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HEMISPHERX BIOPHARMA INC

Form S-3

September 15, 2004

As filed with the Securities and Exchange Commission on September 15, 2004  
Registration No. 333-\_\_\_\_\_

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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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

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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.)

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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)

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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:  
Richard Feiner, Esq.  
Silverman Sclar Shin & Byrne PLLC  
381 Park Avenue South, Suite 1601  
New York, New York, 10016  
(212) 779-8600  
Fax (212) 779-8858

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

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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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CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share (4)	Propo Aggre Price
Common Stock	3,617,306 (1)	\$2.56	\$
Common Stock	1,085,193 (2) (3)	\$2.86	\$
Common Stock	150,480 (2) (3)	\$2.08	\$
Total Registration Fee			

- (1) Represent shares owned by certain selling stockholders.
- (2) Represent shares issuable upon exercise of warrants owned by certain selling stockholders.
- (3) Pursuant to Rule 416 of the Securities Act of 1933, there are also being registered an indeterminate number of additional shares of common stock as may become offered, issuable or sold to prevent dilution resulting from stock splits, stock dividends or similar transactions.

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- (4) Estimated solely for the purpose of computing the registration fee in accordance with Rules 457(c) of the Securities Act based on the closing price of the shares of common stock of the Registrant reported on the American Stock Exchange on September 8, 2004.

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.

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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 September 15, 2004

HEMISPHERX BIOPHARMA, INC.

4,852,979 Shares of Common Stock

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### The Offering:

This prospectus covers 4,852,979 shares of common stock that may be offered for resale by the selling stockholders named in on page 16 of this prospectus and the persons to whom such selling stockholders may transfer their shares. No securities are being offered or sold by us pursuant to this prospectus. The selling stockholders acquired the common stock and the warrants to purchase common stock directly from us in transactions exempt from the registration requirements of federal and state securities laws. We will not receive any of the proceeds from the sale of these shares by the selling stockholders, but we will receive proceeds from the cash exercise of warrants, if any.

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 September 14, 2004 was \$2.46.

The selling stockholders may sell their shares from time to time on the American Stock Exchange or otherwise, in one or more transactions at fixed prices, at prevailing market prices at the time of sale or at prices negotiated with purchasers. The selling stockholders will be responsible for any commissions or discounts due to brokers or dealers. We will pay substantially all expenses of registration of the shares covered by this prospectus.

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Please see the risk factors beginning on page 3 to read about certain factors you should consider before buying shares of common stock.

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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 September \_\_, 2004

## PROSPECTUS SUMMARY

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a "shelf" registration statement. The selling stockholders may from time to time sell their shares of our common stock in one or more transactions. This prospectus provides you with a general description of the common stock being offered. You should read this prospectus, including all documents incorporated herein by reference, together with additional information described under the heading "Where You Can Find More Information."

The registration statement that contains this prospectus, including the exhibits to the registration statement, contains additional information about us and the securities being offered under this prospectus. You should read the registration statement and the accompanying exhibits for further information. The registration statement and exhibits can be read and are available to the public over the Internet at the SEC's website at <http://www.sec.gov> as described under the heading "Where You Can Find More Information."

### 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. We recently completed a phase III clinical trial in the U.S. for use of Ampligen in treatment of ME/CFS and are in the process of assembling and analyzing the obtained data preparatory to completing and filing a New Drug Application("NDA") with the U.S. Food and Drug Administration("FDA"). We are also testing Ampligen in Phase IIb Clinical Trials in the U.S. for the treatment of newly emerging multi-drug resistant HIV, and for the induction of cell mediated immunity in HIV patients that are under control using potentially toxic drug cocktails.

Our proprietary drug technology utilizes specifically configured ribonucleic acid ("RNA") and is protected by more than 250 patents worldwide, with over 16 additional patent applications pending to provide further proprietary protection in various international markets. Certain patents apply to the use of Ampligen(R) alone and certain patents apply to the use of Ampligen(R) in combination with certain other drugs. Some compositions of matter patents pertain to other new RNA compounds, which have a similar mechanism of action.

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

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together with a limited license to sell ALFERON N Injection(R), a natural alpha interferon that has been approved for commercial sale for the intralesional treatment of refractory or recurring external condylomata

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acuminata ("genital warts") in patients 18 years of age or older in the United States. In March 2004, we acquired from ISI the balance of ISI's rights to its product as well as ISI's production facility. We are marketing the ALFERON N Injection(R) in the United States through sales facilitated via third party agreements. Additionally, we intend to implement studies testing the efficacy of ALFERON N Injection(R) in multiple sclerosis and other chronic viral diseases. In this regard, the FDA recently authorized a Phase II clinical study designed to investigate the activity and safety of Alferon LDO(R) in early stage HIV positive patients.

Our principal executive offices are located at One Penn Center, 1617 JFK Boulevard, Philadelphia, Pennsylvania 19103, and its telephone number is 215-988-0080.

### Securities Offered

We are registering for resale by the selling stockholders 3,617,306 shares of our common stock initially acquired directly from us in transactions exempt from the registration requirements of federal and state securities laws. In addition, we are registering for resale 1,235,673 shares of our common stock issuable upon exercise of warrants outstanding on the date hereof. We are also registering for resale any additional shares of common stock which may become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration, which results in an increase in the number of outstanding shares of our common stock.

