HEMISPHERX BIOPHARMA INC
Form 424B3
May 17, 2004

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

PROSPECTUS SUPPLEMENT
Number 1
to
Prospectus dated April 9, 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 March 31, 2004 filed by us with the Securities and Exchange Commission.

Our common stock is listed on the American Stock Exchange under the symbol HEB.

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 May 14, 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 March 31, 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)

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). / / Yes /X/ No

42,363,928 shares of common stock were issued and outstanding as of April 26, 2004.

## PART I - FINANCIAL INFORMATION

ITEM 1: Financial Statements

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

| | December 31, 2003 | March 31, 2004 |
|---|---|---|
| | (Unaudited) | |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $ 3,764 | $ 3,249 |
| Short term investments | 1,495 | 3,989 |
| Inventory | 2,896 | 2,785 |
| Accounts and other receivables | 282 | 280 |
| Prepaid expenses and other current assets | 170 | 139 |
| Total current assets | 8,607 | 10,442 |
| Property and equipment, net | 94 | 3,387 |
| Patent and trademark rights, net | 1,027 | 992 |
| Investments | 408 | 408 |
| Deferred acquisition costs | 1,546 | - |
| Deferred financing costs | 393 | 495 |
| Advance receivable | 1,300 | 1,300 |
| Other assets | 29 | 29 |
| Total assets | $ 13,404 | $ 17,053 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |

| | | |
|---|---|---|
| Current liabilities: | | |
| Accounts payable | $ 488 | $ 424 |
| Accrued expenses | 1,119 | 899 |
| Deferred revenue | - | 497 |
| Current portion of long-term debt (net of discounts of $1,330) | - | 670 |
| Redemption obligation | - | 2,191 |
| Total current liabilities | 1,607 | 4,681 |
| Long-Term Debt-net of current portion and discounts of $4,533 and $3,136, respectively | 2,058 | 1,916 |
| Commitments and contingencies: | | |
| Redeemable Common Stock | 491 | 1,166 |
| Stockholders' equity: | | |
| Common stock | 39 | 42 |
| Additional paid-in capital | 123,054 | 131,136 |
| Treasury stock - at cost | (2) | (2) |
| Accumulated deficit | (113,843) | (121,886) |
| Total stockholders' equity | 9,248 | 9,290 |
| Total liabilities and stockholders' equity | $ 13,404 | $ 17,053 |

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 March 31, | |
|---|---|---|
| | 2003 | 2004 |
| | (Unaudited) | (Unaudited) |
| Revenues: | | |
| Sales of product, net | $ 19 | $ 259 |
| Clinical treatment programs | 47 | 49 |
| | 66 | 308 |
| Costs and expenses: | | |
| Production/cost of goods sold | 118 | 601 |
| Research and development | 873 | 964 |
| General and administrative | 667 | 2,844 |
| Total cost and expenses | 1,658 | 4,409 |
| Interest and other income | 50 | 11 |
| Interest expenses | (17) | (101) |
| Financing costs | (58) | (3,851) |

| | | |
|---|---|---|
| Net loss | $(1,617) | $(8,042) |
| Basic and diluted loss per share | $ (.05) | $ (.20) |
| Basic and diluted weighted average common shares outstanding | 32,393,754 | 40,668,478 |

See accompanying notes to condensed consolidated financial statements.

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

| | (Unaudited) For the Three months ended March 31, | |
|---|---|---|
| | 2003 | 2004 |
| Cash flows from operating activities: | | |
| Net loss | $(1,617) | $(8,042) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation of property and equipment | 22 | 23 |
| Amortization of patents rights | 36 | 134 |
| Amortization of deferred financing costs | 57 | 2,905 |
| Financing costs related to redemption obligation | - | 946 |
| Stock warrant compensation expense | - | 1,769 |
| Changes in assets and liabilities: | | |
| Inventory | - | 111 |
| Accounts receivable | (12) | 2 |
| Deferred Revenue | - | 497 |
| Prepaid expenses and other current assets | (72) | 30 |
| Accounts payable | 189 | 21 |
| Accrued expenses | (336) | (118) |
| Other assets | 41 | - |
| Net cash used in operations | (1,692) | (1,722) |
| Cash flows from investing activities: | | |
| Purchase of land and building | - | (143) |
| Additions to patent rights | (18) | (99) |
| Maturity of short term investments | 520 | 1,496 |
| Purchase of short term investments | - | (3,986) |
| Net cash provided by(used in) investing activities | 502 | (2,732) |
| Cash flows from financing activities: | | |
| Proceeds from exercise of stock warrants | - | 244 |

| | | |
|---|---|---|
| Proceeds from long-term borrowings | 3,100 | 4,000 |
| Payments on long-term borrowings | (440) | - |
| Deferred financing costs | (268) | (305) |
| Purchase of treasury stock | (49) | - |
| Net cash provided by (used in) financing activities | 2,343 | 3,939 |
| Net increase (decrease) in cash and cash equivalents | 1,153 | (515) |
| Cash and cash equivalents at beginning of period | 2,256 | 3,764 |
| Cash and cash equivalents at end of period | $ 3,409 | $3,249 |
| Supplementary disclosures of cash flow information: | | |
| Issuance of common stock for accounts payable | $ - | $ 85 |
| Issuance of common stock for purchase of building | $ - | $1,626 |
| Issuance of common stock for debt conversion and interest payments | $ - | $3,641 |

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:

| | March 31, 2003 | March 31, 2004 |
|---|---|---|
| Risk-free interest rate | 5.23% | - % |
| Expected dividend yield | - | - |
| 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 three months ended March 31, 2003 and 2004 would have been as follows:

| | (In Thousands) Three Months Ended March 31, 2003 | 2004 |
|---|---|---|
| Net (loss) as reported | $(1,617) | $(8,042) |
| 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 | (137) | - |
| Pro forma net loss | $(1,754) | $(8,042) |
| Basic and diluted loss per share | | |
| As reported | $(.05) | $(.20) |
| Pro forma | $(.05) | $(.20) |

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.

