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HEMISPHERX BIOPHARMA INC

Form S-8

November 18, 2005

As filed with the Securities and Exchange Commission on November 18, 2005

Registration No.333-

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SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM S-8  
REGISTRATION STATEMENT  
Under the Securities Act of 1933

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

Delaware 52-0845822  
(State or other jurisdiction of (I.R.S. Employer Identification No.)  
incorporation or organization)

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

(Address of Registrant's Principal Executive Office) (Zip Code)

OFFICERS, DIRECTORS, AND EMPLOYEES STOCK COMPENSATION PROGRAM - 1996  
OFFICERS, DIRECTORS AND EMPLOYEES STOCK COMPENSATION PROGRAM - 1998;  
OFFICERS, DIRECTORS AND EMPLOYEES STOCK COMPENSATION PROGRAM -2001;  
OFFICERS, DIRECTORS AND EMPLOYEES STOCK COMPENSATION PROGRAM - 2002;  
OFFICERS, DIRECTORS AND EMPLOYEES STOCK COMPENSATION PROGRAM - 2003

(full title of the plan)

William A. Carter, M.D., CEO  
Hemispherx Biopharma, Inc.  
1617 JFK Boulevard, Suite 660  
Philadelphia, PA 19103  
(215) 988-0080

(Name, Address & Telephone number, including area code, of agent for service)

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CALCULATION OF REGISTRATION FEE

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Title of Securities	Proposed Maximum	Proposed Maximum
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to be Registered	Amount to be Registered(1)	Offering Price Per Share(2)	Aggregate Offering Price
Shares of Common Stock, \$.001 par value, issuable upon exercise of options/warrants .....	5,578,650	\$3.28	\$18,297,972
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Total Registration Fee.....			
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(1) Pursuant to Rule 416(c) under the Securities Act of 1933, this registration statement also covers an indeterminate amount of interests to be offered or sold pursuant to the Plans described in this registration statement.

(2) Pursuant to Rule 457(h)(1) under the Securities Act of 1933, calculated on the basis of the average of the weighted average exercise price of outstanding options/warrants to purchase shares of common stock under the Plans.

Pursuant to Rule 429 under the Securities Act of 1933, as amended, the prospectus included in this Registration Statement also relates to the remaining unsold shares which were previously registered by the Registrant on Form S-8 under Registration Statement Nos. 333-57134 and 333-118903.

EXPLANATORY NOTE

We prepared this registration statement in accordance with the requirements of Form S-8 under the Securities Act of 1933, as amended, to register an aggregate of 5,578,650 shares of our common stock, \$.001 par value per share, to be issued pursuant to the Officers, Directors and Employee Stock Compensation Programs set forth below. Each Plan consists of options/warrants issued to officers, directors, employees and consultants by our Board of Directors in the years indicated.

- o Officers, Directors and Employees Stock Compensation Program - 1996
- o Officers, Directors and Employees Stock Compensation Program - 1998
- o Officers, Directors and Employees Stock Compensation Program - 2001
- o Officers, Directors and Employees Stock Compensation Program - 2002
- o Officers, Directors and Employees Stock Compensation Program - 2003

The foregoing plans, along with the 1990 Stock Option Plan (registered on Form S-8 Registration Statement No. 333-57134) and the 2003 Directors Compensation Plan and 2004 Equity Incentive Plan (registered on Form S-8 Registration Statement No. 333-118903) are collectively referred to herein as the "Plans."

Under cover of this Form S-8 is our reoffer prospectus, prepared in accordance with Part I of Form S-3 under the Securities Act of 1933 Act. This reoffer prospectus has been prepared pursuant to Instruction C of Form S-8, in accordance with the requirements of Part I of Form S-3. It may be used for reoffers and resales of shares of Common Stock acquired upon exercised stock options/warrants under the Plans prior to the initial filing of this registration statement or who may be deemed to be our "affiliates" (as such term is defined in Rule 405 Securities Act).

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## PART I

### INFORMATION REQUIRED IN THE SECTION 10(A) PROSPECTUS

We will provide the documents containing information specified in Part I of Form S-8 to each employee as specified by Rule 428(b)(1). We are not required to file such documents with the Securities and Exchange Commission either as part of this registration statement or as prospectuses or prospectus supplements pursuant to Rule 424. These documents and the documents incorporated by reference in this registration statement pursuant to Item 3 of Part 2 of this form taken together constitute a prospectus that meets the requirements of Section 10(a) of the Securities Act of 1933.

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 Commission's public reference rooms in Washington, D.C., New York, N.Y., and Chicago, IL. Please call the Commission at 1-800-SEC-0330 for further information on the public reference rooms. Our Commission filings are also available to the public from the Commission's web site at <http://www.sec.gov>. The Commission allows us to "incorporate by reference" information into this registration statement, which means that we can disclose important information to you by referring you to another document filed separately with the Commission. The information incorporated by reference is considered to be part of this registration statement, and later information that we file with the Commission will automatically update this registration statement.

### REOFFER PROSPECTUS

7,771,524 SHARES  
HEMISPHERX BIOPHARMA, INC.  
Common Stock (\$.001 par value)

This prospectus relates to the reoffer and resale by certain selling stockholders of shares (the "Shares") of our Common Stock that: (i) are issuable upon exercise of options/warrants that have been issued by us to the selling stockholders pursuant to our Officers, Directors and Employees Stock Compensation Programs and our 2004 Equity Incentive Plan and (ii) have been issued to certain selling stockholders pursuant to our 2003 Directors Compensation Plan. The shares are being reoffered and resold for the account of the selling stockholders and we will not receive any of the proceeds from the resale of the Shares.

