

HEMISPHERX BIOPHARMA INC

Form S-3

June 17, 2008

As filed with the Securities and Exchange Commission on June 17, 2008

Registration No. 333-

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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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

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

Delaware

2836

52-0845822

(State or other jurisdiction of  
incorporation or organization)

(Primary Standard Industrial  
Classification Code Number)

(I.R.S. Employer  
Identification Number)

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

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

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

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

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

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

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

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

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. "

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer "                      Accelerated filer x  
 Non-accelerated filer "                      Smaller Reporting Company "

**CALCULATION OF REGISTRATION FEE**

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee (1)
Common Stock, \$0.001 par value per share	(2)	(3)	(3)	(3)
Preferred Stock, \$0.01 par value per share	(2)	(3)	(3)	(3)
Warrants	(2)	(3)	(3)	(3)
Debt Securities	(2)	(3)	(3)	(3)
<b>Total</b>			<b>\$ 50,000,000</b>	<b>\$ 1,965.00</b>

(1) Calculated pursuant to Rule 457(o) under the Securities Act.

- (2) There are being registered hereunder such indeterminate number of shares of common stock and preferred stock, such indeterminate number of warrants to purchase common stock or preferred stock, and such indeterminate principal amount of debt securities as shall have an aggregate initial offering price not to exceed in the aggregate \$50,000,000. If any debt securities are issued at an original issue discount, then the offering price of such debt securities shall be in such greater principal amount at maturity as shall result in an aggregate offering price not to exceed \$50,000,000, less the aggregate dollar amount of all securities previously issued hereunder. Any securities registered hereunder may be sold separately or as units with other securities registered hereunder. The proposed maximum initial offering price per security will be determined, from time to time, by the registrant in connection with the issuance by the registrant of the securities registered hereunder. The securities registered also include such indeterminate number of shares of common stock and preferred stock and amount of debt securities as may be issued upon conversion of or exchange for preferred stock or debt securities that provide for conversion or exchange, upon exercise of warrants or pursuant to the anti-dilution provisions of any such securities. In addition, pursuant to Rule 416 under the Securities Act, the securities being registered hereunder include such indeterminate number of shares of common stock and preferred stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.
- (3) The proposed maximum aggregate offering price per class of security will be determined from time to time by the registrant in connection with the issuance by the registrant of the securities registered hereunder and is not specified as to each class of security pursuant to General Instruction II.D. of Form S-3 under the Securities Act.

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

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

**Subject to Completion**  
**Preliminary Prospectus Dated June 17, 2008**  
**\$50,000,000**

***HEMISPHERX BIOPHARMA, INC.***

Common Stock  
Preferred Stock  
Warrants  
Debt Securities

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This prospectus relates to common stock, preferred stock, debt securities and warrants to purchase common stock, preferred stock or debt securities, either individually or in units, as well as common stock or preferred stock upon conversion of debt securities, common stock upon conversion of preferred stock, or common stock or preferred stock upon the exercise of warrants that we may sell from time to time in one or more offerings up to a total public offering price of \$50,000,000 on terms to be determined at the time of sale. We will provide specific terms of these securities in supplements to this prospectus. If there is any inconsistency between the information in this prospectus and a prospectus supplement, you should rely on the information in that prospectus supplement. You should read this prospectus and any supplement carefully before you invest.

**This prospectus may not be used to offer and sell securities unless accompanied by a prospectus supplement for those securities.**

**See “Risk Factors” beginning on page 4 for a discussion of material risks that you should consider before you invest in our securities being sold with this prospectus.**

Our common stock is traded on the American Stock Exchange under the symbol “HEB.” On June 2, 2008, the last reported sale price for our common stock on the American Stock Exchange was \$0.71 per share.

As of June 2, 2008, the aggregate market value of our outstanding common stock held by non-affiliates was approximately \$52,623,459, based on 74,117,549 shares of outstanding common stock, of which approximately 56,344,296 shares are held by non-affiliates, and a per share price of \$0.71 based on the closing sale price of our common stock on that date. As of the date hereof we have not offered any securities pursuant to General Instruction I.B.6 of Form S-3 during the prior 12 calendar month period that ends on and includes the date hereof.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The date of this prospectus is \_\_\_\_\_, 2008.

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## PROSPECTUS SUMMARY

### *Important Notice about the Information Presented in this Prospectus*

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or SEC, utilizing a “shelf” registration process. Under this shelf process, we may from time to time sell any combination of securities described in this prospectus in one or more offerings. The aggregate amount of securities that we may offer under the registration statement is \$50,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of the securities being offered. That prospectus supplement may include a discussion of any risk factors or other special consideration that apply to those securities. The prospectus supplement may also add, update or change information contained in this prospectus. If there is any inconsistency between the information in this prospectus and a prospectus supplement, you should rely on the information in that prospectus supplement. You should read both this prospectus and any applicable prospectus supplement together with additional information described under the heading “Where You Can Find More Information.”