Inventories consist of the following:

| | March 31, 2004 | December 31, 2003 |
|---|---|---|
| Raw materials-work in process | $ 1,729,000 | $1,729,000 |
| Finished goods | 1,056,000 | 1,167,000 |
| | $ 2,785,000 | $2,896,000 |

NOTE 5: REVENUE AND LICENSING FEE INCOME

We executed a Memorandum of Understanding 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 option period ends 12 weeks after Fuji has had a chance to review the report on the results of our Amp 516 clinical trial and meet with the trial's principal investigators. We received an initial fee of 400,000 Euros (approximately $497,000 US). If we do not provide Fuji with the full report by May 31, 2004 we will be required to repay half of this fee and if we do not provide them with the report by December 31, 2004, 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. Although we anticipate preparing and issuing the AMP 516 report in the time frame noted, we cannot ensure this will occur. We also cannot ensure that Fuji will exercise the option or that the proposed terms of the Sales and Distribution Agreement will not change materially.

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 received to date. The Fuji initial fee of $497,000 has been deferred as of March 31, 2004.

During the periods ending December 31, 2003 and March 31, 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 Interferon Sciences, Inc.'s ("ISI") inventory of ALFERON N Injection, a pharmaceutical product used for the treatment of certain types of genital warts, and a limited license for the production, manufacture, use, marketing and sale of this product. As consideration, we issued 487,028 shares of our common stock, assumed certain liabilities and agreed to pay ISI 6% of the net sales of product. Pursuant to our agreements with ISI, we registered the foregoing shares for public sale.

Except for 62,500 of the shares issued to ISI, we had guaranteed the market value of the shares retained by ISI as of March 11, 2005, the termination date, to be $1.59 per share. ISI is permitted to periodically sell certain amounts of its shares. If, within 30 days after the termination date, holders of the guaranteed shares request that we honor the guarantee, we would have been obligated to reacquire the holders' remaining guaranteed shares and pay the holders $1.59 per share for a total of $675,000. Accordingly, certain shares issued in connection with this transaction were initially recorded as redeemable common stock outside of stockholders' equity. As of March 31, 2004, ISI had sold the 424,528 guaranteed shares at prices in excess of $1.59 per share.

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, two creditors of ISI, to continue to pay royalties of 6% on net sales of Alferon N and other consideration, e.g., paying off a third creditor and paying a real estate tax liability.

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. The value of these guaranteed shares totaled $925,000 and these shares were redeemable under certain conditions, accordingly they were initially reflected as redeemable common stock and deferred acquisition costs on the balance sheet as of December 31, 2003. As of March 31, 2004, GP Strategies had sold all of their 267,296 shares and the American National Red Cross had not sold their 314,465 shares. Additionally other liabilities associated with the real estate in the amount of $621,000 had been recorded as deferred acquisition costs. Upon ISI stockholder approval, which occurred on March 17, 2004, substantially all of the deferred purchase price was allocated to real estate.

Additionally, 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 as its production facility in New Brunswick, NJ. Except for 62,500 of the 487,028 shares issued to ISI at closing of this second asset acquisition, we have guaranteed the market value of the shares retained by ISI on terms substantially

similar to those for the guaranteed shares issued to ISI on the first acquisition of ISI assets. As a result, the liability for ISI redeemable stock was $675,000 as of March 31, 2004. Pursuant to our agreement with ISI, we registered the foregoing shares for public sale.

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 |

As of March 31, 2004 the 314,465 guaranteed shares held by the American National Red Cross had not been sold. As a result, the liability for this redeemable stock was $491,000.

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.

| | Three Months Ended March 31, | |
|---|---|---|
| | 2003 | 2004 |
| | (in thousands except for share data) | |
| Net revenues | $ 308 | $308 |
| Expenses | (2,493) | (8,365) |
| Net Loss | $(2,185) | $(8,057) |
| Basic and diluted loss per share | $(.07) | $(.20) |
| Weighted average shares outstanding | 33,046,092 | 41,080,579 |

Note 7: DEBENTURE FINANCING

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 proceeds of $4,650,000. Pursuant to the terms of the March Debentures, $1,550,000 of the proceeds from the sale of the March Debentures were to have been held back and released to us if, and only if, we acquired ISI's facility

within a set timeframe. Although we had not acquired ISI's facility, these funds were released to us in June 2003. The March Debentures were to mature on January 31, 2005 with 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 was 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. On March 12, 2004, the exercise price of the Warrants was to 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 March 13, 2003 and March 11, 2004 (but in no event less than $1.176 per share). The exercise price (and the reset price) under the Warrants also was subject to similar adjustments for anti-dilution protection. All of these warrants have been exercised.

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 $5,426,000 principal of the March Debentures into 3,716,438 shares of our common stock. The total imputed interest on these Debentures was $111,711 of which $17,290 was paid in cash and $94,421 was paid by the issuance of 39,080 shares of common stock. The investors exercised the 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 Debentures") and an aggregate of 507,102 Warrants (the "July 2008 Warrants") to the same investors who purchased the March 12, 2003 Debentures, in a private placement for aggregate anticipated gross proceeds of $4,650,000. Pursuant to the terms of the July Debentures, $1,550,000 of the proceeds from the sale of the July Debentures were to have been held back and will be released to us if, and only if, we acquired ISI's facility within a set timeframe. Although we had not acquired ISI's facility, these funds were released to us in October 2003. The July 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. Pursuant to the terms and conditions of the July 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.

The July 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 Debentures was fixed at $2.14 per share; however, as part of the debenture placement closed on October 29, 2003 (see below), the conversion price under the July 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.