### RISK FACTORS

#### Special Note Regarding Forward-Looking Statements

Certain statements in this prospectus constitute "forward-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

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actual results, performance or achievements of Hemispherx and its subsidiaries to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements and other factors referenced in this prospectus. We do not undertake and specifically decline any obligation to publicly release the results of any revisions which may be made to any forward-looking statement to reflect events or circumstances after the date of such statements or to reflect the occurrence of anticipated or unanticipated events.

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

No assurance of successful product development

Ampligen(R) and related products. The development of Ampligen(R) and our other related products is subject to a number of significant risks. Ampligen(R) may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale, be uneconomical to market or be precluded from commercialization by proprietary right of third parties. Our products are in various stages of clinical and pre-clinical development and, require further clinical studies and appropriate regulatory approval processes before any such products can be marketed. We do not know when, if ever, Ampligen(R) or our other products will be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the U.S. Food and Drug Administration ("FDA") for commercial sale.

ALFERON N Injection(R). Although ALFERON N Injection(R) is approved for marketing in the United States for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older, to date it has not been approved for other indications. We face many of the risks discussed above, with regard to developing this product for use to treat other ailments such as multiple sclerosis and cancer.

Our drug and related technologies are investigational and subject to regulatory approval. If we are unable to obtain regulatory approval, our operations will be significantly affected.

All of our drugs and associated technologies other than ALFERON N Injection(R) are investigational and must receive prior regulatory approval by appropriate regulatory authorities for general use and are currently legally available only through clinical trials with specified disorders. At present, ALFERON N Injection(R) is only approved for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of ALFERON N Injection(R) for other indications will require regulatory approval. In this regard, Interferon Sciences, Inc. ("ISI"), the company from which we obtained our rights to ALFERON N Injection(R), conducted clinical trials related to use of ALFERON N Injection(R) for treatment of HIV and Hepatitis C. In both instances, the FDA determined that additional studies were necessary in order to fully evaluate the efficacy of ALFERON N Injection(R) in the treatment of

HIV and Hepatitis C diseases. We have no obligation or immediate plans to conduct these additional studies at this time.

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Our products, including Ampligen(R), are subject to extensive regulation by numerous governmental authorities in the U.S. and other countries, including, but not limited to, the FDA in the U.S., the Health Protection Branch ("HPB") of Canada, and the European Medical Evaluation Agency ("EMEA") in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen(R) or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen(R) will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligen(R) is authorized for use in clinical trials in the United States and other countries, we cannot assure you that additional clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials. If Ampligen(R) or one of our other products does not receive regulatory approval in the U.S. or elsewhere, our operations most likely will be materially adversely affected.

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

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses, as we pursued our clinical trial effort and expanded our efforts in Europe. As of June 30, 2004 our accumulated deficit was approximately \$127,841,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

We may require additional financing which may not be available.

The development of our products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of June 30, 2004, we had approximately \$9,433,000 in cash and cash equivalents and short-term investments. We believe that these funds plus 1) the gross proceeds received from the exercise of warrants and the Additional Investment Rights of approximately \$4,198,980 on July 13, 2004, 2) the gross proceeds from the August 2004 Private Placement of equity securities on August 5, 2004 of approximately \$7,500,000, 3) the projected net cash flow from the sale of ALFERON N Injection(R) and 4) the proceeds from licensing agreements should be sufficient to meet our operating cash requirements including debt service for the next 24 months. We may need to raise additional funds through additional equity

or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes and begin commercializing Ampligen(R) products. There can be no assurances that we will raise adequate funds from these or other sources, which may have a material adverse effect on our ability to develop our products.

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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) and Alferon N Injection(R) for a particular disease in order to obtain exclusive rights for the commercial sale of such drug for such disease. Our success depends, in large part, on our ability to preserve and obtain patent protection for our products and to obtain and preserve our trade secrets and expertise. Certain of our know-how and technology is not patentable, particularly the procedures for the manufacture of our drug product which are carried out according to standard operating procedure manuals. We have been issued certain patents including those on the use of Ampligen(R) and Ampligen(R) in combination with certain other drugs for the treatment of HIV. We also have been issued patents on the use of Ampligen(R) in combination with certain other drugs for the treatment of chronic Hepatitis B virus, chronic Hepatitis C virus, and a patent which affords protection on the use of Ampligen(R) in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of Ampligen(R) as a sole treatment for any of the cancers, which we have sought to target. With regard to ALFERON N Injection(R), we have acquired from ISI its patents for natural alpha interferon produced from human peripheral blood leukocytes and its production process. We cannot assure that our competitors will not seek and obtain patents regarding the use of similar products in combination with various other agents, for a particular target indication prior to our doing such. If we cannot protect our patents covering the use of our products for a particular disease, or obtain additional patents, we may not be able to successfully market our products.

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

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

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

If we cannot enforce the patent rights we currently hold we may be required to obtain licenses from others to develop, manufacture or market our products. There can be no assurance that we would be able to obtain any such



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licenses on commercially reasonable terms, if at all. We currently license certain proprietary information from third parties, some of which may have been developed with government grants under circumstances where the government maintained certain rights with respect to the proprietary information developed. No assurances can be given that such third parties will adequately enforce any rights they may have or that the rights, if any, retained by the government will not adversely affect the value of our license.

