HEMISPHERX BIOPHARMA INC
Form 424B3
April 13, 2004

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

HEMISPHERX BIOPHARMA, INC.

12,998,647 Shares of Common Stock

This prospectus relates to the resale of 12,998,647 shares of our common stock that may be offered and sold from time to time by selling shareholders, consisting of: (1) 135% of 1,682,664 shares of common stock issuable upon the conversion, redemption or other payments relating to our 6% Senior Convertible Debentures Due January 2006 ("January 2004 Debentures") and as payment of interest thereon and 135% of 790,514 shares of common stock issuable upon the exercise of the related warrants ("2009 Warrants"); (2) 135% of 813,970 shares of common stock issuable upon the conversion, redemption or other payments relating to our January 2004 Debentures and as payment of interest thereon, which January 2004 Debentures are issuable upon exercise of Additional Investment Rights held by the holders of the January 2004 Debentures; (3) 135% of 1,585,978 shares of common stock issuable upon the conversion, redemption or other payments relating to our 6% Senior Convertible Debentures Due October 2005 ("October Debentures") and as payment of interest thereon and 135% of 410,134 shares of common stock issuable upon the exercise of the related warrants ("October 2008 Warrants"); (4) 135% of 1,137,650 shares of common stock issuable upon the conversion, redemption or other payments relating to our 6% Senior Convertible Debentures Due July 2005 ("July Debentures") and as payment of interest thereon and 135% of 507,102 shares of common stock issuable upon the exercise of the related warrants ("July 2008 Warrants") and 135% of 1,000,000 shares of common stock issuable upon the exercise of warrants issued to the Debenture holders in June 2003 ("June 2008 Warrants"); (5) 1,302,410 shares of common stock issuable upon exercise of other warrants; and (6) 993,420 shares of common stock to be sold by certain of the selling stockholders listed on page 64 of this prospectus. We are registering these shares of common stock pursuant to commitments to register the securities with the selling stockholders.

We will not receive any proceeds from the sale of the shares of common stock by the selling stockholders other than payment of the exercise price of the warrants.

Our common stock is listed on the American Stock Exchange under the symbol HEB. The reported last sale price on the American Stock Exchange on April 6, 2004 was $3.66.

Please see the risk factors beginning on page 6 to read about certain factors you should consider before buying shares of common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined that this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 9, 2004

PROSPECTUS SUMMARY

In the following summary, we have highlighted information that we believe is the most important about us. However, because this is a summary, it may not contain all information that may be important to you. You should read this entire prospectus, including the information incorporated by reference and the financial data and related notes, before making an investment decision. When used in this prospectus, the terms "we," "our" and "us" refer to Hemispherx and not to the selling stockholders.

About Hemispherx

In the course of almost three decades, we have established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of nucleic acids to enhance the natural antiviral defense system of the human body and the development of therapeutic products for the treatment of chronic diseases. Our strategy is to obtain the required regulatory approvals which will allow the progressive introduction of Ampligen(R) (our proprietary drug) for treating Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome ("ME/CFS"), HIV, Hepatitis C ("HCV") and Hepatitis B ("HBV") in the U.S., Canada, Europe and Japan. Ampligen(R) is currently in the open label portion of phase III clinical trials in the U.S. for use in treatment of ME/CFS and is in Phase IIb Clinical Trials in the U.S. for the treatment of newly emerging multi-drug resistant HIV, and for the induction of cell mediated immunity in HIV patients that are under control using potentially toxic drug cocktails.

Our proprietary drug technology utilizes specifically configured ribonucleic acid ("RNA") and is protected by more than 350 patents worldwide, with over 60 additional patent applications pending to provide further proprietary protection in various international markets. Certain patents apply to the use of Ampligen(R) alone and certain patents apply to the use of Ampligen(R) in combination with certain other drugs. Some compositions of matter patents pertain to other new RNA compounds, which have a similar mechanism of action.

In March 2003 we obtained from Interferon Sciences, Inc. ("ISI") all of its raw materials, work-in-progress and finished product ALFERON N Injection(R), together with a limited license to sell ALFERON N Injection(R), a natural alpha interferon that has been approved for commercial sale for the intralesional treatment of refractory or recurring external condylomata acuminata ("genital warts") in patients 18 years of age or older in the United States. In March 2004, we acquired from ISI the balance of ISI's rights to its product as well as ISI's production facility. We are marketing the ALFERON N Injection(R) in the United States through sales facilitated via third party marketing agreements. Additionally, we intend to implement studies testing the efficacy of ALFERON N Injection(R) in multiple sclerosis and other chronic viral diseases. In this regard, the FDA recently authorized a Phase II clinical study designed to investigate the activity and safety of Alferon LDO(R) in early stage HIV positive patients.

We were incorporated in Maryland in 1966 under the name HEM Research, Inc., and originally served as a supplier of research support products. Our business was redirected in the early 1980's to the development of nucleic acid pharmaceutical technology and the commercialization of RNA drugs. We were reincorporated in Delaware and changed our name to HEM Pharmaceutical Corp., in 1991 and to Hemispherx Biopharma, Inc., in June 1995. We have three domestic subsidiaries `BioPro Corp., BioAegean Corp., and Core BioTech Corp., all of which are incorporated in Delaware. Our foreign subsidiaries include Hemispherx Biopharma Europe N.V./S.A. established in Belgium in 1998 and Hemispherx Biopharma Europe S.A. ("Hemispherx, S.A.") incorporated in Luxembourg in 2002.

Our principal executive offices are located at One Penn Center, 1617 JFK

Boulevard, Philadelphia, Pennsylvania 19103, and its telephone number is 215-988-0080.

