

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

HEMISPHERX BIOPHARMA INC
Form 10-Q/A
April 15, 2003

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q/A-1

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

For the Quarterly Period Ended September 30, 2002

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.

/X/ Yes / / No

32,080,270 shares of common stock issued and outstanding as of October 31, 2002.

PART I - FINANCIAL INFORMATION

ITEM 1: Financial Statements

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands)

December 31, September 30,
2001 2002

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

(Unaudited)

ASSETS

Current assets:

Cash and cash equivalents	\$3,107	\$3,471
Short Term investments	5,310	837
Accounts receivable	8	12
Prepaid expenses and other current assets	381	98
	-----	-----
Total current assets	8,806	4,418
Property and equipment, net	246	177
Patent and trademark rights, net	1,025	1,087
Investments in unconsolidated affiliates	1,878	1,128
Other assets	80	53
	-----	-----
Total assets	\$12,035	\$ 6,863
	=====	=====

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$ 979	\$ 703
Accrued expenses	293	231
	-----	-----
Total current liabilities	1,272	934
	-----	-----

Commitments and contingencies:

Minority interest in subsidiary (Note 5)	-	946
--	---	-----

Stockholders' equity:

Common stock	33	33
Additional paid-in capital	106,832	107,115
Accumulated other comprehensive income	17	17
Treasury stock - at cost	(4,470)	(4,520)
Accumulated deficit	(91,649)	(97,662)
	-----	-----
Total stockholders' equity	10,763	4,983
	-----	-----
Total liabilities and stockholders' equity	\$12,035	\$ 6,863
	=====	=====

See accompanying notes to condensed consolidated financial statements.

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

For the Three months ended
September 30,

	-----	-----
(Unaudited)		
2001		2002
	-----	-----

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

Revenues:		
Cost recovery - clinical treatment programs	\$ 76	\$ 79
	-----	-----
Costs and expenses:		
Research and development	1,589	1,194
General and administrative	673	767
	-----	-----
Total cost and expenses	2,262	1,961
Interest and other income	68	23
Equity in loss of unconsolidated affiliate	(27)	(32)
	-----	-----
Net loss	\$ (2,145)	\$ (1,891)
	=====	=====
Basic and diluted loss per share	\$ (.07)	\$ (.06)
	=====	=====
Basic and diluted weighted average common shares outstanding	30,528,322	32,093,066
	=====	=====

See accompanying notes to condensed consolidated financial statements.

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

For the Nine months ended
September 30,

(Unaudited)
2001 2002

Revenues:		
Cost recovery - clinical treatment programs	\$ 304	\$ 263

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

License fee income	-	563
	-----	-----
	304	826
Costs and expenses:		
Research and development	4,765	3,732
General and administrative	2,677	2,447
	-----	-----
Total cost and expenses	7,442	6,179
Interest and other income	248	90
Loss on investment due to impairment	-	(678)
Equity in loss of unconsolidated affiliate	(78)	(72)
	-----	-----
Net loss	\$ (6,968)	\$ (6,013)
	=====	=====
Basic and diluted loss per share	\$ (.23)	\$ (.19)
	=====	=====
Basic and diluted weighted average common shares outstanding	30,202,583	32,083,957
	=====	=====

See accompanying notes to condensed consolidated financial statements.

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

For the Nine months ended
September 30,

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

	(Unaudited)	
	2001	2002
	-----	-----
Cash flows from operating activities:		
Net loss	\$(6,968)	\$(6,013)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	99	69
Amortization of patents rights	290	79
Write-off of patent rights	29	2
Stock option and warrant compensation and service expense	673	132
Equity in loss of unconsolidated affiliates	77	72
Loss in investment due to impairment	-	678
Changes in assets and liabilities:		
Accounts receivable	47	(4)
Prepaid expenses and other current assets	259	283
Accounts payable	(278)	(190)
Accrued expenses	32	(62)
Other assets	3	27
	-----	-----
Net cash (used in) operating activities	(5,737)	(4,927)
	-----	-----
Cash flows from investing activities:		
Additions to patent rights	(100)	(143)
Maturity of short term investments	4,613	5,310
Purchase of short term investments	(1,220)	(837)
Investments in unconsolidated affiliates	(22)	-
	-----	-----
Net cash provided by investing activities	3,271	4,330
	-----	-----
Cash flows from financing activities:		
Proceeds from issuance of common stock	73	6
Proceeds from exercise of warrants	2,050	59
Proceeds from issuance of preferred stock of subsidiary	-	946
Purchase of treasury stock	(519)	(50)
	-----	-----
Net cash provided by financing activities	1,604	961
	-----	-----
Net (decrease) increase in cash and cash equivalents	(862)	364
Cash and cash equivalents at beginning of period	3,721	3,107
	-----	-----
Cash and cash equivalents at end of period	\$2,859	\$3,471
	=====	=====
Supplemental disclosures of cash flow information:		
Issuances of common stock for accounts payable	-	\$ 86
	=====	=====

See accompanying notes to condensed consolidated financial statements.

