HEMISPHERX BIOPHARMA INC
Form S-3/A
June 04, 2003

As filed with the Securities and Exchange Commission on June 4, 2003
Registration No. 333-104229

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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

PRE-EFFECTIVE AMENDMENT NO. 2 TO

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

HEMISPHERX BIOPHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

52-0845822
(I.R.S. Employer Identification No.)

1617 JFK Boulevard
Philadelphia, Pennsylvania 19103
(215) 988-0080

(Address, including zip code, and telephone number, including area code,
of registrant's principal executive offices)

William A. Carter, M.D., Chief Executive Officer
Hemispherx Biopharma, Inc.
1617 JFK Boulevard
Philadelphia, Pennsylvania 19103
(215) 988-0080

(Name, address, including zip code, and telephone number, including area code,
of agent for service)

Copies of all communications to:
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381 Park Avenue South, Suite 1601
New York, New York, 10016
(212) 779-8600

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Approximate date of proposed sale to the public: From time to time or at one time after the effective date of this Registration Statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. |_|

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 ("Securities Act"), other than securities offered only in connection with dividend or reinvestment plans, check the following box. |X|

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. |_|

If this form is a post-effective amendment filed pursuant to 462(c) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. |_|

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. |_|

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The Registrant hereby amends this registration statement on the date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on a date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be amended. Neither we nor the selling stockholders may sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where an offer or sale is not permitted.

Subject to Completion
Preliminary Prospectus Dated June 4, 2003

HEMISPHERX BIOPHARMA, INC.

7,457,591 Shares of Common Stock

The Offering:

This prospectus relates to the resale of 6,970,563 shares of common stock, which consist of 135% of 4,162,725 shares of common stock issuable upon the conversion, redemption or other payments relating to our 6% Senior Convertible Debentures Due 2005 ("Debentures") and as payment of interest thereon, 135% of 743,288 shares of common stock issuable upon the exercise of the related warrants ("Warrants") and 347,445 shares of common stock that are currently outstanding. All of these shares and Warrants were issued and sold pursuant to private placements to the selling stockholders listed on page 18 of this prospectus. We are registering these shares of common stock pursuant to commitments to register the shares 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 June 2, 2003 was $2.94.

Please see the risk factors beginning on page 3 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 June , 2003

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 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 emerged 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 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 patents apply to the use of Ampligen(R) in combination with certain other drugs. Some compositions of matter patents pertain to other new medications, which have a similar mechanism of action.

We have obtained from Interferon Sciences, Inc. all of its raw materials, work-in-progress and finished product Alferon N(R), together with a limited license to sell Alferon N(R), a natural alpha interferon that has been approved for commercial sale for the treatment of genital warts, in the United States. We intend to market the Alferon N(R) in the United State through sales facilitated via third party marketing agreements. Additionally, we intend to implement studies testing the efficacy of Alferon N(R) in multiple sclerosis and other chronic viral diseases.

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.

RISK FACTORS

Special Note Regarding Forward-Looking Statements

Certain statements in this document constitute "forwarding-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1995 (collectively, the "Reform Act"). Certain, but not necessarily all, of such forward-looking statements can be identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should," or "anticipates" or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. All statements other than statements of historical fact, included in this 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 declines any obligation to publicly release the results of any revisions which may be made to any forward-looking statement to reflect events or circumstances after the date of such statements or to reflect the occurrence of anticipated or unanticipated events.

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

ALFERON N Injection(R). Although ALFERON N Injection is approved for marketing for the treatment of genital warts, to date it has not been approved for other applications. 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 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 is only approved for the treatment of genital warts. Use of ALFERON N Injection for other applications will require regulatory approval. In this regard, Interferon Sciences, Inc., the Company from which we obtained our

rights to ALFERON N Injection, conducted clinical trials related to use of ALFERON N Injection 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 plans to conduct these additional studies at this time. Our principal development efforts are currently focused on Ampligen(R), which has not been approved for commercial use. 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 will be materially adversely effected.

We may continue to incur substantial losses and our future profitability is uncertain.

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses, as we pursued our clinical trial effort and expanded our efforts in Europe. As of March 31, 2003 our accumulated deficit was

approximately $101,000,000. 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 profitability.