The July 2008 Warrants received by the investors, as amended, are to acquire at any time commencing on July 26, 2004 through January 31, 2009 an aggregate of 507,102 shares of common stock at a price of $2.46 per share. On July 10, 2004, the exercise price of these July 2008 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 11, 2003 and July 9, 2004 (but in no event less than $2.14 per share). The exercise price (and the reset price) under the July 2008 Warrants also is subject to similar adjustments for anti-dilution protection.

We entered into a Registration Rights Agreement with the investors in connection with the issuance of the July Debentures and the July 2008 Warrants. The Registration Rights Agreement requires that we register on behalf of the holders the shares of common stock issuable upon conversion of the Debentures, as interest shares under the Debentures and upon exercise of the July 2008 Warrants. These shares have been registered for public sale.

On June 25, 2003, we issued to each of the March 12, 2003 Debenture holders a warrant (collectively, the "June 2008 Warrants") 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. On June 25, 2004, the exercise price of these June 2008 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 June 26, 2003 and June 24, 2004 (but in no event less than $1.68 per share). The exercise price (and the reset price) under the June 2008 Warrants also is subject to adjustments for anti-dilution protection similar to those in the July 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.

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 Debentures") and an aggregate of 410,134 Warrants (the "October 2008 Warrants") in a private placement for aggregate anticipated gross proceeds of $3,550,000. Pursuant to the terms of the October Debentures, $1,550,000 of the proceeds from the sale of the October Debentures have been held back and will be released to us if, and only if, we acquired ISI's facility within 90 days of October 29, 2003 and provide a mortgage on the facility as further security for the October Debentures. The debenture holders extended the deadline to 90 days after January 26, 2004. The October 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. Pursuant to the terms and conditions of the October 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.

Upon completing the sale of the October Debentures, we received $3,275,000 in net proceeds consisting of $1,725,000 from the October Debentures and $1,550,000 that had been withheld from the July Debentures. As noted above, $1,550,000 of the proceeds from the October Debentures were held back pending our completing the acquisition of the ISI facility and our mortgaging that facility to the

debentureholders.
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 the New Brunswick, New Jersey, from ISI. As a result, the proceeds held back from the October Debenture amounting to $1,550,000 were released to the Company in April 2004. As required by the Debentures, we are in the process of providing a mortgage on the facility as further security for the Debentures.

The October 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 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 are to acquire at any time commencing on July 26, 2004 through April 30, 2009 an aggregate of 410,134 shares of common stock at a price of $2.32 per share. On October 29, 2004, the exercise price of these October 2008 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 October 29, 2003 and October 27, 2004 (but in no event less than $2.19 per share). The exercise price (and the reset price) under the October 2008 Warrants also is subject to similar adjustments for anti-dilution protection.

We entered into a Registration Rights Agreement with the investors in connection with the issuance of the October Debentures and the October 2008 Warrants. The Registration Rights Agreement requires that we register on behalf of the holders the shares of common stock issuable upon conversion of the October Debentures, as interest shares under the October Debentures and upon exercise of the 2008 Warrants. If, subject to certain exceptions, sales of all shares required to be registered cannot be made pursuant to the registration statement, then we will be required to pay to the investors their pro rata share of $3,635 for each day such conditions exist.

As of January 26, 2004, with respect to the July and October 2003 Debenture Amendments, specifically, the extension of time of the investor's ability to exercise warrants, the Company revalued the July and October 2003 warrants, using the Black Scholes Method. This revaluation resulted in an increased adjustment to Debenture discounts of $282,000, reflected as additional paid in capital, and an adjustment to the amortization of Debenture discounts of approximately $77,000, reflected in financing costs, for the three months ended March 31, 2004.

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 "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) ("AIR") in a private placement for aggregate anticipated 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 six months after issuance, the Company is 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 the Company's option, in shares of common stock. Any shares of common stock issued to the investors as installment payments shall be valued at 95% of the average closing price of the common stock during the 10-day trading period commencing on and including the eleventh trading day immediately preceding the date that the installment is due. Pursuant to the terms and conditions of the January 2004 Debentures, we pledged all of our assets, other than our intellectual property, as collateral and were subject to comply with certain financial and negative covenants.

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 is 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.

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 (but in no event less than $2.58 per share with regard to the Class A warrants and $3.54 per share with regard to the Class B warrants). The exercise price (and the reset price) under the July 2009 Warrants also is subject to similar adjustments for anti-dilution protection.

The Company also issued to the investors Additional Investment Rights ("AIR") pursuant to which the investors have the right to acquire up to an additional $2,000,000 principal amount of January 2004 Debentures from the Company. These Debentures are identical to the January 2004 Debentures except that the conversion price is $2.58. The AIR are exercisable commencing on July 26, 2004 (the "Trigger" date) for a period of 90 days from the Trigger Date or 90 days from the date which the registration statement registering the shares issuable upon the conversion of the January 2004 Debentures to be issued pursuant to the AIR is declared effective, whichever is longer.

The Company entered into a Registration Rights Agreement with the investors in connection with the issuance of the January 2004 Debentures (including any Debentures issued pursuant to the AIR), the shares, and the January 2009 Warrants. Pursuant to the Registration Rights Agreement the Company registered on behalf of the investors the shares issued to the investors and 135% of the shares issuable upon conversion of the Debentures (including payment of interest thereon) and upon exercise of the January 2009 Warrants. If the Registration Statement containing these shares had not been filed within the time period required by the agreement, had not declared effective within the time period required by the agreement or, after it was declared effective and subject to certain exceptions, sales of all shares required to be registered thereon cannot be made pursuant thereto, then we would have been required to pay to the investors their pro rata share of $3,635 for each day any of the above conditions exist with respect to this Registration Statement.

