACCOUNTING PRONOUNCEMENTS

In February 2006, the FASB issued SFAS No. 155, "Accounting for Certain Hybrid Financial Instruments" ("FAS 155") - an amendment of FASB Statements No. 133 and 140. FAS 155 amends SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"), and SFAS No. 140 ("FAS 140"), "Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities", to permit fair value re-measurement of any hybrid financial instrument that contains an embedded derivative that would otherwise require bifurcation. Additionally, FAS 155 seeks to clarify which interest-only strips and principal-only strips are not subject to the requirements of FAS 133 and to clarify that concentrations of credit risk in the form of subordination are not embedded derivatives. This Statement is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. Management does not believe the adoption of this standard will have a material impact on the financial condition or the results of operations of the Company.

On July 13, 2006, the Financial Accounting Standards Board issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"). The requirements are effective for fiscal years beginning after December 15,

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

2006. 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. Management does not believe the adoption of this standard will have a material impact on the financial condition or the results of operations of the Company.

21

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.

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

Our flagship products include Ampligen(R) and Alferon N Injection(R). Ampligen(R) is an experimental drug currently undergoing clinical development for the treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome ("ME/CFS" or "CFS") and HIV, and clinical testing for treatment/prevention of avian and seasonal influenza.

22

Alferon N Injection(R) 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(R) is also in clinical development for treating Multiple Sclerosis and West Nile Virus ("WNV").

### New Accounting Pronouncements

In February 2006, the FASB issued SFAS No. 155, "Accounting for Certain Hybrid Financial Instruments" ("FAS 155") - an amendment of FASB Statements No. 133 and 140. FAS 155 amends SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"), and SFAS 140 ("FAS 140"), "Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities", to permit fair value re-measurement of any hybrid financial instrument that contains an embedded derivative that would otherwise require bifurcation. Additionally, FAS 155 seeks to clarify which interest-only strips and principal-only strips are not subject to the requirements of FAS 133 and to clarify that concentrations of credit risk in the form of subordination are not embedded derivatives. This Statement is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. We do not believe the adoption of this standard will have a material impact on our financial condition or the results of our operations.

On July 13, 2006, the Financial Accounting Standards Board issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"). The requirements are effective for fiscal years beginning after December 15, 2006. 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. Management does not believe the adoption of this standard will have a material impact on the financial condition or the results of operations on us.

### 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/A for the year ended December 31, 2005.

### RESULTS OF OPERATIONS

Three months ended September 30, 2005 versus Three months ended September 30, 2006

Net loss

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

Our net loss for the three months ended September 30, 2006 was approximately \$3,807,000 or an increase of \$1,164,000 compared to the same period in 2005. As discussed in more detail below, this 44% increase primarily consists of 1) an increase of \$215,000 in production (manufacturing), 2) a \$1,525,000 increase in research and development due to the continued development of our products. These increases were offset by a \$108,000 decrease in general and administration expenses and a \$481,000 decrease in financing costs.

Net loss per share was \$.06 for the current period versus \$.05 for the same period in 2005.

23

### Revenues

Revenues for the three months ended September 30, 2006 were \$232,000 as compared to revenues of \$271,000 for the same period in 2005. Alferon N Injection(R) sales were down \$27,000 or 13% while Ampligen(R) sold under the cost recovery clinical program was down \$12,000 or 22%. The decline in Alferon N Injection(R) sales can be attributed to continued pressure from rival products. Ampligen(R) 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 many years and is offered as a treatment option to patients severely affected by ME/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(R) and 2) collection of clinical data relating to the patients' treatment and results. We are in the process of changing our marketing strategy for Alferon N Injection(R). We are looking into conducting a pilot program with a contract sales organization ("CSO"). As part of this strategic change, we have eliminated our direct sales force.

### Production costs/cost of goods sold

Our costs for production/cost of goods sold increased \$215,000 for the three months ended September 30, 2006 compared to the same period in 2005. This increase was primarily due to higher production costs representing excess production capacity during the current period amounting to \$161,000. Cost of goods sold for the three months ended September 30, 2005 and 2006 were \$93,000 and \$147,000, respectively.

As previously reported, we executed a Manufacturing and Safety Agreement with Hyaluron, Inc. ("Hyaluron") of Burlington, Massachusetts, for the formulation, packaging and labeling of Alferon N Injection(R). During the second quarter 2006, Hyaluron conducted three production runs for stability testing of Alferon N Injection(R)'s new vial material. The stability test results at the three month check point met the required specifications. We believe all stability and validation testing will be completed by year end 2006.

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

### Research and Development costs

Overall research and development costs for the three months ended September 30, 2006 were \$2,512,000 as compared to \$987,000 for the same period a year ago representing an increase of \$1,525,000 or 155%. The higher costs reflect an increase in the direct costs associated with our effort to develop



## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

our lead products, Ampligen(R), as a therapy in treating acute and chronic diseases, cancers and on-going clinical trials involving patients with HIV and pre-clinical and clinical testing for possible treatment for avian and seasonal influenza viruses.

Much of this increase in R&D cost is related to the production of polymer at our new polymer production line recently installed at our New Brunswick facility. The New Brunswick facility produced two lots of Poly I and two lots of Poly C12U, which have been shipped to Hollister-Stier (our contract manufacturer) for use in producing Ampligen(R) doses.

The initial three production lots produced by Hollister-Stier are being used for validity and stability testing. The results of these tests will be used in our Ampligen NDA submission. All costs relating to the production of polymers and Ampligen doses are expensed pursuant to SFAS No. 2 "Accounting for Research and Development Cost" as Ampligen is an experimental drug with no present commercial value.

24

We continue to focus our research and development efforts on three areas that have the greatest potential for commercialization:

- o The preparation of a new drug application (NDA) for our experimental drug, Ampligen(R), for the treatment of Chronic Fatigue Syndrome (CFS). CFS is a severe chronic disease that does not have recognized treatment therapy.
- o The formulation of a broad-spectrum biodefense strategy built on the use of our experimental compounds consisting of Ampligen(R) and Alferon LDO(Low Dose Oral). The initial phase of this program is focused on the treatment of Avian and seasonal flu.
- o The validation of suggestions that Alferon N Injection(R), already approved for treating HPV-related genital warts, may have application in treating Vulvar Vestibulitis Syndrome (VVS).