The selling stockholders have advised us that the resale of their Shares may be effected from time to time in one or more transactions on the American Stock Exchange, in negotiated transactions or otherwise, at market prices prevailing at the time of the sale or at prices otherwise negotiated. See "Plan of Distribution." We will bear all expenses in connection with the preparation of this prospectus.

Our common stock is currently traded on the American Stock Exchange under the symbol "HEB" The closing price of our common stock as reported on the American

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Stock Exchange on November 15, 2005, was \$2.76 per share.  
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THE SHARES OF COMMON STOCK OFFERED PURSUANT TO THIS REGISTRATION STATEMENT INVOLVE A HIGH DEGREE OF RISK. PLEASE SEE THE RISK FACTORS BEGINNING ON PAGE 1 TO READ ABOUT CERTAIN FACTORS YOU SHOULD CONSIDER BEFORE BUYING SHARES OF OUR 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 November 18, 2005

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### ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement we filed with the SEC. You should rely only on the information provided or incorporated by reference in this prospectus or any related supplement. We have not authorized anyone else to provide you with different information. The Selling Stockholders will not make an offer of 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 other date than the date on the front of those documents.

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## 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 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 FDA for commercial sale.

The clinical development of the experimental therapeutic, Ampligen(R) for CFS was initiated approximately 16 years ago. To date federal health agencies have yet to reach a consensus regarding various aspects of ME/CFS,

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including parameters of "promising therapies" for ME/CFS and which aspects of ME/CFS are anticipated to be "serious or life-threatening".

Over its developmental history, Ampligen(R) has received various designations, including Orphan Drug Product Certification (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports (AHRQ, Agency Health Research Quality). However to date, the FDA has determined it has yet to receive sufficient information to support the potential of Ampligen(R) to treat a serious or life threatening aspect of ME/CFS. The definition of the "seriousness of a condition", according to Guidance for Industry documents published in July, 2004 is "a matter of judgment, but generally based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one". The FDA has recently requested a "complete and audited report of the Amp 516 study to determine whether Ampligen(R) has a clinically meaningful benefit on a serious or life threatening aspect of ME/CFS in order to evaluate whether the Amp 516 study results do or do not support a "fast track designation". The FDA has also invited us to include a schedule for completion of all ME/CFS studies as well as a proposed schedule for our NDA submission. Because we believe our ME/CFS studies are complete, we intend to request a pre-NDA meeting to obtain advice on preparing and submitting our NDA. At the same time we will continue with our existing ongoing efforts to prepare a complete and audited report of our various studies, including the well-controlled Amp 516 study. We are using our best efforts to complete the requisite reports including the hiring of new staff and various recognized expert medical/regulatory consultants, but can provide no assurance as to whether the outcome of this large data collection and filing process (approximately 750 patients, treated more than 45,000 times) will be favorable or unfavorable, specifically with respect to the FDA's perspective. Also, we can provide no guidance as to the tentative date at which the compilation and filing of such data will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the ability of Hollister-Stier facilities (or the facilities of such other manufacturer as we may retain in the event that we do not come to definitive terms with Hollister-Stier) to interface with our own New Brunswick staff/facilities to meet the manufacturing regulatory standards.

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, 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

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evaluate the efficacy of ALFERON N Injection(R) in the treatment of HIV and Hepatitis C diseases. We have no immediate plans to conduct these additional studies at this time.

Our products, including Ampligen(R), are subject to extensive regulation by numerous governmental authorities in the U.S. and other countries, including, but not limited to, the FDA in the U.S., the Health Protection Branch ("HPB") of Canada, and the Agency for the Evaluation of Medicinal Products ("EMA") 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, 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.

Although preliminary in vitro testing indicates that Ampligen(R) enhances the effectiveness of different drug combinations on avian influenza, preliminary testing in the laboratory is not necessarily predictive of successful results in clinical testing or human treatment.

Ampligen(R) is undergoing pre-clinical testing for possible treatment of avian flu. Although preliminary in vitro testing indicates that Ampligen(R) enhances the effectiveness of different drug combinations on avian flu, preliminary testing in the laboratory is not necessarily predictive of successful results in clinical testing or human treatment. No assurance can be given that similar results will be observed in clinical trials. Use of Ampligen(R) in the treatment of Avian flu requires prior regulatory approval. Only the FDA can determine whether a drug is safe, effective or promising for treating a specific application. As discussed in the prior risk factor, obtaining regulatory approvals is a rigorous and lengthy process.

In addition, Ampligen(R) is being tested on one strain of avian flu. There are a number of strains and strains mutate. No assurance can be given that a Ampligen(R) will be effective on any strains that might infect humans.

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 September 30, 2005 our accumulated deficit was approximately \$147,741,000. 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.

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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 September 30, 2005, we had approximately \$11,632,000 in cash and cash equivalents and short-term investments. These funds should be sufficient to meet our operating cash requirements, including debt service, for the near term. However, 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 including the commercializing of Ampligen(R) products. There can be no assurances that we will raise adequate funds which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

Under the common stock purchase agreement signed with Fusion Capital on July 8, 2005, we only have the right to receive \$40,000 per trading day unless our stock price equals or exceeds \$2.00, in which case the daily amount may be increased under certain conditions as the price of our common stock increases (For a more detailed description of the terms of this agreement, see the agreement filed as an exhibit to our Current Report on Form 8-K filed with the SEC on July 11, 2005). Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than \$1.00. Since we initially registered 10,000,000 shares purchasable by Fusion Capital pursuant to the common stock purchase agreement, the selling price of our common stock to Fusion Capital will have to average at least \$2.00 per share for us to receive the maximum proceeds of \$20.0 million without registering additional shares of common stock. As of November 15, 2005, we need an average selling price of \$2.09 per share for the remainder of the agreement to realize the \$20,000,000 in proceeds. The closing price of our stock was \$2.76 on November 15, 2005. Subject to approval by our board of directors, we have the right, but not the obligation, to issue more than 10,000,000 shares to Fusion Capital. In the event we elect to issue more than 10,000,000 shares, we will be required to file a new registration statement and have it declared effective by the Securities and Exchange Commission. In the event that we decide to issue more than 10,113,278 (19.99% of our outstanding shares of common stock as of the date of our agreement), we would first be required to seek stockholder approval in order to be in compliance with the American Stock Exchange Market rules.