When acquiring any securities discussed in this prospectus, you should rely on the information provided in this prospectus and the prospectus supplement, including the information incorporated by reference. Neither we, nor any underwriters or agents, have authorized anyone to provide you with different information. We are not offering the securities in any state where such an offer is prohibited. You should not assume that the information in this prospectus, any prospectus supplement, or any document incorporated by reference, is truthful or complete at any date other than the date mentioned on the cover page of those documents. You should also carefully review the section entitled “Risk Factors,” which highlights certain risks associated with an investment in our securities, to determine whether an investment in our securities is appropriate for you.

References in this prospectus to “Hemispherx,” the “Company,” “we,” “us” and “our” are to Hemispherx Biopharma, Inc.

### ***About Hemispherx***

We are a biopharmaceutical company engaged in the clinical development, manufacture, marketing and distribution of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. We were founded in the early 1970s doing contract research for the National Institutes of Health. Since that time, 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 certain chronic diseases.

Our current strategic focus is derived from four applications of our two core pharmaceutical technology platforms Ampligen® and Alferon N Injection®. The commercial focus for Ampligen includes application as a treatment for Chronic Fatigue Syndrome (CFS) and as a vaccine enhancer (adjuvant) for both therapeutic and preventative vaccine development. Alferon N Injection® is an FDA approved product with an indication for refractory or recurring genital warts. Alferon LDO (Low Dose Oral) is an application currently under early stage development targeting influenza and viral diseases both as an adjuvant as well as a single entity anti-viral.

Ampligen® is an experimental drug currently undergoing clinical development for the treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (“ME/CFS” or “CFS”), and HIV. We completed Phase III clinical trials using Ampligen® to treat ME/CFS patients and are presently in the registration process for a new drug application (“NDA”) with the Food and Drug Administration (“FDA”). On December 5, 2007 we received a Refusal to File (“RTF”) letter from the FDA as our NDA filing was deemed “not substantially complete”. We responded to the FDA’s concerns on January 8, 2008 addressing their fourteen pre-clinical and clinical questions. A scheduled Guidance Meeting with the FDA on February 8, 2008 resulted in resolving nine of the fourteen concerns. These nine are no longer considered filing issues. The five remaining issues can be grouped into two categories: 1) administrative items which include the submission of additional clinical records, the clarification of some documents previously submitted, additional clinical data reconciliation and additional charts, which summarize specific parts of the clinical data, and 2) the reformatting and enlarged analysis of the existing reports to more closely align with current International Committee on Harmonization Guidelines. These five NDA filing issues have been addressed by our clinical and scientific staff with the filing of amendments to our NDA on April 25, 2008. These amendments should allow the FDA reviewers to better evaluate independently the statistical efficacy/safety conclusions of our NDA for the use of Ampligen in treating ME/CFS.

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, New Jersey primarily designed to produce Alferon N. In 2006, we completed the installation of a polymer production line to produce Ampligen® raw materials on a more reliable and consistent basis.

Our principal executive offices are located at One Penn Center, 1617 JFK Boulevard, Philadelphia, Pennsylvania 19103, and our telephone number is 215-988-0080. We maintain a website at “<http://www.hemispherx.net>.” Information contained on our website is not considered to be a part of, nor incorporated by reference in, this prospectus.

## **RISK FACTORS**

The following cautionary statements identify important factors that could cause our actual results 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:

### **Risks Associated With Our Business**

#### *No assurance of successful product development.*

Ampligen® and related products. The development of Ampligen® and our other related products is subject to a number of significant risks. Ampligen® 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® 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. Please see the next risk factor.

Alferon N Injection®. Although Alferon N Injection® is approved for marketing in the United States for the intra-lesional 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.

***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 adversely affected.***

All of our drugs and associated technologies, other than Alferon N Injection®, are investigational and must receive prior regulatory approval by appropriate regulatory authorities for general use and are currently legally available only through clinical trials with specified disorders. At present, Alferon N Injection® is only approved for the intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection® for other indications will require regulatory approval.

Our products, including Ampligen®, 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® or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen® will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligen® is authorized for use in clinical trials including a cost recovery program in the United States and Europe, 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.

We filed an NDA with the FDA for treatment of CFS on October 10, 2007. On December 5, 2007 we received an RTF letter from the FDA as our NDA filing was deemed “not substantially complete”. We responded to the FDA’s concerns on January 8, 2008 addressing their fourteen pre-clinical and clinical questions. A scheduled Guidance Meeting with the FDA on February 8, 2008 resulted in resolving nine of the fourteen concerns. These nine are no longer considered filing issues. The five remaining issues can be grouped into two categories: 1) administrative items which include the submission of additional clinical records, the clarification of some documents previously submitted, additional clinical data reconciliation and additional charts, which summarize specific parts of the clinical data, and 2) the reformatting and enlarged analysis of the existing reports to more closely align with current International Committee on Harmonization Guidelines.