### Ampligen NDA

We continue our efforts with respect to preparing a New Drug Application ("NDA") for submission to the Food and Drug Administration ("FDA") for using Ampligen(R) to treat patients afflicted with Chronic Fatigue Syndrome ("CFS"). CFS is a debilitating disease in which patients suffer complex symptoms such as fatigue, flu-like ailments, headaches and muscle pain. At this time, there are no approved treatment therapies. The Center for Disease Control ("CDC") has added CFS to its priority list of emerging diseases. The preparation of the NDA is a time consuming and laborious process and basically involves the preparation of multiple technical documents including those covering 1) safety data results from animal and humans exposed to Ampligen(R), 2) the data collection and analysis of data from human clinical trials proving the efficacy of Ampligen(R) and 3) the capacity and ability to produce Ampligen(R) on a consistent basis in commercial quantities. We have experienced technical teams assigned to preparing each of these three segments. When completed these three technical documents will be consolidated into the common technical document for submitting to the FDA. While the results of our AMP 516 Phase III clinical study is the basis for filing the NDA we must also include the safety data collected on all patients that ever received Ampligen(R) (some 800 patients from clinical trials for CFS, HIV, Hepatitis, cancer, etc.) All of this is time consuming as our clinical monitors and research assistants must visit and audit the records of clinical investigators involved in our Ampligen clinical studies conducted over the last

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

15 years. Our pre-NDA meeting with the FDA on August 2, 2006 resulted in constructive guidance with respect to the various data segments of our anticipated NDA filing. We may request additional meetings in the near future to complete our pre-NDA requests for guidance.

We have engaged an independent contractor to assist in filing the NDA electronically to facilitate the review by the FDA. We can not yet provide guidance as to the tentative date at which the compilation and filing of the NDA will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the ability of Hollister-Stier facilities to interface with our own New Brunswick staff/facilities to meet the manufacturing regulatory standards. Also, 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(R) 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(R).

25

### Biodefense

Ampligen(R) is a nucleic acid-based molecule with potent immune stimulatory activity and we believe that it has the potential to safely enhance the effectiveness of flu vaccines. Alferon LDO(R) is a new experimental drug delivery platform for our natural source alpha interferon. Preclinical results indicate that Alferon LDO has systemic biological activity on upregulation of Interferon related genes. Potential applications include respiratory infections including influenza. An update on our research and development with respect to these concepts follows.

Our collaborative research partners in Japan, headed by Dr. Hideki Hasegawa, M.D., Ph.D. presented new data on augmentation of influenza vaccines using Ampligen(R) at the Second International Conference on Vaccines for the World on October 20, 2006 in Vienna, Austria. Preclinical research conducted by the National Institute of Infectious Diseases of Japan indicate that certain influenza vaccines augmented with Ampligen can provide cross-protection against Avian Flu viral mutations in animals. Influenza vaccines, both seasonal and avian flu specific, share certain limitations which researcher hope may be overcome using vaccine enhancing agents such as Ampligen, our experimental therapeutic. Additional studies are planned.

A pre-clinical animal study is being conducted by Defence R&D Canada, Suffield (DROC Suffield), an agency of the Canadian department of National Defence, to evaluate the antiviral efficacy of our experimental drug, Ampligen(R) and for protection against human respiratory influenza in validated animal models. The results of this study are expected to be available by year end 2006.

A pre-clinical study being conducted by research affiliates of the National Institute of Health at Utah State University to examine if Ampligen(R) enhances the effectiveness of different drug combinations on avian influenza. The ongoing research is comparing the relative protection conveyed by Tamiflu (Oseltamivir, Roche) and Relenza (Zanamivir, GlaxoSmithKline) with Ampligen(R), alone and in combination, against the avian flu virus. Early results indicate that there is improved protection when Ampligen(R) is combined with Tamiflu and Relenza, and

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

also suggest the potential benefits of Ampligen(R) given as monotherapy. This study is ongoing.

### Vulvar Vestibulitis Syndrome

Alferon N. Injection(R) is our registered trademark for our injectable formulation of Natural Alpha Interferon, and is approved by the FDA for the intralesional treatment of refractory or recurring external genital warts (condylomata acuminata) in patients.

Our strategy is to pursue a modified FDA approval for a related ailment with a large market opportunity and little competition. Vulvar vestibulitis syndrome is a perplexing and debilitating disorder involving pain limited to the vulvar vestibule. The condition impairs sexual function, social interactions and creates psychological distress and despair in millions of women. Its cause is probably multi-factorial, and a number of studies have shown vulvar vestibulitis syndrome to be linked to HPV.

The market opportunity is very large and represents approximately 14 million women in the United States alone.

We are collaborating with others in this effort.

26

### Other Clinical Projects

A clinical study conducted at the Princess Margaret Hospital in Hong Kong evaluated the use of Alferon LDO (Low Dose Oral Interferon Alfa-N3, Human Leukocyte Derived) to determine the affect on genes associated with anti-viral and immunological functions in normal volunteers. This study completed the dosing of ten patients during the fourth quarter 2005. The initial analysis of data from this study is complete. A more definitive evaluation protocol is being developed to further validate the results.

A clinical study to evaluate the use of Alferon LDO in HIV infected volunteers was initiated during the second quarter 2005 in Philadelphia, PA. The study is currently being conducted at two sites, Drexel University and Philadelphia FIGHT, a comprehensive AIDS service organization providing primary care, consumer education, advocacy and research on potential treatments and vaccines. The study is designed to determine whether Alferon LDO can resuscitate the broad-spectrum antiviral and immunostimulatory genes. The initial patient enrolled in this study in July 2005 and, as of October 2006, nineteen patients have enrolled and completed dosing.