THE OFFERING

Common stock to be offered by the selling stockholders	12,998,647 Shares
Common stock outstanding prior to this offering	41,617,249 Shares
Use of Proceeds	We will not receive any of the proceeds from the sale of the shares of common stock because they are being offered by the selling stockholders and we are not offering any shares for sale under this prospectus, but we may receive proceeds from the exercise of warrants held by certain of the selling stockholders. We will apply such proceeds, if any, toward funding our research and development efforts, working capital and, possibly, acquisitions. See "Use of Proceeds."
American Stock Exchange symbol	HEB

The 12,998,647 shares of our common stock offered consist of:

- 135% of 1,682,664 shares of common stock issuable upon the conversion, redemption or other payments relating to our 6% Senior Convertible Debentures Due January 2006 ("January 2004 Debentures") and as payment of interest thereon;
- 135% of 790,514 shares of common stock issuable upon the exercise of the related warrants ("2009 Warrants");
- 135% of 813,970 shares of common stock issuable upon the conversion, redemption or other payments relating to our January 2004 Debentures and as payment of interest thereon, which January 2004 Debentures are issuable upon exercise of Additional Investment Rights held by the holders of the January 2004 Debentures;
- 135% of 1,585,978 shares of common stock issuable upon the conversion, redemption or other payments relating to our 6% Senior Convertible Debentures Due October 2005 ("October Debentures") and as payment of interest thereon;
- 135% of 410,134 shares of common stock issuable upon the exercise of the related warrants ("October 2008 Warrants"); o 135% of 1,137,650 shares of common stock issuable upon the conversion, redemption or other payments relating to our 6% Senior Convertible Debentures Due July 2005 ("July Debentures") and as payment of interest thereon;
- 135% of 507,102 shares of common stock issuable upon the exercise of the related warrants ("July 2008 Warrants");
- 135% of 1,000,000 shares of common stock issuable upon the exercise of warrants issued to the Debenture holders in June 2003 ("June 2008

Warrants");

- 1,302,410 shares of common stock issuable upon exercise of other warrants; and

- 993,420 shares of common stock owned by certain of the selling stockholders.

We are registering these shares of common stock pursuant to commitments to register the securities with the selling stockholders.

Summary Consolidated Financial Data

In the table below, we provide you with our summary historical financial data. We have prepared this information using our audited financial statements for each of the five years in the period ended December 31, 2003.

It is important that you read this summary historical financial data in conjunction with our historical financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus.

(in thousands except share and per share data)
Year ended December 31,

Consolidated Statements of Operations Data:	1999	2000	2001	2002	2003
Revenues:					
Sale of Products	$ --	$ --	$ --	$ --	$
Clinical Treatment Programs	678	788	390	341	
License Fees Income	--	--	--	563	
Total Revenues	678	788	390	904	
Cost & Expenses:					
Production Costs/ Costs of Goods Sold					
Research & Development	4,737	6,136	5,780	4,946	3
General & Administrative(1)	8,721	3,695	3,412	2,015	4
Total Cost and Expenses	13,458	9,831	9,192	6,961	7
Interest and Other Income	482	572	284	103	
Interest Expense	--	--	--	--	
Financing Costs(3)	--	--	--	--	(7
Other Expense	--	(81)	(565)	(1,470)	

Net Loss	$(12,298)	$(8,552)	$(9,083)	$(7,424)	$(14
Basic and Diluted Loss Per Share	$ (.47)	$ (.29)	$ (.29)	$ (.23)	$
Basic and Diluted	26,380,351		31,443,208		35,234
Weighted Average Shares Outstanding		29,251,846		32,095,776	

Other Cash Flow Data					
Cash Used in Operating Activities	$(6,990)	$(8,074)	$(7,281)	$(6,409)	$(7,022)
Capital Expenditures	(251)	(171)	--	--	19

Balance Sheet Data:	December 31,					Pro Forma Adju For Asset Acqui
	1999	2000	2001	2002	2003	2003(4)(5
						(unaudite
Working Capital	$ 9,507	$ 7,550	$ 7,534	$2,925	$ 7,000	$ 7,000
Total Assets	14,168	13,067	12,035	6,040	13,404	15,070
Shareholders' Equity	12,657	11,572	10,763	3,630	9,248	9,462

(1) General and Administrative expenses include stock compensation expense totaling $4,618, $397, $673, $132 and $237for the years ended December 31, 1999, 2000, 2001, 2002 and 2003, respectively.

(2) For information concerning recent acquisitions of certain assets of Interferon Sciences, Inc. ("ISI") and related financing see notes 1, 4 and 7 to our consolidated financial statements for the year ended December 31, 2003, contained elsewhere in this prospectus.

(3) In accounting for the March 12, 2003, July 10, 2003, and October 29, 2003 issuances of 6% Senior Convertible Debentures in the principal amounts of $5,426,000, $5,426,000, and $4,142,357, respectively, and related embedded conversion features and warrant issuances, we recorded debt discounts of approximately $11.3 million which, in effect, reduced the carrying value of the debt to $1.6 million. Excluding the application of related accounting standards, our debt outstanding as of December 31, 2003 totaled approximately $6.6 million. Through December 31, 2003, we have recorded charges of approximately $7.3 million for amortization of original issue discount and other related debt costs. Such amounts have been reflected as financing costs in the statement of operations. For additional information refer to note 7 to our consolidated financial statements for the year ended December 31, 2003.

