

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

HEMISPHERX BIOPHARMA INC
Form 424B3
August 11, 2004

Filed Pursuant to Rule 424(b)(3)
Registration Nos. 333-108645, 333-111135, 333-113796 and 333-117178

PROSPECTUS SUPPLEMENT
Number 2
to
Prospectus dated August 2, 2004
of
HEMISPHERX BIOPHARMA, INC.

This Prospectus Supplement includes the attached Quarterly Report on Form 10-Q of Hemispherx Biopharma, Inc. for the quarter ended June 30, 2004 filed by us with the Securities and Exchange Commission.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS SUPPLEMENT. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this Prospectus Supplement is August 10, 2004

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 June 30, 2004

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)

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

/X/ Yes // No

45,285,606 shares of common stock were issued and outstanding as of July 28, 2004.

PART I - FINANCIAL INFORMATION

ITEM 1: Financial Statements

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

	December 31, 2003	June 30, 2004
	-----	-----
		(Unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,764	\$ 4,464
Short term investments	1,495	4,969
Inventory	2,896	2,623
Accounts and other receivables	282	156
Prepaid expenses and other current assets	170	245
	-----	-----
Total current assets	8,607	12,457
Property and equipment, net	94	3,357
Patent and trademark rights, net	1,027	988
Investments	408	408
Deferred acquisition costs	1,546	-
Deferred financing costs	393	406
Advance receivable	1,300	1,300
Other assets	29	17
	-----	-----
Total assets	\$ 13,404	\$ 18,933
	=====	=====

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

Accounts payable	\$ 488	\$ 598
Accrued expenses	1,119	607
Deferred revenue	-	497
Current portion of long-term debt (net of discounts of \$1,536)	-	1,130
	-----	-----
Total current liabilities	1,607	2,832
Long-Term Debt-net of current portion and discounts of \$4,533 and \$1,811, respectively	2,058	2,055
Commitments and contingencies:		
Redeemable Common Stock	491	-
Stockholders' equity:		
Common stock	39	44
Additional paid-in capital	123,054	141,845
Treasury stock - at cost	(2)	(2)
Accumulated deficit	(113,843)	(127,841)
	-----	-----
Total stockholders' equity	9,248	14,046
	-----	-----
Total liabilities and stockholders' equity	\$ 13,404	\$ 18,933
	=====	=====

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 June 30,	
	2003	2004
	-----	-----
	(Unaudited)	(Unaudited)
Revenues:		
Sales of product, net	\$ 60	\$ 289
Clinical treatment programs	34	42
	-----	-----
	94	331
Costs and expenses:		
Production/cost of goods sold	37	692
Research and development	855	758
General and administrative	838	1,076
	-----	-----
Total cost and expenses	1,730	2,526
Interest and other income	1	13
Interest expenses	(82)	(105)
Financing costs	(1,972)	(3,669)
	-----	-----
Net loss	\$ (3,689)	\$ (5,956)
	=====	=====

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

Basic and diluted loss per share	\$ (.11)	\$ (.14)
	=====	=====
Basic and diluted weighted average common shares outstanding	33,519,275	43,871,350
	=====	=====

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 Six months ended June 30,	
	2003	2004
	(Unaudited)	(Unaudited)
Revenues:		
Sales of product, net	\$ 79	\$ 548
Clinical treatment programs	81	91
	-----	-----
	160	639
Costs and expenses:		
Production/cost of goods sold	155	1,293
Research and development	1,728	1,720
General and administrative	1,505	3,921
	-----	-----
Total cost and expenses	3,388	6,934
Interest and other income	51	24
Interest expenses	(82)	(206)
Financing costs	(2,047)	(7,520)
	-----	-----
Net loss	\$ (5,306)	\$ (13,997)
	=====	=====
Basic and diluted loss per share	\$ (.16)	\$ (.33)
	=====	=====
Basic and diluted weighted		

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

average common shares outstanding	32,872,905	42,040,412
	=====	=====

See accompanying notes to condensed consolidated financial statements.

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

	(Unaudited) For the Six months ended June 30,	
	2003	2004
	-----	-----
Cash flows from operating activities:		
Net loss	\$ (5,306)	\$ (13,997)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	43	53
Amortization of patents rights	70	160
Amortization of deferred financing costs	2,030	6,573
Financing costs related to redemption obligation	-	686
Stock warrant compensation expense	-	1,769
Changes in assets and liabilities:		
Inventory	(400)	273
Accounts receivable	1,455	125
Deferred Revenue	-	497
Prepaid expenses and other current assets	(168)	(76)
Accounts payable	452	365
Accrued expenses	(443)	(314)
Other assets	42	14
	-----	-----
Net cash used in operations	(2,225)	(3,872)
	-----	-----
Cash flows from investing activities:		
Purchase of land and building	(19)	(143)
Additions to patent rights	(161)	(121)
Maturity of short term investments	520	1,496
Purchase of short term investments	-	(4,969)
Deferred acquisition costs	(160)	-
	-----	-----
Net cash provided by (used in) investing activities	180	(3,737)
	-----	-----
Cash flows from financing activities:		
Proceeds from exercise of stock warrants	-	2,911
Proceeds from long-term borrowings	5,426	5,808
Payments on long-term borrowings	(440)	-
Deferred financing costs	(455)	(410)
Purchase of treasury stock	(83)	-
	-----	-----

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

Net cash provided by financing activities	4,448	8,309
	-----	-----
Net increase in cash and cash equivalents	2,403	700
Cash and cash equivalents at beginning of period	2,256	3,764
	-----	-----
Cash and cash equivalents at end of period	\$ 4,659	\$4,464
	=====	=====
Supplementary disclosures of cash flow information:		
Issuance of common stock for accounts payable	\$ -	\$ 255
Issuance of common stock for purchase of building	\$ -	\$1,626
Issuance of common stock for debt conversion and interest payments	\$ -	\$6,072

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

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 (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 amendment no. 1 to our annual report on Form 10-K/A for the year ended December 31, 2003, as filed with the SEC on March 30, 2004.

NOTE 2: STOCK BASED COMPENSATION

The Company follows Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock-Based Compensation." We chose to apply Accounting Principal Board Opinion 25 and related interpretations in accounting for stock options granted to our employees.

The Company provides pro forma disclosures of compensation expense under the fair value method of SFAS No. 123, "Accounting for Stock-Based Compensation," and SFAS No. 148, "Accounting for Stock-Based Compensation- Transition and Disclosure."

The weighted average assumptions used for the period presented are as follows:

	June 30,	
	2003	2004
Risk-free interest rate	5.23%	-
Expected dividend yield	-	-

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

Expected lives	2.5 years	- years
Expected volatility	63.17%	- %

Had compensation cost for the Company's option plans been determined using the fair value method at the grant dates, the effect on the Company's net loss and loss per share for the six months ended June 30, 2003 and 2004 would have been as follows:

	(In Thousands)	
	Six Months Ended	
	June 30,	

	2003	2004
	-----	-----
Net (loss) as reported	\$(5,306)	\$(13,997)
Add: Stock based employee compensation expense Included in reported net loss, net of Related tax effects	-	-
Deduct:		
Total stock based employee compensation determined under fair value method for all awards, net of related tax effects	(274)	-
	-----	-----
Pro forma net loss	\$(5,580)	\$(13,997)
	=====	=====
Basic and diluted loss per share		
As reported	\$ (.16)	\$ (.33)
Pro forma	\$ (.17)	\$ (.33)

Note 3: INVESTMENT IN UNCONSOLIDATED AFFILIATES

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 the Company's common stock from the treasury. On October 12, 2000, the Company issued an additional 50,000 shares of its common stock and on March 7, 2001 the Company issued 12,000 more shares of its common stock from the treasury to Chronix for an aggregate equity investment of \$700,000. The percentage ownership in Chronix is approximately 5.4% and is accounted for under the cost method of accounting. During the quarter ended December 31, 2002, we recorded a non cash charge of \$292,000 with respect to our investment in Chronix. This impairment reduces our carrying value to reflect a permanent decline in Chronix's market value based on its then proposed investment offerings.

NOTE 4: INVENTORIES

The Company uses the lower of first-in, first-out ("FIFO") cost or market method of accounting for inventory.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

Inventories consist of the following:

	June 30, 2004	December 31, 2003
Raw materials-work in process	\$ 1,729,000	\$1,729,000
Finished goods	894,000	1,167,000
	-----	-----
	\$ 2,623,000	\$2,896,000
	=====	=====

NOTE 5: REVENUE AND LICENSING FEE INCOME

We executed a Memorandum of Understanding (MOI) in January 2004 with Fujisawa Deutschland GmbH, ("Fuji") a major pharmaceutical corporation, granting them an exclusive option for a limited number of months to enter a Sales and Distribution Agreement with exclusive rights to market Ampligen(R) for ME/CFS in Germany, Austria and Switzerland. The MOI required us to file the full report on the results of our AMP 516 Clinical Trial with Fuji by May 31, 2004. If the full report was not provided to Fuji by May 31, 2004 and Fuji did not wish to exercise its option, we would have been required to refund one half of the 400,000 Euro fee. We submitted our initial report to Fuji on May 28, 2004 and received their response requesting additional information, which we provided in June 2004. The option period ends 12 weeks after the later of Fuji's review of the full report on the results of our Amp 516 clinical trial and Fuji's meeting with the trial's principal investigators. We received an initial fee of 400,000 Euros (approximately \$497,000 US). If we do not provide them with the full report by December 31, 2004 and Fuji does not wish to exercise its option, we will be required to refund the entire fee. If Fuji exercises the option, Fuji would be required to pay us an additional 1,600,000 Euros upon execution of the Sales and Distribution agreement, purchase Ampligen(R) exclusively from us and meet certain annual minimum purchase quotas. We would be required to file an application with the EMEA for commercial sale of Ampligen(R) for ME/CFS on or before December 31, 2005. Upon our filing of that application, we would receive an additional 1,000,000 Euros and, upon approval by the EMEA, an additional 2,000,000 Euros. If we failed to meet the December 31, 2005 filing deadline, we would be required to return 40% of all payments that we had received from Fuji. We would be required to sell Ampligen(R) to Fuji at a 20% price discount until the aggregate amount of the discount reached \$1,000,000 Euros (representing 50% of the initial 2,000,000 fee paid to us on and prior to execution of the definitive agreement). The foregoing is a summary of the memorandum of understanding. We cannot assure that we can prepare and issue the AMP 516 report within the time frames noted or that Fuji will exercise the option or that the proposed terms of the Sales and Distribution Agreement will not change materially. The initial fee has been recorded on our balance sheet at June 30, 2004 as deferred revenue.

Revenues for non-refundable license fees are recognized under the Performance Method-Expected Revenue. This method considers the total amount of expected revenue during the performance period, but limits the amount of revenue recognized in a period to total non-refundable cash received to date. This limitation is appropriate because future milestone payments are contingent on future events.