We are currently receiving data from this study and we are in the process of analyzing the results along with the results from the Alferon LDO study conducted in Hong Kong. This methodology may have implications for treating other emerging viruses such as avian influenza (bird flu). Present production methods for vaccines involve the use of millions of chicken eggs and would be slow to respond to an outbreak according to a recently convened World Health Organization expert panel in November 2004. Health officials are also concerned that bird flu could mutate to cause the next pandemic and render present vaccines under development ineffective.

Forty (40) HIV patients have participated in our AMP-720 HIV clinical trial. This clinical trial is designed to study the affects of Ampligen with respect to boosting the immune system of HIV patients while they are off of their highly active anti-retroviral therapy ("HAART"). The use of various combinations of three or more of these drugs is referred to as HAART. HAART has

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

provided dramatic decreases in morbidity and mortality of HIV Infection. Often, HIV patients must go off of their HAART regiment due to cumulative build up of toxicities. This off period is referred to strategic therapeutic interruption ("STI"). We believe that the use of Ampligen(R) (an anti-viral compound) during the STI period will aid in the suppression of HIV allowing patients to remain off HAART for longer periods of time (longer STI periods allow the HIV patients more time to rid their bodies of the toxicities). Patients, who have completed at least nine months of Ampligen(R) therapy, were able to stay off HAART for a total STI duration with a mean time of 29.0 weeks whereas the control group, which was also taken off HAART, but not given Ampligen(R), had earlier HIV rebound with a mean duration of 18.7 weeks. Thus, on average, Ampligen(R) therapy spared the patients excessive exposure to HAART, with its inherent toxicities, for more than 11 weeks. The rate of enrollment in this HIV trial depends on patient availability and on other products being in clinical trials for the treatment of HIV, causing competition for the same patient population. At present, more than 18 FDA approved drugs for HIV treatment all competing for available patients. The length, and subsequently the expense of these studies, will also be determined by an analysis of the interim data, which will determine when completion of the ongoing Phase IIb trial is appropriate and whether a Phase III trial will be conducted or not. In case a Phase III study is required, the FDA might require a patient population exceeding the current one which will influence the cost and time of the trial. Accordingly, the number of "unknowns" is sufficiently great to be unable to predict when, or whether, we may obtain revenues from our HIV treatment indications. This study has been temporarily suspended pending the filing of our Ampligen/CFS NDA.

27

Two toxicology studies have been completed at the Lovelace clinic in Albuquerque, New Mexico. These studies involved the use of Ampligen as a vaccine immunostimulant. We plan to conduct a study in Australia to study the immunostimulant effect of Ampligen(R) on influenza vaccination in the elderly.

### General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended September 30, 2005 and 2006 were approximately \$1,384,000 and \$1,276,000, respectively. The decrease in G&A expenses of \$108,000 or 8%, during this period is primarily due to lower professional fees related to public relations services as compared to the same period a year ago.

### Interest and Other Income and Expense

Interest and other income and expense for the three months ended September 30, 2005 and 2006 amounted to \$250,000 and \$356,000, respectively. The increase in interest and other income and expense during the current quarter can primarily be attributed to the timing of maturing marketable securities during the comparable periods. All funds in excess of our immediate need are invested in short-term high quality securities.

### Interest Expense and Financing Costs

Interest expense and non-cash financing costs were approximately \$299,000 for the three months ended September 30, 2006 versus \$700,000 in charges for the same three months a year ago. Non-cash financing costs consist of the amortization of Original Issue Discounts and the amortization of costs associated with beneficial conversion features of our Debentures and the relative fair value of the warrants relating to the Debentures. These charges are reflected in the Consolidated Statements of Operations under the caption "Financing Costs." These charges are amortized over the life of the Debentures.

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

The main reason for the decrease in interest expense and financing costs of \$401,000 can be attributed to decreased amortization charges on the debt discounts on the convertible Debentures. This was slightly offset by an increase in interest expense of \$104,000 due to liquidated damages incurred during the current quarter. Please see Note 5 in the consolidated financial statements contained herein for more details on these transactions.

Nine months ended September 30, 2005 versus Nine months ended September 30, 2006

### Net loss

Our net loss of \$14,807,000 for the nine months ended September 30, 2006 was up \$5,839,000 or 65% compared to the same period in 2005. This increase in loss was primarily due to: 1) Higher G&A expense of \$2,521,000 related primarily to the adoption of FAS 123R amounting to higher stock compensation expense of \$1,998,000 and higher accounting fees mainly related to the restatement of our financial statements of \$697,000, 2) Higher research and development costs of \$4,117,000 due to an increase in direct costs associated with developing Ampligen(R) and Alferon N Injection(R) for new and existing indications and costs associated with stability studies for Ampligen(R) and Alferon N Injection(R) related to manufacturing at our new contract manufacturer's sites, Hollister Stier and Hylaron, and 3) higher production costs of approximately \$711,000 due to excess manufacturing capacity. Offsetting these increased expenditures, was a decrease in our interest expense and financing costs of approximately \$1,651,000 as the amortization of the discounts on our convertible Debentures decreases as they near maturity. Net losses per share were \$.24 for current period versus \$.18 for the same period 2005.

28

### Revenues

Revenues for the nine months ended September 30, 2006 were \$715,000 as compared to revenues of \$829,000 for the same period in 2005. Ampligen(R) sold under the cost recovery clinical program was up \$2,000 or 1% and Alferon N Injection(R) sales were down \$116,000 or 17%. The decline in Alferon N Injection(R) sales can be attributed to increased competition from rival products. Ampligen(R) 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 many years and is offered as a treatment option to patients severely affected by ME/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(R) and 2) collection of clinical data relating to the patients' treatment and results. We are changing our marketing strategy for Alferon N Injection(R). We are looking into conducting a pilot program with a contract sales organization ("CSO"). As part of this strategic change, we have eliminated our direct sales force. In the future, our focus will be on using CSO's to sell Alferon N Injection(R) in the United States and overseas markets.