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: BASIS OF PRESENTATION

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

The accompanying consolidated financial statements include the accounts of Hemispherx BioPharma, Inc., a Delaware corporation and its subsidiaries. All significant intercompany accounts and transactions have been eliminated.

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, 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 year 2001 consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2001, as filed with the SEC on April 9, 2002.

NOTE 2: STOCK COMPENSATION

This charge consists of the fair market value of warrants issued to outside parties for services rendered on behalf of the Company. Stock warrant compensation expense has no effect on shareholder equity as it is offset by an increase in additional paid in capital.

The Company recorded \$673,000 in non-cash stock compensation expense in the first nine months of 2001. These charges were the result of actions taken by the Board of Directors in 1) extending the expiration date of certain non-public warrants which produced stock compensation expense of \$262,000 and 2) the granting of warrants to certain financial advisors which produced stock compensation expense of \$411,000. Approximately \$132,000 was booked in the first nine months of 2002 for stock compensation expense for services provided.

On August 14, 2002, the company 1) extended the expiration date of 1,722,000 stock warrants previously granted to certain Officers, Directors and Employees that were scheduled to expire in the near term with a weighted average exercise price of \$3.59, 2) granted 1,200,000 stock warrants in connection with the extension of employment contracts with two officers, and 3) granted 410,000 stock warrants to various Officers, Directors and Employees. These stock warrants have an exercise price of \$2.00 per share and expire on August 13, 2008.

In accordance to FASB Interpretation No. 44, Accounting for Certain Transaction Involving Stock Compensation, no compensation expense is recognized as the exercise price at the extension date exceeded the fair of value of the underlying common stock.

Note 3: INVESTMENTS

Investments in unconsolidated affiliates:

In 1998, the Company invested \$1,074,000 for a 3.3% equity interest in R.E.D. Laboratories ("R.E.D."). R.E.D. is a privately held biotechnology company for the development of diagnostic markers for Chronic Fatigue Syndrome and other chronic immune diseases. We have a research collaboration agreement with R.E.D. to assist in this development. R.E.D. is headquartered in Belgium. The investment was recorded at cost. In June, 2002 we recorded a non-cash charge of \$678,000 to operations with respect to our investment in R.E.D. This charge was the result of our determination that R.E.D.'s business had not yet evolved to

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

the point that our initial carrying value of this investment could be supported. Our net investment as of September 30, 2002 was \$396,000.

On May 11, 1999, the Company acquired a 15% interest in California Institute of Molecular Medicine ("CIMM") for \$375,000. On May 16, 2000, the Company acquired an additional 15% interest in CIMM. The Company currently has a total interest of 30% in CIMM for a total of \$750,000. CIMM is developing therapy for treating Hepatitis C virus. The investment has been recorded by the equity method. During the fourth quarter of 2001, the Company recorded a non-cash charge of \$485,000 to operations with respect to the Company investment in CIMM. This charge was the result of the Company's determination that CIMM'S operation had not yet evolved to the point where the Company's full carrying value of this investment could be supported pursuant to the guidelines of APB opinion No. 18. The \$485,000 represents the unamortized balance of goodwill included as part of the Company's investment. The Company's net investment in CIMM was \$32,234 at September 30, 2002.

Other investments include an initial equity investment of \$290,625 in Chronix Biomedical ("Chronix"). Chronix focuses upon the development of diagnostics for chronic diseases. This initial investment was made in May 31, 2000 by the issuance of 50,000 shares of Hemispherx Biopharma, Inc. common stock from the treasury. On October 12, 2000, the Company issued an additional 50,000 shares of Hemispherx Biopharma, Inc. common stock and on March 7, 2001 the Company issued 12,000 more shares of Hemispherx Biopharma, Inc. common stock from the treasury to Chronix for an aggregate equity investment of \$700,000.

Note 4: REVENUE AND LICENSING FEE INCOME

Revenue from the sale of Ampligen(R) under cost recovery clinical treatment protocols approved by the FDA is recognized when the treatment is provided to the patient.

Revenues for non-refundable license fees are recognized under the performance method. This method recognizes revenue to the extent of performance to date under a licensing agreement. In computing earned revenue, it considers only the amount of non-refundable cash actually received to date. This method considers future payments to be contingent and thus ignores the possibility of future milestone payments when computing the amount of revenue earned in a current period.