Upon receipt, the upfront non-refundable payment is deferred. The non-refundable upfront payments plus non-refundable payments arising from the achievement of defined milestones are recognized as revenue over the performance period based on the lesser of (a) percentage of completion or (b) non-refundable cash earned (including the upfront payment).

This method requires the computation of a ratio of cost incurred to date to total expected costs and then apply that ratio to total expected revenue. The amount of revenue recognized is limited to the total non-refundable cash

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

received to date. The Fuji initial fee of \$497,000 has been deferred as of June 30, 2004.

During the periods ending December 31, 2003 and June 30, 2004. The Company did not receive any grant monies from local, state and or Federal Agencies.

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 from the sale of product are recognized when the product is shipped, as title is transferred to the customer. The Company has no other obligation associated with its products once shipment has occurred.

Note 6: ACQUISITION OF ASSETS OF INTERFERON SCIENCES, INC.

On March 11, 2003, we acquired from ISI, ISI's inventory of ALFERON N Injection(R) and a limited license for the production, manufacture, use, marketing and sale of this product. As partial consideration, we issued 487,028 shares of our common stock to ISI Pursuant to our agreements with ISI, we registered these shares for public sale and ISI has reported that it has sold all of these shares. We also agreed to pay ISI 6% of the net sales of ALFERON N Injection(R).

On March 11, 2003, we also entered into an agreement to purchase from ISI all of its rights to the product and other assets related to the product including, but not limited to, real estate and machinery. For these assets, we agreed to issue to ISI an additional 487,028 shares and to issue 314,465 shares and 267,296 shares, respectively to the American National Red Cross and GP Strategies Corporation, two creditors of ISI. We guaranteed the market value of all but 62,500 of these shares to be \$1.59 per share on the termination date. As discussed below, we issued all of these shares and ISI, GP Strategies and the American National Red Cross have reported that they have sold all of their shares.

We also agreed to satisfy other liabilities of ISI which were past due and secured by a lien on ISI's real estate and to pay ISI 6% of the net sales of products containing natural alpha interferon.

On May 30, 2003, we issued the shares to GP Strategies and the American National Red Cross. Pursuant to our agreements with ISI and these two creditors, we registered the foregoing shares for public sale. As of June 30, 2004, GP Strategies and the American National Red Cross had sold all of their shares.

In March 2004, we issued 487,028 shares to ISI to complete the acquisition of the balance of ISI's rights to market its product as well its production facility in New Brunswick, New Jersey. As of June 30, 2004, ISI has sold all of its shares.

On March 17, 2004, the Company acquired the land and buildings located in New Brunswick, NJ. The aggregated cost of the land and buildings was approximately \$3,316,000. The cost of the land and buildings was allocated as follows:

Land	\$ 423,000
Buildings	2,893,000

Total cost	\$ 3,316,000

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

=====

We accounted for these transactions as a Business Combination under Statement of Financial Accounting Standards ("SFAS") No. 141 Accounting for Business Combinations.

The following table represents the Unaudited pro forma results of operations as though the ISI acquisitions had occurred on January 1, 2002.

	Six Months Ended June 30,	
	2003	2004
	----	----
	(in thousands except for share data)	
Net revenues	\$ 402	\$639
Expenses	(6,254)	(14,636)
	-----	-----
Net Loss	\$ (5,852)	\$ (13,997)
	=====	=====
Basic and diluted loss per share	\$ (.18)	\$ (.33)
	-----	-----
Weighted average shares outstanding	33,058,557	42,246,462
	=====	=====

Note 7: DEBENTURE FINANCING

Long term debt consists of the following:

	(in thousands)	
	December 31, 2003	June 30,
2004		
July 2003 Debenture	\$ 2,334	\$ 600
October 2003 Debenture	4,257	2,071
January 2004 Debenture		3,861
	-----	-----
Total	6,591	6,532
Less Discounts	(4,533)	(3,347)
	-----	-----
Balance	2,058	3,185
Less Current Portion of long-term debt (net of discounts of \$1,536)	-	(1,130)
	-----	-----
Total long-term debt	\$ 2,058	\$ 2,055
	=====	=====

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

On March 12, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due January 2005 (the "March Debentures") and an aggregate of 743,288 warrants to two investors in a private placement for aggregate gross proceeds of \$4,650,000. The March Debentures were to mature on January 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 were 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 March Debentures, we pledged all of our assets, other than our intellectual property, as collateral and were subject to comply with certain financial and negative covenants, which include but were not limited to the repayment of principal balances upon achieving certain revenue milestones.

The March Debentures were convertible at the option of the investors at any time through January 31, 2005 into shares of our common stock. The conversion price under the March Debentures was fixed at \$1.46 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.

The investors also received Warrants to acquire at any time through March 12, 2008 an aggregate of 743,288 shares of common stock at a price of \$1.68 per share.

We entered into a Registration Rights Agreement with the investors in connection with the issuance of the March Debentures and the Warrants. The Registration Rights Agreement requires that we register the shares of common stock issuable upon conversion of the Debentures, as interest shares under the Debentures and upon exercise of the Warrants. In accordance with this agreement, we have registered these shares for public sale.

As of December 31, 2003, the investors had converted the total \$5,426,000 principal of the March Debentures into 3,716,438 shares of our common stock. The total interest on these debenture was \$111,711 of which \$17,290 was paid in cash and \$94,421 was paid by the issuance of shares of our common stock. The investor exercised all 743,288 warrants in July 2003 which produced proceeds in the amount of \$1,248,724.

On July 10, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due July 31, 2005 (the "July 2003 Debentures") and an aggregate of 507,102 Warrants (the "July 2008 Warrants") to the same investors who purchased the March Debentures, in a private placement for aggregate proceeds of \$4,650,000. Pursuant to the terms of the July 2003 Debentures, \$1,550,000 of the proceeds from the sale of the July 2003 Debentures were to have been held back and released to us if, and only if, we acquired ISI's facility within a set timeframe. These funds were released to us in October 2003 although we had not acquired ISI's facility at that time. The July 2003 Debentures mature on July 31, 2005 and bear 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 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.

The July 2003 Debentures are convertible at the option of the investors at any time through July 31, 2005 into shares of our common stock. The conversion price under the July 2003 Debentures was fixed at \$2.14 per share; however, as part of the new debenture placement closed on October 29, 2003 (see below), the conversion price under the July 2003 Debentures was lowered to \$1.89 per share. The conversion price is subject to adjustment for anti-dilution protection for

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

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 we do 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 our common stock during the three trading days ending on and including the conversion date.

The July 2008 Warrants received by the investors, as amended, were an aggregate of 507,102 shares of common stock at a price of \$2.46 per share. These Warrants were exercised in July 2004 which produced gross proceeds in the amount of \$1,247,470.

On June 25, 2003, we issued to each of the March 12, 2003 Debenture holders a warrant to acquire at any time through June 25, 2008 an aggregate of 500,000 shares of common stock at a price of \$2.40 per share (the "June 2008 Warrants"). Pursuant to our agreement with the Debenture holders, we have registered the shares issuable upon exercise of these June 2008 Warrants for public sale. These warrants were exercised in May 2004 and we received gross proceeds of \$2,400,000.

On October 29, 2003, we 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 us if, and only if, we acquired ISI's facility within 90 days of January 26, 2004 and provide a mortgage on the facility as further security for the October 2003 Debentures. In March 2004, we acquired the facility and we subsequently provided the mortgage of the facility to the Debenture holders. The October 2003 Debentures mature on October 31, 2005 and bear 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 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.

Upon completing the sale of the October 2003 Debentures, we received \$3,275,000 in net proceeds consisting of \$1,725,000 from the October 2003 Debentures and \$1,550,000 that had been withheld from the July 2003 Debentures. As noted above, pursuant to the terms of the October 2003 Debentures, \$1,550,000 of the proceeds from the sale of the October 2003 Debentures had been held back. However, these proceeds were released to us in April 2004. As required by the Debentures, we have provided a mortgage on the ISI facility as further security for the Debentures.

The October 2003 Debentures are convertible at the option of the investors at any time through October 31, 2005 into shares of our 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 we do 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 our common stock during the three trading days ending on and including the 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 \$951,510.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

On January 26, 2004, we 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 158,103 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 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. 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. Commencing January 26, 2004, we are required to start repaying the then outstanding principal amount under the January 2004 Debentures in monthly installments amortized over 18 months in cash or, at our 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.

The January 2004 Debentures are convertible at the option of the investors at any time through January 31, 2006 into shares of our 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 we do 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 our common stock during the three trading days ending on and including the conversion date. Following completion of the August 2004 Private Placement (see Note 9 - Subsequent Events), the conversion price was lowered to \$2.08 per share.

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 will 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. Following completion of the August 2004 Private Placement (see Note 9 - Subsequent Events), the exercise price was lowered to \$2.58 per share.

We also issued to the investors Additional Investment Rights pursuant to which the investors have the right to acquire up to an additional \$2,000,000 principal amount of January 2004 Debentures (the "July 2004 Debentures") from us. 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. Following completion of the August 2004 Private Placement (see Note 9 - Subsequent Events), the conversion price was lowered to \$2.08 per share.

Pursuant to the terms and conditions of all of the outstanding Debentures (collectively, the "Debentures"), we have pledged all of our assets, other than our intellectual property, as collateral, and we are subject to comply with

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

certain financial and negative covenants.

On May 14, 2004, in consideration for the Debenture holders' exercise of all of the June 2008 Warrants, we issued to the holders warrants (the "May 2009 Warrants") to purchase an aggregate of 1,300,000 shares of our common stock. We issued 1,000,000 shares of common stock and received gross proceeds of \$2,400,000 from the exercise of the June 2008 Warrants.

The May 2009 Warrants are to acquire at any time commencing on November 14, 2004 through April 30, 2009 an aggregate of 1,300,000 shares of common stock at a price of \$4.50 per share. On May 14, 2005, the exercise price of these May 2009 Warrants will reset to 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 May 15, 2004 and May 13, 2005. The exercise price (and the reset price) under the May 2009 Warrants also is subject to adjustments for anti-dilution protection similar to those in the other Warrants. Notwithstanding the foregoing, the exercise price as reset or adjusted for anti-dilution, will in no event be less than \$4.008 per share. This transaction generated a non-cash charge of about \$2,300,000 financing costs in the second quarter of 2004. Following completion of the August 2004 Private Placement (see Note 9 - Subsequent Events), the exercise price was lowered to \$4.008 per share.

We entered into Registration Rights Agreements with the investors in connection with the issuance of (i) the Debentures; (ii) the June 2008, July 2008, October 2008, July 2009, and May 2009 Warrants (collectively, the "Warrants"); and (iii) the shares issued in January 2004. Pursuant to the Registration Rights Agreements we have registered on behalf of the investors the shares issued to them in January 2004 and 135% of the shares issuable upon conversion of the Debentures and upon exercise of all of the Warrants. If, subject to certain exceptions, sales of all shares so registered cannot be made pursuant to the registration statements, then we will be required to pay to the investors their pro rata share of \$.00067 times the outstanding principal amount of the relevant Debentures for each day the above condition exists.