These five NDA filing issues have been addressed by our clinical and scientific staff with the filing of amendments to our NDA on April 25, 2008. These amendments should allow the FDA reviewers to better evaluate independently the statistical efficacy/safety conclusions of our NDA for the use of Ampligen in treating ME/CFS. However, there are no assurances the FDA will accept the amended NDA for review, and if accepted, there are no assurances that the NDA will be approved.

If Ampligen® 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® 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® is undergoing pre-clinical testing for possible treatment of avian flu. Although preliminary in vitro testing indicates that Ampligen® 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® 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® is being tested on two strains of avian influenza virus. There are a number of strains and strains mutate. No assurance can be given that Ampligen® 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 to get our experimental drug, Ampligen®, approved. As of March 31, 2008, our accumulated deficit was approximately \$188,355,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

***We may require additional financing which may not be available.***

The development of our products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of May 31, 2008, we had approximately \$10,763,000 in cash and cash equivalents and short-term investments. We anticipate, but cannot assure, that these funds will be sufficient to meet our operating cash requirements for the next 13 months.

We anticipate, but cannot assure, that we will be able to raise additional capital from the sale of securities registered herein. In addition, in April 2006, we entered into a common stock purchase agreement with Fusion Capital pursuant to which Fusion Capital agreed, under certain conditions and with certain limitations, to purchase on each trading day \$100,000 of our common stock until August 1, 2008. Fusion Capital does 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. Unless and until the market price for our common stock increases to at least \$1.00 (the closing sale price of the common stock on June 2, 2008 was \$0.71), no additional shares will be sold to Fusion Capital under the agreement. Should our price so rise, and assuming a purchase price of \$1.00 per share and the purchase by Fusion Capital of the remaining 1,061,189 shares, total gross proceeds to us from the remaining shares would only be approximately \$1,061,000.

Assuming no material financing from the sale of securities pursuant to this prospectus or from Fusion Capital and if we are unable to commercialize and sell Ampligen® and/or increase sales of Alferon N Injection® or our other products, we will need to secure other sources of funding through additional equity or debt financing or from other sources in order to satisfy our working capital needs and to complete the necessary clinical trials and the regulatory approval processes including the commercializing of Ampligen® 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.

***We may not be profitable unless we can protect our patents and/or receive approval for additional pending patents.***

We need to preserve and acquire enforceable patents covering the use of Ampligen® for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen® for such disease. We obtained all rights to Alferon N Injection®, 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 experimental drug, Ampligen®, which is carried out according to standard operating procedure manuals. We have been issued certain patents including those on the use of Ampligen® and Ampligen® in combination with certain other drugs for the treatment of HIV. We also have been issued patents on the use of Ampligen® 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® in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of Ampligen® as a sole treatment for any of the cancers, which we have sought to target. With regard to Alferon N Injection®, we have acquired from ISI its patents for natural alpha interferon produced from human peripheral blood leukocytes and its production process and we have filed a patent application for the use of Alferon® LDO in treating viral diseases including avian influenza. We cannot assure that our competitors will not seek and obtain patents regarding the use of similar products in combination with various other agents, for a particular target indication prior to our doing such. If we cannot protect our patents covering the use of our products for a particular disease, or obtain additional patents, we may not be able to successfully market our products.

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

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

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

If we cannot enforce the patent rights we currently hold we may be required to obtain licenses from others to develop, manufacture or market our products. There can be no assurance that we would be able to obtain any such licenses on commercially reasonable terms, if at all. We currently license certain proprietary information from third parties, some of which may have been developed with government grants under circumstances where the government maintained certain rights with respect to the proprietary information developed. No assurances can be given that such third parties will adequately enforce any rights they may have or that the rights, if any, retained by the government will not adversely affect the value of our license.

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

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

***We have limited marketing and sales capability. If we are unable to obtain additional distributors and our current and future 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 in large part on the efforts of third parties, and there is no assurance that these efforts will be successful.

Our commercialization strategy for Ampligen-CFS may include licensing/co-marketing agreements utilizing the resources and capacities of a strategic partner(s). We are currently seeking worldwide marketing partner(s), with the goal of having a relationship in place before approval is obtained. In parallel to partnering discussions, appropriate pre-marketing activities will be undertaken. We intend to control manufacturing of Ampligen on a worldwide basis.

We cannot assure that our U.S. or foreign marketing strategy will be successful 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. Our inability to establish viable marketing and sales capabilities would most likely 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® and/or Ampligen®.***

A number of essential materials are used in the production of Alferon N Injection®, 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.