On March 20, 2002 our European Subsidiary Hemispherx Biopharma Europe, S.A. ("Hemispherx, S.A.") entered into a Sales and Distribution agreement with Laboratorios del Dr. Esteve S.A. ("Esteve"). Pursuant to the terms of the Agreement, Esteve was granted the exclusive right to market Ampligen(R) in Spain, Portugal and Andorra for the treatment of Myalgic Encephalitis/Chronic Fatigue Syndrome ("ME/CFS"). Esteve paid the initial and non refundable fee of 625,000 Euros (approximately \$563,000) to Hemispherx S.A. on April 24, 2002

The terms of the agreement granting the licensee marketing rights for Ampligen(R) for the treatment of myalgic/chronic fatigue syndrome ("ME/CFS") in Spain, Portugal and Andorra require the Company to provide the licensee with technical, scientific and commercial information. The Company fulfilled the requirements during the first quarter of 2002. The agreement terms required no additional performance on the part of the Company.

The agreement also requires the licensee to pay of 1,000,000 Euros after FDA approval of Ampligen(R) for the treatment of ME/CFS and a fee of 1,000,000 after issuance in Spain of final marketing approval authorization for Ampligen(R) for the treatment of ME/CFS.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

Note 5: MINORITY SHAREHOLDER INTEREST

Laboratorios del Dr. Esteve S.A. purchased 1,000,000 Euros of Hemispherx Biopharma Europe S.A.'s convertible preferred equity certificates on May 23, 2002. Currently these securities will pay a 7% dividend and will be converted into 1.14% of the outstanding common stock of Hemispherx Biopharma Europe S.A. upon completion of an initial public offering ("IPO") on a European stock exchange or before September 30, 2003, whichever comes earlier. The terms and conditions of these securities are being changed so that these preferred equity certificates will be converted into the common stock of Hemispherx Biopharma, Inc. in the event that a European IPO is not completed by September 30, 2003. The conversion rate is 300 shares of Hemispherx Biopharma, Inc.'s common shares for each 1000 Euro convertible preferred certificate.

The contingent conversion price was more than the then market value of the parent company's or subsidiaries's common stock at each of that respective measurement dates. As a result and in accordance with Emerging Issues Task Force (EITF) No. 00-27 Application of Issue No. 98-5 (Accounting for Convertible Securities-with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios) to Certain Convertible Instruments, the Company did not ascribe any value to any contingent conversion feature.

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

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS Certain statements in this Report on Form 10-Q ("Form 10-Q"), constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform 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. 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 Biopharma, Inc. and its subsidiaries (collectively, the "Company", "we" or "us") 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 Form 10-Q. The Company does not undertake and specifically declines 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 Hemispherx Biopharma, Inc. is a biopharmaceutical Company that is focusing on the development of Nucleic Acid compounds to enhance the natural anti-viral defense systems of the human body. Using Nucleic Acid technologies, the Company is developing therapeutic products for treating viral diseases and certain cancers. The Company's lead compound, Ampligen(R), is a new class of specifically configured ribonucleic acids targeted to treat Myalgic Encephalomyelitis/Chronic Fatigue Syndrome ("ME/CFS"), HIV, Hepatitis B, Hepatitis C and certain cancers such as renal cell carcinoma and metastatic malignant melanoma.

The Company currently has four clinical trials underway in the United States consisting of 1) an open label study of using Ampligen(R) to treat patients with severely debilitating ME/CFS. This study was approved by the FDA as a cost recovery treatment program. Patients enrolled in this program pay for costs related to treatment. 2) A Phase III multi-center, double blind,

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

randomized, placebo-controlled study of using Ampligen(R) to treat patients with severely debilitating ME/CFS. A total of 230 patients will have participated in this study when enrollment is completed in the near future. 3) A Phase IIb multi-center, randomized, controlled study of the biological actions of using Ampligen(R) as an adjunct in HIV patients receiving HAART (cocktail of various anti-HIV drugs). 4) An open label, prospective randomized, controlled study of using Ampligen(R) to treat HIV patients already controlling their HIV with HAART as a way to improve HIV control while off HAART during a Strategic Treatment Intervention ("STI"). STI is designed to help prevent serious drug toxicities that develop in patients on HAART.

We have three domestic subsidiaries: BioPro Corp., BioAegean Corp. and Core BioTech Corp., all of which are incorporated in Delaware. Our foreign subsidiaries include Hemispherx BioPharma Europe, N.V./S.A. which was established in Belgium in 1998 and Hemispherx Biopharma Europe, S.A. which was established in Luxembourg during 2002. Our principal executive offices are located at One Penn Center, 1617 JFK Boulevard, Philadelphia, Pennsylvania 19103, and our telephone number is (215) 988-0080.

Risk Factors

The following cautionary statements identify important factors that could cause our actual results to differ materially from those projected in the forward-looking statements made in this Annual Report. Among the key factors that have a direct bearing on our results of operations are:

No assurance of successful product development of Ampligen(R).

The development of Ampligen(R) and our other 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 rights 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, or if ever, Ampligen(R) or our other products will be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale.