As of June 30, 2004, the investors have converted \$12,400,329 of debt from the Debentures issued in March, July and October 2003 and January 2004 into 7,307,440 shares of our common stock. The March Debentures have been fully converted. The remaining principal balance on the outstanding Debentures is convertible into shares of our stock at the option of the investors at any time, through the maturity date. In addition, we have paid \$1,300,000 into the debenture cash collateral account as required by the terms of the October 2003 Debentures. The amounts paid through June 30, 2004 have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of June 30, 2004. The cash collateral account provides partial security for repayment of the outstanding Debentures in the event of default.

By agreement with Cardinal Securities, LLC, for general financial advisory services and in conjunction with the private debenture placements in July and October 2003 and in January, May and July 2004 (see Note 9 - Subsequent Events), we paid Cardinal Securities, LLC an investment banking fee equal to 7% of the investments made by the two Debenture holders and issued to Cardinal the following common stock purchase warrants: (i) 112,500 exercisable at \$2.57 per share; (ii) 87,500 exercisable at \$2.42 per share; and (iii) 100,000 exercisable at \$3.04 per share. The \$2.57 warrants expire on July 10, 2008, the \$2.42 warrants expire on October 29, 2008 and the \$3.04 warrants expire on January 5, 2009. With regard to the exercise of the June 2008 Warrants and issuance of the May 2009 Warrants, Cardinal received an investment banking fee of 7%, half in cash and half in shares. With regard to the exercise of the Additional Investment Rights, the July 2008 and October 2008 Warrants and issuance of the July 2009 Warrants, Cardinal received an investment banking fee of 7%, 146,980 in cash and 22,703 in shares as well as 50,000 warrants exercisable at \$4.07 expiring on July 12, 2009. By agreement with Cardinal, we have registered all of

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

the foregoing shares and shares issuable upon exercise of the above mentioned warrants for public sale and we have agreed to register the balance.

Section 713 of the American Stock Exchange ("AMEX") Company Guide provides that we 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 our outstanding common stock (the "Exchange Cap"). Taken separately, the July 2003, October 2003 and January 2004 Debenture transactions do not trigger Section 713. However, the AMEX has taken the position that the three 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 we 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, we recorded on January 26, 2004, a redemption obligation of approximately \$1,244,000. This liability represents the fair market value of the warrants and beneficial conversion feature related to the 1,299,000 shares.

In addition, in accordance with EITF 00-19, we revalued this redemption obligation associated with the beneficial conversion feature and warrants as of March 31, 2004. We recorded an additional redemption obligation and finance charge of \$947,000 as a result of this revaluation. Upon stockholder approval, our redemption obligation will be recorded as additional paid in capital as of the date approval is received.

The requisite stockholder approval was obtained at our Annual Meeting of Stockholders on June 23, 2004. In accordance with EITF 00-19, we revalued this redemption obligation associated with the beneficial conversion feature and warrants as of June 23, 2004. We recorded a reduction in the value of the redemption obligation and financing charge of \$260,000 as a result of this revaluation. In addition, upon receiving the requisite stockholder approval, this redemption obligation was reclassified as additional paid in capital as of the date the approval was received on June 23, 2004.

In connection with the Debenture agreements, we have outstanding letters of credit of \$1 million as additional collateral.

Note 8: EXECUTIVE COMPENSATION

In order to facilitate the Company's need to obtain financing and prior to our stockholders approving an amendment to our corporate charter to increase the number of authorized shares, Dr. Carter agreed to waive his right to exercise certain warrants and options unless and until our stockholders approved an increase in our authorized shares of Common Stock.

In October 2003, in recognition of this action as well as Dr. Carter's prior and on-going efforts relating to product development securing critically needed financing and the acquisition of a new product line, the Compensation Committee determined that Dr. Carter be awarded bonus compensation in 2003 consisting of \$196,636 and a grant of 1,450,000 stock warrants with an exercise price of \$2.20 per share. This additional compensation was reviewed by an independent valuation firm and found to be fair and reasonable within the context of total compensation paid to chief executive officers of comparable biotechnology companies.

In the quarter ended March 31, 2004, Dr. Carter was awarded an additional bonus of \$99,481 by the Compensation Committee. In addition, The Company recorded a non-cash stock compensation charge of \$1,769,000 during the first quarter 2004 resulting from warrants issued to Dr. Carter in 2003 that vested upon the

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

execution of the second ISI asset closing on March 17, 2004. This was determined by subtracting the exercise price from the stock closing price on March 17, 2004 and multiplying the result by the number of warrants.

Note 9- SUBSEQUENT EVENT

On July 13, 2004, the Debenture holders exercised all of the July 2003 and October 2003 Warrants and the Additional Investment Rights amounting to approximately \$4,198,980 in gross proceeds to the Company. We issued to these holders warrants (the "June 2009 Warrants") to purchase an aggregate of 1,300,000 shares of common stock.

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 will reset to 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 the foregoing, the exercise price as reset or adjusted for anti-dilution, will in no event be less than \$3.33 per share. Following completion of the August 2004 Private Placement (see below), the exercise price was lowered to \$3.33 per share. This transaction is subject to a non-cash financing charge of \$1,676,000 to be amortized over the remaining life of the October 2003 Debentures. 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 (see Note 7 - Debenture Financing). Pursuant to this obligation, the Company has so registered the shares.

On August 5, 2004, the Company closed a private placement with select institutional investors of approximately 3,617,300 shares of its Common Stock and warrants to purchase an aggregate of up to approximately 1,085,200 shares of its Common Stock. Jefferies & Company, Inc. acted as Placement Agent for which it received a fee and Common Stock Purchase Warrants. The Company raised approximately \$7,524,000 in gross cash proceeds from this private offering.

The Warrant issued to each purchaser is exercisable for up to 30% of the number of shares of Common Stock purchased by such Purchaser, at an exercise price equal to \$2.86 per share. Each Warrant has a term of five years and is fully exercisable from the date of issuance.

Pursuant to the Registration Rights Agreement, made and entered into as of August 5, 2004 (the "Rights Agreement"), the Company has agreed to file with the Securities and Exchange Commission a registration statement covering resales of the shares issued to the Purchasers and shares issuable upon the exercise of the Warrants.

Closing of the August 2004 Private Placement triggered the anti-dilution provisions of the January 2004 Debentures and the July 2004 Debentures and the July 2009 Warrants and the June 2009 Warrants. The conversion price adjustment for the Debentures noted above will result in an adjustment in the third quarter 2004 to the Debenture discount and additional paid-in-capital. Any adjustment to the Debenture discount will be amortized over the remaining life of the Debentures. The exercise price adjustment for the above warrants will result in a non-cash financing adjustment in the third quarter 2004 upon revaluing the warrants at the new anti-dilution pricing using the Black-Scholes Method.

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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

and Results of Operations.

Special Note Regarding Forward-Looking Statements

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

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

Overview

We were founded in the early 1970s as a contract researcher for the National Institutes of Health (NIH). Dr. William A. Carter, M.D., joined us in 1976 and ultimately became our CEO in 1988. He has focused us on exploring, understanding and mastering the mechanism of nucleic acid technology to produce a promising new class of drugs for treating chronic viral diseases and disorders of the immune system. In the course of almost three decades, 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 the development of therapeutic products for the treatment of chronic diseases. Our strategy is to obtain the required regulatory approvals which will allow the progressive introduction of Ampligen(R) (our proprietary drug) for treating Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome ("ME/CFS"), HIV, Hepatitis C ("HCV") and Hepatitis B ("HBV") in the U.S., Canada, Europe and Japan. Ampligen(R) is currently in the open label portion of phase III clinical trials in the U.S. for use in treatment of ME/CFS and is in Phase IIb Clinical Trials in the U.S. for the treatment of newly emerging multi-drug resistant HIV, and for the induction of cell mediated immunity in HIV patients that are under control using potentially toxic drug cocktails.

In March 2003 we obtained from Interferon Sciences, Inc. ("ISI") all of its raw materials, work-in-progress and finished product ALFERON N Injection(R), together with a limited license to sell ALFERON N Injection(R), a natural alpha interferon that has been approved for commercial sale for the intralesional treatment of refractory or recurring external condylomata acuminata ("genital warts") in patients 18 years of age or older in the United States. In March 2004, we acquired from ISI the balance of ISI's rights to its product as well as ISI's production facility. We are marketing the ALFERON N Injection(R) in the

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

United States through sales facilitated via third party agreements. Additionally, we intend to implement studies testing the efficacy of ALFERON N Injection(R) in multiple sclerosis and other chronic viral diseases. In this regard, the FDA recently authorized a Phase II clinical study designed to investigate the activity and safety of Alferon LDO(R) in early stage HIV positive patients.

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.

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:

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 be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the U.S. Food and Drug Administration ("FDA") for commercial sale.

ALFERON N Injection(R). Although ALFERON N Injection(R) is approved for marketing in the United States for the intralesional 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 intralesional 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, Interferon Sciences, Inc. ("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 obligation or immediate plans to conduct these additional studies at this time.

Our products, including Ampligen(R), are subject to extensive regulation by

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

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 European Medical Evaluation Agency ("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 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 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 U.S. or elsewhere, our operations most likely will be materially adversely affected.

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 June 30, 2004 our accumulated deficit was approximately \$127,841,000. 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 June 30, 2004, we had approximately \$9,433,000 million in cash and cash equivalents and short-term investments. We believe that these funds plus 1) the gross proceeds received from the exercise of warrants and the Additional Investment Rights of approximately \$4,198,980 on July 13, 2004, 2) the gross proceeds from the August 2004 Private Placement of equity securities on August 5, 2004 of approximately \$7,500,000, 3) the projected net cash flow from the sale of ALFERON N Injection(R) and 4) the proceeds from licensing agreements should be sufficient to meet our operating cash requirements including debt service during the next 18 months. 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 and begin commercializing Ampligen(R) 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.

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. When we obtained all rights to

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

ALFERON N Injection(R), we need to preserve and acquire enforceable patents covering its use for a particular disease too. 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. We cannot assure that our competitors will not seek and obtain patents regarding the use of similar products in combination with various other agents, for a particular target indication prior to our doing such. If we cannot protect our patents covering the use of our products for a particular disease, or obtain additional patents, we may not be able to successfully market our products.

The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves complex legal and factual questions.

To date, no consistent policy has emerged regarding the breadth of protection afforded by pharmaceutical and biotechnology patents. There can be no assurance that new patent applications relating to our products or technology will result in patents being issued or that, if issued, such patents will afford meaningful protection against competitors with similar technology. It is generally anticipated that there may be significant litigation in the industry regarding patent and intellectual property rights. Such litigation could require substantial resources from us and we may not have the financial resources necessary to enforce the patent rights that we hold. No assurance can be made that our patents will provide competitive advantages for our products or will not be successfully challenged by competitors. No assurance can be given that patents do not exist or could not be filed which would have a materially adverse effect on our ability to develop or market our products or to obtain or maintain any competitive position that we may achieve with respect to our products. Our patents also may not prevent others from developing competitive products using related technology.