### Production costs/cost of goods sold

Production/cost of goods sold increased \$711,000 for the nine months ended September 30, 2006 compared to the same period in 2005. This increase was primarily due to higher production costs representing excess production capacity during the nine months ended September 30, 2006, amounting to \$611,000. Cost of goods sold for the nine months ended September 30, 2005 and 2006 were \$294,000 and \$394,000, respectively.

### Research and Development costs

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

Overall research and development direct costs for the nine months ended September 30, 2005 and 2006 were \$3,413,000 and \$7,530,000, respectively, representing an increase of \$4,117,000 or 121%. For more information on research and development activities, see the research and development section contained within the results of operations for the three months ended September 30, 2005 versus three months ended September 30, 2006 discussed above.

### General and Administrative Expenses

General and Administrative ("G&A") expenses for the nine months ended September 30, 2005 and 2006 were approximately \$3,933,000 and \$6,454,000, respectively, representing an increase of a \$2,521,000 or 64%. The increase in G&A expenses relates primarily to the adoption of FAS 123R which has increased stock compensation expense approximately \$1,998,000 during the current period versus a year ago. In addition, we have incurred higher accounting fees related to the restatement of our financial statements which has increased these fees by approximately \$697,000 from the same period a year earlier. These increased costs within G&A expenses were slightly offset by a decrease in costs related to investment banking fees of approximately \$154,000 during the current period versus a year ago.

### Interest and Other Income

Interest and other income for the nine months ended September 30, 2005 and 2006 totaled \$543,000 and \$516,000, respectively. The decrease in interest and other income during the current period can primarily be attributed to the timing of the maturities of our marketable securities during the 2006 period versus the same period a year earlier. All funds in excess of our immediate need are invested in short-term high quality securities.

29

### Interest Expense and Financing Costs

Interest expense and non-cash financing costs were approximately \$1,049,000 for the nine months ended September 30, 2006 versus \$2,700,000 for the same nine months a year ago. The main reason for the decrease in interest expense and financing costs of \$1,651,000 can be attributed to decreased amortization charges on debt discounts during the current period versus the same period a year earlier as well as fewer charges related to the conversion of the Debentures being incurred during the current period (Please see Note 5 in the consolidated financial statements contained herein for more details on these transactions).

### Liquidity And Capital Resources

Cash used in operating activities for the nine months ended September 30, 2006 was \$9,328,000 compared to \$5,283,000 for the same period a year earlier. This increase of \$4,045,000 was primarily due to higher research and development activity for our experimental products. Cash used in investing activities was \$3,246,000 for the nine months ended September 30, 2006. This was mainly due to the net effect of purchases and maturities within our short term investments as well as capital additions to our New Jersey facility relating to our raw material production line. Cash provided by financing activities for this period amounted to \$13,265,000, primarily from the sale of our common stock. As of September 30, 2006, we had approximately \$19,023,000 in cash and cash equivalents and short-term investments, an increase of \$2,819,000 from December 31, 2005. These funds should be sufficient to meet our operating cash requirements including debt service for the next 18 months.

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

On February 27, 2006, the Debenture holders converted \$333,334 principal amount of the January 2004 Debentures into 160,257 shares of common stock. On March 21, 2006, the Debenture holders converted \$500,000 of the July 2004 Debentures into 240,385 shares of common stock.

Due to our inability to timely file our annual report on Form 10-K for the year ended December 31, 2005, our registration statements, and the prospectus contained therein, registering the shares issuable upon conversion of and interest under the Debentures and upon exercise of related warrants were no longer current. As a result, we were subject to liquidated damages until the time that such shares were again registered for public resale or eligible for resale pursuant to Rule 144(k) under the Securities Act. The securities were again covered by a registration statement declared effective by the SEC on August 7, 2006. We have calculated the liquidated damages to be approximately \$350,000.

Pursuant to the terms of the July 8, 2005 common stock purchase agreement, as of April 3, 2006, Fusion Capital had purchased an aggregate of 8,791,838 shares amounting to our receipt of approximately \$20,000,000 in gross proceeds which completed the terms of the agreement. Pursuant to the agreement, the Company also issued 785,597 commitment fee shares and 10,000 shares as reimbursement for expenses.

On April 12, 2006, we entered into a common stock purchase agreement (the "2006 Purchase Agreement") with 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 \$50,000,000 over a period of approximately 25 months as described below. We have the right to suspend such purchases or terminate the agreement at any time. The purchase price of the shares of common stock will be equal to a price based upon the future market price of the common stock. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than \$1.00.

The purchase price per share will be equal to the lesser of (i) the lowest sale price of our common stock on the purchase date; or (ii) the average of the three lowest closing sale prices of our common stock during the twelve consecutive trading days prior to the date of a purchase by Fusion Capital.

30

The purchase price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction. Fusion Capital may not purchase shares of our common stock under the common stock purchase agreement if it, together with its affiliates, would beneficially own more than 9.9% of our common stock outstanding at the time of the purchase by Fusion Capital. Fusion Capital has the right at any time to sell any shares purchased under the 2006 Purchase Agreement which would allow it to avoid the 9.9% limitation. Due to American Stock Exchange requirements (the "AMEX Cap"), without prior stockholder approval, we do not have the right or the obligation under the Agreement to sell shares to Fusion Capital in excess of 12,386,723 shares (i.e. 19.99% of the 61,964,598 outstanding shares of our common stock on April 12, 2006, the date of the 2006 Purchase Agreement) inclusive of the commitment shares (discussed below). Notwithstanding the foregoing, Fusion Capital cannot purchase more than 27,386,723 shares, inclusive of the commitment shares under the common stock purchase agreement. On September 20, 2006 our stockholders voted to approve the issuance of up to 27,386,723 shares pursuant to the terms of the agreement.

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

We also have the right to increase the daily purchase amount at any time, provided however, we may not increase the daily purchase amount above \$100,000 unless our stock price is above \$1.90 per share for five consecutive trading days. Specifically, for every \$0.10 increase in Threshold Price (as defined below) above \$1.90, we have the right to increase the daily purchase amount by up to an additional \$10,000. The "Threshold Price" is the lowest sale price of our common stock during the five trading days immediately preceding our notice to Fusion Capital to increase the daily purchase amount. If at any time during any trading day the sale price of our common stock is below the Threshold Price, the applicable increase in the daily purchase amount will be void.