The extent to which we rely on Fusion Capital as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. Specifically, Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than \$1.00. If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive and if we are unable to commercialize and sell Ampligen(R) and/or increase sales of ALFERON N Injection(R) or our other products, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full \$20.0 million under the common stock purchase agreement with Fusion Capital, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences would materially adversely affect our business, operating results, financial condition and prospects.

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

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

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

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

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

If we cannot enforce the patent rights we currently hold we may be required to obtain licenses from others to develop, manufacture or market our products. There can be no assurance that we would be able to obtain any such licenses on commercially reasonable terms, if at all. We currently license certain proprietary information from third parties, some of which may have been

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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 ("Bioclones"), 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. On December 27, 2004, we initiated a lawsuit in Federal Court identifying a conspiratorial group seeking to illegally manipulate our stock for purposes of bringing about the hostile takeover of Hemispherx. This conspiratorial group includes Bioclones and the potential legal action may adversely effect our agreement with Bioclones and the potential for marketing and distribution capacity in South America, Africa, United Kingdom, Australia and New Zealand.

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

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

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.

At present, we do not have any agreements with third parties for the supply of any polymers for use in manufacturing Ampligen(R). We are establishing relevant manufacturing operations within our New Brunswick, New Jersey facility for the production of Ampligen(R) raw materials in order to obtain polymers on a more consistent manufacturing basis. The establishment of an Ampligen(R) raw materials production line within our own facilities, while having obvious advantages with respect to regulatory compliance (other parts of the 43,000 sq. ft. wholly owned facility are already in compliance for Alferon N Injection(R)

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manufacture), may delay certain steps in the commercialization process, specifically a targeted NDA filing.

If we are unable to obtain or manufacture the required raw materials, we may be required to scale back our operations or stop manufacturing. The costs and availability of products and materials we need for the production of Ampligen(R) and the commercial production of ALFERON N Injection(R) and other products which we may commercially produce are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, and FDA and other governmental regulations and there can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all.

There is no assurance that successful manufacture of a drug on a limited scale basis for investigational use will lead to a successful transition to commercial, large-scale production.

Small changes in methods of manufacturing, including commercial scale-up, may affect the chemical structure of Ampligen(R) and other RNA drugs, as well as their safety and efficacy, 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) has been only produced in limited quantities for use in our clinical trials and we are dependent upon 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 pertaining to current Good Manufacturing Practices ("cGMP") regulations. There can be no assurance that such facilities can be used, built, or acquired on commercially acceptable terms, or that such facilities, if used, built, or acquired, will be adequate for our long-term needs.

In connection with settling various manufacturing infractions previously noted by the FDA, Schering-Plough ("Schering") entered into a "Consent Decree" with the FDA whereby, among other things, it agreed to discontinue various contract (third party) manufacturing activities at various facilities including its San Juan, Puerto Rico, plant. Ampligen(R) (which was not involved in any of the cited infractions) was produced at this Puerto Rico plant from year 2000-2004. Operating under instructions from the Consent Decree, Schering has advised us that it would no longer manufacture Ampligen(R) in this facility beyond 2004 and would assist us in an orderly transfer of said activities to other non Schering facilities.

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On September 9, 2005, we signed a Letter of Intent ("LOI") with Hollister-Stier Laboratories LLC of Spokane, Washington ("Hollister-Stier"), for the contract manufacturing of Ampligen(R). In November 2005, we paid \$100,000 upon executing the LOI in order to initiate the manufacturing project. The LOI shall remain in full force and effect for 90 calendar days or until a definitive agreement is reached. The achievement of the initial objectives described in the LOI, in combination with our polymer production facility under construction in New Brunswick, N.J., may enable us to manufacture the raw materials for approximately 10,000 doses of Ampligen(R) per week. Based on the LOI, Hollister-Stier has agreed to formulate and bottle Ampligen(R) using raw materials received from us. We have an executed confidentiality agreement in place and; therefore, have commenced the preliminary transfer of our manufacturing technology to Hollister-Stier. Our decision to transfer relevant manufacturing technology absent of an executed agreement, was done in part to expedite the eventual manufacture of Ampligen(R) by Hollister-Stier. If we are unable to negotiate and finalize an agreement with Hollister-Stier, in a timely manner our plans to file an NDA for Ampligen(R) and, eventually, to market and sell Ampligen(R) will be delayed.

We have identified two other capable cGMP facilities in the US for the manufacture of Ampligen(R) and obtained proposals from both. If either of these two facilities are acceptable, we would be able to maintain a minimum of two independent production sites. We are in the process of reviewing these other proposals.

The purified drug concentrate utilized in the formulation of ALFERON N Injection(R) is manufactured in our New Brunswick, New Jersey facility and ALFERON N Injection(R) was formulated and packaged at a production facility formerly owned and operated by Abbott Laboratories located in Kansas. Abbott Laboratories has sold the facility to Hospira. Hospira recently completed the production of 12,000 vials. Hospira is ceasing the labeling and packaging of Alferon N Injection(R) as they are seeking larger production runs for cost efficiency purposes. We have identified five new potential contract manufacturers, obtained proposals from all five, and have audited two, concerning the future formulation and packaging of Alferon N Injection(R). If we are unable to secure a new facility within a reasonable period of time to formulate and package ALFERON N Injection(R) at an acceptable cost, our ability to sell ALFERON N Injection(R) and to generate profits there from will be adversely affected.