(4) The unaudited Pro Forma consolidated statements of operations data for the year ended December 31, 2003 have been prepared giving effect to the

acquisition of certain assets of ISI and the related funding of the transaction, by our March 12, 2003 6% senior convertible debentures, as if they occurred on January 1, 2003.

The unaudited Pro Forma consolidated balance sheet data has been prepared as if the second portion of the acquisition of certain assets of ISI had occurred on December 31, 2003.

(5) Does not reflect the issuance of the January 26, 2004 $4,000,000 6% Senior Convertible Debenture resulting in net cash proceeds to us of $3,695,000.

RISK FACTORS

Special Note Regarding Forward-Looking Statements

Certain statements in this prospectus 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 prospectus 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 prospectus. 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.

The following cautionary statements identify important factors that could cause our actual result to differ materially form those projected in the forward-looking statements made in this prospectus. 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 December 31,

2003 our accumulated deficit was approximately $113,843,000. 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 December 31, 2003, we had approximately $5.3 million in cash and short term investments. We believe that these funds plus 1) the $3,695,000 in net proceeds from the January Debenture placement, 2) the anticipated infusion of approximately $1.55 million in remaining net proceeds from the October Debentures, 3) the projected net cash flow from the sale of ALFERON N Injection(R), 4) the proceeds from licensing agreements and/or the expected infusion of $2,000,000 in

proceeds from our investors exercising their additional investment rights should be sufficient to meet our operating cash requirements including debt service during the 2004 fiscal year. We may need to raise additional funds through additional equity or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes and begin commercializing Ampligen(R) products. There can be no assurances that we will raise adequate funds from these or other sources, which may have a material adverse effect on our ability to develop our products.

We have guaranteed the value of a number of shares 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 18, 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 6, 2004 was $3.66 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;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards; and
- the occurrence of any of the risks described in these "Risk Factors."

Our common stock is listed for quotation on the American Stock Exchange. For the 12-month period ended December 31, 2003, the price of our common stock has ranged from $1.33 to $2.96. We expect the price of our common stock to

remain volatile. The average daily trading volume of our common stock varies significantly. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

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

Our stock price may be adversely affected if a significant amount of shares, primarily those registered herein and in a prior registration statement, are sold in the public market.

As of April 6, 2004, approximately 1,055,333 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 Additional Investment Rights (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 shareholder 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 12.3% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at $.01 per Right under certain circumstances.

Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Our research in clinical efforts may continue for the next several years and we may continue to incur losses due to clinical costs incurred in the development of Ampligen(R) for commercial application. Possible losses may fluctuate from quarter to quarter as a result of differences in the timing of significant expenses incurred and receipt of licensing fees and/or cost recovery treatment revenues in Europe, Canada and in the United States.

USE OF PROCEEDS

Proceeds, if any, from stockholders exercising some or all of the Warrants will be used to fund our research and development efforts, working capital and possible acquisitions.

DIVIDEND POLICY

We have not paid any cash dividends since our inception and do not anticipate paying cash dividends in the foreseeable future.

PRICE RANGE OF COMMON STOCK

Since October 1997, our common stock has been listed and traded on the American Stock Exchange ("AMEX") under the symbol HEB. The following table sets forth the high and low sales prices for our Common Stock for the last two fiscal years as reported by the AMEX.

COMMON STOCK	High	Low

Year Ended December 31, 2002		
First Quarter	$4.95	$3.40
Second Quarter	4.00	2.30
Third Quarter	2.89	.75
Fourth Quarter	2.95	1.10
Year Ending December 31, 2003		
First Quarter	2.19	1.33
Second Quarter	3.35	1.33
Third Quarter	2.35	1.85
Fourth Quarter	2.94	1.83

On April 6, 2004, the closing sale price of our common stock as reported on the AMEX was $3.66 per share. As of April 6, 2004, there were approximately 267 holders of record of our common stock not including holders in street name. We estimate that there are some 3,300 holders if you include shares held in street name.

SELECTED CONSOLIDATED FINANCIAL DATA

Our selected historical consolidated financial information presented as of December 31, 1999, 2000, 2001, 2002 and 2003 and for each of the five years ended December 31, 2003 was derived from our audited consolidated financial statements.

This information should be read in conjunction with the historical financial statements and related notes included herein, and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

(in thousands except share and per share data)

Consolidated Statements of Operations Data:	Year ended December 31,				
	1999	2000	2001	2002	2003
Revenues:					
Sale of Products	$ --	$ --	$ --	$ --	$
Clinical Treatment Programs	678	788	390	341	
License Fee Income	--	--	--	563	
Total Revenues	678	788	390	904	
Cost & Expenses:					
Production Costs/ Cost of Goods Sold	--	--	--	--	
Research & Development	4,737	6,136	5,780	4,946	
General & Administrative(1)	8,721	3,695	3,412	2,015	

Total Cost and Expenses	13,458	9,831	9,192	6,961	
Interest and Other Income	482	572	284	103	
Interest Expense	--	--	--	--	
Financing Costs(3)	--	--	--	--	(
Other Expense	--	(81)	(565)	(1,470)	
Net Loss	$(12,298)	$(8,552)	$(9,083)	$(7,424)	$(1
Basic and Diluted Loss Per Share	$ (.47)	$ (.29)	$ (.29)	$ (.23)	$
Basic and Diluted Weighted Average Shares Outstanding	26,380,351	29,251,846	31,443,208	32,095,776	35,23

Other Cash Flow Data						
Cash Used in Operating Activities	$(5,853)	$(6,990)	$(8,074)	$(7,281)	$(6,409)	$(7,022)
Capital Expenditures	(151)	(251)	(171)	--	--	(19)

Balance Sheet Data: December 31,

	1999	2000	2001	2002	2003
Working Capital	$ 9,507	$ 7,550	$ 7,534	$2,925	$ 7,000
Total Assets	14,168	13,067	12,035	6,040	13,404
Shareholders' Equity	12,657	11,572	10,763	3,630	9,248
Book value per share(4)	$.48	$.40	$.34	$.11	$.24

(1) General and Administrative expenses include stock compensation expense totaling $397, $673, $132, $132 and $237 for the years ended December 31, 1999, 2000, 2001, 2002 and 2003, respectively.