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. Based upon our current operating plan, we anticipate that we will need approximately $5,400,000 over the next 12 months, inclusive of revenues and financing, to sustain our operations. In March 2003, we received $2,873,000 in initial net proceeds from the sale of the Debentures and Warrants and, pursuant to the terms of the Debentures, if and when we close on the second Interferon Sciences asset acquisition, we will receive additional net proceeds of $1,550,000. We anticipate receipt of revenues and proceeds from the sales of

Ampligen(R) under the Cost Recovery Clinical Programs and, possibly, funds from the exercise of outstanding non-public warrants. We also anticipate significant revenues from our recently acquired commercial product, Alferon N. As of June 2, 2003, we had approximately $2.9 Million in cash and short term investments. We believe that these funds plus 1) the anticipated infusion of approximately $1.55 million in remaining net proceeds from the Debenture placement and 2) the projected net cash flow from the sale of ALFERON N should be sufficient to meet our operating requirement for the next 12 months. We may need to raise additional funds through additional equity or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes and begin commercializing Ampligen(R) products. There can be no assurances that we will raise adequate funds from these or other sources, which may have a material effect on our ability to develop our products. In addition, if we do not timely complete the second ISI asset acquisition, our financial condition could be materially and adversely affected (see the next risk factor).

If we do not complete the second Interferon Sciences asset acquisition, our ability to generate revenues from the sale of ALFERON N Injection and our financial condition will be adversely affected.

In March, 2003 we executed two agreements with Interferon Sciences, Inc. ("ISI") to purchase certain assets of ISI. In the first agreement we acquired ISI's inventory of ALFERON N Injection(R) and a limited license for the production, manufacture, use, marketing and sale of this product. Our ability to generate sustained revenues from sales of this product is dependent, among other things, on our completing the terms of the second agreement to acquire the balance of ISI's rights to its product as well as ISI's production facility used to formulate and purify the drug concentrate of ALFERON N Injection(R). In addition, pursuant to the terms of the Debentures, we are required to acquire ISI's facility within 90 days from March 12, 2003 and, unless and until we acquire the facility, $1,550,000 of the proceeds from the sale of the

Debentures has been held back. Consummation of the second agreement requires, among other things, approval by ISI's shareholders and certain environmental approvals with regard to the sale of the facility. As of the date hereof, it is probable that either or both approvals may not be obtained within the required 90 day period. Our failure to complete the acquisition within the 90 day period will be a technical default of the terms of the Debentures and, absent consent from the Debenture holders for additional time, most likely would result in our having to redeem the securities. If we do not receive the additional Debenture funds as planned and, especially if we are required to redeem the Debentures, our financial condition would be materially and adversely affected and we would probably have to reduce or possibly curtail operational spending including some critical clinical effort. In addition, although we have not yet completed the acquisition, we issued an aggregate of 581,761 shares to GP Strategies and the American National Red Cross, two creditors of ISI, as partial consideration for the acquisition and we may be required to repurchase some or all of these shares in the future at $1.59 per share (see the risk factor "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 18 months after the dates of issuance of the guaranteed shares, our financial condition could be adversely affected" below). If we do not complete the acquisition, we will look to ISI to pay us the value of the shares that we issued to these two creditors. No assurance can be given that we will be able to so recoup the value of these shares.

The limited number of unissued and unreserved authorized shares of Common Stock severely restricts our ability to raise funds through the sale of our securities.

We have 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. As of June 2, 2003, only approximately 700,000 shares of our authorized shares of Common Stock will not be issued or reserved for issuance. Unless and until we are able to increase the number of authorized shares of Common Stock, our ability to raise funds through the sale of Common Stock or instruments that are convertible into or exercisable for Common Stock will be severely restricted. Although we intend to ask our stockholders at our next annual meeting to approve an amendment to our Certificate of Incorporation to increase the shares of Common Stock we are authorized to issue, we cannot assure you that we will be able to obtain this approval.

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 18 months after the dates of issuance of the guaranteed shares, our financial condition could be adversely affected.