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

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

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

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

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

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There are no long-term agreements with suppliers of required materials. If we are unable to obtain the required raw materials, we may be required to scale back our operations or stop manufacturing ALFERON N Injection.

A number of essential materials are used in the production of ALFERON N Injection(R), including human white blood cells. We do not have long-term agreements for the supply of any of such materials. There can be no assurance we can enter into long-term supply agreements covering essential materials on commercially reasonable terms, if at all. If we are unable to obtain the required raw materials, we may be required to scale back our operations or stop manufacturing ALFERON N Injection(R). The costs and availability of products and materials we need for the commercial production of ALFERON N Injection(R) and other products which we may commercially produce are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, and FDA and other governmental regulations and there can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all.

There is no assurance that successful manufacture of a drug on a limited scale

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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

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("cGMP") regulations. There can be no assurance that such facilities can be used, built, or acquired on commercially acceptable terms, or that such facilities, if used, built, or acquired, will be adequate for our long-term needs.

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

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

We have never produced Ampligen(R) or any other products in large commercial quantities. Ampligen(R) is currently produced for use in clinical trials. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture

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commercial quantities of Ampligen(R) or enter into third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Also, each production lots of Alferon N Injection(R) is subject to FDA review and approval prior to releasing the lots to be sold. This review and approval process could take considerable time, which would delay our having product in inventory to sell. Alferon N Injection(R) has a shelf life of 18 months after having been bottled.

Rapid technological change may render our products obsolete or non-competitive.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Most of these entities have significantly greater research and development capabilities than us, as well as substantial marketing, financial and managerial resources, and represent significant competition for us. There can be no assurance that developments by others will not render our products or technologies obsolete or noncompetitive or that we will be able to keep pace with technological developments.

Our products may be subject to substantial competition.

Ampligen(R). Competitors may be developing technologies that are, or in the future may be, the basis for competitive products. Some of these potential products may have an entirely different approach or means of accomplishing similar therapeutic effects to products being developed by us. These competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments may offer competition to our products. Furthermore, many of our competitors have significantly greater experience than us in pre-clinical testing and human clinical trials of pharmaceutical

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products and in obtaining FDA, HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, HPB or other regulatory product approvals more rapidly than us. There are no drugs approved for commercial sale with respect to treating ME/CFS in the United States. The dominant competitors with drugs to treat HIV diseases include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs, Glaxo Smithkline, Merck and Schering-Plough Corp. These potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Although we believe our principal advantage is the unique mechanism of action of Ampligen(R) on the immune system, we cannot assure that we will be able to compete.

ALFERON N Injection(R). Many potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. ALFERON N Injection(R) currently competes with Schering's injectable recombinant alpha interferon product (INTRON(R) A) for the treatment of genital warts. 3M Pharmaceuticals also received FDA approval for its immune-response modifier, Aldara(R), a self-administered topical cream, for the treatment of external genital and perianal warts. ALFERON N Injection(R) also competes with surgical, chemical, and other methods of treating genital warts. We cannot assess the impact products developed by our competitors, or advances in other methods of

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the treatment of genital warts, will have on the commercial viability of ALFERON N Injection(R). If and when we obtain additional approvals of uses of this product, we expect to compete primarily on the basis of product performance. Our potential competitors have developed or may develop products (containing either alpha or beta interferon or other therapeutic compounds) or other treatment modalities for those uses. In the United States, three recombinant forms of beta interferon have been approved for the treatment of relapsing-remitting multiple sclerosis. There can be no assurance that, if we are able to obtain regulatory approval of ALFERON N Injection(R) for the treatment of new indications, we will be able to achieve any significant penetration into those markets. In addition, because certain competitive products are not dependent on a source of human blood cells, such products may be able to be produced in greater volume and at a lower cost than ALFERON N Injection(R). Currently, our wholesale price on a per unit basis of ALFERON N Injection(R) is higher than that of the competitive recombinant alpha and beta interferon products.

General. Other companies may succeed in developing products earlier than we do, obtaining approvals for such products from the FDA more rapidly than we do, or developing products that are more effective than those we may develop. While we will attempt to expand our technological capabilities in order to remain competitive, there can be no assurance that research and development by others or other medical advances will not render our technology or products obsolete or non-competitive or result in treatments or cures superior to any therapy we develop.

Possible side effects from the use of Ampligen(R) or ALFERON N Injection(R) could adversely affect potential revenues and physician/patient acceptability of our product.

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Ampligen(R). We believe that Ampligen(R) has been generally well tolerated with a low incidence of clinical toxicity, particularly given the severely debilitating or life threatening diseases that have been treated. A mild flushing reaction has been observed in approximately 15% of patients treated in our various studies. This reaction is occasionally accompanied by a rapid heart beat, a tightness of the chest, urticaria (swelling of the skin), anxiety, shortness of breath, subjective reports of "feeling hot," sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by slowing the infusion rate. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, transient visual disturbances, slow or irregular heart rate, decreases in platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills, fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months. One or more of the potential side effects might deter usage of Ampligen(R) in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

ALFERON N Injection(R). At present, ALFERON N Injection(R) is only approved for the intralesional (within the lesion) treatment of refractory or recurring external genital warts in adults. In clinical trials conducted for the treatment of genital warts with ALFERON N Injection(R), patients did not experience serious side effects; however, there can be no assurance that unexpected or unacceptable side effects will not be found in the future for this use or other potential uses of ALFERON N Injection(R) which could threaten or limit such product's usefulness.