(2) For information concerning recent acquisitions of certain assets of ISI and related financing see notes 4 and 7 to our consolidated financial statements for the year ended December 31, 2003, contained elsewhere in this prospectus.

(3) In accounting for the March 12, 2003, July 10, 2003, and October 29, 2003 issuances of 6% Senior Convertible Debentures in the principal amounts of $5,426,000, $5,426,000, and $4,142,357, respectively, and related embedded conversion features and warrant issuances, we recorded debt discounts of approximately $11.3 million which, in effect, reduced the carrying value of the debt to $1.6 million. Excluding the application of related accounting standards, our debt outstanding as of December 31, 2003 totaled approximately $6.6 million. Through December 31, 2003, we have recorded charges of approximately $7.3 million for amortization of original issue

discount and other related debt costs. Such amounts have been reflected as financing costs in the statement of operations. For additional information refer to note 7 to our consolidated financial statements for the year ended December 31, 2003.

(4) Book value per share is computed by dividing shares outstanding into shareholders' equity as of the above date.

MANAGEMENT'S DISCUSSION AND ANALYSIS
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our financial statements and related notes included elsewhere in this prospectus. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of a number of factors including, but not limited to, those set forth under "Risk Factors" and elsewhere in this prospectus.

Background

We have reported net income only from 1985 through 1987. Since 1987, we have incurred, as expected, substantial operating losses due to our conducting clinical testing.

We have established a strong foundation of laboratory and pre-clinical data with respect to the development of nucleic acid to enhance the natural antiviral defense system of the human body and the development of the therapeutic products for the treatment of chronic disease. Our strategy is to obtain the required regulatory approval which will allow the progressive introduction of Ampligen(R) (our proprietary drug) for treating Myalgic Encephalomyelitis Chronic Syndrome (ME/CFS"), HIV, hepatitis C ("HCV") and hepatitis B ("HBV") in the U.S., Canada, Europe and Japan. In February, 2004, we completed the double-blind segment of the AMP 516 Phase III clinical trial for use of Ampligen(R) in treating ME/CFS. The 14 remaining patients are enrolled in the open label portion of the trial and should complete this segment by June, 2004. With the conclusion of the double-blind segment we can finalize data collection and start date analysis in anticipation of preparing the NDA for submission to the FDA. Ampligen(R) is also in Phase IIb Clinical trials in the U.S. for the treatment of newly emerged multi-drug resistant HIV, and for the induction of Cell mediated immunity in HIV patients that are under control using potentially toxic drug cocktail.

Our proprietary drug technology utilizes specifically configured ribonucleic acid ("RNA") and is protected by more than 350 patents worldwide as well as over 80 additional patent applications pending to provide further proprietary protection in various international markets. Certain patents apply to the use of Ampligen(R) alone and certain patent apply to the use of Ampligen(R) in combination with certain other drugs. Some composition of matter patents pertain to other new medication, which have a similar mechanism of action.

In March, 2003, we acquired from 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) of. In March 2004, we acquired from ISI the balance of ISI's rights to its product as well as ISI's production facility. We

intend to market this product in the United States through sales facilitated via third party marketing agreements. Additionally, we intend to implement studies, beyond those conducted by ISI, for testing the potential treatment of HIV, Hepatitis C and other indications, including multiple sclerosis.

Result of Operations

Years Ended December 31, 2003 vs. 2002

During the year ended December 31, 2003, we 1) acquired certain assets and patent rights to ALFERON N Injection(R), 2) privately placed the March 2005, the July 2005, and October 2005, 6%

convertible debentures with an aggregate maturity value of $14,994,357 (gross proceeds of $12,850,000), 3) continued our efforts to develop Ampligen(R) for the treatment of patients afflicted with ME/CFS and HIV, 4) activated the ISI New Brunswick production facility to process doses of Alferon N and 5) produced some 21,000 doses of Alferon N for sale in 2003.

Net loss

Our net loss was approximately $14,770,000 for the year ended December 31, 2003 versus a net loss of $7,424,000 in 2002. Per share loss in 2003 was $0.42 cents versus a per share loss of $0.23 in 2002. This year-to-year increase in losses of $7,346,000 is primarily due to non-cash financing costs of $7,345,000 relating to our March 2005, July 2005, and October 2005 6% convertible debentures. These non-cash charges account for 48% of our net losses for the year ended December 31, 2003. In addition, our losses during this period include $957,000 in operating expenses relating to our new Alferon division. Solely for comparison purposes, excluding our 2003 losses for these two factors, our losses were $6,775,000 in 2003 compared to $7,424,000 in 2002 or a reduction totaling $649,000. This was primarily due to a decrease in research and development direct costs of $1,800,000 in 2003 due to reduced costs associated with the development of Ampligen(R) to treat ME/CFS patients. During 2002, our AMP 516 ME/CFS Phase III clinical trial was in full force and effect therefore increasing our manufacturing and clinical support expenses during that period (See "Research and Development Costs" below). This was offset by the recovery of certain legal expenses in 2002 of approximately $1,050,000 related to the Asensio lawsuit and trial from our insurance carrier. This recovery produced a one-time reduction in G&A Expenses for 2002 (See "General and Administrative Expenses" below).