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

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

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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

our competitors.

To protect our rights, we require certain employees and consultants to enter into confidentiality agreements with us. There can be no assurance that these agreements will not be breached, that we would have adequate and enforceable remedies for any breach, or that any trade secrets of ours will not otherwise become known or be independently developed by competitors.

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

We have limited marketing and sales capability. We are dependent upon existing and, possibly future, marketing agreements and third party distribution agreements for our products in order to generate significant revenues and become profitable. As a result, any revenues received by us will be dependent on the efforts of third parties, and there is no assurance that these efforts will be successful. Our agreement with Accredo offers the potential to provide some marketing and distribution capacity in the United States while agreements with Bioclones (Proprietary), Ltd, Biovail Corporation and Laboratorios Del Dr. Esteve S.A. may provide a sales force in South America, Africa, United Kingdom, Australia and New Zealand, Canada, Spain and Portugal.

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.

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. 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). The costs and availability of products and materials we need for 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.

Small changes in methods of manufacturing may affect the chemical structure of Ampligen(R) and other 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(R) 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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

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) 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 and 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 and HPB 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.

The purified drug concentrate utilized in the formulation of ALFERON N Injection(R) is manufactured in ISI's facility and ALFERON N Injection(R) is formulated and packaged at a production facility operated by Abbott Laboratories located in Kansas. In March 2004, we acquired ISI's New Brunswick, NJ facility. We still will be dependent upon Abbott Laboratories and/or another third party for product formulation and packaging.

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 commercial quantities. Ampligen(R) is currently produced for use in clinical trials. 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 lots 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. Alferon N Injection(R) has a shelf life of 18 months after having been bottled.

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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

with technological developments.

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 Smithkline, 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, 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.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

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 intralesional (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 limit such product's usefulness.

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 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 and/or Alferon N Injection product liability claims. A successful product liability claim against us in excess of Ampligen's \$1,000,000 in insurance coverage; \$3,000,000 in aggregate, or in excess of Alferon'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 million on the life of Dr. Carter and we have an employment agreement with Dr. Carter that,

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

as amended, runs until May 8, 2008. However, Dr. Carter has the right to terminate his employment upon not less than 30 days prior written notice. The loss of Dr. Carter or other personnel, or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

Uncertainty of health care reimbursement for our products.

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

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

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

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

The market price of our common stock has been and is likely to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- 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 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;
- o 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 June 30, 2004, the price of our common stock has ranged

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

from \$1.82 to \$5.40. 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, primarily those registered herein and in a prior registration statement, are sold in the public market.

As of July 23, 2004, approximately 180,851 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act of 1933. 84,112 of these shares are registered herein or in a prior registration statement pursuant to agreements between us and the holders of these shares. In addition, we have registered 11,647,995 shares issuable (i) upon conversion of approximately 135% of the January 2004 Debentures, the October 2003 Debentures, the July 2003 Debentures and the July 2004 Debentures; (ii) as payment of 135% of the interest on all of the Debentures; (iii) upon exercise of 135% of the July 2009 Warrants issued in conjunction with the January 2004 Debentures, the May 2009 Warrants and the June 2009 Warrants; and (iv) upon exercise of certain other warrants and stock options. 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.

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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

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 11.3% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at \$.01 per Right under certain circumstances.

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

NEW ACCOUNTING PRONOUNCEMENTS

In November 2002, the FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others" ("Interpretation No. 45"). Interpretation No. 45 elaborates on the existing disclosure requirements for most guarantees, including loan guarantees such as standby letters of credit. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair market value of the obligations it assumes under the guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and measurement provisions of Interpretation No. 45 apply on a prospective basis to guarantees issued or modified after December 31, 2002. Interpretation No. 45 did not have an effect on our financial statements.

In December 2002, the FASB issued Statement No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure", and amendment of FASB Statement No. 123 ("SFAS"). SFAS 148 amends FASB Statement No. 123, Accounting for Stock-Based Compensation, to provide alternative method of transition for an entity that voluntarily changes to the fair value based of accounting for stock-based employee compensation. It also amends the disclosure provisions of that Statement to require prominent disclosure about the effects on reported net income of an entity's accounting policy decisions with respect to stock-based employee compensation. Finally, this Statement amends Accounting Principles Board ("APB") Opinion No. 28, Interim Financial Reporting to require disclosure about those effects in interim financial information. SFAS 148 is effective for financial statements for fiscal years ending after December 15, 2002. We will continue to account for stock-based compensation using the intrinsic value method of APB Opinion No. 25, "Accounting for Stock Issued to Employees," but have adopted the enhanced disclosure requirements of SFAS 148.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities" ("Interpretation No. 46"), that clarifies the application of Accounting Research Bulletin No. 51, Consolidated Financial Statements, "to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. Interpretation No. 46 is applicable immediately for variable interest entities created after January 31, 2003. For variable interest entities created prior to January 31, 2003, the provisions of Interpretation No. 46 have been deferred to the first quarter of 2004. This Interpretation did not have an effect on our consolidated financial statements.

In May 2003, the FASB issued Statement No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity" ("SFAS 150"). SFAS 150 requires an issuer to classify certain financial instruments, such as mandatory redeemable shares and obligations to repurchase the issuers equity shares, as liabilities. The guidance is effective for financial instruments entered into or modified subsequent to May 31, 2003, and is otherwise effective at the beginning of the first interim period after June 15, 2003. SFAS 150 did not have an impact on our financial condition or results of operations.

Disclosure About Off-Balance Sheet Arrangements

Prior to our annual meeting of stockholders in September 2003, we had a limited number of shares of Common Stock authorized but not issued or reserved for issuance upon conversion or exercise of outstanding convertible and exercisable securities such as debentures, options and warrants. Prior to the meeting, to permit consummation of the sale of the July 2003 Debentures and the related warrants, Dr. Carter agreed that he would not exercise his warrants or options unless and until our stockholders approve an increase in our authorized shares of common stock. For Dr. Carter's waiver of his right to exercise certain options and warrants prior to approval of the increase in our authorized shares, we have agreed to compensate Dr. Carter. See "Executive Compensation; Employment Agreements" in amendment no. 1 to our annual report on Form 10-K for the year ended December 31, 2003, as filed with the SEC on March 30, 2004, for details related to how Dr. Carter has been compensated with respect to this matter.

In connection with the debenture agreements, HEB has outstanding letters of credit of \$1,000,000 as additional collateral.

Critical Accounting Policies

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our significant accounting policies are described in Notes to the Consolidated Financial Statements. The significant accounting policies that we believe are most critical to aid in fully understanding our reported financial results are the following:

Revenue

Revenues for non-refundable license fees are recognized under the Performance Method-Expected Revenue. This method considers the total amount of expected revenue during the performance period, but limits the amount of revenue recognized in a period to total non-refundable cash received to date. This limitation is appropriate because future milestone payments are contingent on future events.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

Upon receipt, the upfront non-refundable payment is deferred. The non-refundable upfront payments plus non-refundable payments arising from the achievement of defined milestones are recognized as revenue over the performance period based on the lesser of (a) percentage of completion or (b) non-refundable cash earned (including the upfront payment).

This method requires the computation of a ratio of cost incurred to date to total expected costs and then apply that ratio to total expected revenue. The amount of revenue recognized is limited to the total non-refundable cash received to date.

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 from the sale of product are recognized when the product is shipped, as title is transferred to the customer. We have no other obligation associated with our products once shipment has occurred.

Patents and Trademarks

Effective October 1, 2001, we adopted a 17-year estimated useful life for the amortization of our patents and trademark rights in order to more accurately reflect their useful life. Prior to October 1, 2001, we were using a ten year estimated useful life.

Patents and trademarks are stated at cost (primarily legal fees) and are amortized using the straight-line method over the life of the assets. We review our 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 our respective capitalized cost. In addition, management's review addresses whether each patent continues to fit into our strategic business plans.

Concentration of Credit Risk

Financial instruments that potentially subject us to credit risks consist of cash equivalents and accounts receivable.

Our policy is to limit the amount of credit exposure to any one financial institution and place investments with financial institutions evaluated as being credit worthy, or in short-term money markets, which are exposed to minimal interest rate and credit risks. At times, we have bank deposits and overnight repurchase agreements that exceed federally insured limits.

Concentration of credit risk, with respect to receivables, is limited through our credit evaluation process. We do not require collateral on our receivables. Our receivables consist principally of amounts due from wholesale drug companies as of June 30, 2004.

RESULTS OF OPERATIONS

Three months ended June 30, 2004 versus Three months ended June 30, 2003

Net loss

Our net loss was approximately \$5,956,000 for the three months ended June 30, 2004 versus a net loss of \$3,689,000 for the same period a year ago. Per share loss for the three months ended June 30, 2004 was \$0.14 per share versus \$0.11 a year earlier for the same period. This year-to-year increase in losses of

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

\$2,267,000 primarily consists of 1) an increase in non-cash financing costs of \$1,697,000 related to our debentures and related securities; 2) an increase in production/cost of goods sold due to increased Alferon N Injection sales, 3) the cost of preparing the New Brunswick facility for further production, and 4) an increase of \$238,000 in G&A expenses.

Revenues

Revenues for the three months ended June 30, 2004 were \$331,000 as compared to revenues of \$94,000 for the same period in 2003. Revenues from our ME/CFS cost recovery treatment programs principally underway in the U.S., Canada and Europe were \$42,000 for the three months ended June 30, 2004 versus \$34,000 for the three months ended June 30, 2003. These clinical programs allow us to provide Ampligen(R) therapy at our cost to severely debilitated ME/CFS patients. Under this program the patients pay for the cost of Ampligen(R) doses infused. These costs total approximately \$7,200 for a 24-week treatment program.

In addition, revenues for the three months ended June 30, 2004 from sales of ALFERON N totaled \$289,000 versus \$60,000 for the same period a year ago. Sales of Alferon N are anticipated to increase as we have more product available and intend to expand our marketing/sales programs on an international basis.

Since acquiring the right to manufacture and market Alferon N on March 11, 2003, we have focused on converting the work-in-progress inventory into finished goods. This work-in-progress inventory included three production lots totaling the equivalent of approximately 55,000 vials (doses) at various stages of the manufacturing process. In August 2003, we released the first lot of product to Abbott Laboratories for bottling and realized some 21,000 vials of ALFERON N. In July 2004, we initiated the process of converting the second lot of approximately 16,000 vials from work-in-progress to finished goods inventory. We anticipate shipping the lot to Abbott Laboratories for bottling by the end of the third quarter 2004. Our production and quality control personnel in our newly acquired New Brunswick, NJ facility are involved in the extensive process of manufacturing and validation required by the FDA.

A third lot of some 18,000 vials is now in very early stages of production.

Our marketing and sales plan for ALFERON N consists of engaging the services of sales contract organizations and supplementing their sales efforts with marketing support. This marketing support consists of building awareness of ALFERON N with physicians as a successful and effective treatment of refractory on recurring external genital warts in patients of age 18 or older and to assist primary prescribers in expanding their practice.