In March 2003 we issued 487,028 shares to Interferon Sciences and, upon the completion of the second Interferon Sciences asset acquisition, we will issue an additional 487,028 shares to Interferon Sciences. In May 2003, we issued an aggregate of 581,761 shares to two of Interferon Sciences' creditors. We anticipate, but cannot assure, that we will close the second Interferon Sciences asset acquisition by August, 2003. We have guaranteed the value of up to 1,430,817 of these shares to be $1.59 per share or $2,275,000 in the aggregate on the relevant termination dates. The termination dates are 18 months after the dates of issuance of the guaranteed shares to ISI and GP Strategies, 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 Interferon Sciences and the two creditors 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 1,430,817 shares are still held on the relevant termination dates, we would be obligated to pay to Interferon Sciences and these two creditors an aggregate of $2,275,000. The reported last sale price for our common stock on the American Stock Exchange

on June 2, 2003 was $2.94 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 18 month period 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, 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, Interferon Sciences, Inc. has a patent for Natural Alpha Interferon produced from human peripheral blood leukocytes and its production process and has additional patent applications pending. We will acquire this patent and related patent applications if and when we close on the second Interferon Sciences asset acquisition We cannot assure you that any of these applications will be approved or that our competitors will not seek and obtain patents regarding the use of our products in combination with various other agents, for a particular target indication prior to us. If we cannot protect our patents covering the use of our products for a particular disease, or obtain additional pending 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 the 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 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 product successfully, we may not generate significant revenues or become profitable.

We have limited marketing and sales capability. We need to enter into marketing agreements and third party distribution agreements for our products in order to generate significant revenues and become profitable. To the extent that we enter into co-marketing or other licensing arrangements, any revenues received by us will be dependent on the efforts of third parties, and there is no assurance that these efforts will be successful. Our agreement with Gentiva Health Services offers the potential to provide significant marketing and distribution capacity in the United States while licensing and marketing agreements with certain foreign

firms should provide an adequate sales force in South America, Africa, United Kingdom, Australia and New Zealand, Canada, Austria, Spain and Portugal.

We cannot assure that our domestic or our foreign marketing partners will be able to successfully distribute our products, or that we will be able to establish future marketing or third party distribution agreements on terms acceptable to us, or that the cost of establishing these arrangements will not exceed any product revenues. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a materially adverse effect on us.

No Guaranteed Source Of Required Materials.

A number of essential materials are used in the production of ALFERON N

Injection, including human white blood cells, and we have a limited number of sources from which to obtain such materials. 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. The costs and availability of products and materials we need for the commercial production of ALFERON N Injection 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 is manufactured in Interferon Science's facility and ALFERON N Injection is formulated and packaged at a production facility operated by

Abbott. if and when we close on the second Interferon Sciences asset acquisition, we will acquire this 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.

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 and we have no knowledge of any ME/CFS drugs being developed by others. The dominant competitors with drugs to treat HIV diseases include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs and Schering-Plough Corp. ("Shering"). 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 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 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 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. 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, two 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 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. Currently, Interferon Sciences' wholesale price on a per unit basis of ALFERON N Injection is substantially 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 could adversely effect 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, irregular heart rate, decreased visual activity 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 effect potential revenues and physician/patient acceptability of our product.

ALFERON N Injection(R). At present, ALFERON N Injection is only sold for the intralesional (with in 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, 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 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 effected from the litigation costs, settlement expenses and lost product sales inherent to these claims. While we will continue to attempt to take appropriate precautions, we cannot assure that we will avoid significant product liability exposure. Although we currently maintain 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. 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, clinical trials. The loss of Dr. Carter's services could have a material adverse effect on our operations and chances for success. While we have an employment agreement with Dr. Carter, and have secured key man life insurance in the amount of $2 million on the life of Dr. Carter, the loss of Dr. Carter or other 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, 2002, the price of our common stock has ranged from $0.74 to $4.95. We expect the price of our common stock to remain volatile. The average daily trading volume in 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, are sold in the public market.

As of June 2, 2003, approximately 1,416,206 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act of 1933. In addition, we have registered 5,967,820 shares issuable upon the conversion of 135% of the Debentures and as payment of interest thereon. All but 1,068,789 of the issued restricted shares are registered herein pursuant to agreements between us and the purchasers in our recent private placements, requiring us to register their shares for resale under the Securities Act and we are obligated to register the balance in the future. Registration of the shares permits the sale of the shares of common stock in the open market or in privately negotiated transactions without compliance with the requirements of Rule 144. In addition, as of June 2, 2003, we had options and warrants outstanding for the purchase of an aggregate of approximately 9,115,914 shares of our common stock, which includes 135% of the shares issuable upon exercise of the Warrants. To the extent the exercise price of the options and warrants is less than the market price of the common stock, the holders of the options

and 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. Moreover, we anticipate that we will be issuing and registering for public resale 487,028 shares if and when we acquire additional assets from Interferon Sciences, Inc. and, possibly, additional shares to raise funding or 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 William A. Carter, M.D., our chief executive officer, who already beneficial owns 11.4% of the 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.