Revenues

Our revenues were $657,000 in 2003 compared to revenues of $904,000 in 2002. Our 2002 revenues included a licensing fee payment of approximately $563,000 which was not repeated in 2003.

Revenues from our ME/CFS cost recovery treatment programs principally underway in the U.S., Canada and Europe were $148,000 in 2003 versus $341,000 in 2002. 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 weeks treatment program. In addition, since the March 11, 2003, acquisition of inventory from ISI, revenues from sales of ALFERON N totaled $509,000. Sales of Alferon N are anticipated to increase as we are producing more product and our marketing/sales programs are underway.

Revenues from the cost recovery treatment programs in 2002 were $341,000 or 57% higher than 2003 revenues. We expected revenues in the U.S. to decline due to our efforts to complete the AMP 516 ME/CFS Phase III trials and the focus of our clinical resources on the start up of the AMP 720 HIV clinical trials. The clinical data collected from treating patients under the cost recovery treatment programs will augment and supplement the clinical data collected in the U.S. AMP 516 Phase III ME/CFS trial.

In 2002, We received a licensing fee of 625,000 Euros ($563,000) from Laboratorios Del Dr. Esteve S.A. ("Esteve") pursuant to a sales and distribution agreement in which Esteve was granted the exclusive right to market Ampligen(R) in Spain, Portugal and Andorra for the treatment of ME/CFS in turn we provided to Esteve technical scientific and commercial information. The agreement terms require no additional performance by us.

Since acquiring the right to manufacture and market Alferon N in March 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 the New Brunswick 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.

On August 18, 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.

Production costs

Production costs were $502,000 for the year ended December 31, 2003. These costs reflect approximately $240,000 for the cost of sales of ALFERON N Injection(R) during the period of April 1, 2003 through December 31, 2003. In addition, we recorded $262,000 of production costs at the New Brunswick facility. We ramped up the facility in April 2003 and started production on three lots of Alferon N Injection(R) work in process inventory of which one lot was completed and is ready to be sold.

Research and Development costs

Our overall research and development direct costs in 2003 were $3,150,000

compared to research and development direct costs in 2002 of $4,946,000. 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 consists of on-going clinical trials involving patients with HIV. Our research and development direct costs are $1,796,000 lower in 2003 due to reduced costs associated with the development of Ampligen(R) to treat ME/CFS patients. During 2002, our AMP 516 ME/CFS Phase III clinical trial was in full force and effect, therefore, increasing our manufacturing and clinical support expenses during that period.

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. 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. The AMP 719 study is presently on hold as we devote our efforts on the AMP 720 study.

AMP 516

Over 230 patients have participated in our ME/CFS Phase III clinical trial. Approximately 14 patients are in the open label phase of the clinical process. We have completed the randomized placebo controlled phase of this study and expect to complete data collection and start the data analysis process with the expectation of filing an NDA (New Drug Application) with the FDA by the end of 2004. As with any experimental drug being tested for use in treating human diseases, the FDA must approve the testing and clinical protocols employed and must render their decision based on the safety and efficacy of the drug being tested. Historically this is a long and costly process. Our ME/CFS AMP 516 clinical study is a Phase III study, which based on favorable results, will serve as the basis for us to file a new drug application with the FDA. The FDA review process could take 18-24 months and result in one of the following events; 1) approval to market Ampligen(R) for use in treating ME/CFS patients, 2) required more research, development, and clinical work, 3) approval to market as well as conduct more testing, or 4)reject our application. Given these variables, we are unable to project when material net cash inflows are expected to commence from the sale of Ampligen(R).

AMP 719 and AMP 720

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

time.

In July 2003, Dr. Blick, a principal investigator in our HIV studies, presented updated results on our Amp 720 HIV study at the 2nd IAS CONFERENCE ON HIV PATHOGENESIS AND TREATMENT in Paris France. In this study using Strategic Treatment Interruption (STI), patients' antiviral HAART regimens are interrupted and Ampligen(R) is substituted as mono-immunotherapy. Ampligen(R) is an experimental immunotherapeutic designed to display both antiviral an immune enhancing characteristics. Prolonged use of Highly Active Antiretroviral Therapy (HAART) has been associated with long-term, potentially fatal, toxicities. The clinical study AMP 720 is designed to address these issues by evaluating the administration of our lead experimental agent, Ampligen(R), a double stranded RNA drug acting potentially both as an immunomodulator and antiviral. Patients, who have completed at least nine months of Ampligen(R) therapy, were able to stay off HAART for a total STI duration with a mean time of 29.0 weeks whereas the control group, which was also taken off HAART, but not given Ampligen(R), had earlier HIV rebound with a mean duration of 18.7 weeks. Thus, on average, Ampligen(R) therapy spared the patients excessive exposure to HAART, with its inherent toxicities, for more than 11 weeks. As more patients are enrolled, the related clinical costs will continue to increase with some offset to our overall expenses due to the diminishing cost of the ME/CFS clinical trial. It is difficult to estimate the duration or projected costs of these two clinical trials due to the many variables involved, i.e.: patient drop out rate, recruitment of clinical investigators, etc. The length of the study and costs related to our clinical trials cannot be determined at this time as such will be materially influenced by (a) the number of clinical investigators needed to recruit and treat the required number of patients, (b) the rate of accrual of patients and (c) the retention of patients in the studies and their adherence to the study protocol requirements. Under optimal conditions, the cost of completing the studies could be approximately $2.0 to $3.0 million. The rate of enrollment depends on patient availability and on other products being in clinical trials for the treatment of HIV, as there is competition for the same patient population. At present, more than 18 FDA approved drugs for HIV

treatment may compete for available patients. The length, and subsequently the expense of these studies, will also be determined by an analysis of the interim data, which will determine when completion of the ongoing Phase IIb is appropriate and whether a Phase III trial be conducted or not. In case a Phase III study is required; the FDA might require a patient population exceeding the current one which will influence the cost and time of the trial. Accordingly, the number of "unknowns" is sufficiently great to be unable to predict when, or whether, we may obtain revenues from our HIV treatment indications.