As of April 26, 2004, the investors have converted $11,902,610 of debt from the March, July and October Debentures into 7,073,234 shares of our common stock. The March Debentures have been fully converted. The remaining principal balance on the remaining 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 Debentures. The amounts paid through March 31, 2004 have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of March 31, 2004. The cash collateral account provides partial security for repayment of the July and October 2003 and January 2004 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 March, July and October 2003 and in January 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 certain warrants. A portion of the investment banking fee was paid with the issuance of 30,000 shares of our common stock. Cardinal also received 612,500 warrants to purchase common stock, of which 112,500 are exercisable at $1.74 per share, 112,500 are exercisable at $2.57 per share, 200,000 are exercisable at $2.50 per share, 87,500 are exercisable at $2.42 per share and 100,000 are exercisable at $3.04 per share. The $1.74 warrants expire on July 10, 2008, the $2.57 and $2.50 warrants expire on March 12, 2008, the $2.42 warrants expire on October 30, 2008 and the $3.04 warrants expire on January 5, 2009. By agreement with Cardinal, we have registered all shares issuable upon exercise of the warrants for public sale.

In connection with the debenture agreements, we have outstanding letters of credit of $1 Million as additional collateral.

The March 2003, July 2003, October 2003, and January 2004 debenture issuances of $5,426,000, $5,426,000, $4,142,357, and $4,000,000, respectively, and warrant issuances, were accounted for in accordance with EITF 98-5: Accounting for convertible securities with beneficial conversion features or contingency adjustable conversion and with EITF No. 00-27: Application of issue No. 98-5 to Certain convertible instruments. The Company determined the fair values to be ascribed to detachable warrants issued with the convertible debentures utilizing the Black-Scholes method.

As a result, the Company recorded debt discounts of approximately $11.8 and $2.9 million for the 2003 and 2004 debenture issuances, respectively, which, in effect, reduced the carrying value of our debt. As debt is converted to common stock, the remaining unamortized debt discount is charged to finance costs. These costs were initially deferred and charged to finance costs over the life of the debentures. As of March 31, 2004, the amount of debt discount amortized to finance cost totaled approximately $10.2 million.

Costs associated with the financings aggregated approximately $1.3 million. These costs are also deferred and expensed as finance costs over the life of the debentures.

Excluding the application of related accounting standards, and remaining debt discounts of $4.4 million, the Company's outstanding debt as of March 31, 2004 totaled $7.1 million with $2.0 million maturing in 2004 and the balance in 2005.

Section 713 of the American Stock Exchange ("AMEX") Company Guide provides that the Company must obtain stockholder approval before issuance, at a price per share below market value, of common stock, or securities convertible into common stock, equal to 20% or more of its 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 is required for the issuance of common stock for a portion of the potential exercise of the warrants and conversion of the Debentures in connection with the January 2004 Debentures. The amount of potential shares that the Company could exceed the Exchange Cap amounted to approximately 1,299,000. In accordance with EITF 00-19, Accounting For Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock, the Company

recorded on January 26, 2004, a redemption obligation of approximately $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, the Company revalued this redemption obligation associated with the beneficial conversion feature and warrants as of March 31, 2004. The Company recorded an additional redemption obligation and finance charge of $947,000 as a result of this revaluation. If the Company obtains stockholder approval, the Company's redemption obligation will be recorded as additional paid in capital on the date approval is received.

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 current quarter resulting from warrants issued to Dr. Carter in 2003 that vested upon the 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 May 14, 2004, we issued to the debentureholders warrants to purchase an aggregate of 1,300,000 shares ("the May 2009 Warrants"). In consideration of the foregoing, the debentureholders exercised the June 2008 warrants. As a result, we issued an aggregate of 1,000,000 shares and received gross proceeds of approximately $2,400,000.

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 (but in no event less than $4.008 per share). The exercise price (and the reset price) under the May 2009 Warrants also is subject to adjustments for anti-dilution projection similar to those in the other warrants.

In addition, the debentureholders agreed to amend the provisions of all of the outstanding warrants and debentures (including the debentures issuable pursuant to the AIR) 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.

These transactions could result in us recording an additional redemption obligation for the reasons discussed in Note 7 and will result in additional financing charges beginning in the second quarter of 2004.

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

Special Note Regarding Forward-Looking Statements

Certain statements in this document constitute "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 use our proprietary drug, Ampligen(R), to treat diseases for which adequate treatment is not available. We seek the required regulatory approvals which will allow the progressive introduction of Ampligen(R) for 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 development in the U.S. for the treatment of patients with HIV infection.

In March, 2003, we acquired from Interferon Sciences Inc. ("ISI"), all of ISI's raw materials, work-in-progress and finished product of Alferon N Injection(R),

together with a limited license for the production, manufacture, use, marketing and sale of the product. Alferon N Injection(R) [interferon alfa- n3 (human derived)] is a natural alpha interferon that has been approved by the U.S. Food and Drug Administration ("FDA") for commercial sale for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. We have begun to market this product in the United States through sales facilitated via third party marketing agreements. We are in the process of implementing studies, beyond those conducted by ISI, for testing the potential treatment of HIV, Hepatitis C and other indications, including multiple sclerosis.

In March 2003, we entered into an agreement with ISI subject to certain events that would grant us global rights to sell Alferon N Injection(R) as well as acquire certain other assets of ISI which include but are not limited to real estate and property, plant and equipment.

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 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 March 31, 2004, our accumulated deficit was $121,866,000. 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 March 31, 2004, we had approximately $7,238,000 million in cash and cash equivalents and short-term investments. We believe that these funds plus 1) the gross proceeds received from the exercising of warrants of approximately $2,400,000, 2) the infusion of approximately $1,550,000 million in remaining net proceeds from the October Debentures in April 2004, 3) the projected net cash flow from the sale of ALFERON N Injection(R) and 4) the proceeds from licensing agreements and/or the expected infusion of $2,000,000 in proceeds from our investors exercising their AIR should be sufficient to meet our operating cash requirements including debt service during the next 12 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.