LEGAL PROCEEDINGS

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

In June 2002, a former ME/CFS clinical trial patient and her husband filed a claim in the Superior Court of New Jersey, Middlesex County, against us, one of our clinical trial investigators and others alleging that she was harmed in the ME/CFS clinical trial as a result of negligence and breach of warranties. We believe the claim is without merit and we are defending the claim against us through our product liability insurance carrier.

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

In July 2002, we filed suit against Federal Insurance Company ("Federal") seeking (1) a judicial order declaring our rights and the obligations of Federal under the insurance policy Federal sold to us (2) monetary damage for breach of contract resulting from Federal's refusal to fully defend us in connection with the Asensio litigation (3) monetary damages to compensate us for Federal's breach of its fiduciary duty faith and dealing and (4) monetary damages, interest,

costs, and attorneys fees to compensate us for Federal's violation of the Pennsylvania Bad Faith Statute. On March 31, 2003 we settled our outstanding claim with our insurance company relating to reimbursement of expenses in connection with our Asensio law suits. The net settlement amount of approximately $1,050,000 is recorded as a reduction in General and Administrative expenses in our statement of operations for the year ended December 31, 2002.

In March 2003, the law firm of Schnader, Harrison, Segal & Lewis, LLP filed a complaint in the Court of Common Pleas of Philadelphia County against us for alleged legal fees in the sum of $65,051. We believe the claim is without merit and we are defending the claim.

DIVIDEND POLICY

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

SELLING STOCKHOLDERS

We are registering all 6,970,563 shares of common stock covered by this prospectus on behalf of the selling stockholders named in the table below. We issued the shares, the Debentures convertible into shares, and the Warrants exercisable for shares to the selling stockholders in private placements. We have registered the shares to permit the selling stockholders and their respective transferees, assignees or other successors-in-interest that receive their shares from a selling stockholder to resell the shares, from time to time, when they deem appropriate.

The table below identifies the selling stockholders and other information regarding the beneficial ownership of the common stock held by each of the selling stockholders. For the Debenture holders (the first two stockholders listed below), the second column lists the number of shares of common stock beneficially owned by each selling stockholder as of May 16, 2003, based on each selling stockholder's ownership of Debentures and Warrants, and assumes the

conversion of all the Debentures and the exercise of all Warrants. Because the conversion price of the Debentures and the exercise price of the Warrants are subject to adjustment for anti-dilution protection, the interest on the Debentures may be paid in cash or common stock, and the value attributed to any shares issued to the investors as interest (the "Interest Shares") depends on 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, and the number of repayment shares depends on the amount of our consolidated revenues, the numbers listed in the second column may change. For the other selling stockholder, the second column lists the number of shares of common stock beneficially owned by the selling stockholder as of June 2, 2003, based on each selling stockholder's ownership of shares of common stock, and does not assume the conversion of any of the Debentures, the exercise of any Warrants or the payment of any interest on the Debentures in the form of common stock rather than cash.

The third column lists each selling stockholder's portion, based on agreements with us, of the 6,970,563 shares of common stock being offered by this prospectus. With regard to the first two selling stockholders, the number of shares being offered by this prospectus was determined in accordance with the terms of the registration rights agreement with them, in which we agreed to register the resale of 135% of (x) the number of shares of common stock issuable upon conversion of the Debentures, plus (y) the number of shares of common stock issuable upon exercise of the related Warrants, plus (z) an estimate of the number of Interest Shares that may be issued to the selling stockholders as interest payments on the Debentures (assuming interest is paid exclusively in Interest Shares over the full term of the Debentures, rather than in cash). As we stated above, the number of shares that will actually be issued may be more or less than the 6,970,563 shares being offered by this prospectus.

Under the terms of the Debentures and the Warrants, no selling stockholder who owns Debentures or Warrants may convert such Debentures or exercise its Warrants to the extent that the conversion or exercise would cause the selling stockholder, together with its affiliates, to beneficially own more than 4.99% of the shares of our then outstanding common stock following such conversion or exercise. For purposes of making this determination, shares of common stock issuable upon conversion of the Debentures which have not been converted and upon exercise of the related Warrants which have not been exercised are excluded. The number of shares in the second and third columns does not reflect this limitation.

Any selling stockholder may sell all, some or none of its respective shares in this offering. See "How The Shares May Be Distributed" below.