Our drug and related technologies are investigational and subject to regulatory approval

All of our drugs and associated technologies 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. Our principal development efforts are currently focused on Ampligen(R), which has not been approved for commercial use. Ampligen(R) and other proposed products are subject to extensive regulation by numerous governmental authorities in the U.S. and other countries, including, but not limited to, the Food and Drug Administration in the U.S., the Health Protection Branch of Canada, and the European Medicines Evaluation Agency 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 royalties. We cannot assure you that the drug will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligen(R) is authorized for use in

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

clinical trials in the United States and other countries, 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 proposed products does not receive regulatory approval in the U.S. or elsewhere, our operations will be materially adversely effected.

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, 2002 our accumulated deficit was approximately \$97,662,000. 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 profitably.

Additional financing requirements.

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. Based on our current operating plan, we anticipate receipt of limited revenues and proceeds from the sale of Ampligen(R) under the Cost Recovery Treatment Clinical Programs and holders of non-public warrants exercising warrants from time to time. We believe these proceeds and the cash on hand will be sufficient to meet our capital requirements through May 2003. The Company will need to raise substantial 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 and begin commercializing its products. There can be no assurances that our non-public Warrants will be exercised or that we will raise any proceeds from possible equity financing, which may have a material effect on our ability to develop our products.

No regulatory agency has approved the full commercial sale of any of the our products.

We cannot assure you that Ampligen(R) or any of our other products being developed will ultimately be demonstrated to be safe or efficacious. While Ampligen(R) is authorized for use in clinical trials in the United States and other countries, 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 United States or elsewhere, our operations will be significantly affected.

We may not be profitable unless we can protect our patents and/or receive approval for additional pending patents.

We need to acquire enforceable patents covering the use of Ampligen(R) and other products for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen(R) for such disease. Our success depends, in large part, on our ability to obtain patent protection for our products and to obtain and preserve our trade secrets and expertise. 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 have also been issued

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

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 been issued any patents in the United States for the use of Ampligen as a sole treatment for any of the cancers which we have sought to target. We cannot assure you that any of these applications will be approved or that our competitors will not seek and obtain patents regarding the use of Ampligen(R) in combination with various other agents, for a particular target indication prior to us. If we cannot protect our patents covering the use of Ampligen(R) for a particular disease, or obtain additional pending patents, we may not be able to successfully market Ampligen(R).

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 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. 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 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 a different technology.

There can be no assurance that we will have the financial resources necessary to enforce patent rights we may hold.

If we cannot enforce the patent rights we currently hold we may be required to obtain licenses from others to develop, manufacture or market our products. There can be no assurance that we would be able to obtain any such licenses on commercially reasonable terms, if at all. We currently license certain proprietary information from third parties, some of which may have been developed with government grants under circumstances where the government maintained certain rights with respect to the proprietary information developed. No assurances can be given that such third parties will adequately enforce any rights they may have or that the rights, if any, retained by the government will not adversely affect the value of our license. Certain of our know-how and technology is not fully patentable, particularly the procedures for the manufacture of our Ampligen(R) drug product which are carried out according to standard operating procedure manuals.

We may not be profitable unless we can produce Ampligen(R) in commercial quantities at costs acceptable to us.

We have never produced Ampligen(R) or any other products in large commercial quantities. Ampligen(R) is currently produced only for use in clinical trials. We must manufacture our products in compliance with regulatory requirements in 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. We are dependent upon certain third party supplies for key components of the proposed products and for substantially all of the production process. If we cannot manufacture commercial quantities of Ampligen(R) or enter into third party agreements for its manufacture at costs

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

acceptable to us, our operations will be significantly affected.

If our distributors do not market our product successfully, we may not generate significant revenues or become profitable.

We have limited marketing and sales capability. Accordingly we may need to enter into marketing agreements and third party distribution agreements for our products in order to generate significant revenues and become profitable. To the extent that we enter into co-marketing or other licensing arrangements, 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 Gentiva Health Services offers the potential to provide significant marketing and distribution capacity in the United States while licensing and marketing agreements with certain foreign firms should provide an adequate sales force in South America, Africa, United Kingdom, Australia and New Zealand, Canada, Austria, Spain and Portugal.

Our partners may not be able to deliver treatment and services to chronic disease patients including infusion services, home nursing and other medical services through a national network of more than 500 locations. We cannot assure that our domestic or our 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.

Ampligen(R) safety profile and scientific literature.

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 erythema, a tightness of the chest, tachycardia, 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, urticaria (swelling of the skin), bronchospasm, transient hypotension, photophobia, rash, bradycardia, transient visual disturbances, arrhythmias, 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 effect 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 effect potential revenues and physician/patient acceptability of our product. In general, we believe that the relative safety profile to date has been well tolerated given the severe Chronic diseases being targeted.