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We may be subject to product liability claims from the use of Ampligen(R) or other of our products which could negatively affect our future operations.

We face an inherent business risk of exposure to product liability claims in the event that the use of Ampligen(R) or other of our products results in adverse effects. This liability might result from claims made directly by patients, hospitals, clinics or other consumers, or by pharmaceutical companies or others manufacturing these products on our behalf. Our future operations may be negatively affected from the litigation costs, settlement expenses and lost product sales inherent to these claims. While we will continue to attempt to take appropriate precautions, we cannot assure that we will avoid significant product liability exposure. Although we currently maintain product liability insurance coverage, there can be no assurance that this insurance will provide adequate coverage against Ampligen and/or Alferon N Injection product liability claims. A successful product liability claim against us in excess of Ampligen's \$1,000,000 in insurance coverage; \$3,000,000 in aggregate, or in excess of Alferon's \$5,000,000 in insurance coverage; \$5,000,000 in aggregate; or for which coverage is not provided could have a negative effect on our business and financial condition.

The loss of Dr. William A. Carter's services could hurt our chances for success.

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Our success is dependent on the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen(R), and his knowledge of our overall activities, including patents and clinical trials. The loss of Dr. Carter's services could have a material adverse effect on our operations and chances for success. We have secured key man life insurance in the amount of \$2 million on the life of Dr. Carter and we have an employment agreement with Dr. Carter that, as amended, runs until May 8, 2008. However, Dr. Carter has the right to terminate his employment upon not less than 30 days prior written notice. The loss of Dr. Carter or other personnel, or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

Uncertainty of health care reimbursement for our products.

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

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

Our business involves the controlled use of hazardous materials, carcinogenic chemicals and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with the standards prescribed by applicable regulations, the risk of accidental contamination or injury from these materials

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cannot be completely eliminated. In the event of such an accident or the failure to comply with applicable regulations, we could be held liable for any damages that result, and any such liability could be significant. We do not maintain insurance coverage against such liabilities.

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

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

- o announcements of the results of clinical trials by us or our competitors;
- o adverse reactions to products;
- o governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- o changes in U.S. or foreign regulatory policy during the period of product development;

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- o developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- o announcements of technological innovations by us or our competitors;
- o announcements of new products or new contracts by us or our competitors;
- o actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- o changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- o conditions and trends in the pharmaceutical and other industries;
- o new accounting standards; and
- o the occurrence of any of the risks described in these "Risk Factors."

Our common stock is listed for quotation on the American Stock Exchange. For the 12-month period ended August 15, 2004, the price of our common stock has ranged from \$1.82 to \$5.40 per shares. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

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

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

As of September 13, 2004, approximately 5,023,323 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act of 1933. 4,941,120 of these shares are registered herein or in a prior registration statement pursuant to agreements between us and the holders of these shares. In addition, we have registered 10,843,964 shares issuable (i) upon conversion of approximately 135% of Debentures that we issued in 2003 and

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2004; (ii) as payment of 135% of the interest on all of the Debentures; (iii) upon exercise of 135% of an aggregate of 3,390,514 warrants that we issued in January, May and July 2004; and (iv) upon exercise of certain other warrants and stock options. Registration of the shares permits the sale of the shares in the open market or in privately negotiated transactions without compliance with the requirements of Rule 144. To the extent the exercise price of the warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the conversion price and exercise price of these securities are adjusted pursuant to anti-dilution protection, the securities could be exercisable or convertible for even more shares of common stock. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock. Sales of substantial amounts of our common stock in the public market could cause

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the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

Provisions of our Certificate of Incorporation and Delaware law could defer a change of our management which could discourage or delay offers to acquire us.

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November, 2002 we adopted a stockholder rights plan and, under the Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one unit of preferred stock for \$30.00. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Dr. Carter, our chief executive officer, who already beneficially owns 10.6% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at \$.01 per Right under certain circumstances.

Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or reflect the occurrence of

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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.

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### SELLING STOCKHOLDERS

The following table provides information regarding the selling stockholders and the number of shares of common stock they are offering, which includes shares issuable upon exercise of warrants held by the selling stockholders. Under the rules of the SEC, beneficial ownership includes shares over which the indicated beneficial owner exercises voting or investment power. Shares of common stock subject to warrants and options that are currently exercisable or will become exercisable within 60 days are deemed outstanding for computing the percentage ownership of the person holding the options but are not deemed outstanding for computing the percentage ownership of any other person. Notwithstanding the foregoing, certain of the selling stockholders elected, at the time of the initial issuance of the warrants, to include provisions in the warrant, which provide that the warrants may not be exercised if such action would result in the holder, together with its affiliates, beneficially owning more than 4.999% of our common stock for purposes of Section 13(d) of the Exchange Act, unless the holder of the warrant waives the restriction in which case the restriction is lifted on the 61st day after the waiver. In addition, certain of the selling stockholders elected, at the time of the initial issuance of the warrants, to include provisions in the warrant, which provide that the warrants may not be exercised if such action would result in the holder, together with its affiliates, beneficially owning more than 9.999% of our common stock for purposes of Section 13(d) of the Exchange Act, which restriction cannot be waived by the holder. These restrictions do not apply to mergers or other business combinations or reclassifications.