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. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen(R) or enter into third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Also, each production lot 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.

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

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

Our products may be subject to substantial competition.

Ampligen(R). Competitors may be developing technologies that are, or in the future may be, the basis for competitive products. Some of these potential products may have an entirely different approach or means of accomplishing similar therapeutic effects to products being developed by us. These competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments may offer competition to our products. Furthermore, many of our competitors have significantly greater experience than us in pre-clinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, HPB or other regulatory product approvals more rapidly than us. There are no drugs approved for commercial sale with respect to treating ME/CFS in the United States. The dominant competitors with drugs to treat HIV diseases include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs, Glaxo Smithkline, Merck and Schering-Plough Corp. These potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Although we believe our principal advantage is the unique mechanism of action of Ampligen(R) on the immune system, we cannot assure that we will be able to compete.

ALFERON N Injection(R). Many potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. ALFERON N Injection(R) currently competes with Schering's injectable recombinant alpha interferon product (INTRON(R) A) for the treatment of genital warts. 3M Pharmaceuticals also received FDA approval for its immune-response modifier, Aldara(R), a self-administered topical cream, for the treatment of external genital and perianal warts. ALFERON N Injection(R) also competes with surgical, chemical, and other methods of treating genital warts. We cannot assess the impact products developed by our competitors, or advances in other methods of the treatment of genital warts, will have on the commercial viability of ALFERON N Injection(R). If and when we obtain additional approvals of uses of this product, we expect to compete primarily on the basis of product performance. Our potential competitors have developed or may develop products (containing either alpha or beta interferon or other therapeutic compounds) or other treatment modalities for those uses. In the United States, three recombinant forms of beta interferon have been approved for the treatment of relapsing-remitting multiple sclerosis. There can be no assurance that, if we are able to obtain regulatory approval of ALFERON N Injection(R) for the treatment of new indications, we will be able to achieve any significant penetration into those markets. In addition, because certain competitive products are not dependent on a source of human blood cells, such products may be able to be produced in greater volume and at a lower cost than ALFERON N Injection(R). Currently, our wholesale price on a per unit basis of ALFERON N Injection(R) is higher than that of the competitive recombinant alpha and beta interferon products.

General. Other companies may succeed in developing products earlier than we do, obtaining approvals for such products from the FDA more rapidly than

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

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

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

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

We may be subject to product liability claims from the use of Ampligen(R), Alferon N Injection(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(R) and/or Alferon N Injection(R) product liability claims. A successful product liability claim against us in excess of Ampligen(R)'s \$1,000,000 in insurance coverage; \$3,000,000 in aggregate, or in excess of Alferon N Injection(R)'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 \$2,000,000 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, flammable solvents and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with the standards prescribed by applicable regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident or the failure to comply with applicable regulations, we could be held liable for any damages that result, and any such liability could be significant. We do not maintain insurance coverage against such liabilities.

Risks Associated With and Investment in Our Common Stock

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; 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 September 30, 2005, the price of our common stock has ranged from \$1.25 to \$2.50 per share. 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 prior registration statements, are sold in the public market.

As of November 15, 2005, approximately 1,132,457 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act of 1933, 402,798 of which are registered for public sale. Also, we have registered 21,106,907 shares issuable (i) to Fusion Capital pursuant to the common stock purchase agreement with Fusion Capital; (ii) upon conversion of approximately 135% of Debentures that we issued in 2003 and 2004; (iii) as payment of 135% of the interest on all of the Debentures; (iv) upon exercise of 135% of the certain Warrants; and (v) upon exercise of certain other warrants. In addition we will be registering an aggregate of 1,224,983 shares representing 135% of shares issuable upon exercise of the October 2009 Warrants and as additional interest shares (resulting from the amendment to the Debentures. Registration of the shares permits the sale of the shares in the open market or in privately negotiated transactions without compliance with the requirements of Rule 144. To the extent the exercise price of the warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the conversion price and exercise price of these securities are adjusted pursuant to anti-dilution protection, the securities could be exercisable or convertible for even more shares of common stock. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock. Sales of substantial amounts of our common stock in the public market could cause the market price for our

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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.

The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by Fusion Capital and other shares by Selling Stockholders listed in this prospectus and another prospectus could cause the price of our common stock to decline.

The sale by Fusion Capital and other selling stockholders listed in this prospectus and another prospectus of our common stock will increase the number of our publicly traded shares, which could depress the market price of our common stock. Moreover, the mere prospect of resales by Fusion Capital and other selling stockholders could depress the market price for our common stock. The issuance of shares to Fusion Capital under the common stock purchase agreement dated July 8, 2005, will dilute the equity interest of existing stockholders and could have an adverse effect on the market price of our common stock.

The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement will fluctuate based on the price of our common stock. All shares sold to Fusion Capital are freely tradable. Fusion Capital may sell none, some or all of the shares of common stock purchased from us at any time. We expect that the shares will be sold over a period of in excess of 25 months from August 3, 2005. Depending upon market liquidity at the time, a sale of shares under this offering at any given time could cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock to Fusion Capital pursuant to the purchase agreement, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

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 10.3% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at \$.01 per Right under certain circumstances.

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

### INFORMATION ABOUT US

We are a biopharmaceutical company engaged in the clinical development, manufacture, marketing and distribution of new drug entities based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. We were founded in the early 1970s, as a contract researcher for the National Institutes of Health. After almost 30 years, 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 to aid the development of therapeutic products for the treatment of chronic diseases. We own a U.S. Food and Drug Administration ("FDA") approved GMP (good manufacturing practice) manufacturing facility in New Jersey.