Selling Stockholder	Common Stock Owned Prior To Offering	No. of Shares Being Offered	Common Stock Owned After The Offering
Portside Growth & Opportunity Fund	2,229,863(1)	3,311,559	--
Leonardo L.P.	2,229,863(2)	3,311,559	--
Provesan SA	347,445	347,445	--

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(1) Represents (a) up to 1,858,219 shares of common stock issuable upon conversion of the Debentures and (b) up to 371,644 shares of common stock issuable upon exercise of the Warrants. Ramius Capital Group, LLC ("Ramius Capital") is the investment adviser of Portside Growth & Opportunity Fund ("Portside") and consequently has voting control and investment discretion over securities held by Portside. Ramius Capital disclaims beneficial ownership of the shares held by Portside. Peter A. Cohen, Morgan B. Stark and Thomas W. Strauss are the sole managing members of C4S& Co., LLC, the sole managing member of Ramius Capital. As a result, Messrs. Cohen, Stark and Strauss may be considered beneficial owners of any shares deemed to be beneficially owned by Ramius Capital. Messrs. Cohen, Stark and Strauss disclaim beneficial ownership of these securities.

(2) Represents (a) up to 1,858,219 shares of common stock issuable upon conversion of the Debentures and (b) up to 371,644 shares of common stock issuable upon exercise of the Warrants. Angelo, Gordon & Co., L.P. ("Angelo, Gordon") is the sole director of the general partner of Leonardo, L.P. ("Leonardo") and consequently has voting control and investment discretion over securities held by Leonardo. Angelo, Gordon disclaims beneficial ownership of the shares held by Leonardo. Mr. John M. Angelo, the Chief Executive Officer of Angelo, Gordon, and Mr. Michael L. Gordon, the Chief Operating Officer of Angelo, Gordon, are the sole general partners of AG Partners, L.P., the sole general partner of Angelo, Gordon. As a result, Messrs. Angelo and Gordon may be considered beneficial owners of any shares deemed to be beneficially owned by Angelo, Gordon. Messrs. Angelo and Gordon disclaim beneficial ownership of these securities.

The selling stockholders have not been employed by, held office in, or had any other material relationship with us or any of our affiliates within the past three years except as described below.

March 2003 Issuance Of 6% Senior Convertible Debentures Due January 31, 2005.

On March 12, 2003, We issued an aggregate of $5,426,000 in principal amount of 6% Senior Convertible Debentures due January 31, 2005 and an aggregate of 743,288 Warrants to investors in a private placement for aggregate anticipated gross proceeds of $4,650,000. The investors include Portside Growth & Opportunity Fund and Leonardo, L.P. The Debentures mature on January 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 Debentures are 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 Debentures is 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 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 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.

We entered into a registration rights agreement with the investors in connection with the issuance of the Debentures and the Warrants. The registration rights agreement requires that we

register the shares of common stock covered by this registration statement. If the registration statement 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.

March 2003 Acquisition of Assets From Interferon Sciences, Inc.

On March 11, 2003, we acquired from Interferon Sciences, Inc. ("ISI"), ISI's inventory of ALFERON N Injection(R), a pharmaceutical product used for the treatment of certain types of genital warts, and a limited license for the production, manufacture, use, marketing and sale of this product. As partial consideration, we issued 487,028 shares of our common stock to ISI Pursuant to our agreements with ISI, we have agreed to register the foregoing shares for public sale.

Except for 62,500 of the shares issued to ISI, we have guaranteed the market value of the shares retained by ISI as of September 11, 2005, the termination date, to be $1.59 per share. ISI is permitted to periodically sell certain amounts of its shares. If, within 30 days after the termination date, holders of the guaranteed shares request that we honor the guarantee, we will be obligated to reacquire the holders' remaining guaranteed shares and pay the holders $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 18 months after the dates of issuance of the guaranteed shares, our financial condition could be adversely affected" in "Risk Factors," above.

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 have 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 on terms substantially similar to those for the initial acquisition of the ISI assets. The termination date for these guarantees is 18 months after the date of issuance of the guaranteed shares to ISI and GP Strategies, and 12 months after the date of issuance of the guaranteed shares to the American National Red Cross. 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 agreed to register the foregoing shares for public sale.

March 2003 Issuance of Our Shares in Exchange for Outstanding Preferred Equity Certificates of Our Luxembourg Subsidiary.