There is no assurance that successful manufacture of a drug on a limited scale basis for investigational use will lead to a successful transition to commercial, large-scale production.

Small changes in methods of manufacturing may affect the chemical structure of Ampligen and other such RNA drugs, as well as their safety and efficacy. Changes in methods of manufacture, including commercial scale-up may affect the chemical structure of Ampligen 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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

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 efforts 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.

Rapid technological change.

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 we do, 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.

Substantial competition.

Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these 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 will 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, EMEA HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA EMEA and HPB product approvals more rapidly than us. If any of our products receive regulatory approvals and we commence commercial sales of our products, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have no experience. Our competitors may possess or obtain patent protection or other intellectual property rights that prevent, limit or otherwise adversely affect our ability to develop or exploit our products.

Limited manufacturing experience and capacity.

Ampligen(R) is currently produced only in limited quantities for use in our clinical trials and we are dependent upon certain third party suppliers for key components of our products. The failure to continue these 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. Our current facilities are not adequate for the production of our proposed products for large-scale commercialization. We intend to utilize third-party facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. We will need to comply with regulatory requirements for such facilities, including those of the FDA EMEA and HPB pertaining to Good Manufacturing Practices ("GMP") regulations. There can be no assurance that such facilities can be used, built, or acquired on commercially acceptable terms, that such facilities, if used, built, or acquired, will be adequate for our long-term needs.

We may be subject to product liability claims from the use of Ampligen(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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

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 effected 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 worldwide product liability insurance coverage, there can be no assurance that this insurance will provide adequate coverage against product liability claims. While no product liability claims are pending or threatened against us to date, a successful product liability claim against us in excess of our insurance coverage could have a negative effect on our business and financial condition.

Members of our Scientific Advisory Board may have conflicting interests and may disclose data and technical know how to our competitors.

All of our Scientific Advisory Board members are employed by other entities, which may include our competitors. Although we require each of our Scientific Advisory Board members to sign a non-disclosure and non-competition agreement with respect to the data and information that he or she receives from us, we cannot assure you that members will abide by them. If a member were to reveal this information to outside sources, accidentally or otherwise, our operations could be negatively effected. Since our business depends in large part on our ability to keep our technical expertise confidential, any revelation of this information to a competitor or other source could have an adverse effect on our operations.

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.

The loss of Dr. 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 co-inventor of Ampligen(R) and his knowledge of the Company's overall activities, including patents, clinical trials, corporate relationships and relationships with various governmental regulatory agencies. The loss of Dr. Carter's services could have a material adverse effect on our operations. While we have an employment agreement with Dr. William A. Carter, and have secured key man life insurance in the amount of \$2 million on the life of Dr. Carter, the loss of Dr. Carter or other key personnel, such as Dr. David Strayer or Dr. Carol Smith, or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

Uncertainty of health care reimbursement and potential legislation.

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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

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.

Hazardous materials.

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

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

Critical Accounting Policies

Financial Reporting Release No. 60., which was released by the Securities and Exchange Commission, requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. The significant accounting policies that we believe are most critical to aid in fully understanding our reported financial results are the following: Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Actual results could differ from those estimates.

Impairment of Long-Lived Assets

Statement of Financial Accounting Standards ("SFAS") No. 121. "Accounting for Long-Lived Assets and Long Lived Assets to be disposed of," requires that long-lived assets and certain identifiable intangibles, including goodwill, be held and used by an entity, be reviewed for impairment whenever events or changes in circumstances indicated that the carrying amount of the assets may not be recoverable. We assess the recoverability of fixed assets and intangibles

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

based on undiscounted estimated future operating cash flows. If we determine that the carrying values have been impaired, the measurement and recognition of the impairment will be based on estimated future operating cash flows. During the fourth quarter of 2001, we recognized an impairment of \$485,000 in connection with goodwill related to equity investments of ours. In June, 2002 we recognized an impairment of \$678,000 with respect to another investment whose operations had not evolved to the point where the company's full carrying value could be supported. As of June 30, 2002, management believes that the carrying value of the remaining long-lived assets and identifiable intangibles have not been impaired.

Patents and Trademarks

Patents and trademarks are stated at cost (primarily legal fees) and are amortized using the straight line method over the life of the assets. The Company reviews its patents and trademark rights periodically to determine whether they have continuing value. Such review includes an analysis of the patent and trademark's ultimate revenue and profitability potential on an undiscounted cash basis to support the realizability of its respective capitalized cost. In addition, management's review addresses whether each patent continues to fit into Company's strategic business plans.

Research and Developments Costs

Research and development costs are direct costs related to both future and present products and are charged to operations as incurred. The Company recognized research and development costs of \$4,765,000 and \$3,732,000 in the nine month period ending September 30, 2001 and 2002 respectively.