Our flagship products include Ampligen(R) and Alferon N Injection(R). Ampligen(R) is an experimental drug undergoing clinical development for the treatment of: Myalgic Encephalomyelitis/Chronic Fatigue Syndrome ("ME/CFS" or "CFS"), and HIV. In August 2004, we completed a Phase III clinical trial ("AMP 516") treating over 230 ME/CFS patients with Ampligen(R) and are in the process of preparing a new drug application ("NDA") to be filed with the FDA. Over its developmental history, Ampligen(R) has received various designations, including Orphan Drug Product Certification (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports (AHRQ, Agency Health Research Quality). However to date, the FDA has determined it has yet to receive sufficient information to support the potential of Ampligen(R) to treat a serious or life threatening aspect of ME/CFS. The definition of the "seriousness of a condition", according to Guidance for Industry documents published in July, 2004 is "a matter of judgment, but generally based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one". The FDA has recently requested a "complete and audited report of the Amp 516 study to determine whether Ampligen(R) has a clinically meaningful benefit on a serious or life threatening aspect of ME/CFS in order to evaluate whether the Amp 516 study results do or do not support a "fast track designation". The FDA has also invited us to include a schedule for completion of all ME/CFS studies as well as a proposed schedule for our NDA submission. Because we believe our ME/CFS studies are complete, we intend to request a pre-NDA meeting to obtain advice on preparing and submitting our NDA. At the same time we will continue with our existing ongoing efforts to prepare a complete and audited report of our various studies, including the well-controlled Amp 516 study. We are using our best efforts to complete the requisite reports including the hiring of new

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staff and various recognized expert medical/regulatory consultants, but can provide no assurance as to whether the outcome of this large data collection and filing process (approximately 750 patients, treated more than 45,000 times) will be favorable or unfavorable, specifically with respect to the FDA's perspective. Also, we can provide no guidance as to the tentative date at which the compilation and filing of such data will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the ability of Hollister-Stier facilities (or the facilities of such other manufacturer as we may retain in the event that we do not come to definitive terms with Hollister-Stier) to interface with our own New Brunswick staff/facilities to meet the manufacturing regulatory standards. In addition, Ampligen(R) is undergoing pre-clinical testing for possible treatment of avian influenza ("bird flu"). Alferon N Injection(R) is the registered trademark for our injectable formulation of natural alpha interferon, which is approved by the FDA for the treatment of genital warts. Alferon N Injection(R) is also in clinical development for treating Multiple Sclerosis and West Nile Virus ("WNV").

With the threat of an avian influenza pandemic rising and health officials warning that the virus could develop resistance to current flu treatments, the pursuit of a cost-effective and complementary treatment to existing antivirals and vaccines has become critical. This combination may permit the use of lower dosages and fewer injections of the antivirals and vaccines used to combat avian flu, thereby decreasing the cost of both immunization programs and treatment programs for the full-blown disease.

In antimicrobial (antibacterial) therapy, which is the best-studied clinical model, synergistic drug combinations may result in curative conditions/outcomes, often not observed when the single drugs are given alone. In the case of avian influenza where global drug supplies are presumptively in very limited supply relative to potential needs, therapeutic synergistic combinations could not only affect the disease outcome, but also the number of individuals able to access therapies.

We recently announced that true therapeutic synergy had been observed in the interaction between Ampligen(R) and Tamiflu in the inhibition of the Avian influenza virus. Cell destruction was measured in vitro using different drug combinations. True therapeutic synergy is defined by mathematical equations which indicate that the therapeutic effect observed is in fact greater than the expected arithmetic sum of the two drugs working independently, and is referred to by pharmacologists as the "Chou/Talalay" equations developed at Johns Hopkins University.

In a recently reported study from a vaccine group in Japan, the incorporation of poly I: poly C (dsRNA) into a nasal administration of a killed influenza A preparation converted a poorly immunogenic response into a highly efficacious vaccine in protection of mice from lethal infection from human influenza A. Ampligen is a dsRNA which currently is undergoing testing in this animal model.

We have over 100 patents worldwide with 9 additional patents pending comprising our intellectual property. We continually review our patents rights to determine whether they have continuing value. Such review includes an analysis of the patent's ultimate revenue and profitability potential on an undiscounted cash basis to support the realizability of our respective capitalized cost. In addition, management's review addresses whether each patent continues to fit into our strategic business plans. We have a fully commercialized product (Alferon N Injection(R)), and a GMP certified manufacturing facility.

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In March 2004, we completed the step-by-step acquisition from Interferon Sciences, Inc. ("ISI") of ISI's commercial assets, Alferon N Injection(R) inventory, a worldwide license for the production, manufacture, use, marketing and sale of Alferon N Injection(R). As well as, a 43,000 square foot manufacturing facility in New Jersey and the acquisition of all intellectual property related to Alferon N Injection(R). Alferon N Injection(R) is a natural alpha interferon that has been approved by the FDA for commercial sale for the intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. The acquisition was completed in Spring 2004 with the acquisition of all world wide commercial rights.

We outsource certain components of our research and development, manufacturing, marketing and distribution while maintaining control over the entire process through our quality assurance group and our clinical monitoring group.

Since the completion of our AMP 516 ME/CFS Phase III clinical trial for use of Ampligen(R) in the treatment of ME/CFS we have received inquiries from and, under confidentiality agreements, are having dialogue with other companies regarding marketing opportunities. No proposals or agreements have resulted from the dialogue, nor can we be assured that any proposals or agreements will result from these inquiries.

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

### USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the common stock offered by this prospectus. Proceeds from the exercising of the options/warrants will be used for conducting clinical trials and related activities, research and development and general corporate purposes.