If stockholders do not approve the issuance of certain shares of our common stock upon conversion of our debentures and exercise of related warrants at our 2004 annual stockholders' meeting, a portion of the debentures may no longer be convertible, certain of the warrants will not be exercisable and we will be required to pay the holders in cash the difference between the conversion or exercise price and the market price in lieu of shares. As a result, our financial condition would be adversely affected.

The American Stock Exchange ("AMEX") has taken the position that the July Debenture, October Debenture and January 2004 Debenture transactions and the May 2009 Warrant transactions should be aggregated and, as such, under AMEX rules, stockholder approval is required for our issuance of a significant number of shares pursuant to the exercise of the warrants and conversion of the Debentures (see Note 7 to the unaudited financial statements in Part I, Item 1 above). If stockholders do not approve the issuance of such shares at our 2004 annual stockholders' meeting, a portion of the debentures may no longer be convertible, certain of the warrants will not be exercisable and we will be required to pay the holders the lesser of (a) the difference between (X) the conversion price (with regard to the debentures) and/or the exercise price (with regard to the warrants) and (Y) the market price of our shares or (b) 119.9% of the relevant conversion price, with regard to the debentures and/or 19.9% of the relevant warrant exercise price, in lieu of shares. At present, the market price is above the conversion price of all of the debentures and the exercise price of all but one series of warrants. If we are required to pay cash rather than issue shares upon conversion of a material amount of debentures and/or exercise of a material number of warrants, our financial condition would be materially adversely affected.

We have guaranteed the value of a number of shares issued and to be issued as a result of our acquisition of assets from Interferon Sciences. If our share price is not above $1.59 per share 12 or 24 months after the dates of issuance of the guaranteed shares, our financial condition could be adversely affected.

In March 2004, when we consummated the second ISI asset acquisition, we issued 487,028 shares to ISI. In May 2003 we issued an aggregate of 581,761 shares to two of ISIs' creditors. We have guaranteed the value of all but 62,500 of these shares to be $1.59 per share on the relevant termination dates. As of March 31, 2004 738,993 of the guaranteed shares have not been sold. The termination dates are 24 months after the dates of issuance and delivery of the guaranteed shares to ISI and 12 months after the date of issuance of the guaranteed shares to the American National Red Cross. The guarantee relates only to those shares still held by ISI and the American National Red Cross on the applicable termination date. If, within 30 days after the relevant termination date, holders of the guaranteed shares request that we honor the guarantees, we will reacquire the holders' remaining guaranteed shares and pay the holders $1.59 per share. By way of example, assuming that all remaining 738,993 shares are still held on the relevant termination dates, we would be obligated to pay to ISI $675,000 and the American National Red Cross $500,000. The reported last sale price for our common stock on the American Stock Exchange on April 26, 2004 was $4.32 per share. If, during the 31 days commencing on the relevant termination dates, the market price of our stock is not above $1.59 per share, we most likely would be requested and obligated to pay the guaranteed amount on the guaranteed shares outstanding on the relevant termination dates. We believe that the number of guaranteed shares still outstanding on the relevant termination dates will be a factor of the market price and sales volume of our common stock during the 24 and 12 month periods prior to the relevant termination date.

If the holders of the guaranteed shares do not sell a significant amount of their guaranteed shares prior to the relevant termination dates and the price of our common stock during the 31 day period commencing on the relevant termination

dates is not above $1.59 per share, we most likely will be required to repurchase a significant number of guaranteed shares and our financial condition could be materially and adversely affected.

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. If and when we obtain all rights to ALFERON N Injection(R), we will 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 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. should 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 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 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.

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 product liability claims. A successful product liability claim against us in excess of our $1,000,000 in insurance coverage 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, 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:

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors; o changes in financial

estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards; and 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 March 31, 2004, the price of our common stock has ranged from $1.33 to $4.85. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if without merit or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

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

As of April 26, 2004, approximately 801,623 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act of 1933. Substantially all 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 12,006,977 shares issuable (i) upon conversion of approximately 135% of the Debentures issued in January 2004 (the "January 2004 Debentures"), the October Debentures, the July Debentures and the January 2004 Debentures issuable upon exercise of AIR (issued in conjunction with the January 2004 Debentures); (ii) as payment of 135% of the interest on all of the Debentures; (iii) upon exercise of 135% of the 2009 Warrants issued in conjunction with the January 2004 Debentures, the October 2008 Warrants, the July 2008 Warrants and the June 2008 Warrants; (iv) upon exercise of certain other warrants and stock options and (v) shares issued to certain suppliers and service providers. 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 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 12.1% 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.

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 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.

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 March 31, 2004.

RESULTS OF OPERATIONS

Three months ended March 31, 2004 versus Three months ended March 31, 2003

Net loss

Our net loss was approximately $8,042,000 for the three months ended March 31, 2004 versus a net loss of $1,617,000 for the same period a year ago. Per share loss for the three months ended March 31, 2004 was $0.20 per share versus $0.05 a year earlier for the same period. This year-to-year increase in losses of $6,425,000 is primarily due to non-cash financing costs of $3,851,000 relating to our July Debentures, October Debentures and January 2004 Debentures (Collectively, the "Debentures") as well as 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 execution of the second ISI asset closing 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. In addition, our loss during the current period includes $606,000 in operating losses relating to our new Alferon division. The operating loss for the period March 11, 2003 through March 31, 2003 for our Alferon division amounted to $170,000. These three factors represent 77% of our net loss for the three months ended March 31, 2004. For comparative purposes, excluding our March 31, 2004 losses for these three factors, our losses were $1,816,000 for the three months ended March 31, 2004 compared to $1,447,000 for the same period in 2003 after adjustment for the Alferon division losses or an increase of approximately $369,000. The primary reason for the increase was attributed to higher general corporate legal costs and director's fees.