New Accounting Pronouncements

In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB statements No. 4, 44 and 64, Amendment of FASB statement No. 13, and Technical Corrections" ("SFAS 145"). FASB No. 4 required that gains and losses from extinguishment of debt that were included in the determination of net income be aggregated and, if material, be classified as an extraordinary item, net of related income tax. Effective January 1, 2003, pursuant to SFAS 145, the treatment of debt is to be included in "Other Income" in the Financial Statements. Currently the Company believes that the adoption of SFAS 145 will not have an impact on it's financial position and results of operations.

On July 30, 2002, the FASB issued FASB Statement No. 146, Accounting for Costs Associated with Exit or Disposal Activities, which nullifies EITF Issues No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)" and No. 88-10, Costs Associated with Lease Modification or Termination." Statement 146 fundamentally changes how a company should account for future "restructurings." The company believes that the adoption of SFAS 146 will not have an impact on it's financial position and results of operations.

RESULTS OF OPERATIONS

Three months ended September 30, 2002 versus Three months ended September 30, 2001

Our losses in the three months ended September 30, 2002 were approximately \$1,891,000 or some \$254,000 less than the \$2,145,000 loss recorded for the three months ended September 30, 2001. These losses include non-cash stock compensation expense of \$132,000 in 2002 and \$78,000 in 2001. Excluding these non-cash stock compensation charges, our recorded losses were \$1,759,000 in 2002 and \$2,067,000 in 2001.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

Research and Development ("R&D") costs were lower by \$395,000 in the three months ended September 30, 2002 compared to the same period in 2001. Drug production costs were down approximately \$135,000 primarily due to smaller purchases of raw materials used to manufacture Ampligen(R). In 2001, we spend \$289,000 for raw material compared to \$154,000 in 2002. Drug production was ramped up in 2001 in order to build up sufficient drug inventory for use in the ongoing CFS clinical trials and the newly initiated HIV clinical trials. Direct costs relating to the ME/CFS clinical trials were lower by \$228,000 in 2002 compared to 2001 reflecting less activity as enrollment in the Phase III ME/CFS trial nears completion. The expenses relating to the Phase IIb HIV trials increased some \$145,000 as patient enrollment increased. Other expenses relating to R&D work in the U.S. and Europe were lower in the three months ended September 30, 2002 compared to the same period in 2001.

Exclusion of non-cash stock compensation charges, general and administration ("G&A") expenses were approximately \$634,000 in 2002 versus \$595,000 in 2001 for the three months ended September 30, 2002. Legal and related costs were higher in 2002 primarily due to a credit in the amount of \$107,000 received in 2001 from our insurance underwriter to reimburse us for certain legal fees previously paid to defend against the Asensio lawsuit. Public Relations expenses were lower in 2002 by some \$96,000. Increased expenses include office rents, insurance premiums and corporate travel totaling approximately \$23,000.

We had stock compensation expense of \$132,000 in the three month ended September 30, 2002 reflecting the grant of stock warrants to outside parties for services provided. In this same period in 2001, we recorded a non-cash charge of \$78,000 reflecting the grant of warrants to purchase common stock to certain individuals that serve as financial advisors to the Company.

Interest income was \$23,000 for the three months ended September 30, 2002 versus interest income of \$68,000 during the same period in 2001. This decrease in interest income reflects the significant drop in rates earned on money market securities.

Nine months ended September 30, 2002 versus nine months ended September 30, 2001 Our losses for the nine months ended September 30, 2002 were down \$955,000 when compared the same period on 2001. The losses recorded for the nine months ended 2002 were \$6,013,000 compared to losses of \$6,968,000 in 2001. This reduction in losses is due to several factors as outlined below.

Overall revenue in 2002 were \$826,000 compared to \$304,000 in 2001. The Company's revenues basically consist of income from the ME/CFS cost recovery treatment programs and licensing fees. In 2002, licensing fee income was \$563,000 compared to no licensing fee income in 2001. Cost recovery treatment income was \$263,000 in 2002 versus \$304,000 in 2001. Cost recovery treatment revenues have declined in the past two years as the Company has focused all resources toward initiating and conducting the Phase III ME/CFS clinical trial and the two Phase IIb HIV clinical trials. The \$563,000 licensing fee income in 2002 is the product of the Laboratorios del Dr. Esteve, S.A. ("Esteve") agreement executed in March, 2002. This agreement gives Esteve the exclusive right, upon regulatory approval, to market and distribute Ampligen(R) in Spain, Portugal and Andorra for the treatment of patients afflicted with ME/CFS.