Unless otherwise indicated in the footnotes below, we believe that the persons and entities named in the table have sole voting and investment power with respect to all shares beneficially owned. The information regarding shares beneficially owned after the offering assumes the sale of all shares offered by each of the selling stockholders. The percentage ownership data is based on 49,110,571 shares of our common stock issued and outstanding as of September 13, 2004, including 3,617,306 shares of our common stock covered by this prospectus.

The shares of common stock covered by this prospectus may be sold by the selling stockholders, by those persons or entities to whom they transfer, donate, devise, pledge or distribute their shares or by other successors in interest. We are registering the shares of our common stock for resale by the selling stockholders defined below. The shares are being registered to permit public secondary trading of the shares, and the selling stockholders may offer the shares for resale from time to time. See "How The Shares May Be Distributed" below

On August 5, 2004, pursuant to the Securities Purchase Agreement dated July 30, 2004, we issued and sold 3,617,306 shares of our common stock and warrants exercisable for up to 1,085,193 additional shares of our common stock



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at a combined unit price of \$2.08 per unit in a private placement transaction (the "Private Placement") for aggregate gross cash proceeds to us of approximately \$7.5 million. The warrant issued to each selling stockholder in the Private Placement is exercisable for up to 30% of the number of shares of our common stock purchased by such selling stockholder at an exercise price equal to \$2.86 per share. In addition, we issued a warrant to Jefferies & Company, Inc. exercisable for up to 150,480 shares of our common stock.

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Each warrant has a term of five years, is fully exercisable from the date of issuance. The selling stockholders acquired the common stock and warrants to purchase common stock to which this prospectus relates directly from us in transactions exempt from the registration requirements of the federal and state securities laws. All of the securities were issued and sold solely to accredited investors, as defined in Rule 501 of Regulation D pursuant to the Securities Act.

In connection with the Private Placement, we agreed to file the registration statement of which this prospectus forms a part with the SEC covering the resale of the offered shares. We also agreed to prepare and file all amendments and supplements necessary to keep the registration statement effective until the earlier of two years after the date that this registration statement is declared effective by the SEC, subject to extension as set forth in the registration rights agreement, the date on which the selling stockholders may resell all the shares covered by the registration statement without volume restrictions pursuant to Rule 144 under the Securities Act or any successor rule of similar effect and the date on which the selling stockholders have sold all the shares covered by the registration statement.

The following table has been prepared based solely upon information furnished to us as of the date of this prospectus by the selling stockholders listed below. The selling stockholders identified below may have sold, transferred or otherwise disposed of, in transactions exempt from the registration requirements of the Securities Act, all or a portion of their shares since the date on which the information in the following table is presented.

None of the selling stockholder has had any position, office or other material relationship with us or any of our affiliates within the past three years, other than as a stockholder.

Selling Stockholder	Common Stock Owned Prior To Offering	No. of Shares Being Offered	Comm Own The
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Portside Growth & Opportunity Fund*(1)	4,474,524	1,250,000	
UBS O'Connor LLC(2)	130,000	130,000	
Kingsbridge Capital Ltd.(3)	125,000	125,000	
Fennmore Holdings(4)	156,250	156,250	
Smithfield Fiduciary, LLC*(5)	312,499	312,499	

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Spectra Investments, LLC*(6)	156,250	156,250
Gemini Master Fund, Ltd. (7)	31,249	31,249
Provident Premier Master Fund, Ltd. (8)	156,250	156,250
Asset Managers International(9)	1,249,999	1,249,999
JMG Capital Partners, LP(10)	312,501	312,501
JMG Triton Offshore Fund, Ltd. (11)	312,501	312,501
Winton Capital Holdings, Ltd. (12)	260,000	260,000
Iroquois Capital LP(13)	249,999	249,999
Jefferies & Company, Inc. (14)	150,480	150,480

\* This selling stockholder has identified itself as an affiliate of a registered broker-dealer. The selling stockholder has informed us that it acquired the common stock in the ordinary

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course of its business for its own account for investment purposes only and not with a view to, or for, distributing the securities and, at the time of purchase, it did not have any agreements, plans or understandings, directly or indirectly, with any person or entity to distribute the securities.

- (1) Shares offered represent (a) 961,538 shares and an additional 288,462 shares issuable upon exercise of warrants issued in the Private Placement. The balance of the shares beneficially owned by the selling stockholder have been registered in prior registration statements and are eligible for resale pursuant to a separate prospectus. These shares represent (a) up to 1,321,690 shares of common stock issuable upon conversion of Debentures issued in January and July 2004, (b) up to 1,695,257 shares of common stock issuable upon exercise of additional outstanding warrants, and (c) 207,577 shares of common stock. 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, Thomas W. Strauss and Jeffrey M. Solomon are the sole managing members of C4S& Co., LLC, the sole managing member of Ramius Capital. As a result, Messrs. Cohen, Stark, Strauss and Solomon may be considered beneficial owners of any shares deemed to be beneficially owned by Ramius Capital. Messrs. Cohen, Stark, Strauss and Solomon disclaim beneficial ownership of these shares.
- (2) Shares offered and owned includes 30,000 shares issuable upon exercise of warrants issued in the Private Placement. The shares are beneficially owned by O'Connor PIPES Corporate Strategies Master Ltd. UBS O'Connor LLC is the investment manager for O'Connor PIPES Corporate Strategies Master Ltd. UBS O'Connor LLC is a wholly owned subsidiary of UBS AG, which is traded on the NYSE.
- (3) Shares offered and owned includes 28,846 shares issuable upon exercise of

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warrants issued in the Private Placement. The selling stockholder has identified Adam Gurney, as a natural person with voting and investment control over shares of our common stock beneficially owned by the selling stockholder.