General and Administrative Expenses

General and Administrative expenses ("G&A") were $4,257,000 during the year ended December 31, 2003, which includes $957,000 of expenses relating to our new Alferon Division and $237,000 for a non cash stock compensation charge. Excluding the Alferon expenses, our G&A costs were $3,300,000 compared to $2,015,000 of expenses in 2002. This increase of $1,285,000 is primarily due to the recovery of certain legal expenses in 2002 of approximately $1,050,000 related to the Asensio lawsuit and trial from our insurance carrier. This recovery produced a one time reduction in G&A Expenses for 2002. Also, we recorded non-cash stock compensation expenses of $237,000 in 2003 as compared to $133,000 in 2002.

Equity Loss-Unconsolidated Affiliates

In the year ended December 31, 2002, we recorded a non-cash charge of $1,470,000 to operations with respect to our investments in unconsolidated affiliates. $1,074,000 of these charges were related to our investment in R.E.D. These charges were the result of our determination that R.E.D.'s business and financial position had deteriorated to the point that our investment had been permanently impaired.

We also recorded a non-cash charge of $292,000 with respect to our investment in Chronix Biomedical. This impairment reduced our carrying value in this investment to reflect a permanent decline in Chronix's market value based on its then proposed equity offerings.

These charges are reflected in the Consolidated Statements of Operations under the caption "Equity loss in unconsolidated affiliate." Please see "Research And Development/Collaborative Agreements" in "Our Business" for more details on these transactions.

Other Income/Expense

Interest and other income totaled $80,000 in 2003 compared to $103,000 recorded in 2002. Lower cash available for investment basically accounted for the difference as interest rates remained relatively low in 2003. 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 $7,598,000 in 2003. Non-cash financing costs consist of $581,000 for the amortization of debenture closing costs, $1,066,000 for the amortization of Original Issue Discounts and $5,698,000 for the amortization of costs associated with beneficial conversion features of the debentures and the fair value of the warrants relating to the January 2005, July 2005 and October 2005 6% convertible debentures. These charges are reflected in the Consolidated Statements of Operations under the caption "Financing Costs." Please see Note 16 in the consolidated financial statements contained herein for more details on these transactions.

Years Ended December 31, 2002 vs. 2001

Net loss

Our net loss was approximately $7,424,000 for the year ended December 31, 2002 versus a net loss of $9,083,000 in 2001. Per share loss in 2002 was $0.23 versus a per share loss of $0.29 in 2001. This year to year decrease in losses of $1,659,000 was primarily due to higher revenues and lower costs in 2002. Revenues were up $514,000 in 2002 and total expenses were down by $2,231,000 offset by a write down in the carrying value of our investments in the amount of $1,366,000 for a net cost decrease of $865,000.

Revenues

Our revenues came from our ME/CFS cost recovery treatment programs principally underway in the U.S., Canada and Europe. 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 weeks treatment program. Revenues from cost recovery treatment programs totaled some $341,000 in 2002. In 2001, these revenues were $390,000 or 14% higher than 2002 revenues. We expected revenues in the U.S. to decline due to the focus of our clinical

resources on conducting and completing the AMP 516 ME/CFS Phase III clinical trial as well as the start up of the AMP 719 and AMP 720 HIV clinical trials. The clinical data collected from treating patients under the cost recovery treatment programs will augment and supplement the data collected in the U.S. Phase III ME/CFS trial.

We received a licensing fee of 625,000 Euros (some $563,000) from Esteve pursuant to a sales and distribution agreement in which Esteve was granted the exclusive right to market Ampligen(R) in Spain, Portugal and Andorra for the treatment of ME/CFS in turn we provided to Esteve technical scientific and commercial information. The agreement terms require no additional performance by us. Our total revenues, including this licensing fee, in 2002 was $904,000 compared to revenues of $390,000 in 2001.

Research and Development costs

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.

At December 31, 2002, Ampligen was being tested in a Phase III clinical trial, in the U.S., for use in treatment of ME/CFS, the so-called AMP-516 study. It also was 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.

AMP 516

As of December, 2002, the AMP 516 clinical trial was fully enrolled with more than the targeted 230 patients in order to potentially compensate for "drop outs". The last patients completed the randomized segment of this clinical trial in February, 2004. The next stage of the program is final data

collection, quality assurance of the data to insure its accuracy and analysis of the data according to regulatory guidelines to facilitate the New Drug Application (NDA), expected to be filed by the end of 2004. The date of potential commercial approval depends on whether we receive Fast Track Status from the FDA. In case of Fast Track the FDA approval time is maximum six months. If we are not granted Fast Track Designation, the approval time can take substantially longer, depending on the progress made by the FDA in review of the application. The FDA may deny full commercial approval to the drug at any time, including after Fast Track Status has been awarded.