On March 13, 2003, we issued 347,445 shares of our common stock to Provesan SA, an affiliate of Laboratorios Del Dr. Esteve S.A. ("Esteve"), in exchange for 1,000,000 Euros of convertible preferred equity certificates of our Luxembourg subsidiary, Hemispherx Biopharma

Europe, S.A., owned by Esteve. We agreed to register the shares issued to Provesan SA, and we have registered these shares for public sale in this prospectus.

Our European subsidiary, Hemispherx Biopharma Europe, S.A. ("Hemispherx, S.A.") entered into a Sales and Distribution agreement with Esteve, pursuant to which Esteve was granted the exclusive right to market Ampligen(R) in Spain, Portugal and Andorra for the treatment of Myalgic/Chronic Fatigue Syndrome ("ME/CFS"). In addition to other terms and other projected payments, Esteve paid an initial and non-refundable fee of 625,000 Euros (approximately $545,000) to Hemispherx S.A. on April 24, 2002. Esteve is to pay a fee of 1,000,000 Euros after U.S. Food and Drug Administration approval of Ampligen(R) for the treatment of ME/CFS and a fee of 1,000,000 Euros upon Spain's approval of the final marketing authorization for using Ampligen(R) for the treatment of ME/CFS.

The agreement runs for the longer of 10 years from the date of first arms-length sale in the territory, the expiration of the last Hemispherx patent exploited by Esteve or the period of regulatory data protection for the product in the applicable territory. Esteve is required to purchase certain minimum annual amounts of the product. The agreement is terminable by either party if the product is withdrawn form the territory for a specified period due to serious adverse health or safety reasons; bankruptcy, insolvency or related issues of one of the parties; or material breach of the agreement. Hemispherx may transform the agreement into a non-exclusive agreement or terminate the agreement in the event that Esteve does not meet specified percentages of its annual minimum purchase requirements under the agreement. Esteve may terminate the agreement in the event that Hemispherx fails to supply the product to the territory for a specified period of time or certain clinical trials being conducted by Hemispherx are not successful.

HOW THE SHARES MAY BE DISTRIBUTED

The shares to be sold in this offering are in the process of being listed on the American Stock Exchange, subject to official notice of issuance. The selling stockholders may sell their shares of common stock from time to time in various ways and at various prices. The common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions that may involve crosses or block transactions. Some of the methods by which the selling stockholders may sell the shares include:

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;

- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;

- privately negotiated transactions;
- block trades in which the broker or dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker or dealer as principal and resale by that broker or dealer for the selling stockholder's account under this prospectus;
- sales under Rule 144 rather than by using this prospectus;
- through the settlement of short sales;
- a combination of any of these methods of sale; or
- any other legally permitted method.

In connection with sales of the common stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the common stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of common stock short and deliver shares of common stock to close out short positions, provided that the selling stockholders may not close out short positions entered into prior to the effective date of the registration statement of which this prospectus is a part with any shares of common stock included in this prospectus. The selling stockholders may also pledge their shares as collateral for a margin loan under their customer agreements with their brokers. If there is a default by the selling stockholders, the brokers may offer and sell the pledged shares from time to time under this prospectus or an amendment to this prospectus under Rule 424(b)(3) or other applicable provisions of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

Brokers or dealers may receive commissions or discounts from the selling stockholders (or, if the broker-dealer acts as agent for the purchaser of the shares, from that purchaser) in amounts to be negotiated. These commissions may exceed those customary in the types of transactions involved.

We cannot estimate at the present time the amount of commissions or discounts, if any, that will be paid by the selling stockholders in connection with sales of the shares.

The selling stockholders and any broker-dealers or agents that participate with the selling stockholders in sales of the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In that event, any commissions received by the broker-dealers or agents

and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of the shares of common stock. There is no underwriter or coordinating broker acting in connection with the proposed sale of shares by the selling stockholders. In addition, each of the investors has advised us that:

- it purchased the shares in the ordinary course of business; and

- at the time of the purchase of the shares to be resold, it had no agreements or understandings, directly or indirectly, with any person to distribute the shares.

Under the securities laws of certain states, the shares may be sold in those states only through registered or licensed broker-dealers. In addition, the shares may not be sold unless the shares have been registered or qualified for sale in the relevant state or unless the shares qualify for an exemption from registration or qualification.

We do not know whether any selling stockholder will sell any or all of the shares of common stock registered by the shelf registration statement of which this prospectus forms a part.

We have agreed to pay all fees and expenses incident to the registration of the shares, including certain fees and disbursements of counsel to the selling stockholders. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Certain of the selling stockholders have also agreed to indemnify us, our directors, officers, agents and representatives against certain liabilities, including certain liabilities under the Securities Act.