Revenues

Revenues for the three months ended March 31, 2004 were $308,000 as compared to revenues of $66,000 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 $49,000 for the three months ended March 31, 2004 versus $47,000 for the three months ended March 31, 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 March 31, 2004 from sales of ALFERON N totaled $259,000 versus $19,000 for the 20-day period of March 11, 2003, the date we acquired the rights to the Alferon N business from ISI, through March 31, 2003. Sales of Alferon N are anticipated to increase as we are producing more product and our marketing/sales programs are underway.

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. Preliminary work has started on completing the second lot of approximately 16,000 vials. 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. Plans are underway for completing the third lot of some 18,000 vials 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 addition, in August 2003, we entered into a sales and marketing agreement with Engitech, LLC. to distribute ALFERON N on a nationwide basis. The agreement stipulated that Engitech will deploy a sales force of 100 sales representatives within one year in the U.S. domestic market and further expand the sales team up to 250 sales representative in the second year and after that as many as it takes to continually drive market share. Engitech, Inc. is to develop and implement marketing plans including extensive scientific and educational programs for use in marketing ALFERON N.

We executed a Memorandum of Understanding 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 option period ends 12 weeks after Fuji has had a chance to review the report on the results of our Amp 516 clinical trial and meet with the trial's principal investigators. We received an initial fee of 400,000 Euros (approximately $497,000 US). If we do not provide Fuji with the full report by May 31, 2004 we will be required to repay half of this fee and if we do not provide them with the report by December 31, 2004, 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 March 31, 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. In addition, there are currently 70 sales representatives in the U.S domestic market, which we provide with sales training and professional marketing materials. We will also continue to focus our efforts on a worldwide sales plan for Alferon N.

Production costs/cost of goods sold

Production costs for the three months ended March 31, 2004 and 2003 were $601,000 and $118,000, respectively. These costs reflect approximately $111,000 for the cost of sales of ALFERON N Injection(R) for the three months ended March 31, 2004. In addition, costs of salesfor Alferon N Injection(R) for the period March 11, 2003 (acquisition date of inventory from ISI) through March 31, 2003 amounted to $12,000. The remaining production costs represent expenditures associated with the ramping up of the New Brunswick facility for further production of Alferon N Injection(R).

Research and Development costs

Overall research and development direct costs for the three months ended March 31, 2004 were $964,000 as compared to $873,000 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.

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 19.4% vs. 5.1% in the placebo group (p=0.022). 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.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended March 31, 2004 and 2003 were approximately $2,844,000 and $667,000, respectively. The increase in G&A expenses of $2,177,000 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 execution of the second ISI asset closing on March 17, 2004. Aside from the expenses related to our Alferon division totaling $265,000 and $58,000 in 2004 and 2003, respectively, and the non-cash stock compensation charge noted above, our G&A expenses were $810,000 for the three months ended March 31, 2004 as compared to $609,000 during the same three months in 2003. The primary reason for the increase in G&A costs of $201,000 was attributable to higher general corporate legal costs and directors' fees in the current quarter.

Other Income/Expense

Interest and other income for the three months ended March 31, 2004 and 2003 totaled $11,000 and $50,000, respectively. The primary reason for the decrease in interest and other income during the current quarter 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

Interest expense and financing costs were $3,952,000 for the three months ended March 31, 2004 versus $75,000 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 connection with the January 2004 Debentures, we recorded additional financing costs of approximately $947,000. 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 three months ended March 31, 2004 was $1,722,000. Cash provided by financial activities for the three months ended March 31, 2004 amounted to $3,939,000, substantially from proceeds from a debenture offering (see below). As of March 31, 2004, we had approximately $7,238,000 million in cash and short-term investments. We believe that these funds plus 1) the gross proceeds received from the exercising of warrants of approximately $2,400,000, 2) the infusion of approximately $1,550,000 million in remaining net proceeds from the October Debentures in April 2004, 3) the projected net cash flow from the sale of ALFERON N Injection(R), and 4) the proceeds from licensing agreements and/or the expected infusion of $2,000,000 in proceeds from our investors exercising their AIR should be sufficient to meet our operating cash requirements including debt service during the next 12 months. Sales of ALFERON N Injection(R) could be greater than expected which would improve our cash position during the next twelve months. 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 proceeds of $4,650,000. Pursuant to the terms of the March Debentures, $1,550,000 of the proceeds from the sale of the March Debentures were to have been held back and released to us if, and only if, we acquired ISI's facility within a set timeframe. Although we had not acquired ISI's facility, these funds were released to us in June 2003. The March Debentures were to mature on January 31, 2005 with 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 was 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. On March 12, 2004, the exercise price of the Warrants was to 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 March 13, 2003 and March 11, 2004 (but in no event less than $1.176 per share). The exercise price (and the reset price) under the Warrants also was subject to similar adjustments for anti-dilution protection. All of these warrants have been exercised.

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 $5,426,000 principal of the March Debentures into 3,716,438 shares of our common stock. The total imputed interest on these Debentures was $111,711 of which $17,290 was paid in cash and $94,421 was paid by the issuance of 39,080 shares of common stock. The investors exercised the 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 Debentures") and an aggregate of 507,102 Warrants (the "July 2008 Warrants") to the same investors who purchased the March 12, 2003 Debentures, in a private placement for aggregate anticipated gross proceeds of $4,650,000. Pursuant to the terms of the July Debentures, $1,550,000 of the proceeds from the sale of the July Debentures were to have been held back and will be released to us if, and only if, we acquired ISI's facility within a set timeframe. Although we had not acquired ISI's facility, these funds were released to us in October 2003. The July 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. Pursuant to the terms and conditions of the July 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.

The July 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 Debentures was fixed at $2.14 per share; however, as part of the debenture placement closed on October 29, 2003 (see below), the conversion price under the July 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.