As with any experimental drug being tested for use in treating human diseases, the FDA must approve the testing and clinical protocols employed and must render their decision based on the safety and efficacy of the drug being tested. Historically this is a long and costly process. Our ME/CFS AMP 516 clinical study is a Phase III study, which based on favorable results, will serve as the basis for us to file a new drug application with the FDA. The FDA review process could take 18-24 months and result in one of the following events; 1) approval to market Ampligen(R) for use in treating ME/CFS patients, 2) require more research, development, and clinical work, 3) approval to market

as well as conduct more testing, or 4) reject our application. Given these variables, we are unable to project when material net cash inflows are expected to commence from the sale of Ampligen(R).

AMP 719 and AMP 720

As of December 2002, approximately 55 patients had been enrolled in both studies combined and they were being treated in approximately 10 different active sites around the U.S.

The length of the study and the costs related to these trials cannot be determined at this time as it will be materially influenced by (a) the number of clinical investigators needed to fulfill the required number of patients, (b) the rate of accrual of patients and (c) the retention of patients on the protocol and their adherence to the protocol requirements. See "AMP 719 and AMP 720" in "Result of Operations; Years Ended December 31, 2003 vs. 2002; Research and Development costs" above.

Our overall research and development direct costs in 2002 were $4,946,000 compared to direct research and development costs in 2001 of $5,780,000 and $6,136,000 in 2000. We estimate that 80% of these expenditures to be related to our ME/CFS research and development and 20% related to our HIV studies.

General and Administrative Expenses

Excluding stock compensation expense, general and administrative expenses were approximately $1,882,000 in 2002 versus $2,741,000 in 2001. This decease in expenses of $859,000 in 2002, is due to several factors including the recovery of certain legal expenses of approximately $1,050,000 relating to the Asensio lawsuit from our insurance carrier and lower overall legal expenses due to less litigation, partially offset by higher Insurance premiums.

Stock compensation expenses was $133,000 or $538,000 lower than recorded in the year 2001. The compensation reflects the imputed non-cash expense recorded to reflect the cost of warrants granted to outside parties for services rendered to us.

Equity Loss-Unconsolidated Affiliates

During the three months ended June 2002 and December 2002, we recorded a non-cash charge of $678,000 and $396,000 respectively, to operations with respect to our $1,074,000 investment in R.E.D. These charges were the result of our determination that R.E.D.'s business and financial position had

deteriorated to the point that our investment had been permanently impaired. Please see "Research And Development/Collaborative Agreements" in "Our Business" for more details on these transactions.

In May 2000, we acquired an equity interest in Chronix Biomedical Corp. ("Chronix") for $700,000. During the quarter ended December 31, 2002, we recorded a noncash 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 equity offerings. Please see "Research And Development/Collaborative Agreements" in "Our Business" for more details on these transactions.

In April, 1999 we acquired a 30% equity position in the California Institute of Molecular Medicine ("CIMM") for $750,000. During the fourth quarter

of 2001 we recorded a non-cash charge of $485,000 with respect to our investment in CIMM. This was a result of our determination that CIMM's operations have not yet evolved to the point where the full carrying value of our investment could be supported based on that company's financial position and operating results. This amount represented the unamortized balance of goodwill included as part of our investment. During 2002, CIMM continued to suffer significant losses resulting in a deterioration of its financial condition. The $485,000 written off during 2001 represented the un-amortized balance of goodwill included as part of our investment. Additionally, during 2001 we reduced our investment in CIMM based on our percentage interest in CIMM's continued operating losses. Our remaining investment at December 12, 2002 in CIMM, representing a 30% interest in CIMM's equity at such date, was completely written off during 2002. Such amount was not material.

These charges are reflected in the Consolidated Statements of Operations under the caption "Equity loss in unconsolidated affiliate." Please see "Research And Development/Collaborative Agreements" in "Our Business" for more details on these transactions.

Interest and Other Income

Interest and other income totaled $103,000 in 2002 compared to $284,000 recorded in 2001. Significantly lower interest rates on money market accounts and lower cash available for investment basically account for the difference. All funds in excess of our immediate need are invested in short term high quality securities, which earned much lower interest income in 2002.

Liquidity And Capital Resources

Cash used in operating activities for the twelve months ended December 31, 2003 was $7,022,000. Cash provided by financial activities for twelve months ended December 31, 2003 amounted to $10,317,000, substantially from proceeds from debentures (see below). As of December 31, 2003, we had approximately $5,260,000 in cash, cash equivalents and short term investments. We believe that these funds plus the net proceeds of approximately $3.7 million from the recently placed January 2004 Debentures, 2) the potential receipt of the $1.55 million of proceeds held back pending the acquisition of the ISI facility and pledging of such facility as additional security under the Debentures), 3) potential licensing fee income, 4) the $2,000,000 in proceeds we expect when the investors exercise their additional investment rights, and 5) and the projected revenue from the acquisition of the ALFERON N Injection(R) business will be sufficient to meet our operating requirements including debt service during the 2004 fiscal year. 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. If we do not timely complete the second ISI asset acquisition, our financial condition could be adversely affected (see the risk factor "If we do not complete the second Interferon Sciences asset acquisition, our ability to generate revenues from the sales of ALFERON N Injection(R) and our financial condition will be adversely affected").

On March 12, 2003, we issued an aggregate of $5,426,000 in principal amount of 6% Senior Convertible Debentures due January 2005 (the "March Debentures") and an aggregate of 743,288 warrants to two investors in a private placement for aggregate gross proceeds of $4,650,000. 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. These funds were released to us in June 2003 although we had not acquired ISI's facility at that time. The March Debentures were to mature on January 31, 2005 and bore interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest were valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Pursuant to the terms and conditions of the March Debentures, we pledged all of our assets, other than our intellectual property, as collateral and were subject to comply with certain financial and negative covenants, which include but were not limited to the repayment of principal balances upon achieving certain revenue milestones.