The selling stockholders and other persons participating in the distribution of the shares offered under this prospectus are subject to the applicable requirements of Regulation M promulgated under the Exchange Act in connection with sales of the shares.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus is a part effective until all the shares registered under the registration statement have been resold.

USE OF PROCEEDS

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

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file at the Securities and Exchange Commission's public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the public reference rooms. Many of our Securities and Exchange Commission filings are also available to the public from the Securities and Exchange Commission's Website at "http://www.sec.gov."

We have filed with the Securities and Exchange Commission a registration statement (which contains this prospectus) on Form S-3 under the Securities Act of 1933. The registration statement relates to the securities offered by the selling stockholders. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Please refer to the registration statement and its exhibits and schedules for further information with respect to us, the common stock and the Warrants. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of that contract or document filed as an exhibit to the Registration Statement. You may read and obtain a copy of the registration statement and its exhibits and schedules from the SEC, as described in the preceding paragraph.

INFORMATION INCORPORATED BY REFERENCE

The Commission allows us to "incorporate by reference" the information that we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the Commission will automatically update and supercede this information. We incorporate by reference the following documents and any future filing made with the Commission under Sections 13(a), 14 or 15(d) of the Securities Exchange Act of 1934 until we and the selling stockholders sell all the securities included in this prospectus:

(a) Our amended annual report on Form 10-K for our fiscal year ended December 31, 2002, File No. 0-27072.

(b) Our quarterly report on Form 10-Q for the quarterly period ended March 31, 2003.

(c) Our current report on Form 8-K filed on March 13, 2003, File No. 0-27072.

(d) Our proxy statement on schedule 14A for our 2002 annual meeting, File No. 0-27072.

(e) A description of our common stock contained in our registration statement on Form S-1, File No. 33-93314, and any amendment or report filed for the purpose of updating this description filed subsequent to the date of this prospectus and prior to the termination of this offering.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address: Hemispherx Biopharma, Inc., 1617 JFK Boulevard, Philadelphia, Pennsylvania 19103, telephone number 215-988-0080.

You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. We and the selling stockholders will not make offers to these shares in any state

where the offer is not permitted. You should not assume that the information in this prospectus or any supplement is accurate as of any date other that the date

on the front of those documents.

DESCRIPTION OF SECURITIES

The following section does not purport to be complete and is qualified in all respects by reference to the detailed provisions of our certificate of incorporation and by-laws, as amended, copies of which have been filed with the Securities and Exchange Commission.

Our authorized capital stock consist of: (i) 50,000,000 shares of common stock, $.001 par value; and (ii) 5,000,000 shares of preferred stock, .01 par value. 33,778,942 shares of common stock were issued and outstanding as of the date of this prospectus. As of this date, there were approximately 212 record holders 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.

Common Stock

Shares of our common stock are entitled to one vote per share, either in person or by proxy, on all matters that may be voted upon by the owners of our shares at meetings of our stockholders. There is no provision for cumulative voting with respect to the election of directors by the holders of common stock. Therefore, the holder of more than 50% of our shares of outstanding common stock can, if they choose to do so, elect all of our directors. In this event, the holders of the remaining shares of common stock will not be able to elect any directors.

The holders of common stock:

- have equal rights to dividends from funds legally available therefore, when and if declared by our board of directors;
- are entitled to share ratably in all of our assets available for distribution to holders of common stock upon liquidation, dissolution or winding up of our affairs; and
- do not have preemptive rights, conversion rights, or redemption of sinking fund provisions.

The outstanding shares of our common stock are duly authorized, validly issued, fully paid and nonassessable.

Preferred Stock.

Under our certificate of incorporation, as amended, our board of directors is authorized, subject to certain limitations prescribed by law, without further stockholder approval, from time to time to issue up to an aggregate of 5,000,000 shares of preferred stock. At this time, there are no preferred shares outstanding.

TRANSFER AGENT AND REGISTRAR

The transfer agent and registrar for our common stock and warrants is Continental Stock Transfer and Trust Co., 17 Battery Place, 8th Floor, New York, New York 10004.

LEGAL MATTERS

The validity of the common stock offered in this prospectus has been passed upon for us by Silverman Sclar Byrne Shin & Byrne P.C., 381 Park Avenue South, Suite 1601, New York, New York 10016.