The July 2008 Warrants received by the investors, as amended, are to acquire at any time commencing on July 26, 2004 through January 31, 2009 an aggregate of 507,102 shares of common stock at a price of $2.46 per share. On July 10, 2004, the exercise price of these July 2008 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 11, 2003 and July 9, 2004 (but in no event less than $2.14 per share). The exercise price (and the reset price) under the July 2008 Warrants also is subject to similar adjustments for anti-dilution protection.

We entered into a Registration Rights Agreement with the investors in connection with the issuance of the July Debentures and the July 2008 Warrants. The Registration Rights Agreement requires that we register on behalf of the holders the shares of common stock issuable upon conversion of the Debentures, as interest shares under the Debentures and upon exercise of the July 2008 Warrants. These shares have been registered for public sale.

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. On June 25, 2004, the exercise price of these June 2008 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 June 26, 2003 and June 24, 2004 (but in no event less than $1.68 per share). The exercise price (and the reset price) under the June 2008 Warrants also is subject to adjustments for anti-dilution protection similar to those in the July 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.

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 Debentures") and an aggregate of 410,134 Warrants (the "October 2008 Warrants") in a private placement for aggregate anticipated gross proceeds of $3,550,000. Pursuant to the terms of the October Debentures, $1,550,000 of the proceeds from the sale of the October Debentures have been held back and will be released to us if, and only if, we acquired ISI's facility within 90 days of October 29, 2003 and provide a mortgage on the facility as further security for the October Debentures. The debenture holders extended the deadline to 90 days after January 26, 2004. The October 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. Pursuant to the terms and conditions of the October 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.

Upon completing the sale of the October Debentures, we received $3,275,000 in net proceeds consisting of $1,725,000 from the October Debentures and $1,550,000 that had been withheld from the July Debentures. As noted above, $1,550,000 of the proceeds from the October Debentures were held back pending our completing the acquisition of the ISI facility and our mortgaging that facility to the debentureholders. 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 the New Brunswick, New Jersey, from ISI. As a result, the proceeds held back from the October Debenture amounting to $1,550,000 were released to the Company in April 2004. As required by the Debentures, we are in the process of providing a mortgage on the facility as further security for the Debentures.

The October 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 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 are to acquire at any time commencing on July 26, 2004 through April 30, 2009 an aggregate of 410,134 shares of common stock at a price of $2.32 per share. On October 29, 2004, the exercise price of these October 2008 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 October 29, 2003 and October 27, 2004 (but in no event less than $2.19 per share). The exercise price (and the reset price) under the October 2008 Warrants also is subject to similar adjustments for anti-dilution protection.

We entered into a Registration Rights Agreement with the investors in connection with the issuance of the October Debentures and the October 2008 Warrants. The

Registration Rights Agreement requires that we register on behalf of the holders the shares of common stock issuable upon conversion of the October Debentures, as interest shares under the October Debentures and upon exercise of the 2008 Warrants. If, subject to certain exceptions, sales of all shares required to be registered cannot be made pursuant to the registration statement, then we will be required to pay to the investors their pro rata share of $3,635 for each day such conditions exist.

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 "2009 Warrants") and 158,103 shares of common stock, and AIR (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 anticipated 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 six months after issuance, the Company is 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 the Company's option, in shares of common stock. Any shares of common stock issued to the investors as installment payments shall be valued at 95% of the average closing price of the common stock during the 10-day trading period commencing on and including the eleventh trading day immediately preceding the date that the installment is due. Pursuant to the terms and conditions of the January 2004 Debentures, we pledged all of our assets, other than our intellectual property, as collateral and were subject to comply with certain financial and negative covenants.

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 is 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.

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 (but in no event less than $2.58 per share with regard to the Class A warrants and $3.54 per share with regard to the Class B warrants). The exercise price (and the reset price) under the July 2009 Warrants also is subject to similar adjustments for anti-dilution protection.

The Company also issued to the investors AIR pursuant to which the investors have the right to acquire up to an additional $2,000,000 principal amount of January 2004 Debentures from the Company. These Debentures are identical to the January 2004 Debentures except that the conversion price is $2.58. The AIR are exercisable commencing on July 26, 2004 (the "Trigger" date) for a period of 90 days from the Trigger Date or 90 days from the date which the registration statement registering the shares issuable upon the conversion of the January 2004 Debentures to be issued pursuant to the AIR is declared effective, whichever is longer.

The Company entered into a Registration Rights Agreement with the investors in connection with the issuance of the January 2004 Debentures (including any Debentures issued pursuant to the AIR), the shares, and the January 2009 Warrants. Pursuant to the Registration Rights Agreement the Company registered on behalf of the investors the shares issued to the investors and 135% of the shares issuable upon conversion of the Debentures (including payment of interest thereon) and upon exercise of the January 2009 Warrants. If the Registration Statement containing these shares had not been filed within the time period required by the agreement, had not declared effective within the time period required by the agreement or, after it was declared effective and subject to certain exceptions, sales of all shares required to be registered thereon cannot be made pursuant thereto, then we would have been required to pay to the investors their pro rata share of $3,635 for each day any of the above conditions exist with respect to this Registration Statement.

As of April 26, 2004, the investors have converted $11,902,610 of debt from the March, July and October Debentures into 7,073,234 shares of our common stock. The March Debentures have been fully converted. The remaining principal balance on the remaining 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 Debentures. The amounts paid through March 31, 2004 have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of March 31, 2004. The cash collateral account provides partial security for repayment of the July and October 2003 and January 2004 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 March, July and October 2003 and in January 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 certain warrants. A portion of the investment banking fee was paid with the issuance of 30,000 shares of our common stock. Cardinal also received 612,500 warrants to purchase common stock, of which 112,500 are exercisable at $1.74 per share, 112,500 are exercisable at $2.57 per share, 200,000 are exercisable at $2.50 per share, 87,500 are exercisable at $2.42 per share and 100,000 are exercisable at $3.04 per share. The $1.74 warrants expire on July 10, 2008, the $2.57 and $2.50 warrants expire on March 12, 2008, the $2.42 warrants expire on October 30, 2008 and the $3.04 warrants expire on January 5, 2009. By agreement with Cardinal, we have registered all warrants and underlying shares for public sale.