In August 2003, we entered into a sales and marketing agreement with Engitech, LLC. to distribute ALFERON N on a nationwide basis. This agreement stipulates that Engitech deploy a sales force to develop and implement marketing plans including scientific and educational programs for use in marketing ALFERON N. We are also negotiating with other contract sales organizations to meet our ALFERON N sales goals.

We executed a Memorandum of Understanding (MOI) in January 2004 with Fujisawa Deutschland GmbH, ("Fuji") a major pharmaceutical corporation, granting them an exclusive option for a limited number of months to enter a Sales and Distribution Agreement with exclusive rights to market Ampligen(R) for ME/CFS in Germany, Austria and Switzerland. The MOI required us to file the full report on the results of our AMP 516 Clinical Trial with Fuji by May 31, 2004. If a full report was not provided to Fuji by May 31, 2004 and Fuji did not wish to exercise its option, we would have been required to refund one half of the 400,000 Euro fee paid by Fuji. We submitted our initial report to Fuji on May 28, 2004 and received their response asking for additional information. We provided additional information to Fuji in June 2004 and any additional communication has been determined to be conducted via conference call. Fuji's

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

option period ends 12 weeks after the later of Fuji's review of the full report on the results of our Amp 516 clinical trial and Fuji's meeting with the trial's principal investigators. We received an initial fee of 400,000 Euros (approximately \$497,000 US). If we do not provide them with the full report by December 31, 2004 and Fuji does not wish to exercise its option, we will be required to refund the entire fee. If Fuji exercises the option, Fuji would be required to pay us an additional 1,600,000 Euros upon execution of the Sales and Distribution agreement, purchase Ampligen(R) exclusively from us and meet certain annual minimum purchase quotas. We would be required to file an application with the EMEA for commercial sale of Ampligen(R) for ME/CFS on or before December 31, 2005. Upon our filing of that application, we would receive an additional 1,000,000 Euros and, upon approval by the EMEA, an additional 2,000,000 Euros. If we failed to meet the December 31, 2005 filing deadline, we would be required to return 40% of all payments that we had received from Fuji. We would be required to sell Ampligen(R) to Fuji at a 20% price discount until the aggregate amount of the discount reached \$1,000,000 Euros (representing 50% of the initial 2,000,000 fee paid to us on and prior to execution of the definitive agreement). The foregoing is a summary of the memorandum of understanding. We cannot assure that we can prepare and issue the AMP 516 report within the time frames noted or that Fuji will exercise the option or that the proposed terms of the Sales and Distribution Agreement will not change materially. The initial fee has been recorded on our balance sheet at June 30, 2004 as deferred revenue.

On March 17, 2004, we closed on the acquisition of all of the worldwide rights of ALFERON N as well as the FDA approved biological production facility in New Brunswick, New Jersey. We intend to expand our marketing/sales programs on an international basis.

Production costs/cost of goods sold

Production costs for the three months ended June 30, 2004 and 2003 were \$692,000 and \$37,000, respectively. These costs reflect approximately \$130,000 and \$37,000 for the cost of sales of ALFERON N Injection(R) for the three months ended June 30, 2004 and 2003. The remaining production costs in 2004 represent expenditures associated with preparing the New Brunswick facility for additional production of Alferon N Injection(R). In July 2004, we initiated the process of converting the second lot of inventory from work-in-progress to finished goods. We anticipate shipping the lot to Abbott Laboratories for bottling by the end of the third quarter 2004.

Research and Development costs

Overall research and development direct costs for the three months ended June 30, 2004 were \$758,000 as compared to \$855,000 during the same period a year earlier. These costs primarily reflect the direct costs associated with our effort to develop our lead product, Ampligen(R), as a therapy in treating chronic diseases and cancers. At this time, this effort primarily consists of on-going clinical trials involving patients with HIV. The primary reason for the decrease in research and development costs of \$97,000 in the current Quarter versus the same period a year ago was due to a reduction in costs related to the AMP 516 ME/CFS study partially offset by increased costs for the AMP 720 HIV study.

Our strategy is to develop our lead compound, the experimental immunotherapeutic Ampligen(R), to treat chronic diseases for which there is currently no adequate treatment available. We seek the required regulatory approval, which will allow the commercial introduction of Ampligen for ME/CFS and HIV/AIDS in the U.S., Canada, Europe and Japan.

We recently completed the double-blind segment of our AMP 516 ME/CFS Phase III clinical trial for use of Ampligen(R) in the treatment of ME/CFS.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

Clinical data on the primary endpoint exercise treadmill duration was presented at the 17th International Conference on Anti-viral Research in Tucson, AZ on May 3, 2004. The data showed that patients receiving Ampligen for 40 weeks improved exercise treadmill performance by a medically and statistically significant amount compared to the placebo group. Ampligen is also currently in two Phase IIb studies for the treatment of HIV to overcome multi-drug resistance, virus mutation and toxicity associated with current HAART therapies. One study, the AMP-719, is a Salvage Therapy, conducted in the U.S. and evaluating the potential synergistic efficacy of Ampligen in multi-drug resistant HIV patients for immune enhancement. The second study, the AMP-720, is a clinical trial designed to evaluate the effect of Ampligen under Strategic Treatment Intervention and is also conducted in the U.S. Enrollment in the AMP 719 study is presently on hold as we devote our efforts on the AMP 720 study.

AMP 516

Over 230 patients have participated in our ME/CFS Phase III clinical trial. A few remaining patients are completing Stage II of the AMP 516 Phase III protocol. The dosing of these patients is anticipated to be completed in August 2004. We have completed the randomized placebo controlled phase of this study and expect to complete data collection and start the data analysis process with the expectation of filing an NDA (New Drug Application) with the FDA by the end of 2004 and/or the first quarter 2005. As with any experimental drug being tested for use in treating human diseases, the FDA must approve the testing and clinical protocols employed and must render their decision based on the safety and efficacy of the drug being tested. Historically this is a long and costly process. Our ME/CFS AMP 516 clinical study is a Phase III study, which based on favorable results, will serve as the basis for us to file a new drug application with the FDA. The FDA review process could take 18-24 months and result in one of the following events; 1) approval to market Ampligen(R) for use in treating ME/CFS patients, 2) required more research, development, and clinical work, 3) approval to market as well as conduct more testing, or 4) reject our application. Given these variables, we are unable to project when material net cash inflows are expected to commence from the sale of Ampligen(R).

AMP 720

We are currently focused on recruiting additional clinical investigators and HIV patients to participate in the AMP 720 HIV clinical trial. Our efforts to do this have been somewhat hampered in late 2003 as most of our clinical resources have been directed to completing the AMP 516 ME/CFS clinical trial. Now that the AMP 516 patients have completed the randomized segment of the clinical trial, we expect to devote more resources toward the AMP 720 HIV clinical trial. Our AMP 719 HIV clinical trial has been put on hold at this time.

In July 2003, Dr. Blick, a principal investigator in our HIV studies, presented updated results on our Amp 720 HIV study at the 2nd IAS CONFERENCE ON HIV PATHOGENESIS AND TREATMENT in Paris France. In this study using Strategic Treatment Interruption (STI), patients' antiviral HAART regimens are interrupted and Ampligen(R) is substituted as mono-immunotherapy. Ampligen(R) is an experimental immunotherapeutic designed to display both antiviral and immune enhancing characteristics. Prolonged use of Highly Active Antiretroviral Therapy (HAART) has been associated with long-term, potentially fatal, toxicities. The clinical study AMP 720 is designed to address these issues by evaluating the administration of our lead experimental agent, Ampligen(R), a double stranded RNA drug acting potentially both as an immunomodulator and antiviral. 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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

inherent toxicities, for more than 11 weeks. As more patients are enrolled, the related clinical costs will continue to increase with some offset to our overall expenses due to the diminishing cost of the ME/CFS clinical trial. It is difficult to estimate the duration or projected costs of these two clinical trials due to the many variables involved, i.e.: patient drop out rate, recruitment of clinical investigators, etc. The length of the study and costs related to our clinical trials cannot be determined at this time as such will be materially influenced by (a) the number of clinical investigators needed to recruit and treat the required number of patients, (b) the rate of accrual of patients and (c) the retention of patients in the studies and their adherence to the study protocol requirements. Under optimal conditions, the cost of completing the studies could be approximately \$2.0 to \$3.0 million. The rate of enrollment depends on patient availability and on other products being in clinical trials for the treatment of HIV, as there is competition for the same patient population. At present, more than 18 FDA approved drugs for HIV treatment may compete 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 is appropriate and whether a Phase III trial 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.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended June 30, 2004 and 2003 were approximately \$1,076,000 and \$838,000, respectively. The increase in G&A cost in expenses of \$238,000 during this period is primarily due to higher investment banking fees, directors' fees and public relations expenses during the current quarter as compared to the same period a year ago.

Other Income/Expense

Interest and other income for the three months ended June 30, 2004 and 2003 totaled \$13,000 and \$1,000, respectively. The primary reason for the increase in interest and other income during the current quarter can be attributed to more cash available for investment purposes versus the same period a year ago. All funds in excess of our immediate need are invested in short-term high quality securities.

Interest Expense and Financing Costs

Non-cash financing costs were \$3,669,000 for the three months ended June 30, 2004 versus \$1,972,000 for the same three months a year ago. Non-cash financing costs consist of the amortization of debenture closing costs, the amortization of Original Issue Discounts and the amortization of costs associated with beneficial conversion features of our debentures and the fair value of the warrants relating to the Debentures. These charges are reflected in the Consolidated Statements of Operations under the caption "Financing Costs."

In connection with the redemption obligation recorded in conjunction with the January 2004 Debentures, we recorded additional financing costs of approximately \$947,000 in the first quarter 2004. In the current quarter, we recorded a reduction in financing costs of approximately \$260,000. Please see Note 7 in the consolidated financial statements contained herein for more details on these transactions.

Six months ended June 30, 2004 versus Six months ended June 30, 2003

Net loss

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

Our net loss was approximately \$13,997,000 for the six months ended June 30, 2004 versus a net loss of \$5,306,000 for the same period a year ago. Per share loss for the six months ended June 30, 2004 was \$0.33 per share versus \$0.16 a year earlier for the same period. This year-to-year increase in losses of \$8,691,000 consists of an increase in non-cash financing costs of \$5,473,000, relating to our July 2003 Debentures, October 2003 Debentures and January 2004 Debentures (Collectively, the "Debentures") as well as an increase in general and administrative expenses of \$2,416,000 primarily due to an increase in investment banking and Directors' fees and a non-cash stock compensation charge of \$1,769,000 resulting from warrants issued to Dr. Carter in 2003 that vested in the first quarter 2004. These warrants vested upon the second ISI asset closing which occurred on March 17, 2004. See "Executive Compensation" in amendment no. 1 to our annual report on Form 10-K for the year ended December 31, 2003, as filed with the SEC on March 30, 2004, for details related to how Dr. Carter has been compensated with respect to this matter. Also contributing to the increase in loss from year-to-year was an increase in production/cost of goods sold of \$1,138,000 due to an increase in sales of Alferon N Injection and preparing the New Brunswick facility for further production. This was partially offset by an increase in revenue of \$479,000 when comparing the six months ended June 30, 2004 and 2003.