Research an development ("R&D") costs were \$3,732,000 in 2002 versus \$4,765,000 in 2001 reflecting a reduction of \$1,033,000 in the first nine months of 2002. Drug production costs were down some \$373,000 in 2002, primarily due to a larger production of Ampligen(R) in 2001. Ampligen(R) inventories were built of in 2001 in anticipation of the increased Ampligen(R) needs in our ME/CFS and

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

HIV clinical trials. Costs relating to the production of Ampligen(R) are expensed as incurred. Costs related to the ME/CFS clinical trials were down some \$588,000 in 2002 compared to 2001 reflecting the lower number of patients enrolled in the ME/CFS cost recovery treatment program and the Phase III ME/CFS clinical trial. The costs related to the ME/CFS clinical trials should continue to decrease as the phase III ME/CFS clinical trial near completion. The cost of the HIV clinical trials increased \$433,000 in 2002 versus 2001 as patient enrollment has steadily increased in 2002. These HIV trials were initiated in 2001. Our cost of filing and maintaining our patent estate, consisting of approximately 350 patents, was lower by \$212,000 in 2002 compared to 2001. In 2001, we abandoned certain foreign patents deemed non-essential and expensed the cost of \$29,000 for these patents.

General and administrative ("G&A") expenses were \$2,447,000 in the nine months ended September 30, 2002 compared to \$2,677,000 in 2001. Excluding stock compensation expenses, G&A expenses were \$2,315,000 in 2002 versus \$2,004,000 in 2001: reflecting an expense increase of \$311,000. This increase was primarily due to increased legal expenses relating to the January, 2002 Asensio trial in Philadelphia. Increased cost in insurance premiums and office rent were basically offset by reduced costs in salaries and temp help. Stock compensation expense was \$132,000 through September, 2002 compared to \$673,000. Stock compensation expense is primarily calculated using the Black-Scholes model for determining the value of non-public warrants granted to non-employee parties providing a service for the company. In 2001, some \$262,000 of the \$673,000 stock compensation expense reflected was due to the Board of Directors extending the expiration date of certain warrants.

Interest income was \$90,000 in 2002 versus \$248,000 in 2001. This reduction in interest income reflects much lower money marketing rates. and less funds available to invest. The company invests any cash on hand in excess of immediate need in short-term market investments.

Included in our 2002 losses is a \$678,000 write off of our \$1,074,000 investment in R.E.D. Labs. In June 2002, we determined that our 3.3% interest in R.E.D. was impaired and accordingly we wrote off \$678,000 of this investment. These charges were the result of our determination that R.E.D.'s business had not yet evolved to the point that our initial carrying value of this investment could not be supported based on that company's financial position.

LIQUIDITY AND CAPITAL RESOURCES

Our cash, cash equivalents and short term investments were \$4,308,000 as of September 30, 2002 compared to \$8,417,000 at December 31, 2001 reflecting a net use of cash in the amount of \$4,109,000 in the first nine months of 2002.

Operating activities utilized \$4,927,000 reflecting cash outlays in support of the Phase III ME/CFS clinical trial as well as the Phase IIb HIV trials now underway. In addition we have significantly invested in expanding our capacity to manufacture liquid Ampligen(R) doses through outside suppliers as well as expended funds to increase our supplies of Ampligen(R). These expenditures were made to assure an adequate and stable supply of Ampligen(R) to support the ongoing clinical trials as well as provide the capacity to manufacture Ampligen(R) in commercial quantities. Some portion of these costs are expected to be recovered under the expanded access, cost-recovery, programs authorized by the FDA and regulatory bodies in other countries. The costs of the Phase IIb HIV trials will increase as more patients are recruited. However, the costs of these HIV trials should be lower overall due to certain inherent efficiencies of running the two clinical trials in parallel.

Proceeds from Financing activities in the first nine months of 2002 are down some \$1,112,000 compared to the same period in 2001. This decrease basically reflects a combination of fewer stock warrants being exercised in the

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

amount of \$1,991,000, offset by a placement of convertible securities totaling \$946,000 with Laboratorios del Dr. Esteve, S.A. ("Esteve") in 2002. The Esteve placement was pursuant to the terms of a sales and distribution agreement executed in March, 2002.

Our major source of financing in 2000 and 2001 was proceeds from warrant holders exercising stock warrants. We received \$9,985,000 in 2000 and \$8,075,000 in 2001. In the first nine months of 2002, warrant holders exercised 12,400 warrants producing proceeds of \$59,000. A major factor contributing to this downturn in warrants being exercised is the state of the stock market and the biotech sector in particular. We have some 2,716,000 non-public outsider warrants outstanding, which, if exercised, would produce proceeds of \$14,814,000. The exercise prices of these warrants range from \$1.75 to \$16.00. Depending on future market conditions and the company's stock price, some of these warrants may be exercised. However the company is not counting on such event at this time.