EXPERTS

The consolidated financial statements incorporated by reference in this prospectus have been audited by BDO Seidman, LLP, independent certified public accountants, to the extent and for the periods set forth in the report of such firm incorporated herein by reference and, are incorporated herein in reliance upon such report given upon the authority of such firm as experts in auditing and accounting.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the Commission this indemnification is against public policy as expressed in the Securities Act and is, therefore unenforceable. In the event that a claim for indemnification against these liabilities, other than our payment of expense incurred or paid by one of our directors, officers, or controlling persons in the successful defense of any action, suit or proceeding, is asserted by that director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by a controlling precedent, submit to a court of appropriate jurisdiction the question whether this indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of these issues.

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No dealer, salesman or any other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell these securities and it is not a solicitation of an offer to buy these securities in any state where the offer or sale is not permitted. The information contained in this Prospectus is current only as of this date.

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6,970,563 SHARES OF
COMMON STOCK

HEMISPHERX BIOPHARMA, INC.

PROSPECTUS

June ___, 2003

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

SEC Filing Fees	$ 925.00
American Stock Exchange Listing Fee*	$17,500.00
Printing and Engraving Expenses*	$ 2,500.00
Accounting Fees and Expenses*	$10,000.00
Legal Fees and Expenses*	$12,500.00
Transfer Agent and Registrar Fees*	$ 1,500.00
Miscellaneous*	$ 3,075.00
Total Expenses*	$48,000.00

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* Estimated.

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Our Amended and Restated Certificate of Incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for (i) any breach of their duty of loyalty to the corporation or its stockholders, (ii) acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (iii) unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law or (iv) any transaction from which the director derives an improper personal benefit.

ITEM 16. EXHIBITS.

Exhibit No. Description

2.1 First Asset Purchase Agreement dated March 11, 2003, by and between the Company and ISI.*

2.2 Second Asset Purchase Agreement dated March 11, 2003, by and between the Company and ISI.*

5.1 Opinion of Silverman Sclar Byrne Shin & Byrne P.C., legal counsel.**

10.1 Forbearance Agreement dated March 11, 2003, by and between ISI, the American National Red Cross and the Company.*

10.2 Forbearance Agreement dated March 11, 2003, by and between ISI, GP Strategies Corporation and the Company.*

10.3 Securities Purchase Agreement, dated March 12, 2003, by and among the Company and the Buyers named therein.*

10.4 Form of 6% Convertible Debenture of the Company.*

10.5 Form of Warrant for Common Stock of the Company.*

10.6 Registration Rights Agreement, dated March 12, 2003, by and among the Company and the Buyers named therein.*

23.1 Consent of BDO Seidman, LLP, independent certified public accountants.

23.2 Consent of Silverman Sclar Byrne Shin & Byrne P.C., legal counsel (included in Exhibit 5.1).**

24.1 Powers of Attorney (included in Signature Pages to this Registration Statement on Form S-3).**

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* Incorporated by reference from the exhibits to the Company's Current Report on Form 8-K filed on March 13, 2003.

** Previously filed.

ITEM 17. UNDERTAKINGS

(a) Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Securities Act") may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter

has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(b) The undersigned registrant hereby undertakes that for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) We, the undersigned Registrant hereby undertake:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to the Registrant Statement to:

(i) Include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) Reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) that individually or in the aggregate represent a fundamental change in the information set forth in the Registration Statement; and

(iii) Include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

provided, however, that paragraphs (i) and (ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the Registration Statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

SIGNATURES

Pursuant to the requirement of the Securities Act of 1933, this Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Amendment No. 2 to

the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Philadelphia, Commonwealth of Pennsylvania, on the 4th day of June, 2003.

HEMISPHERX BIOPHARMA, INC.
(Registrant)

By: /s/ William A. Carter

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

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 2 to the Registration Statement has been signed by the following persons in the capacities indicated on the dates indicated.

Signature	Title	D
/s/ William A. Carter William A. Carter, M.D.	Chairman of the Board, Chief Executive Officer (Principal Executive) and Director	June
* Richard Piani	Director	June
* Robert E. Peterson	Chief Financial Officer and Chief Accounting Officer	June
* Ransom Etheridge	Secretary And Director	June
* William Mitchell, M.D., Ph.D.	Director	June

* By: /s/ William A. Carter

William A. Carter, M.D.,
Attorney-in-Fact

Hemispherx Biopharma, Inc.
Form S-3
Index to Exhibits

Exhibit No. Description

23.1 Consent of BDO Seidman, LLP, independent certified public accountants.