### SELLING STOCKHOLDERS

This prospectus relates to the reoffer and resale of Shares that: (i) are issuable upon exercise of options/warrants that have been issued by us to the selling stockholders pursuant to our Officers, Directors and Employees Stock Compensation Programs and our 2004 Equity Incentive Plan and (ii) have been issued to certain selling stockholders pursuant to our 2003 Directors Compensation Plan. The Officers, Directors and Employees Stock Compensation Programs, 2004 Equity Incentive Plan and 2003 Directors Compensation Plan are collectively referred to as the "Plans."

The information in the table below sets forth, for each selling stockholder, based upon information available to us as of November 10, 2005, the number of shares of our common stock beneficially owned before and after a hypothetical sale of the Shares, the maximum number of Shares that may be sold and the percentage of the outstanding shares of our common stock owned before and after the hypothetical sale of the Shares.

In the table below, "Shares to be Sold" represents the maximum number of Shares that could be sold under this prospectus if the holder sold all of his or her Shares. The amounts listed under "Shares to be Sold" do not constitute commitments to sell any or all of the stated number of Shares. The actual number of Shares to be sold, if any, shall be determined from time to time by each selling stockholder in his or her discretion. We have not been informed whether any selling stockholders intend to sell any Shares at this time.

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Name and Position	Shares Beneficially Owned(1)	Shares To Be Sold(1)	Shares beneficially Owned After The Offering	Percentage Before Offering
William A. Carter, M.D.		6,192,868	5,685,378 (2)	507,490
Robert E. Peterson		575,574	567,574 (3)	8,000
Ransom W. Etheridge		586,800	532,484 (4)	54,316
Richard C. Piani		361,842	337,092 (5)	24,750
William M. Mitchell		342,124	324,484 (6)	17,640
David R. Strayer		150,746	140,000 (7)	10,746
Carol Smith		51,791	51,791 (8)	0
Iraj-Eqhbali Kiani		42,017	42,017 (9)	0
Douglas Hulse		131,067 (10)	41,667 (10)	89,400
Steven Spence		105,770	29,037 (11)	76,733
Mei-June Liao		10,000	10,000 (12)	0
Robert Hansen		10,000	10,000 (12)	0

\* Less than 1.0%

(1) Reflects shares issuable upon the exercise of options/warrants granted pursuant to the Plans.

(2) Includes shares issuable upon the exercise of (i) warrants issued in 2001 to purchase 376,650 shares of common stock consisting of 188,325 exercisable at \$6.00 per share and 188,325 exercisable at \$9.00 per share, all expiring on February 22, 2006; (ii) stock options issued in

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2001 to purchase 10,000 shares of common stock at \$4.03 per share expiring January 3, 2011; (iii) warrants issued in 2002 to purchase 1,000,000 shares of common stock exercisable at \$2.00 per share expiring on August 7, 2007; (iv) warrants issued in 2003 to purchase 1,450,000 shares of common stock exercisable at \$2.20 per share expiring on September 8, 2008; (v) stock options issued in 2004 to purchase 320,000 shares of common stock at \$2.60 per share expiring on September 7, 2014; (vi) Stock Options issued in 2005 to purchase 100,000 shares of common stock at \$1.75 per share expiring on April 26, 2015 and (vii) Stock options issued in 2005 to purchase 465,000 shares of common stock at \$1.86 per share expiring July 1, 2011. Also includes 1,963,728 warrants and options originally issued to William A. Carter and subsequently transferred to Carter Investments of which Dr. Carter is the beneficial owner. These securities consist of warrants issued in 1998(a) to purchase 490,000 shares of common stock consisting of 190,000 exercisable at \$4.00 per share expiring on January 1, 2008 and 300,000 exercisable at \$6.00 per share expiring January 1, 2006; (b) stock options granted in 1991 and extended in 1998 to purchase 73,728 shares of common stock exercisable at \$2.71 per share expiring on August 8, 2008 and (c) Warrants issued in 2002 to purchase 1,400,000 shares of common stock at \$3.50 per share expiring on September 30, 2007. Does not include 507,490 shares of common stock.

- (3) Includes shares issuable upon exercise of (i) options issued in 1997 to purchase 13,750 shares of common stock at \$3.50 per share and expiring on January 22, 2007, (ii) options issued in 2001 to purchase 10,000 shares of common stock at \$4.03 per share and expiring on January 3, 2011, (iii) warrants issued in 2002 to purchase 200,000 shares of common stock at \$2.00 per share expiring on August 13, 2007 and (iv) options issued in 2005 to purchase 100,000 shares of common stock at \$1.75 per share expiring April 26, 2015. Also includes 243,824 warrants/options originally issued to Robert E. Peterson and subsequently transferred to the Robert E. Peterson Trust of which Robert E. Peterson is owner and Trustee. These securities include warrants issued in 1996 to purchase 50,000 shares of common stock exercisable at \$3.50 per share expiring on February 28, 2006; warrants issued in 1998 to purchase 100,000 shares of common stock at \$5.00 per share expiring on April 14, 2006; warrants issued in 2002 to purchase 30,000 shares of common stock exercisable at \$5.00 per share expiring on April 30, 2006 and 63,824 stock options issued in 2004 consisting of 50,000 options to acquire common stock at \$3.44 per share expiring on June 22, 2014 and 13,824 options to acquire common stock at \$2.60 per share expiring on September 7, 2014. Does not include 8,000 shares of common stock.
- (4) Includes shares issuable upon exercise of (i) 20,000 warrants issued in 1998 to purchase common stock at \$4.00 per share, originally expiring on January 1, 2003 and extended to January 1, 2008; (ii) 100,000 warrants issued in 2002 exercisable \$2.00 per share expiring on August 13, 2007; (iii) stock options issued in 2005 to purchase 100,000 shares of common stock exercisable at \$1.75 per share expiring on April 26, 2015 and (iv) stock options issued in 2004 to purchase 50,000 shares of common stock exercisable at \$2.60 per share expiring on September 7, 2014 and (v) 62,484 shares of common stock issued pursuant to the 2003 directors compensation plan. Also includes 200,000 stock options originally granted to Ransom Etheridge in 2003 and subsequently transferred to relatives and family trusts. These stock options are exercisable at \$2.75 per share and expires on December 4, 2013. The transfers consist of 50,000 options to the Etheridge Family Trust; 37,500 options to Julianne Inglima; 37,500 options to Thomas Inglima; 37,500 options to R.Etheridge-BMI Trust; and 37,500 options to R. Etheridge-TCI Trust. Julianne and Thomas are Mr. Etheridge's daughter

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and son-in-law. Does not include 54,316 shares of common stock.