In addition to the daily purchase amount, we may elect to require Fusion Capital to purchase on any single trading day the following:

- o \$250,000 if our common stock trades at \$1.50 or better for five trading days.
- o \$500,000 if our common stock trades at \$3.00 or better for five trading days.
- o \$1,000,000 if our common stock trades at \$5.00 or better for five trading days.
- o \$2,000,000 if our common stock trades at \$8.00 or better for five trading days.

The price at which such shares would be purchased will be the lesser of (i) the lowest Sale Price on the trading day that such purchase notice was received Fusion Capital or (ii) the lowest purchase price (as defined above) during the previous ten trading days prior to the date that such purchase notice was received by Fusion Capital.

We filed a registration statement (the "Registration Statement") with the Securities and Exchange Commission on July 31, 2006 covering the shares of our common stock to be issued under the 2006 Purchase Agreement and are required to keep it effective until the earlier of the date that all shares are sold or can be sold pursuant to the provisions of Rule 144(k) under the Securities Act. The registration statement was declared effective by the Securities and Exchange Commission on August 7, 2006. If we do not keep the registration statement effective, Fusion Capital may terminate the agreement.

Generally, Fusion Capital may terminate the common stock purchase agreement without any liability or payment to us upon the occurrence of any of the following events of default:

31

- o our failure to timely file the registration statement or, once the registration statement is declared effective, the effectiveness of the registration statement lapses for any reason or is unavailable to Fusion Capital for sale of our common stock and such lapse or unavailability continues for a period of 10 consecutive trading days or for more than an aggregate of 30 trading days in any 365-day period;
- o suspension by our principal market of our common stock from trading for a period of three consecutive trading days;
- o the de-listing of our common stock from the American Stock Exchange, our principal market, provided our common stock is not immediately thereafter trading on the Nasdaq National Market, the Nasdaq SmallCap Market or the



## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

New York Stock Exchange or the OTC Bulletin Board;

- o the transfer agent's failure for five trading days to issue to Fusion Capital shares of our common stock which Fusion Capital is entitled to under the 2006 Purchase Agreement;
- o any material breach of the representations or warranties or covenants contained in the 2006 Purchase Agreement or any related agreements which has or which could have a material adverse effect on us subject to a cure period of 10 trading days;
- o any participation or threatened participation in insolvency or bankruptcy proceedings by or against us;
- o a material adverse change in our business, properties, operations, financial condition or results of operations; or
- o the issuance of an aggregate of 12,386,733 shares to Fusion Capital under our agreement and we fail to obtain the requisite stockholder approval.

We have the unconditional right at any time for any reason to give notice to Fusion Capital terminating the 2006 Purchase Agreement. Such notice shall be effective one trading day after Fusion Capital receives such notice.

Under the terms of 2006 Purchase Agreement, Fusion Capital has received 321,751 shares of our common stock as a partial commitment fee and is entitled to receive up to an additional 321,751 commitment shares (collectively, the "Commitment Shares"). These additional commitment shares will be issued in an amount equal to the product of (x) 321,751 and (y) the Purchase Amount Fraction. The "Purchase Amount Fraction" means a fraction, the numerator of which is the purchase price at which the shares are being purchased by Fusion Capital and the denominator of which is \$50,000,000. Unless an event of default occurs these shares must be held by Fusion Capital until 25 months from the date of the 2006 Purchase Agreement or the date such agreement is terminated or in the event that certain conditions precedent are not met.

We anticipate using the proceeds from this financing to extend our New Brunswick facility for the production of Ampligen(R) and Alferon N Injection(R), Research and Development to meet potential government procurement requirements concerning avian influenza treatment and/or prevention and for general corporate purposes.

As of November 1, 2006, Fusion Capital had purchased 922,038 shares for aggregate gross proceeds of approximately \$1,849,000. In addition, we issued to Fusion Capital 11,898 shares towards the remaining commitment fee.

To facilitate a financing undertaken by Chronix Biomedical, Inc. ("Chronix") on October 5, 2006 we terminated a Shareholders Agreement, Investor Rights Agreement and a Co-Sale Agreement between us, Chronix and certain Chronix investors, each dated as of August 25, 2000 (the "Chronix Agreements"). As consideration for terminating the Chronix Agreements we received 250,000 shares of restricted Chronix common stock and entered into a Voting Agreement, Investor Rights Agreement and Co-Sale and Right of First Refusal Agreement with Chronix and certain Chronix investors. We do not believe that this transaction will have a material financial impact on our financial statements.

Please see Note 5 "Debt Financing" and Note 6 "Equity Financing" in the consolidated financial statements contained herein for more details on

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

debenture and stock financings.

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 \$19,023,000 in cash and cash equivalents and short-term investments at September 30, 2006. 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 high quality 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

#### Evaluation of Disclosure Controls and Procedures

An evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this Quarterly Report on Form 10-Q was made under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer. In connection with such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are not effective based on the material weaknesses in internal control over financial reporting described in our Annual Report on Form 10-K/A for the period ended December 31, 2005.

#### Remediation of Material Weaknesses

During the second quarter of 2006, to remedy the material weakness in our internal control over financial reporting, we initiated the process of establishing procedures to enhance controls over the "financial statement close and disclosure" process which included subscribing to CCH's "Accounting Research Manager", a recognized on-line service in order to maintain up-to-date accounting and disclosure guidance. In addition, we have established policies and procedures to include a detailed comprehensive review of the underlying information supporting the amounts included within our consolidated financial

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

statements and disclosures including documented reviews to assist in ensuring: 1) clerical accuracy within our financial statements and disclosures, 2) financial statement groupings within our financial statements are accurate, 3) support utilized in preparation of the consolidated statement of cash flows is accurate, and 4) equity transactions during the reporting period are completely and accurately recorded. We engaged an additional accounting consultant in April 2006 to assist in initiating the implementation of these policies and procedures during the second quarter 2006. The control deficiencies will be fully remediated when in the opinion of our management, the revised control processes have been operating for a sufficient period of time to provide reasonable assurance as to their effectiveness. We believe our management will be able to make this assessment by December 31, 2006.