The March Debentures were convertible at the option of the investors at any time through January 31, 2005 into shares of our common stock. The conversion price under the March Debentures was fixed at $1.46 per share, subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect.

The investors also received Warrants to acquire at any time through March 12, 2008 an aggregate of 743,288 shares of common stock at a price of $1.68 per share. 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 is 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 total $5,426,000 principal of the March Debentures into 3,716,438 shares of our common stock. The total interest on the debenture was $111,711 of which $17,290 was paid in cash and $94,421 was paid by the issuance of shares of our common stock. The investor exercised 742,288 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 507,103 Warrants (the "July 2008 Warrants") to the same investors who purchased the March 12, 2003 Debentures, in a private placement for aggregate anticipated 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 released to us if, and only if, we acquired ISI's facility with in a set timeframe. These funds were released to us in October 2003 although we had not acquired ISI's facility at that time. The July Debentures mature on July 31, 2005 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date.

The July 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 new 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. In addition, in the event that we do not pay the redemption price at maturity, the Debenture holders, at their option, may convert the balance due at the lower of (a) the conversion price then in effect and (b) 95% of the lowest closing sale price of our common stock during the three trading days ending on and including the conversion date.

The July 2008 Warrants received by the investors, as amended, 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 January 26, 2004 and provide a mortgage on the facility as further security for the October Debentures. In March 2004, we acquired the facility and we are in the process of mortgaging the facility to the Debenture holders. 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.

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 have been held back pending our mortgaging of the ISI facility to the Debenture holders. We are in the process of providing this mortgage.

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.

As of March 18, 2004, the investors had converted $12,133,690 of debt from the March, July and October Debentures into 7,221,838 shares of our common stock. The remaining principal balance on the 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 December 31, 2003 have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of December 31, 2003. The cash collateral account provides partial security for repayment of the March, July and October 2003 and January 2004 Debentures in the event of default.

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. These shares have been registered for public sale. 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 exists.

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) in a private placement for aggregate net proceeds of $3,695,000. The January 2004 Debentures mature on January 31, 2006 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction

of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Commencing six months after issuance, we are required to start repaying the then outstanding principal amount under the January 2004 Debentures in monthly installments amortized over 18 months in cash or, at our option, in shares of common stock. Any shares of common stock issued to the investors as installment payments shall be valued at 95% of the average closing price of the common stock during the 10-day trading period commencing on and including the eleventh trading day immediately preceding the date that the installment is due.

The January 2004 Debentures are convertible at the option of the investors at any time through January 31, 2006 into shares of our common stock. The conversion price under the January 2004 Debentures 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. 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.

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.

We also issued to the investors Additional Investment Rights pursuant to which the investors have the right to acquire up to an additional $2,000,000 principal amount of January 2004 Debentures from us. These Debentures are identical to the January 2004 Debentures except that the conversion price is $2.58. The Additional Investment Rights 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 Additional Investment Rights is declared effective, whichever is longer.

We 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 Additional Investment Rights), the shares, and the January 2009 Warrants. The Registration Rights Agreement requires that we register 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 is not filed within the time period required by the agreement, not declared effective within the time period

required by the agreement or, after it is declared effective and subject to certain exceptions, sales of all shares required to be registered thereon cannot be made pursuant thereto, then we will be 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.

By agreement between us and the investors, the date upon which all warrants previously issued to the investors may become exercisable is now July 26, 2004 and the exercise periods of these warrants have been extended accordingly.

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 612,000 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 542,500 shares for public sale and have agreed to register the balance.

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 registered these shares for public sale and ISI has reported that it has sold all of these shares. We also agreed to pay ISI 6% of the net sales of ALFERON N Injection(R).

On March 11, 2003, we also entered into an agreement to purchase from ISI all of its rights to the product and other assets related to the product including, but not limited to, real estate and machinery. For these assets, we agreed to issue to ISI an additional 487,028 shares and to issue 314,465 shares and 267,296 shares, respectively to The American National Red Cross and GP Strategies Corporation, two creditors of ISI. We have guaranteed the market value of all but 62,500 of these shares to be $1.59 per share on the termination date. GP Strategies reports that it has sold all of its shares. The termination date for the remaining guarantees is 24 months after the date of issuance and delivery of the additional 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.

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

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 noted above, GP Strategies had sold all of its shares.

In addition, as of December 31, 2003, we have $200,000 in restricted cash under other letter of credit agreements required by our insurance carrier. 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 2005 Debentures and the related warrants, Dr. Carter agreed that he would not exercise his warrants or options unless and until our stockholders approve an increase in our authorized shares of common stock. For Dr. Carter's waiver of his right to exercise certain options and warrants prior to approval of the increase in our authorized shares, we agreed to compensate Dr. Carter. See "Executive Compensation; Employment Agreements" for details related to how Dr. Carter has been compensated with respect to this matter.

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

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.

Contractual Obligations

	(dollars in thousands) Obligations Expiring by Period			
Contractual Cash Obligations	Total	2004	2005-2006	2007-2008
Operating Leases	$ 784	$286	$ 433	$65

Convertible Debentures July 10, 2003 5,426,000 6% Senior Convertible Debenture	4,257	--	4,257	--
October 29, 2003 $4,142,000 6% Senior Convertible Debenture	2,334	--	2,334	--
Total	$7,375	$286	$7,024	$65

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 2005 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" for details related to how Dr. Carter has been compensated with respect to this matter.

In connection with the debenture agreements, we have 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.