Revenues

Revenues for the six months ended June 30, 2004 were \$639,000 as compared to revenues of \$160,000 for the same period in 2003. Revenues from our ME/CFS cost recovery treatment programs principally underway in the U.S., Canada and Europe were \$91,000 for the six months ended June 30, 2004 versus \$81,000 for the six months ended June 30, 2003. These clinical programs allow us to provide Ampligen(R) therapy at our cost to severely debilitated ME/CFS patients. Under this program the patients pay for the cost of Ampligen(R) doses infused. These costs total approximately \$7,200 for a 24-week treatment program.

In addition, revenues for the six months ended June 30, 2004 from sales of ALFERON N totaled \$548,000 versus \$79,000 for the period of March 11, 2003, the date we acquired the rights to the Alferon N business from ISI, through June 30, 2003. Sales of Alferon N are anticipated to increase as we have more product available and intend to expand our marketing/sales programs on an international basis.

Since acquiring the right to manufacture and market Alferon N on March 11, 2003, we have focused on converting the work-in-progress inventory into finished goods. This work-in-progress inventory included three production lots totaling the equivalent of approximately 55,000 vials (doses) at various stages of the manufacturing process. In August 2003, we released the first lot of product to Abbott Laboratories for bottling and realized some 21,000 vials of ALFERON N. In July 2004, we initiated the process of converting the second lot of approximately 16,000 vials from work-in-progress to finished goods inventory. We anticipate shipping the lot to Abbott Laboratories for bottling by the end of the third quarter 2004. Our production and quality control personnel in our newly acquired New Brunswick, NJ facility are involved in the process of manufacturing and validation required by the FDA. A third lot of some 18,000 vials is now in very early stages of production.

Our marketing and sales plan for ALFERON N consists of engaging sales force contract organizations and supplementing their sales efforts with marketing support. This marketing support would consist of building awareness of ALFERON N with physicians as a successful and effective treatment of refractory on recurring external genital warts in patients of age 18 or older and to assist primary prescribers in expanding their practice.

In August 2003, we entered into a sales and marketing agreement with Engitech, LLC. to distribute ALFERON N on a nationwide basis. This agreement stipulates that Engitech deploy a sales force to develop and implement marketing plans

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

including scientific and educational programs for use in marketing ALFERON N. We are also negotiating with other contract sales organizations to meet our ALFERON N sales goals.

We executed a Memorandum of Understanding (MOI) in January 2004 with Fujisawa Deutschland GmbH, ("Fuji") a major pharmaceutical corporation, granting them an exclusive option for a limited number of months to enter a Sales and Distribution Agreement with exclusive rights to market Ampligen(R) for ME/CFS in Germany, Austria and Switzerland. The MOI required us to file the full report on the results of our AMP 516 Clinical Trial with Fuji by May 31, 2004. If the full report was not provided to Fuji by May 31, 2004 and Fuji did not wish to exercise its option, we would have been required to refund one half of the 400,000 Euro fee. We submitted our initial report to Fuji on May 28, 2004 and received their response in June 2004 requesting additional information, which we provided in June 2004. The option period ends 12 weeks after the later of Fuji's review of the full report on the results of our Amp 516 clinical trial and Fuji's meeting with the trial's principal investigators. We received an initial fee of 400,000 Euros (approximately \$497,000 US). If we do not provide them with the full report by December 31, 2004 and Fuji does not wish to exercise its option, we will be required to refund the entire fee. If Fuji exercises the option, Fuji would be required to pay us an additional 1,600,000 Euros upon execution of the Sales and Distribution agreement, purchase Ampligen(R) exclusively from us and meet certain annual minimum purchase quotas. We would be required to file an application with the EMEA for commercial sale of Ampligen(R) for ME/CFS on or before December 31, 2005. Upon our filing of that application, we would receive an additional 1,000,000 Euros and, upon approval by the EMEA, an additional 2,000,000 Euros. If we failed to meet the December 31, 2005 filing deadline, we would be required to return 40% of all payments that we had received from Fuji. We would be required to sell Ampligen(R) to Fuji at a 20% price discount until the aggregate amount of the discount reached \$1,000,000 Euros (representing 50% of the initial 2,000,000 fee paid to us on and prior to execution of the definitive agreement). The foregoing is a summary of the memorandum of understanding. We cannot assure that we can prepare and issue the AMP 516 report within the time frames noted or that Fuji will exercise the option or that the proposed terms of the Sales and Distribution Agreement will not change materially. The initial fee has been recorded on our balance sheet at June 30, 2004 as deferred revenue.

On March 17, 2004, we closed on the acquisition of all of the worldwide rights of ALFERON N as well as the FDA approved biological production facility in New Brunswick, New Jersey. We intend to expand our marketing/sales programs on an international basis.

Production costs/cost of goods sold

Production costs for the six months ended June 30, 2004 and 2003 were \$1,293,000 and \$155,000, respectively. These costs reflect approximately \$241,000 for the cost of sales of ALFERON N Injection(R) for the six months ended June 30, 2004. In addition, costs of sales for Alferon N Injection(R) for the period March 11, 2003 (acquisition date of inventory from ISI) through June 30, 2003 amounted to \$49,000. The remaining production costs represent expenditures associated with preparing the New Brunswick facility for further production of Alferon N Injection(R). In July 2004, we initiated the process of converting the second lot of inventory from work-in-progress to finished goods. We anticipate shipping this second lot to Abbott Laboratories by the end of the third quarter 2004.

Research and Development costs

Overall research and development direct costs for the six months ended June 30, 2004 were \$1,720,000 as compared to \$1,728,000 during the same period a year earlier. These costs primarily reflect the direct costs associated with our effort to develop our lead product, Ampligen(R), as a therapy in treating

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

chronic diseases and cancers. At this time, this effort primarily consists of on-going clinical trials involving patients with HIV.

Our strategy is to develop our lead compound, the experimental immunotherapeutic Ampligen(R), to treat chronic diseases for which there is currently no adequate treatment available. We seek the required regulatory approval, which will allow the commercial introduction of Ampligen for ME/CFS and HIV/AIDS in the U.S., Canada, Europe and Japan.

We recently completed the double-blind segment of our AMP 516 ME/CFS Phase III clinical trial for use of Ampligen(R) in the treatment of ME/CFS.

Clinical data on the primary endpoint exercise treadmill duration was presented at the 17th International Conference on Anti-viral Research in Tucson, AZ on May 3, 2004. The data showed that patients receiving Ampligen for 40 weeks improved exercise treadmill performance by a medically and statistically significant amount compared to the placebo group. Ampligen is also currently in two Phase IIb studies for the treatment of HIV to overcome multi-drug resistance, virus mutation and toxicity associated with current HAART therapies. One study, the AMP-719, is a Salvage Therapy, conducted in the U.S. and evaluating the potential synergistic efficacy of Ampligen in multi-drug resistant HIV patients for immune enhancement. The second study, the AMP-720, is a clinical trial designed to evaluate the effect of Ampligen under Strategic Treatment Intervention and is also conducted in the U.S. Enrollment in the AMP 719 study is presently on hold as we devote our efforts on the AMP 720 study.

AMP 516

Over 230 patients have participated in our ME/CFS Phase III clinical trial. A few remaining patients are completing Stage II of the AMP 516 Phase III protocol. The dosing of these patients is anticipated to be completed in August 2004. We have completed the randomized placebo controlled phase of this study and expect to complete data collection and start the data analysis process with the expectation of filing an NDA (New Drug Application) with the FDA by the end of 2004 and/or the first quarter 2005. As with any experimental drug being tested for use in treating human diseases, the FDA must approve the testing and clinical protocols employed and must render their decision based on the safety and efficacy of the drug being tested. Historically this is a long and costly process. Our ME/CFS AMP 516 clinical study is a Phase III study, which based on favorable results, will serve as the basis for us to file a new drug application with the FDA. The FDA review process could take 18-24 months and result in one of the following events; 1) approval to market Ampligen(R) for use in treating ME/CFS patients, 2) required more research, development, and clinical work, 3) approval to market as well as conduct more testing, or 4) reject our application. Given these variables, we are unable to project when material net cash inflows are expected to commence from the sale of Ampligen(R).

AMP 720

We are currently focused on recruiting additional clinical investigators and HIV patients to participate in the AMP 720 HIV clinical trial. Our efforts to do this have been somewhat hampered in late 2003 as most of our clinical resources have been directed to completing the AMP 516 ME/CFS clinical trial. Now that the AMP 516 patients have completed the randomized segment of the clinical trial, we expect to devote more resources toward the AMP 720 HIV clinical trial. Our AMP 719 HIV clinical trial has been put on hold at this time.

In July 2003, Dr. Blick, a principal investigator in our HIV studies, presented updated results on our Amp 720 HIV study at the 2nd IAS CONFERENCE ON HIV PATHOGENESIS AND TREATMENT in Paris France. In this study using Strategic Treatment Interruption (STI), patients' antiviral HAART regimens are interrupted and Ampligen(R) is substituted as mono-immunotherapy. Ampligen(R) is an

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

experimental immunotherapeutic designed to display both antiviral and immune enhancing characteristics. Prolonged use of Highly Active Antiretroviral Therapy (HAART) has been associated with long-term, potentially fatal, toxicities. The clinical study AMP 720 is designed to address these issues by evaluating the administration of our lead experimental agent, Ampligen(R), a double stranded RNA drug acting potentially both as an immunomodulator and antiviral. 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. As more patients are enrolled, the related clinical costs will continue to increase with some offset to our overall expenses due to the diminishing cost of the ME/CFS clinical trial. It is difficult to estimate the duration or projected costs of these two clinical trials due to the many variables involved, i.e.: patient drop out rate, recruitment of clinical investigators, etc. The length of the study and costs related to our clinical trials cannot be determined at this time as such will be materially influenced by (a) the number of clinical investigators needed to recruit and treat the required number of patients, (b) the rate of accrual of patients and (c) the retention of patients in the studies and their adherence to the study protocol requirements. Under optimal conditions, the cost of completing the studies could be approximately \$2.0 to \$3.0 million. The rate of enrollment depends on patient availability and on other products being in clinical trials for the treatment of HIV, as there is competition for the same patient population. At present, more than 18 FDA approved drugs for HIV treatment may compete 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 is appropriate and whether a Phase III trial 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.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the six months ended June 30, 2004 and 2003 were approximately \$3,921,000 and \$1,505,000, respectively. The increase in G&A expenses of \$2,416,000 during this period is primarily due to a non-cash stock compensation charge of \$1,769,000 resulting from warrants issued to Dr. Carter in 2003 that vested in the current quarter. These warrants vested upon the second ISI asset closing which occurred on March 17, 2004. For comparative purposes only, excluding the stock compensation charge of 1,769,000 noted above, our G & A expenses were \$2,152,000 and \$1,505,000 for the six months ended June 30, 2004, respectively. The primary reason for this increase in loss of 647,000 can be attributed to higher investment banking, public relations and Director's fees during the first six months in 2004.