- (5) Includes shares issuable upon exercise of (i) 20,000 warrants issued in 1998 to purchase common stock at \$4.00 per share originally expiring on January 1, 2005 and extended to January 1, 2008; (ii) 100,000 warrants issued in 2003 exercisable at \$2.00 per share expiring on August 13, 2007; (iii) options granted in 2004 to purchase 54,608 shares of common stock exercisable at \$2.60 per share expiring on September 17, 2014; (iv) options granted in 2005 to purchase 100,000 shares of common stock exercisable at \$1.75 per share expiring on April 26, 2015 and (v) 62,484 shares of common stock issued pursuant to the Company's Directors Compensation Plan. Excludes (a) 6,850 shares of common stock owned by Mr. Piani; (b) 12,900 shares of common stock owned jointly by Mr. And Mrs. Piani; (c) and 5,000 shares of common stock owned by Mrs. Piani.
- (6) Includes shares issuable upon exercise of (i) warrants issued in 1998 to purchase 12,000 shares of common stock at \$6.00 per share, expiring on August 25, 2008; (ii) 100,000 warrants issued in 2002 exercisable at \$2.00 per share expiring on August 13, 2007; (iii) 50,000 stock options issued in 2004 exercisable at \$2.60 per share expiring on September 7, 2014; (iv) 100,000 stock options issued in 2005 exercisable at \$1.75 per share expiring on April 26, 2015 and (v) 62,484 shares of common stock issued pursuant to the Directors Compensation Plan. Excludes 17,640 shares of common stock.
- (7) (i) stock options issued in 1997 to purchase 20,000 shares of common stock at \$3.50 per share expiring on February 22, 2007; (ii) warrants issued in 1998 to purchase 50,000 shares of common stock exercisable at \$4.00 per share expiring on February 28, 2008; (iii) stock options granted in 2001 to purchase 10,000 shares of common stock exercisable at \$4.03 per share expiring on January 3, 2011; (iv) warrants issued in 2002 to purchase 50,000 shares of common stock exercisable at \$2.00 per share expiring on August 13, 2007 and (v) stock options issued in 2004 to purchase 10,000 shares of common stock exercisable at \$1.90 per share expiring on December 7, 2014. Does not include 10,746 shares of common stock.
- (8) Consists of shares issuable upon exercise of (i) 5,000 warrants issued in 1998 to purchase common stock at \$4.00 per share expiring June 7, 2008; (ii) 20,000 warrants issued in 2002 exercisable at \$2.00 per share expiring in August 13, 2007; (iii) 6,791 stock options issued in 1997 exercisable at \$3.50 expiring January 22, 2007; (iv) 10,000 stock options issued in 2001 exercisable at \$4.03 per share expiring January 3, 2011 and 10,000 stock options issued in 2004 exercisable at \$1.90 expiring on December 7, 2014.
- (9) Consists of shares issuable upon exercise of (i) 12,000 options issued in 2005 exercisable at \$1.63 per share expiring on June 2, 2015; (ii) 15,000 options issued in 2005 exercisable at \$1.75 per share expiring on April 26, 2015 and (iii) 15,017 shares of common stock issued pursuant to the directors compensation plan.
- (10) Consists of 41,667 options exercisable at \$1.55 per share expiring February 14, 2015. Shares owned includes 89,400 shares in which Mr. Hulse has an undivided interest. These shares are held by The Sage Group of which Mr. Hulse is a principal.
- (11) Consists of 15,000 stock options granted in 2005 exercisable at \$1.75 per share expiring on April 26, 2015 and 14,037 shares of common stock issued pursuant to the directors compensation plan. Does not include 76,733 shares of common stock.

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- (12) Consists of stock options granted in 2004 exercisable at \$1.90 per share of common stock expiring on December 7, 2014.

### PLAN OF DISTRIBUTION

The selling stockholders, their donees or other transferees and successors in interest permitted to use Form S-8, under General Instruction A of Form S-8, may sell or transfer common stock for value in one or more transactions in the open market, either directly or through brokers or agents, or in privately negotiated transactions or in a combination of these methods of sale, at market prices prevailing at the time of sale, at prices related to those market prices or at prices otherwise negotiated. The selling stockholders have advised us that, at the date of this prospectus, they do not have any agreement, arrangement or understanding with regard to the sale of the Shares. All selling and other expenses incurred by individual selling stockholders will be borne by those selling stockholders.

We do not know whether or not any of the selling stockholders will sell any or all of their Shares under this prospectus. We may terminate this offering without notice at any time.

### LEGAL MATTERS

Certain legal matters in connection with the issuance of the has been passed upon by our counsel, Silverman Sclar Shin & Byrne PLLC, New York, New York.

### EXPERTS

The financial statements incorporated by reference in this Prospectus have been audited by BDO Seidman, LLP, an independent registered public accounting firm, to the extent and for the periods set forth in their reports incorporated herein by reference, and are incorporated herein in reliance upon such reports given upon the authority of said firm as experts in auditing and accounting.

### INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, until the sale of all the shares of Common Stock that are part of this offering. The documents we are incorporating by reference are as follows:

- (a) Our annual report on Form 10-K for our fiscal year ended December 31, 2004, SEC File No. 1-13441.
- (b) Our quarterly report on Form 10-Q for the quarterly period ended March 31, 2005, SEC File No. 1-13441.
- (c) Our proxy statement on schedule 14A for our 2005 annual meeting, SEC File No. 1-13441.
- (d) Our quarterly report on Form 10-Q for the quarterly period ended June 30, 2005, SEC File No. 1-13441.

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- (e) Our current report on Form 8-K filed on October 20, 2005, SEC File No. 1-13441.
- (f) Our current report on Form 8-K/A filed on October 28, 2005, SEC File No. 1-13441.
- (g) Our quarterly report on Form 10-Q for the quarterly period ended September 30, 2005, 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.

You should rely only on the information incorporated by reference or provided in this registration statement or any supplement. We have not authorized anyone else to provide you with different information. We and the selling stockholders will not make offers of these shares in any state where the offer is not permitted. You should not assume that the information in this registration statement or any supplement is accurate as of any date other than the date on the front of those documents.

Any statement contained in a document or incorporated or deemed to be incorporated by reference shall be deemed to be modified or superseded for purposes of this registration statement to the extent that a statement contained herein or in any subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this registration statement. All information in this registration statement is qualified in its entirety by the information and financial statements (including the notes thereto).

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, Suite 660, Philadelphia, PA, 19103, telephone no. (215) 988-0080.

### WHERE YOU CAN FIND MORE INFORMATION

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

### DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Our Amended and Restated Certificate of Incorporation state that we shall indemnify our directors and officers to the maximum extent permitted by Delaware law.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the Company has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in that act and is

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therefore unenforceable

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### PART II

#### INFORMATION REQUIRED IN THE REGISTRATION STATEMENT

##### Item 3. Incorporation Of Documents By Reference.

We incorporate by reference the following documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, prior to the termination of the offering:

- (a) Our annual report on Form 10-K for our fiscal year ended December 31, 2004, SEC File No. 1-13441.
- (b) Our quarterly report on Form 10-Q for the quarterly period ended March 31, 2005, SEC File No. 1-13441.
- (c) Our proxy statement on schedule 14A for our 2005 annual meeting, SEC File No. 1-13441.
- (d) Our quarterly report on Form 10-Q for the quarterly period ended June 30, 2005, SEC File No. 1-13441.
- (e) Our current report on Form 8-K filed on October 20, 2005, SEC File No. 1-13441.
- (f) Our current report on Form 8-K/A filed on October 28, 2005, SEC File No. 1-13441.
- (g) Our quarterly report on Form 10-Q for the quarterly period ended September 30, 2005, 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.

All documents filed by the Registrant pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Securities Exchange Act of 1934 after the date of this registration statement and prior to the filing of a post-effective amendment to this registration statement, which indicates that all securities offered hereunder have been sold, or which de-registers all securities then remaining unsold under this registration statement, shall be deemed to be incorporated by reference in this registration statement and to be a part hereof from the date of filing of such documents.

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Any statement contained in a document or incorporated or deemed to be incorporated by reference shall be deemed to be modified or superseded for purposes of this registration statement to the extent that a statement contained herein or in any subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this registration statement. All information in this registration statement is qualified in its entirety by the information and financial statements (including the notes thereto).

### Item 4. Description of Securities

Not Applicable.

### Item 5. Interests of named experts and counsel.

Not Applicable.

### Item 6. 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 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 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,

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

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- (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 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 7. Exemption from Registration Claimed

Not applicable.

Item 8. Exhibits

- 4.1 Form of Warrant issued pursuant to the Officers, Directors and Employees Stock Compensation Program - 1996
- 4.2 Form of Warrant issued pursuant to the Officers, Directors and Employees Stock Compensation Program - 1998

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- 4.3 Form of Warrant issued pursuant to the Officers, Directors and Employees Stock Compensation Program - 2001
- 4.4 Form of Warrant issued pursuant to the Officers, Directors and Employees Stock Compensation Program -2002
- 4.5 Form of Warrant issued pursuant to the Officers, Directors and Employees Stock Compensation Program - 2003
- 5.1 Opinion of Silverman Sclar Shin & Byrne PLLC
- 23.1 Consent of Silverman Sclar Shin & Byrne PLLC (included in Exhibit 5.1)
- 23.2 Consent of BDO Seidman, LLP
- 24 Powers of Attorney (included on the signature page of the Registration Statement).

### Item 9. Undertakings

#### A. The undersigned registrant hereby undertakes:

(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;

provided, however, that paragraphs (1)(i) and (1)(ii) herein do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the SEC by the Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in this registration statement

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

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

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

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Philadelphia, state of Pennsylvania, on this 17 day of November 2005.

Hemispherx Biopharma, Inc.

By: /s/ William A Carter

-----  
William A. Carter, M.D., President,  
Chief Executive Officer and Chairman  
of the Board

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POWER OF ATTORNEY

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-8 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.

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

Signature Title Date

/s/ William A. Carter ----- William A. Carter	President, Chairman and Chief Executive Officer	November 17, 2005
/s/ Robert E. Peterson ----- Robert E. Peterson	Chief Financial Officer	November 17, 2005
/s/ Ransom Etheridge ----- Ransom Etheridge	Director	November 17, 2005
/s/ William M. Mitchell ----- William M. Mitchell, M.D., Ph.D.	Director	November __, 2005
/s/ Richard Piani ----- Richard Piani	Director	November 17, 2005
/s/ Iraj-Eqhbali Kiani ----- Iraj-Eqhbali Kiani	Director	November 17, 2005
/s/ Steven D. Spence ----- Steven D. Spence	Director	November 17, 2005

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### Index to Exhibits

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