33

### Changes in Internal Controls

Other than as described above, there was no change in our internal controls over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period covered by this report 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

On September 30, 1998, we filed a multi-count complaint against Manuel P. Asensio, Asensio & Company, Inc. ("Asensio"). The action included claims of defamation, disparagement, tortious interference with existing and prospective business relations and conspiracy, arising out of Asensio's false and defamatory statements. The complaint further alleged that Asensio defamed and disparaged us in furtherance of a manipulative, deceptive and unlawful short-selling scheme in August and September, 1998. In 1999, Asensio filed an answer and counterclaim alleging that in response to Asensio's strong sell recommendation and other press releases, we made defamatory statements about Asensio. We denied the material allegations of the counterclaim. In July 2000, following dismissal in federal court for lack of subject matter jurisdiction, we transferred the action to the Pennsylvania State Court. In March 2001, the defendants responded to the complaints as amended and a trial commenced on January 30, 2002. A jury verdict disallowed the claims against the defendants for defamation and disparagement and the court granted us a directed verdict on the counterclaim. On July 2, 2002 the Court entered an order granting us a new trial against Asensio for defamation and disparagement. Thereafter, Asensio appealed the granting of a new trial to the Superior Court of Pennsylvania. The Superior Court of Pennsylvania has denied Asensio's appeal. Asensio petitioned the Supreme Court of Pennsylvania for allowance of an appeal, which was denied. We now anticipate the scheduling of a new trial against Asensio for defamation and disparagement in the Philadelphia Common Pleas Court.

In June 2002, a former ME/CFS clinical trial patient in Belgium filed a claim in Belgium, against Hemispherx Biopharma Europe, NV/SA, our Belgian subsidiary, and one of our clinical trial investigators alleging that she was harmed in the Belgium ME/CFS clinical trial as a result of negligence and breach of warranties. We believe the claim is without merit and we are defending the claim against us through our product liability insurance carrier.

34

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

In December 2004, we filed a multicount complaint in federal court (Southern District of Florida) against a conspiratorial group seeking to illegally manipulate our stock for purposes of bringing about a hostile takeover of Hemispherx. The lawsuit alleges that the conspiratorial group commenced with a plan to seize control of our cash and proprietary assets by an illegal campaign to drive down our stock price and publish disparaging reports on our management and current fiduciaries. The lawsuit seeks monetary damages from each member of the conspiratorial group as well as injunctions preventing further recurrences of their misconduct. The conspiratorial group includes Bioclones, a privately held South African Biopharmaceutical company that collaborated with us, and Johannesburg Consolidated Investments, a South African corporation, Cyril Donninger, R. B. Kebble, H. C. Buitendag, Bart Goemaere, and John Doe(s). Bioclones, Johannesburg Consolidated Investments, Cyril Donninger, R. B. Kebble and H.C. Buitendag filed a motion to dismiss the complaint, which was granted by the court. We are in the process of appealing this decision to the 11th federal circuit court of appeals.

On January 10, 2005, we initiated a multicount lawsuit in the United States District Court for the Eastern District of Pennsylvania seeking injunctive relief and damages against a conspiratorial group, many of whom are foreign nationals or companies located outside the United States alleging that the conspiratorial group has engaged in secret meetings, market manipulations, fraudulent misrepresentations, utilization of foreign accounts and foreign secrecy laws all in furtherance of an illegal scheme to take over Hemispherx and enrich themselves at the expense of Hemispherx's public shareholders. On February 18, 2005 we filed an amended complaint in the same lawsuit joining Redlabs, USA, Inc. as a defendant with the existing defendants R.E.D. Laboratories, N.V./S.A., Bart Goemaere, Jan Goemaere, Dr. Kenny De Meirleir, Kenneth Schepmans, Johan Goossens, Lieven Vansacker and John Does. Pursuant to an agreement in which R.E.D. Laboratories, N.V./S.A. and Dr. Kenny DeMeirleir agreed not to participate in a hostile takeover of Hemispherx for a period of five years, R.E.D. Laboratories, N.V./S.A. and Dr. Kenny DeMeirleir have been dismissed as defendants in the litigation. We dismissed without prejudice the litigation against the remaining defendants.

In October 2006, litigation was initiated in the Court of Common Pleas, Philadelphia County, Pennsylvania between us and Hospira Worldwide, Inc. with regard to a dispute with respect to fees for services charged by Hospira Worldwide, Inc. to us. The dispute was promptly settled and the litiagion dismissed.

### 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 report. 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(R) and related products. The development of Ampligen(R) and our other related products is subject to a number of significant risks. Ampligen(R) 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(R) or our other products will

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

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.

35

We are in the process of preparing an NDA to be submitted to the FDA for approval to use Ampligen in the treatment of Chronic Fatigue Syndrome. We can provide no guidance as to the tentative data at which the compilation and filing of the NDA will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the ability of Hollister-Stier facilities to interface with our own New Brunswick staff/facilities to meet the manufacturing regulatory standards. Also, 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(R) 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(R).

Alferon N Injection(R). Although Alferon N Injection(R) 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 such as multiple sclerosis and cancer.

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(R), 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(R) 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(R) for other indications will require regulatory approval. In this regard, ISI, the company from which we obtained our rights to Alferon N Injection(R), conducted clinical trials related to use of Alferon N Injection(R) for treatment of HIV and Hepatitis C. In both instances, the FDA determined that additional studies were necessary in order to fully evaluate the efficacy of Alferon N Injection(R) in the treatment of HIV and Hepatitis C diseases. We have no immediate plans to conduct these additional studies at this time.

Our products, including Ampligen(R), 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 ("EMEA") in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen(R) or any other proposed product and receive product revenues or

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

royalties. We cannot assure you that Ampligen(R) will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligen(R) is authorized for use in clinical trials in the United States, 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(R) 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.