Other Income/Expense

Interest and other income for the six months ended June 30, 2004 and 2003 totaled \$24,000 and \$51,000, respectively. The primary reason for the decrease in interest and other income during the first six months in 2004 can be attributed to lower cash available for investment, a shorter holding period for investments and lower interest rates versus the same period a year ago. All funds in excess of our immediate need are invested in short-term high quality securities.

Interest Expense and Financing Costs

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

Interest expense and financing costs were \$7,726,000 for the six months ended June 30, 2004 versus \$2,129,000 for the same six months a year ago. Non-cash financing costs consist of the amortization of debenture closing costs, the amortization of Original Issue Discounts and the amortization of costs associated with beneficial conversion features of our debentures and the fair value of the warrants relating to the Debentures. These charges are reflected in the Consolidated Statements of Operations under the caption "Financing Costs."

In connection with the redemption obligation recorded in conjunction with the January 2004 Debentures, we recorded additional financing costs of approximately \$947,000 in the first quarter 2004. In the current quarter, we recorded a reduction in financing costs of approximately \$260,000. Please see Note 7 in the consolidated financial statements contained herein for more details on these transactions.

Liquidity And Capital Resources

Cash used in operating activities for the six months ended June 30, 2004 was \$3,872,000. Cash provided by financial activities for the six months ended June 30, 2004 amounted to \$8,309,000, substantially from proceeds from a debenture offering (see below) and the exercising of common stock warrants. As of June 30, 2004, we had approximately \$9,433,000 million in cash and short-term investments. We believe that these funds plus 1) the gross proceeds received from the exercise of warrants and the Additional Investment Rights of approximately \$4,198,980 on July 13, 2004, 2) the gross proceeds from the August 2004 Private Placement of equity securities on August 5, 2004 of approximately \$7,500,000, 3) the projected net cash flow from the sale of ALFERON N Injection(R) and 4) the proceeds from licensing agreements should be sufficient to meet our operating cash requirements including debt service during the next 18 months. 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 and begin commercializing Ampligen(R) 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.

On March 12, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due January 2005 (the "March Debentures") and an aggregate of 743,288 warrants to two investors in a private placement for aggregate gross proceeds of \$4,650,000. The March Debentures were to mature on January 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 were 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 March Debentures, we pledged all of our assets, other than our intellectual property, as collateral and were subject to comply with certain financial and negative covenants, which include but were not limited to the repayment of principal balances upon achieving certain revenue milestones.

The March Debentures were convertible at the option of the investors at any time through January 31, 2005 into shares of our common stock. The conversion price under the March Debentures was fixed at \$1.46 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.

The investors also received Warrants to acquire at any time through March 12, 2008 an aggregate of 743,288 shares of common stock at a price of \$1.68 per

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

share.

We entered into a Registration Rights Agreement with the investors in connection with the issuance of the March Debentures and the Warrants. The Registration Rights Agreement requires that we register the shares of common stock issuable upon conversion of the Debentures, as interest shares under the Debentures and upon exercise of the Warrants. In accordance with this agreement, we have registered these shares for public sale.

As of December 31, 2003, the investors had converted the total \$5,426,000 principal of the March Debentures into 3,716,438 shares of our common stock. The total interest on these debenture was \$111,711 of which \$17,290 was paid in cash and \$94,421 was paid by the issuance of shares of our common stock. The investor exercised all 743,288 warrants in July 2003 which produced proceeds in the amount of \$1,248,724.

On July 10, 2003, we issued an aggregate of \$5,426,000 in principal amount of 6% Senior Convertible Debentures due July 31, 2005 (the "July 2003 Debentures") and an aggregate of 507,102 Warrants (the "July 2008 Warrants") to the same investors who purchased the March Debentures, in a private placement for aggregate proceeds of \$4,650,000. Pursuant to the terms of the July 2003 Debentures, \$1,550,000 of the proceeds from the sale of the July 2003 Debentures were to have been held back and released to us if, and only if, we acquired ISI's facility within a set timeframe. These funds were released to us in October 2003 although we had not acquired ISI's facility at that time. The July 2003 Debentures mature on July 31, 2005 and bear 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 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.

The July 2003 Debentures are convertible at the option of the investors at any time through July 31, 2005 into shares of our common stock. The conversion price under the July 2003 Debentures was fixed at \$2.14 per share; however, as part of the new debenture placement closed on October 29, 2003 (see below), the conversion price under the July 2003 Debentures was lowered to \$1.89 per share. The conversion price is 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 we do 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 our common stock during the three trading days ending on and including the conversion date.

The July 2008 Warrants received by the investors, as amended, were an aggregate of 507,102 shares of common stock at a price of \$2.46 per share. These Warrants were exercised in July 2004 which produced gross proceeds in the amount of \$1,247,470.

On June 25, 2003, we issued to each of the March 12, 2003 Debenture holders a warrant to acquire at any time through June 25, 2008 an aggregate of 500,000 shares of common stock at a price of \$2.40 per share (the "June 2008 Warrants"). Pursuant to our agreement with the Debenture holders, we have registered the shares issuable upon exercise of these June 2008 Warrants for public sale. These warrants were exercised in May 2004 and we received gross proceeds of \$2,400,000.

On October 29, 2003, we 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")

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

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 us if, and only if, we acquired ISI's facility within 90 days of January 26, 2004 and provide a mortgage on the facility as further security for the October 2003 Debentures. In March 2004, we acquired the facility and we subsequently provided the mortgage of the facility to the Debenture holders. The October 2003 Debentures mature on October 31, 2005 and bear 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 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.

Upon completing the sale of the October 2003 Debentures, we received \$3,275,000 in net proceeds consisting of \$1,725,000 from the October 2003 Debentures and \$1,550,000 that had been withheld from the July 2003 Debentures. As noted above, pursuant to the terms of the October 2003 Debentures, \$1,550,000 of the proceeds from the sale of the October 2003 Debentures had been held back. However, these proceeds were released to us in April 2004. As required by the Debentures, we have provided a mortgage on the ISI facility as further security for the Debentures.

The October 2003 Debentures are convertible at the option of the investors at any time through October 31, 2005 into shares of our 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 we do 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 our common stock during the three trading days ending on and including the 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 \$951,510.

On January 26, 2004, we 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 158,103 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 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. 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. Commencing January 26, 2004, we are required to start repaying the then outstanding principal amount under the January 2004 Debentures in monthly installments amortized over 18 months in cash or, at our 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.

The January 2004 Debentures are convertible at the option of the investors at any time through January 31, 2006 into shares of our common stock. The conversion price under the January 2004 Debentures was fixed at \$2.53 per share,

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

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 we do 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 our common stock during the three trading days ending on and including the conversion date. Following completion of the August 2004 Private Placement (see Note 9 - Subsequent Events to our financial statements attached hereto), the conversion price was lowered to \$2.08 per share.

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 will 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. Following completion of the August 2004 Private Placement (see Note 9 - Subsequent Events to our financial statements attached hereto), the exercise price was lowered to \$2.58 per share.

We also issued to the investors Additional Investment Rights pursuant to which the investors have the right to acquire up to an additional \$2,000,000 principal amount of January 2004 Debentures (the July 2004 Debentures") from us. 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. Following completion of the August 2004 Private Placement (see Note 9 - Subsequent Events to our financial statements attached hereto), the conversion price was lowered to \$2.08 per share.

Pursuant to the terms and conditions of all of the outstanding Debentures (collectively, the "Debentures"), we have pledged all of our assets, other than our intellectual property, as collateral, and we are subject to comply with certain financial and negative covenants.

On May 14, 2004, in consideration for the Debenture holders' exercise of all of the June 2008 Warrants, we issued to the holders warrants (the "May 2009 Warrants") to purchase an aggregate of 1,300,000 shares of our common stock. We issued 1,000,000 shares of common stock and received gross proceeds of \$2,400,000 from the exercise of the June 2008 Warrants.

The May 2009 Warrants are to acquire at any time commencing on November 14, 2004 through April 30, 2009 an aggregate of 1,300,000 shares of common stock at a price of \$4.50 per share. On May 14, 2005, the exercise price of these May 2009 Warrants will reset to 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 May 15, 2004 and May 13, 2005. The exercise price (and the reset price) under the May 2009 Warrants also is subject to adjustments for anti-dilution protection similar to those in the other Warrants. Notwithstanding the foregoing, the exercise price as reset or adjusted for anti-dilution, will in no event be less than \$4.008 per share. This transaction generated a non-cash charge of about \$2,300,000 in financing costs in the second quarter of 2004. Following completion of the August 2004 Private Placement (see Note 9 - Subsequent Events to our financial statements attached hereto), the exercise price was lowered to \$4.008 per share.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

On July 13, 2004, the Debenture holders exercise of all of the July 2003 and October 2003 Warrants and the Additional Investment Rights. We issued to these holders warrants (the "June 2009 Warrants") to purchase an aggregate of 1,300,000 shares of common stock.

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 will reset to 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 the foregoing, the exercise price as reset or adjusted for anti-dilution, will in no event be less than \$3.33 per share. Following completion of the August 2004 Private Placement (see Note 9 - Subsequent Events to our financial statements attached hereto), the exercise price was lowered to \$3.33 per share. This transaction is subject to a non-cash financing charge \$1,676,000 to be amortized over the remaining life of the October 2003 Debentures.

The Company agreed to register shares issuable upon exercise of the June 2009 Warrants pursuant to substantially the same terms as the registration rights agreement between the Company and the holders (See Note 7 - Debenture Financing). Pursuant to this obligation, the Company has so registered the shares.

We entered into Registration Rights Agreements with the investors in connection with the issuance of (i) the Debentures; (ii) the June 2008, July 2008, October 2008, July 2009, May 2009 and June 2009 Warrants (collectively, the "Warrants"); and (iii) the shares issued in January 2004. Pursuant to the Registration Rights Agreements we have registered on behalf of the investors the shares issued to them in January 2004 and 135% of the shares issuable upon conversion of all outstanding Debentures and upon exercise of all of the Warrants. If, subject to certain exceptions, sales of all shares so registered cannot be made pursuant to the registration statements, then we will be required to pay to the investors their pro rata share of \$.00067 times the outstanding principal amount of the relevant Debentures for each day the above condition exists.

As of July 23, 2004, the investors have converted \$12,400,329 of debt from the Debentures issued in March 2003 July 2003, October 2003 and January 2004 into 7,307,440 shares of our common stock. The March Debentures have been fully converted. The remaining principal balance on the outstanding debentures is convertible into shares of our stock at the option of the investors at any time, through the maturity date. In addition, we have paid \$1,300,000 into the debenture cash collateral account as required by the terms of the October 2003 Debentures. The amounts paid through June 30, 2004 have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of June 30, 2004. The cash collateral account provides partial security for repayment of our outstanding Debentures in the event of default.