- (4) Shares offered and owned includes 36,058 shares issuable upon exercise of warrants issued in the Private Placement. The selling stockholder has identified Mark Nordlicht, as a natural person with voting and investment control over shares of our common stock beneficially owned by the selling stockholder. Mr. Nordlicht disclaims beneficial ownership of the securities held by Fenmore.
- (5) Shares offered and owned includes 72,115 shares issuable upon exercise of warrants issued in the Private Placement. Highbridge Capital Management, LLC is the trading manager of Smithfield Fiduciary LLC and consequently has voting control and investment discretion over securities held by Smithfield. Glenn Dubin and Henry Swieca control Highbridge. Each of Highbridge, Glenn Dubin and Henry Swieca disclaims beneficial ownership of the securities held by Smithfield.

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- (6) Shares offered and owned includes 36,058 shares issuable upon exercise of warrants issued in the Private Placement. The selling stockholder has identified Greg Porges, as a natural person with voting and investment control over shares of our common stock beneficially owned by the selling stockholder. Mr. Porges disclaims beneficial ownership of the securities held by Spectra.
- (7) Shares offered and owned includes 7,211 shares issuable upon exercise of warrants issued in the Private Placement. Shares listed as owned and offered excludes shares beneficially owned by Provident Premier Master Fund, Ltd. The Investment Manager of Gemini Master Fund, Ltd. is Gemini Investment Strategies, LLC. The Managing Members of Gemini Investment Strategies, LLC are Messrs. Steven W. Winters and Mr. Richard S. Yakomin. As such, Messrs. Winters and Yakomin may be deemed beneficial owners of the shares. Messrs. Winters and Yakomin, however, disclaim beneficial ownership of such shares.
- (8) Shares offered and owned includes 36,058 shares issuable upon exercise of warrants issued in the Private Placement. Shares listed as owned and offered excludes shares beneficially owned by Gemini Master Fund, Ltd. The Investment Advisor to Provident Premier Master Fund, Ltd. is Gemini Investment Strategies, LLC. The Managing Members of Gemini Investment Strategies, LLC are Messrs. Steven W. Winters and Mr. Richard S. Yakomin. As such, Messrs. Winters and Yakomin may be deemed beneficial owners of the shares. Messrs. Winters and Yakomin, however, disclaim beneficial ownership of such shares.
- (9) Shares offered and owned includes 288,461 shares issuable upon exercise of warrants issued in the Private Placement. The selling stockholder has identified Adam Benowitz, as a natural person with voting and investment control over shares of our common stock beneficially owned by the selling stockholder. Mr. Benowitz disclaims beneficial ownership of the securities held by Asset Managers International.
- (10) Shares offered and owned includes 72,116 shares issuable upon exercise of warrants issued in the Private Placement. Shares listed as owned and offered excludes shares beneficially owned by JMG Triton Offshore Fund, Ltd. JMG Capital Partners, L.P. ("JMG Partners") is a California limited

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partnership. Its general partner is JMG Capital Management, LLC (the "Manager"), a Delaware limited liability company and an investment adviser registered with the Securities and Exchange Commission. The Manager has voting and dispositive power over JMG Partners' investments, including the Registrable Securities. The equity interests of the Manager are owned by JMG Capital Management, Inc., ("JMG Capital") a Delaware corporation, and Asset Alliance Holding Corp., a Delaware corporation. Jonathan M. Glaser is the Executive Officer and Director of JMG Capital and has sole investment discretion over JMG Partners' portfolio holdings.

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- (11) Shares offered and owned includes 72,116 shares issuable upon exercise of warrants issued in the Private Placement. Shares listed as owned and offered excludes shares beneficially owned by JMG Capital Partners, L.P. JMG Triton Offshore Fund, Ltd. (The "Fund") is an international business company under the laws of the British Virgin Islands. The Fund's investment manager is Pacific Assets Management LLC, a Delaware limited liability company (the "Manager"). The Manager is an investment adviser registered with the Securities and Exchange Commission and has voting and dispositive power over the Fund's investments, including the Registrable Securities. The equity interests of the Manager are owned by Pacific Capital Management, Inc., a Delaware company ("the Pacific") and Asset Alliance Holding Corp., a Delaware company. The equity interests of Pacific are owned by Messrs. Roger Richter, Jonathan M. Glaser and Daniel A. David and Messrs. Glaser and Richter have sole investment discretion over the fund's portfolio holdings.
- (12) Shares offered and owned includes 60,000 shares issuable upon exercise of warrants issued in the Private Placement. The selling stockholder has identified Marc Belzberg, as a natural person with voting and investment control over shares of our common stock beneficially owned by the selling stockholder.
- (13) Shares offered and owned includes 57,692 shares issuable upon exercise of warrants issued in the Private Placement. The selling stockholder has identified Joshua Silverman, as a natural person with voting and investment control over shares of our common stock beneficially owned by the selling stockholder. Mr. Silverman disclaims beneficial ownership of the shares held by Iroquois Capital LP.
- (14) Represents 150,480 shares issuable upon exercise of immediately exercisable warrants. Jefferies acted as the sole placement agent in the financing and is a registered broker-dealer. Based upon representations made to us by Jefferies, the warrant to purchase common stock were acquired in the ordinary course of its business for its own account for investment purposes only and not with a view to, or for, distributing the warrant or the shares of common stock issuable upon exercise thereof. Jefferies does not have any agreements, plans or understandings, directly or indirectly, with any person or entity to distribute the warrant to purchase common stock or the shares of common stock issuable upon exercise of the warrant.