Section 713 of the American Stock Exchange ("AMEX") Company Guide provides that the Company must obtain stockholder approval before issuance, at a price per share below market value, of common stock, or securities convertible into common stock, equal to 20% or more of its 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 is required for the issuance of common stock for a portion of the potential exercise of the warrants and conversion of the Debentures in connection with the January 2004 Debentures. The amount of potential shares that the Company could exceed the Exchange Cap amounted to approximately 1,299,000. In accordance with EITF 00-19, Accounting For Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock, the Company recorded on January 26, 2004, a redemption obligation of approximately $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, the Company revalued this redemption obligation associated with the beneficial conversion feature and warrants as of

March 31, 2004. The Company recorded an additional redemption obligation and finance charge of $947,000 as a result of this revaluation. If the Company obtains stockholder approval, the Company's redemption obligation will be recorded as additional paid in capital on the date approval is received.

The Company anticipates receiving stockholder and Exchange approval for the issuance of the shares in excess of the Exchange limit. However, the Company cannot ensure it will obtain the proper approval from both parties.

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

On March 11, 2003, we acquired from ISI, ISI's inventory of ALFERON N Injection(R), a pharmaceutical product used for intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older, 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 have registered these shares for public sale. ISI 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 have guaranteed the market value of all but 62,500 of these shares to be $1.59 per share on the termination date. The termination date for these guarantees is 18 months after the date of issuance of the guaranteed shares to GP Strategies, 24 months after the date of issuance and delivery of the 487,028 guaranteed shares to ISI and 12 months after the date of issuance of the guaranteed shares to the American National Red Cross. These stockholders are permitted to periodically sell certain amounts of their shares. If, within 30 days after the respective termination date, one or more of these stockholders requests that we honor the guarantee, we will be obligated to reacquire their remaining guaranteed shares and pay them $1.59 per share. Please see "We have guaranteed the value of a number of shares issued and to be issued as a result of our acquisition of assets from Interferon Sciences. If our share price is not above $1.59 per share 12 or 24 months after the dates of issuance of the guaranteed shares, our financial condition could be adversely affected" in "Risk Factors," above.

We also agreed to satisfy other liabilities of ISI which are 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 have registered the foregoing shares for public sale. As of March 31, 2004 GP Strategies had sold all of its shares and the American National Red Cross has not sold any of their 314,465 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 a such as debentures, options and warrants. Prior to the meeting, to permit consummation of the sale of the July 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" 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.

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.

On May 13, 2004, we issued to the debentureholders warrants to purchase an aggregate of 1,300,000 shares ("the May 2009 Warrants"). In consideration of the foregoing, the debentureholders exercised the June 2008 warrants. As a result, we issued an aggregate of 1,000,000 shares and received gross proceeds of approximately $2,400,000.

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 (but in no event less than $4.008 per share). The exercise price (and the reset price) under the May 2009 Warrants also is subject to adjustments for anti-dilution projection similar to those in the other warrants.

In addition, the debentureholders agreed to amend the provisions of all of the outstanding warrants and debentures (including the debentures issuable pursuant to the AIR) 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.
These transactions could result in us recording an additional redemption obligation for the reasons discussed in Note 7 and will result in additional financing charges beginning in the second quarter of 2004.

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 $7,238,000 in cash and cash equivalents and short-term investments at March 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, tortuous interference with existing and prospective business relations and conspiracy, arising out of Asensio's false and defamatory statements. The complaint further alleged that Asensio defamed and disparaged us in furtherance of a manipulative, deceptive and unlawful short-selling scheme in August and September, 1998. In 1999, Asensio filed an answer and counterclaim alleging that in response to Asensio's strong sell recommendation and other press releases, we made defamatory statements about Asensio. We denied the material allegations of the counterclaim. In July 2000, following dismissal in federal court for lack of subject matter jurisdiction, we transferred the action to the Pennsylvania State Court. In March 2001, the defendants responded to the complaints as amended and a trial commenced on January 30, 2002. A jury verdict disallowed the claims against the defendants for defamation and disparagement and the court granted us a directed verdict on the counterclaim. On July 2, 2002 the Court entered an order granting us a new trial against Asensio for defamation and disparagement. Thereafter, Asensio appealed the granting of a new trial. 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. We believe the claim is without merit and we are defending the claim against us through our product liability insurance carrier.

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.

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

During the quarter ended March 31, 2004, the Company issued debentures and warrants in private transactions pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933. In addition, the Company

made certain changes to its Debentures and related warrants. 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 March 31, 2004.

ITEM 3: Defaults in Senior Securities

None.

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

None.

ITEM 5: Other Information

As noted in Part I, on May 14, 2004, we issued to the holders of our debentures warrants to purchase an aggregate of 1,300,000 shares ("the May 2009 Warrants"). In consideration of the foregoing, the debentureholders exercised our June 2008 warrants (for an aggregate of 1,000,000 shares) and we received gross proceeds of $2,400,000. For a description of the May 2009 Warrants please see Part I, ITEM 2: "Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity And Capital Resources."

In addition, the debentureholders agreed to amend the provisions of all of the outstanding debentures (including the debentures issuable pursuant to their Additional Investement Rights) 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.

ITEM 6: Exhibits and Reports on Form 8K

(a) Exhibits

10.1 Form of Warrant for Common Stock issued on May 14, 2004

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/A (amending 8-K filed on March 13, 2003) filed March 26, 2004 Form 8-K filed on March 15, 2004 Form 8-K filed on January 27, 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
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William A. Carter, M.D.
Chief Executive Officer & President

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

Date: May 14, 2004