By agreement with Cardinal Securities, LLC, for general financial advisory services and in conjunction with the private debenture placements in July and October 2003 and in January, May and July 2004, we paid Cardinal Securities, LLC an investment banking fee equal to 7% of the investments made by the two Debenture holders and issued to Cardinal the following common stock purchase warrants: (i) 112,500 exercisable at \$2.57 per share; (ii) 87,500 exercisable at \$2.42 per share; and (iii) 100,000 exercisable at \$3.04 per share. The \$2.57 warrants expire on July 10, 2008, the \$2.42 warrants expire on October 29, 2008 and the \$3.04 warrants expire on January 5, 2009. With regard to the exercise of the June 2008 Warrants and issuance of the May 2009 Warrants, Cardinal received an investment banking fee of 7%, half in cash and half in shares. With regard to

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

the exercise of the Additional Investment Rights, the July 2008 and October 2008 Warrants and issuance of the July 2009 Warrants, Cardinal received an investment banking fee of 7%, 146,980 in cash and 22,703 in shares as well as 50,000 warrants exercisable at \$4.07 expiring on July 12, 2009. By agreement with Cardinal, we have registered all of the foregoing shares and shares issuable upon exercise of the above mentioned warrants for public sale and we have agreed to register the balance.

Section 713 of the American Stock Exchange ("AMEX") Company Guide provides that we 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 our outstanding common stock (the "Exchange Cap"). Taken separately, the July 2003, October 2003 and January 2004 Debenture transactions do not trigger Section 713. However, the AMEX has taken the position that the three 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 we 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, we recorded on January 26, 2004, a redemption obligation of approximately \$1,244,000. This liability represents the fair market value of the warrants and beneficial conversion feature related to the 1,299,000 shares.

In addition, in accordance with EITF 00-19, we revalued this redemption obligation associated with the beneficial conversion feature and warrants as of March 31, 2004. We recorded an additional redemption obligation and finance charge of \$947,000 as a result of this revaluation. Upon stockholder approval, our redemption obligation will be recorded as additional paid in capital as of the date approval is received.

The requisite stockholder approval was obtained at our Annual Meeting of Stockholders on June 23, 2004. In accordance with EITF 00-19, we revalued this redemption obligation associated with the beneficial conversion feature and warrants as of June 23, 2004. We recorded a reduction in the value of the redemption obligation and financing charge of \$260,000 as a result of this revaluation. In addition, upon receiving the requisite stockholder approval, this redemption obligation was reclassified as additional paid in capital as of the date the approval was received or June 23, 2004.

In connection with the Debenture agreements, we have outstanding letters of credit of \$1 million as additional collateral.

On August 5, 2004, the Company closed a private placement with select institutional investors of approximately 3,617,300 shares of its Common Stock and warrants to purchase an aggregate of up to approximately 1,085,200 shares of its Common Stock. Jefferies & Company, Inc. acted as Placement Agent for which it received a fee and Common Stock Purchase Warrants. The Company raised approximately \$7,524,000 in gross cash proceeds from this private offering.

The Warrant issued to each purchaser is exercisable for up to 30% of the number of shares of Common Stock purchased by such Purchaser, at an exercise price equal to \$2.86 per share. Each Warrant has a term of five years and is fully exercisable from the date of issuance.

Pursuant to the Registration Rights Agreement, made and entered into as of August 5, 2004 (the "Rights Agreement"), the Company has agreed to file with the Securities and Exchange Commission a registration statement covering resales of the shares issued to the Purchasers and shares issuable upon the exercise of the Warrants.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

Closing of the August 2004 Private Placement triggered the anti-dilution provisions of the January 2004 Debentures and the July 2004 Debentures and the July 2009 Warrants and the June 2009 Warrants. The conversion price adjustment for the Debentures noted above will result in an adjustment in the third quarter 2004 to the Debenture discount and additional paid-in-capital. Any adjustment to the Debenture discount will be amortized over the remaining life of the Debentures. The exercise price adjustment for the above warrants will result in a non-cash financing adjustment in the third quarter 2004 upon revaluing the warrants at the new anti-dilution pricing using the Black-Scholes Method.

On March 11, 2003, we acquired from ISI, ISI's inventory of ALFERON N Injection(R) and a limited license for the production, manufacture, use, marketing and sale of this product. As partial consideration, we issued 487,028 shares of our common stock to ISI Pursuant to our agreements with ISI, we registered these shares for public sale and ISI has reported that it has sold all of these shares. We also agreed to pay ISI 6% of the net sales of ALFERON N Injection(R).

On March 11, 2003, we also entered into an agreement to purchase from ISI all of its rights to the product and other assets related to the product including, but not limited to, real estate and machinery. For these assets, we agreed to issue to ISI an additional 487,028 shares and to issue 314,465 shares and 267,296 shares, respectively to the American National Red Cross and GP Strategies Corporation, two creditors of ISI. We guaranteed the market value of all but 62,500 of these shares to be \$1.59 per share on the termination date. As discussed below, we issued all of these shares and ISI, GP Strategies and the American National Red Cross have reported that they have sold all of their shares.

We also agreed to satisfy other liabilities of ISI which were past due and secured by a lien on ISI's real estate and to pay ISI 6% of the net sales of products containing natural alpha interferon.

On May 30, 2003, we issued the shares to GP Strategies and the American National Red Cross. Pursuant to our agreements with ISI and these two creditors, we registered the foregoing shares for public sale. As of June 30, 2004, GP Strategies and the American National Red Cross had sold all of their shares.

In March 2004, we issued 487,028 shares to ISI to complete the acquisition of the balance of ISI's rights to market its product as well its production facility in New Brunswick, New Jersey. As of June 30, 2004, ISI has sold all of its shares.

Prior to our annual meeting of stockholders in September 2003, we had a limited number of shares of Common Stock authorized but not issued or reserved for issuance upon conversion or exercise or outstanding convertible and exercisable securities such as debentures, options and warrants. Prior to the meeting, to permit consummation of the sale of the July 2003 Debentures and the related warrants, Dr. Carter agreed that he would not exercise his warrants or options unless and until our stockholders approve an increase in our authorized shares of common stock. For Dr. Carter's waiver of his right to exercise certain options and warrants prior to approval of the increase in our authorized shares, we agreed to compensate Dr. Carter. See "Executive Compensation; Employment Agreements" for details related to how Dr. Carter has been compensated with respect to this matter.

On November 6, 2003 we acquired some of the outstanding ISI property tax lien certificates in the aggregate amount of \$456,839 from certain investors. These tax liens were issued for property taxes and utilities due for 2000, 2001 and 2002.

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

In May 2004, the Debenture holders agreed to amend the provisions of all of the outstanding Debentures (including the July 2004 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.

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 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 \$9,433,000 in cash and cash equivalents and short-term investments at June 2004. 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.

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

Item 4: Controls and Procedures

Our 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 the rules of the Securities and Exchange Commission. 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.

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

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

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. This appeal is now pending in the Superior Court of Pennsylvania.

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. On June 25, 2004 all claims against us were dismissed with prejudice.

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.

In June 2004, One Penn Associates, L.P. filed a claim in the Philadelphia Municipal Court for the Commonwealth of Pennsylvania seeking \$44,242.68 for alleged unpaid rent and charges related to our offices in One Penn Center in Philadelphia. We believe this claim is without merit and are defending same pursuant to the terms of our lease as we were damaged and deprived of the use of a portion of the offices due to water from the landlord's faulty sprinkler system.

ITEM 2: Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities

During the quarter ended June 30, 2004, the Company issued warrants in private transactions pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933. For information on the foregoing, see Part I. Item 2: "Management's Discussion And Analysis Of Financial Condition And Results Of Operations; Liquidity And Capital Resources."

The Company did not repurchase any of its securities during the quarter ended June 30, 2004.

ITEM 3: Defaults in Senior Securities

None.

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

At the Company's Annual Meeting of Stockholders on June 23, 2004, stockholders approved the following:

Total shares voted: 25,978,921 out of 42,363,928 eligible to vote.

Election of Directors:

	For	Withheld
William A. Carter, M.D.	25,275,037	703,884

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

Richard C. Piani, Esq.	25,504,979	473,942
Ransom W. Etheridge, Esq.	25,513,939	464,982
William M. Mitchell. Ph.D., M.D.	25,513,547	465,374
Iraj-Eqhbali Kiani, Ph.D.	25,513,547	465,374
Antoni Esteve, Ph.D.	25,517,307	461,614

Ratification of the selection of BDO Seidman, LLP, as independent auditors of the Company for the year ending December 31, 2004.

For: 25,911,270 Against: 60,449 Abstain: 7,202

Approval of the issuance of 13,686,841 shares of common stock issuable upon exercise of certain warrants and upon conversion of certain outstanding debentures and debentures issuable upon exercise of certain rights to comply with AMEX Company Guide Section 713.

For: 6,493,369* Against: 415,280 Abstain: 18,681 Broker nonvotes: 18,938,489

* Excludes shares owned by the holders of the warrants, debentures and rights described in the proposal.

Approval of the Hemispherx 2004 Equity Incentive Plan.

For: 6,512,751 Against: 507,991 Abstain: 19,690 Broker nonvotes: 18,938,489

ITEM 5: Other Information

On August 5, 2004, the Company closed a private placement with select institutional investors of approximately 3,617,300 shares of its Common Stock and warrants to purchase an aggregate of up to approximately 1,085,200 shares of its Common Stock. Jefferies & Company, Inc. acted as Placement Agent for which it received a fee and Common Stock Purchase Warrants. The Company raised approximately \$7,524,000 in gross cash proceeds from this private offering.

The Warrant issued to each purchaser is exercisable for up to 30% of the number of shares of Common Stock purchased by such Purchaser, at an exercise price equal to \$2.86 per share. Each Warrant has a term of five years and is fully exercisable from the date of issuance.

Pursuant to the Registration Rights Agreement, made and entered into as of August 5, 2004 (the "Rights Agreement"), the Company has agreed to file with the Securities and Exchange Commission a registration statement covering resales of the shares issued to the Purchasers and shares issuable upon the exercise of the Warrants.

Closing of the August 2004 Private Placement triggered the anti-dilution provisions of the January 2004 Debentures and the July 2004 Debentures and the July 2009 Warrants and the June 2009 Warrants. The conversion price adjustment for the Debentures noted above will result in an adjustment in the third quarter 2004 to the Debenture discount and additional paid-in-capital. Any adjustment to the Debenture discount will be amortized over the remaining life of the Debentures. The exercise price adjustment for the above warrants will result in a non-cash financing adjustment in the third quarter 2004 upon revaluing the warrants at the new anti-dilution pricing using the Black-Scholes Method.

ITEM 6: Exhibits and Reports on Form 8K

(a) Exhibits

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form 424B3

- 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

(b) Reports on Form 8-K

Form 8-K filed on June 24, 2004 Form 8-K filed on July 15, 2004 Form 8-K filed on August 2, 2004 Form 8-K filed on August 6, 2004

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: August 10, 2004