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 ABOVE IN THE FOOTNOTES ABOVE.

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### HOW THE SHARES MAY BE DISTRIBUTED

The Selling Stockholders and any of their pledgees, donees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of Common Stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The Selling Stockholders may use any one or more of the following methods when selling shares:

- o ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- o block trades in which the broker-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;
- o purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- o an exchange distribution in accordance with the rules of the applicable exchange;
- o privately negotiated transactions;
- o short sales;
- o broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- o a combination of any such methods of sale; and
- o any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The Selling Stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The Selling Stockholders may from time to time pledge or grant a security interest in some or all of the Shares owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell shares of Common Stock from time to time under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

Upon our being notified in writing by a Selling Stockholder that any material arrangement has been entered into with a broker-dealer for the sale of Common Stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a

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broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such Selling Stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such the shares of Common Stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In addition, upon our being notified in writing by a Selling Stockholder that a donee or pledge intends to sell more than 500 shares of Common Stock, a supplement to this prospectus will be filed if then required in accordance with applicable securities law.

The Selling Stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The Selling Stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such 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. Each Selling Stockholders has represented and warranted to us that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the Common Stock.

We have advised the Selling Stockholders that they are required to comply with Regulation M promulgated under the Securities and Exchange Act during such time as they may be engaged in a distribution of the shares. The foregoing may affect the marketability of the common stock.

We are required to pay all fees and expenses incident to the registration of the shares. We have agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

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.

### USE OF PROCEEDS

We will not receive any proceeds from the sale of the shares of common stock offered by the selling stockholders. Proceeds from the exercising of the Warrants will be used for conducting clinical trials and related activities, research and development and general corporate purposes.

### 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

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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, 2003, SEC File No. 1-13441.
  - (b) Our quarterly report on Form 10-Q for the quarterly period ended March 31, 2004, SEC File No. 1-13441.
  - (c) Our proxy statement on schedule 14A for our 2004 annual meeting, SEC File No. 1-13441.
  - (d) Our current report on Form 8-K filed on July 15, 2004, SEC File No. 1-13441.
  - (e) Our current report on Form 8-K filed on August 2, 2004, SEC File No. 1-13441.
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- (f) Our current report on Form 8-K filed on August 6, 2004, SEC File No. 1-13441.
  - (g) Our quarterly report on Form 10-Q for the quarterly period ended June 30, 2004, SEC File No. 1-13441.
  - (h) A description of our common stock contained in our registration statement on Form S-1, SEC 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.
  - (i) Our Form S-1 Registration Statement, SEC File No. 333-117178, declared effective by the SEC on August 2, 2004.

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(j) Our current report on Form 8-K filed on September 15, 2004, SEC File No. 1-13441.

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 than the date on the front of those documents.

### LEGAL MATTERS

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

### EXPERTS

Our financial statements incorporated by reference in this Prospectus which are included in our Annual Report of Form 10-K/A for the year ended December 31, 2003 have been audited by BDO Seidman, LLP, independent registered public accountants, to the extent and for the periods set forth in their report, and are included in reliance upon such report given upon the authority of said firm as experts in auditing and accounting.

The financial statements of Interferon Sciences, Inc. incorporated by reference in this Prospectus which are included in our registration statement on Form S-1 (SEC file no. 333-117178) have been audited by Eisner LLP, independent registered public accountants, to the extent and for the periods set forth in their report, and are included in reliance upon such report given upon the authority of said firm as experts in auditing and accounting.

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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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4,852,979 SHARES OF  
COMMON STOCK

HEMISPHERX BIOPHARMA, INC.

PROSPECTUS

September \_\_, 2004

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

SEC Filing Fees .....	\$ 1,606.17
American Stock Exchange Listing Fee* .....	\$22,500.00
Printing and Engraving Expenses* .....	\$ 4,000.00
Accounting Fees and Expenses* .....	\$10,000.00
Legal Fees and Expenses* .....	\$12,500.00
Transfer Agent and Registrar Fees* .....	\$ 1,500.00
Miscellaneous* .....	\$ 1,893.83
 Total Expenses* .....	 \$54,000.00

\* Estimated.

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

The Registrant's Amended and Restated Certificate of Incorporation provides that the Registrant shall indemnify to the extent permitted by Delaware law any person whom it may indemnify thereunder, including directors, officers, employees and agents of the Registrant. Such indemnification (other than an order by a court) shall be made by the Registrant only upon a determination that indemnification is proper in the circumstances because the individual met the applicable standard of conduct. Advances for such indemnification may be made pending such determination. In addition, the Registrant's Amended and Restated Certificate of Incorporation eliminates, to the extent permitted by Delaware law, personal liability of directors to the Registrant and its stockholders for monetary damages for breach of fiduciary duty as directors.