36

Although preliminary in vitro testing indicates that Ampligen(R) 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(R) is undergoing pre-clinical testing for possible treatment of avian flu. Although preliminary in vitro testing indicates that Ampligen(R) 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(R) 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(R) is being tested on two strains of avian flu. There are a number of strains and strains mutate. No assurance can be given that Ampligen(R) 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 and expanded our efforts in Europe. As of September 30, 2006 our accumulated deficit was approximately \$162,459,000. 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, 2006, we had approximately \$19,023,000 in cash and cash equivalents and short-term investments. These funds should be sufficient to meet our operating cash requirements, including debt service, for at least the next 18 months.

On April 12, 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC, pursuant to which Fusion Capital has agreed, under certain conditions and with certain limitations, to purchase on each trading day

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

\$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 \$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 12,386,723 shares purchasable by Fusion Capital pursuant to the common stock purchase agreement (inclusive of up to 643,502 additional Commitment Shares), the selling price of our common stock to Fusion Capital will have to average at least about \$4.26 per share for us to receive the maximum proceeds of \$50,000,000 without registering additional shares of common stock. Assuming a purchase price of \$2.03 per share (the closing sale price of the common stock on November 1, 2006) and the purchase by Fusion Capital of the full 12,386,723 shares (inclusive of up to 643,502 additional Commitment Shares) under the common stock purchase agreement, proceeds to us would only be \$23,838,739 unless we choose to register more than 12,386,723 shares, which we have the right, but not the obligation, to do. In the event we elect to issue additional shares to Fusion Capital, we will be required to (i) file a new registration statement and have it declared effective by the Securities and Exchange Commission. In order to be in compliance with the American Stock Exchange rules, our stockholders on September 20, 2006 approved the issuance of up to 27,386,723 shares to accommodate this agreement, if needed. 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, we may realize less than the maximum \$50,000,000 proceeds from the sale of stock under the Purchase Agreement.

37

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(R) and/or increase sales of Alferon N Injection(R) 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(R) 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(R) for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen(R) for such disease. We obtained all rights to Alferon N Injection(R), and we plan to preserve and acquire enforceable patents

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

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 drug product which are carried out according to standard operating procedure manuals. We have been issued certain patents including those on the use of Ampligen(R) and Ampligen(R) in combination with certain other drugs for the treatment of HIV. We also have been issued patents on the use of Ampligen(R) 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(R) in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of Ampligen(R) as a sole treatment for any of the cancers, which we have sought to target. With regard to Alferon N Injection(R), 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.

38

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



## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

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.

39

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 also had an agreement with Bioclones (Proprietary), Ltd ("Bioclones") that covered South America, Africa, United Kingdom, Australia and New Zealand. However, we deem this marketing arrangement with Bioclones void due to the numerous and long standing failures of performance by Bioclones. In addition, in December 2004, we initiated a lawsuit in Federal Court identifying a conspiratorial group seeking to illegally manipulate our stock for purposes of bringing about the hostile takeover of Hemispherx. This conspiratorial group includes Bioclones.

We cannot assure that our domestic 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(R) and/or Ampligen(R).

A number of essential materials are used in the production of Alferon N Injection(R), 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(R). 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(R) raw materials in order to obtain polymers on a more consistent manufacturing basis. The establishment of an Ampligen(R) raw materials production line within our own

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

facilities, while having obvious advantages with respect to regulatory compliance (other parts of our 43,000 sq. ft. wholly owned FDA approved facility are already in compliance for the manufacture of Alferon N Injection(R)), may delay certain steps in the commercialization process, specifically a targeted NDA filing.

If we are unable to obtain or manufacture the required raw materials, 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(R) and the commercial production of Alferon N Injection(R) 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.

40

Small changes in methods of manufacturing, including commercial scale-up, may affect the chemical structure of Ampligen(R) 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(R) 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(R) or other products in commercial quantities at costs acceptable to us.

We have never produced Ampligen(R) or any other products in large

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

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(R) 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(R) 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.

41

Our products may be subject to substantial competition.

Ampligen(R). 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 HIV diseases 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(R) on the immune system, we cannot assure that we will be able to compete.

ALFERON N Injection(R). Many 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. Alferon N Injection(R) currently competes with Schering's injectable recombinant alpha interferon product (INTRON(R) A) for the treatment of genital warts. 3M Pharmaceuticals also received FDA approval for its immune-response modifier, Aldara(R), a self-administered topical cream, for the treatment of external genital and perianal warts. Alferon N Injection(R) also competes with surgical,

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

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(R). If and when we obtain additional approvals of uses of this product, we expect to compete primarily on the basis of product performance. Our potential competitors have developed or may develop products (containing either alpha or beta interferon or other therapeutic compounds) or other treatment modalities for those uses. In the United States, three recombinant forms of beta interferon have been approved for the treatment of relapsing-remitting multiple sclerosis. There can be no assurance that, if we are able to obtain regulatory approval of Alferon N Injection(R) 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(R). Currently, our wholesale price on a per unit basis of Alferon N Injection(R) 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.

42

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

Ampligen(R). We believe that Ampligen(R) 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 slowing the infusion rate. 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(R) in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

Alferon N Injection(R). At present, Alferon N Injection(R) 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(R), 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(R) which could threaten or

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

limit such product's usefulness.

We may be subject to product liability claims from the use of Ampligen(R), Alferon N Injection(R), 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(R) 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(R) and/or Alferon N Injection(R) product liability claims. A successful product liability claim against us in excess of Ampligen(R)'s \$1,000,000 in insurance coverage; \$3,000,000 in aggregate, or in excess of Alferon N Injection(R)'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 Dr. William A. Carter's services 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(R), 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.

43

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.

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

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

We reported material weaknesses in our internal control over financial reporting that, if not remedied, could adversely affect our internal controls.