The company's cash burn rate has declined in recent months primarily due to lower legal costs, the restructuring of our European operation and other management actions. These actions should allow the company to continue operations through May, 2003 with the current cash on hand. In the meantime, we are pursuing additional capital by one or more of the following programs, 1) a private placement of equity in either Hemispherx Biopharma, Inc. or our European subsidiary, Hemispherx Biopharma-Europe, S.A., 2) the granting of licensing agreements to corporate partner, 3) a partnership arrangement with another Biotech Company to develop and market Ampligen(R) .

Any additional equity 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 process, and higher than anticipated expenses and lower than anticipated revenues from certain of our clinical trials for which cost recovery from participants has been approved.

ITEM 3: Quantitative and Qualitative Disclosures About Market Risk

Excluding obligations to pay us for various licensing related fees, we had approximately \$4,308,000 in cash, cash equivalents and short term investments at September 30, 2002. To the extent that our cash and cash equivalents exceed our near term funding needs, we invest the excess cash in three to six month high quality interest bearing financial instruments. The Company employs established conservative policies and procedures to manage any risks with respect to investment exposure.

Item 4: Controls and Procedures

Our management, including the Chairman of the Board (serving as the principal executive officer) and the Chief Financial Officer, have conducted an evaluation of the effectiveness of disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based on that evaluation, the Chairman of the Board and the Chief Financial Officer concluded that the disclosure controls and procedures are effective in ensuring that all material information required to be filed in this quarterly report has been made known to them in a timely fashion. There have been no significant changes in internal controls, or in other factors that could significantly affect internal controls, subsequent to the date the Chairman of the Board and Chief Financial Officer completed their evaluation.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

Part II - OTHER INFORMATION

ITEM 1: Legal Proceedings In 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 the 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 between August, 1998, and the present. 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 resulting in a withdrawal with prejudice of the counterclaim against us. A jury verdict disallowed the claims against the defendants for defamation and disparagement. However, on July 2, 2002 the Court entered an order granting us a new trial against Asensio for defamation and disparagement. On July 10, 2002 Asensio filed a Notice of Appeal to the Superior Court of Pennsylvania from order of July 2, 2002. There has been no material changes in the status of this litigation as of October 31, 2002.

In June 2002 a former ME/CFS clinical trial patient and her husband filed a claim in the Superior Court of New Jersey, Middlesex County, against us, one of our clinical trial investigators and others alleging that she was harmed in the 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.

In July 2002 we filed a multimillion dollar suit against Federal Insurance Company ("Federal") seeking (1) a judicial order declaring our rights and the obligations of Federal under the insurance policy Federal sold to us (2) monetary damage for breach of contract resulting from Federal's refusal to fully defend us in connection with the Asensio litigation (3) monetary damages to compensate us for Federal's breach of its fiduciary duty faith and dealing and (4) monetary damages, interest, costs, and attorneys fees to compensate us for Federal's violation of the Pennsylvania Bad Faith Statute. ITEM 2: Changes in Securities and Use of Proceeds

During the quarter ended September 30, 2002, we issued an aggregate of 7,068 shares of common stock to two parties, for an aggregate of \$15,000 in funds. All of these shares were issued pursuant to the exemption from registration provided by section 4(2) of the Securities Act of 1933. No commissions were paid with regard to these sales.

ITEM 3: Defaults in Senior Securities

None

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

None

ITEM 5: Other Information

None

ITEM 6: Exhibits and Reports on Form 8K

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

(a) Exhibits

- 99.1 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 99.2 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K

None

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

Date: April 15, 2003

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

/S/ Robert E. Peterson

Date: April 15, 2003

Robert E. Peterson
Chief Financial Officer

CERTIFICATION PURSUANT OT RULE 13A-14 AND 15D-14 OF
THE SECURITIES AND EXCHANGE ACT OF 1934

I, Robert E. Peterson, certify that:

1. I have reviewed this quarterly report on Form 10-Q/A-1 of Hemispherx Biopharma, Inc. (the "registrant");

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operation and cash flow of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have;

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

- a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to filing date of this quarterly report (the "Evaluation Date"); and
 - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
- a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls: and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weakness.

Date: April 15, 2003

/s/ Robert E. Peterson

Robert E. Peterson
Chief Financial Officer

CERTIFICATION PURSUANT TO RULE 13A-14 AND 15D-14 OF
THE SECURITIES AND EXCHANGE ACT OF 1934

I, William A. Carter, certify that:

- 5. I have reviewed this quarterly report on Form 10-Q/A-1 of Hemispherx Biopharma, Inc. (the "registrant");
- 6. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
- 7. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operation and cash flow of the registrant as of, and for, the periods presented in this quarterly report;

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 10-Q/A

8. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have;

- d) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
- e) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to filing date of this quarterly report (the "Evaluation Date"); and
- f) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

7. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

- c) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
- d) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

8. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weakness.

Date: April 15, 2003

/s/ William A. Carter

William A. Carter
Chief Executive Officer