The Registrant's authority to indemnify its directors and officers is governed

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by the provisions of Section 145 of the Delaware General Corporation Law, as follows:

- (a) A corporation shall have the power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than action by or in the right of the corporation) by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The termination of

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any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that the person's conduct was unlawful.

- (b) A corporation shall have the power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.
- (c) To the extent that a present or former director or officer of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in subsections (a) and (b) of this section, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.
- (d) Any indemnification under subsections (a) and (b) of this section (unless ordered by a court) shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of the present

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or former director, officer, employee or agent is proper in the circumstances because he has met the applicable standard of conduct set forth in subsections (a) and (b) of this section. Such determination shall be made, with respect to a person who is a director or officer at the time of such determination (1) by a majority vote of the directors who are not parties to such action, suit or proceeding, even though less than a quorum, or (2) by a committee of such directors designated by majority vote of such directors, even though less than a quorum, or (3) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, or (4) by the stockholders.

- (e) Expenses (including attorneys' fees) incurred by an officer or director in defending a civil or criminal action, suit or proceeding may be paid by the corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by the corporation as authorized in this section. Such expenses incurred by former directors and officers and other employees and agents may be so paid upon such terms and conditions, if any, as the corporation deems appropriate.
- (f) The indemnification and advancement of expenses provided by, or granted pursuant to, the other subsections of this section shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any by, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's

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official capacity and as to action in another capacity while holding such office.

- (g) A corporation shall have power to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of his status as such, whether or not the corporation would have the power to indemnify such person against such liability under this section.
- (h) For purposes of this section, references to the "corporation" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had the power and authority to indemnify its directors, officers, and employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under this section with respect to the resulting or surviving corporation as such person would have with respect to such constituent corporation if its separate existence had continued. (i) For purposes of this section, references to "other enterprises" shall include employee benefit plans, references to "fines" shall include any excise taxes assessed on a person with respect to any employee benefit plan, and references to "serving at

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the request of the corporation" shall include any service as a director, officer, employee, or agent with respect to any employee benefit plan, its participants or beneficiaries, and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of any employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the corporation" as referred to in this section.

- (j) The indemnification and advancement of expenses provided by, or granted pursuant to, this section shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.
- (k) The Court of Chancery is hereby vested with exclusive jurisdiction to hear and determine all actions for advancement of expenses or indemnification brought under this section, or under any bylaw, agreement, vote of stockholders or disinterested directors, or otherwise. The Court of Chancery may summarily determine a corporation's obligation to advance expenses (including attorneys' fees).

### ITEM 16. EXHIBITS.

Exhibit No. -----	Description -----
4.1	Securities Purchase Agreement, dated July 30, 2004, by and among the Company and the Purchasers named therein.*
4.2	Form of Warrant for Common Stock of the Company.*
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4.3	Registration Rights Agreement, dated July 30, 2004, by and among the Company and the Purchasers named therein.*
5.1	Opinion of Silverman Sclar Shin & Byrne PLLC, legal counsel.
23.1	Consent of BDO Seidman, LLP, independent registered public accountants.
23.2	Consent of Eisner LLP, independent registered public accountants.
23.2	Consent of Silverman Sclar Shin & Byrne PLLC, 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 Registrant's Current Report on Form 8-K (SEC File No. 1-13441) filed on August 6, 2004.

### ITEM 17. UNDERTAKINGS

A. The undersigned registrant hereby undertakes:

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

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

(ii) To 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) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(iii) To 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.

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(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.

B. The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) 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. Insofar as indemnification for liabilities arising under the Securities Act of 1933 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 Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 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

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Act of 1933, and will be governed by the final adjudication of such issue.

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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 registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Philadelphia, Commonwealth of Pennsylvania, on the 9th day of September, 2004.

HEMISPHERX BIOPHARMA, INC.

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(Registrant)

By: s/William A. Carter

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

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities indicated on the dates indicated.

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints William A. Carter acting alone, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for such person in his name, place and stead, in any and all capacities, in connection with the Registrant's registration statement on Form S-3 under the Securities Act of 1933, including, without limiting the generality of the foregoing, to sign the registration statement in the name and on behalf of the Registrant or on behalf of the undersigned as a director or officer of the Registrant, and any and all amendments or supplements to the registration statement, including any and all stickers and post-effective amendments to the registration statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission and any applicable securities exchange or securities self-regulatory body, granting unto said attorney-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Signature  
-----

Title  
-----

/s/William A. Carter  
-----  
William A. Carter, M.D.

Chairman of the Board, Chief Executive Officer (Principal Executive) and Director

Director

/s/Richard C. Piani  
-----  
Richard C. Piani

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/s/Robert E. Peterson  
-----

Robert E. Peterson

Chief Financial Officer and Chief  
Accounting Officer

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Signature -----	Title -----
/s/Ransom W. Etheridge ----- Ransom W. Etheridge	Secretary, General Counsel And Director
/s/William M. Mitchell ----- William M. Mitchell, M.D., Ph.D.	Director
----- Iraj-Eqhbali Kiani, M.D.	Director
/s/Antoni Esteve ----- Antoni Esteve, Ph.D.	Director

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

Exhibit No. -----	Description -----
5.1	Opinion of Silverman Sclar Shin & Byrne PLLC, legal counsel.
23.1	Consent of BDO Seidman, LLP, independent registered public accountants.
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