We assessed the effectiveness of our internal control over financial reporting as of December 31, 2005. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control--Integrated Framework (COSO). Based on this assessment, our management identified the following material weaknesses as of December 31, 2005. A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

1. Financial Statement Close and Reporting Process - We did not maintain effective controls over the financial statement close and reporting process because we lacked a complement of personnel able to devote sufficient time and adequate financial reporting expertise commensurate with quarterly and year-end financial statement close requirements, which include the financial statement preparation and disclosures. Additionally, we had inadequate policies and procedures providing for a detailed comprehensive review of the underlying information supporting the amounts including in our annual and interim consolidation financial statements and disclosures.

44

2. We did not maintain effective controls over the initial recording of our convertible debentures that contained beneficial conversion features (including incorrect recording of investment banking fees incurred and subsequent conversion price resets) and the accounting for warrants and options issued to non-employees. Our interpretation and application of EITF No. 00-27, FASB Statement 133, EITF 98-5 and EITF 00-19 was not correct at the time the convertible debentures were initially recorded (2003 through July 2004), and our interpretation and application of FASB statement No. 123 was not correct in recording certain warrant and option issuances to non-employees. These control deficiencies resulted in the restatement of the 2004 and 2003 annual consolidated financial statements as well as to the unaudited consolidated interim financial statements for each of the three quarters in the period ended December 31, 2005.

The result of applying the proper accounting treatment increased our net loss applicable to common stockholders by \$0.01, from \$0.42 per share to \$0.43 per share, for the year ended December 31, 2003 and decreased our net loss applicable to common stockholders by \$0.07, from \$0.53 per share to \$0.46 per share, for the year ended December 31, 2004.

Although the recording of the convertible debentures occurred during the periods from March 2003 through July 2004, and we have not issued any debentures

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

since July 2004, we have taken and plan to take, during 2006, additional steps to remediate these internal control weaknesses. We have subscribed to CCH's "Accounting Research Manager," a recognized on-line service in order to maintain up-to-date accounting guidance to enhance internal control over both financial reporting and disclosure requirements. In addition, we have established policies and procedures to include a detailed comprehensive review of the underlying information supporting the amounts included within our consolidated financial statements and disclosures including to assist in ensuring: 1) clerical accuracy within our financial statements and disclosures, 2) financial statement groupings within our financial statements are accurate, 3) support utilized in preparation of the consolidated statement of cash flows is accurate, and 4) equity transactions during the reporting period are complete and accurate. We also engaged an additional accounting consultant in April 2006 to assist in initiating the implementation of these policies and procedures on a going forward basis. Notwithstanding the foregoing, and the measures we have taken and any future measures we may take to remediate the reported internal control weaknesses, we may not be able to maintain effective internal controls over financial reporting in the future. In addition, deficiencies in our internal controls may be discovered in the future. Any failure to remediate the reported material weaknesses, or to implement new or improved controls, or difficulties encountered in their implementation, could harm our operating results, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Any such failure also could affect the ability of our management to certify in our Forms 10-K and 10-Q that our internal controls are effective when it provides an assessment of our internal control over financial reporting, and could affect the results of our independent registered public accounting firm's related attestation report regarding our management's assessment. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our securities.

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

45

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:

- o announcements of the results of clinical trials by us or our competitors;
- o adverse reactions to products;
- o 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;
- o changes in U.S. or foreign regulatory policy during the period of product development;
- o developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- o announcements of technological innovations by us or our competitors;
- o announcements of new products or new contracts by us or our competitors;
- o actual or anticipated variations in our operating results due to the level

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

- of development expenses and other factors;
- o changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- o conditions and trends in the pharmaceutical and other industries; new accounting standards; and
- o 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 November 1, 2006, the price of our common stock has ranged from \$1.80 to \$4.23 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 12,386,723 shares for sale by Fusion Capital and 520,617 shares by others, and may, in the future, register additional shares for sale by Fusion under the common stock purchase agreement. As of November 1, 2006, approximately 1,559,310 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act, 715,409 of which have been registered in prior registration statements. Also, we have registered 10,084,996 shares issuable (i) upon conversion of approximately 135% of Debentures that we issued in 2003 and 2004; (ii) as payment of 135% of the interest on all of the Debentures; (iii) upon exercise of 135% of certain Warrants; and (iv) 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.

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



## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

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 resales by Fusion Capital and other selling stockholders as contemplated in this prospectus 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 this prospectus will be sold over a period of in excess of 25 months. Depending upon market liquidity at the time, a sale of shares under this offering 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 9.0% 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

## Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

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(R) 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, 2006, we issued 1) 303,946 shares issued pursuant to the 2006 Purchase Agreement with Fusion Capital, 2) an aggregate of 24,605 shares for services performed and an aggregate of 311,728 shares for the acquisition of patent rights and royalties.

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, 2006.

### ITEM 3: Defaults upon Senior Securities

None.

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

We held our Annual Meeting of Stockholders on September 20, 2006. At that meeting, total shares voted were 47,903,996 shares out of 62,581,122 shares eligible to vote.

At the meeting, stockholders approved the following:

#### Election of Directors:

	For	Withheld
William A. Carter, M.D.	47,413,813	490,185
Richard C. Piani, Esq.	47,458,016	445,982
Ransom W. Etheridge, Esq.	47,473,955	430,043
William M. Mitchell, M.D., Ph.D.	47,472,928	431,070
Iraj-Eqhbali Kiani, Ph.D.	47,461,968	442,030
Steven D. Spence	47,484,128	419,870

48

Amendment of our Certificate of Incorporation to increase the number of authorized shares of common stock from 100 million to 200 million:

For: 46,714,015 Against: 1,132,755 Abstain: 57,228

Issuance of our common stock to comply with AMEX Company Guide Section 713:

For: 5,634,086 Against: 453,478 Abstain: 41,781,796

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q

The ratification of the appointment of BDO Seidman, LLP as our independent registered public accountants was not voted on as BDO Seidman, LLP has resigned following the filing of this Form 10-Q.

ITEM 5: Other Information

None.

ITEM 6: Exhibits

(a) Exhibits

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

49

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, 2006

50