There are a limited number of manufacturers in the United States available to provide the polymers for use in manufacturing Ampligen®. At present, we do not have any agreements with third parties for the supply of any of these polymers. We have established relevant manufacturing operations within our New Brunswick, New Jersey facility for the production of Ampligen® polymers from raw materials in order to obtain polymers on a more consistent manufacturing basis.

If we are unable to obtain or manufacture the required polymers, 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® and the commercial production of Alferon N Injection® and other products which we may commercially produce are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, and FDA and other governmental regulations and there can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all.

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

Small changes in methods of manufacturing, including commercial scale-up, may affect the chemical structure of Ampligen® 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® has been only produced in limited quantities for use in our clinical trials and we are dependent upon a third party supplier 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.

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

We have never produced Ampligen® 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® 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® 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 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®. 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 disease indications in which we plan to address include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs, Glaxo Smith Kline, 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® on the immune system, we cannot assure that we will be able to compete.

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

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

***Possible side effects from the use of Ampligen® or Alferon N Injection® could adversely affect potential revenues and physician/patient acceptability of our product.***

Ampligen®. We believe that Ampligen® 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 reducing the rate of infusion. 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® in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

Alferon N Injection®. At present, Alferon N Injection® is only approved for the intra-lesional (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®, patients did not experience serious side effects; however, there can be no assurance that unexpected or unacceptable side effects will not be found in the future for this use or other potential uses of Alferon N Injection® which could threaten or limit such product's usefulness.

***We may be subject to product liability claims from the use of Ampligen®, Alferon N Injection®, 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® or other of our products results in adverse effects. This liability might result from claims made directly by patients, hospitals, clinics or other consumers, or by pharmaceutical companies or others manufacturing these products on our behalf. Our future operations may be negatively affected from the litigation costs, settlement expenses and lost product sales inherent to these claims. While we will continue to attempt to take appropriate precautions, we cannot assure that we will avoid significant product liability exposure. Although we currently maintain product liability insurance coverage, there can be no assurance that this insurance will provide adequate coverage against Ampligen® and/or Alferon N Injection® product liability claims. A successful product liability claim against us in excess of Ampligen's® \$1,000,000 in insurance coverage; \$3,000,000 in aggregate, or in excess of Alferon N Injection'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 services of key personnel including Dr. William A. Carter could hurt our chances for success.***

Our success is dependent on the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen®, 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 December 31, 2010. 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 an 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:

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards; and
- the occurrence of any of the risks described in these "Risk Factors."

Our common stock is listed for quotation on the American Stock Exchange. For the 12-month period ended May 31, 2008, the closing price of our common stock has ranged from \$0.61 to \$2.00 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 are sold in the public market.***

We have registered \$50,000,000 of securities for public sale pursuant to this prospectus. In addition, 1,704,691 shares of our common stock are registered for public resale consisting of shares currently owned by Fusion Capital and shares issuable under the Fusion Capital common stock purchase agreement. Also, we have registered 135% of 3,615,514 shares issuable upon exercise of Warrants related to our former convertible debentures and 5,594,104 shares issuable upon exercise of certain other warrants. 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 pursuant to this prospectus or otherwise to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock. Sales of substantial amounts of our common stock in the public market could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

***Significant sales pursuant to this prospectus or to Fusion Capital may cause dilution.***

The issuance of a significant number of securities under this prospectus or shares to Fusion Capital under the common stock purchase agreement will dilute the equity interest of existing stockholders and could have an adverse effect on the market price of our common stock.

***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 7.8% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at \$.01 per Right under certain circumstances.

*Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Our research in clinical efforts may continue for the next several years and we may continue to incur losses due to clinical costs incurred in the development of Ampligen® 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 revenue.*

### **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Certain statements in this prospectus constitute “forwarding-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1995 (collectively, the “Reform Act”). Certain, but not necessarily all, of such forward-looking statements can be identified by the use of forward-looking terminology such as “believes,” “expects,” “may,” “will,” “should,” or “anticipates” or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. All statements other than statements of historical fact, included in this prospectus regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note that statements regarding potential drugs, their potential therapeutic effect, the possibility of obtaining regulatory approval, our ability to manufacture and sell any products, market acceptance or our ability to earn a profit from sales or licenses of any drugs or our ability to discover new drugs in the future are all forward-looking in nature.

Such forward-looking statements involve known and unknown risks, uncertainties and other factors, including but not limited to, the risk factors discussed above, 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.

### **RATIO OF EARNINGS TO FIXED CHARGES**

We have incurred \$17.1 million in fixed charges in the past five years. Fixed charges mainly represent interest expensed as well as amortized discounts related to indebtedness. We have incurred losses totaling \$15.2 million, \$20.9 million, \$12.4 million, \$19.4 million and \$18.1 million for the years ended December 31, 2003, 2004, 2005, 2006 and 2007, respectively. Until we achieve profitability, we will not be able to cover our fixed charges from earnings.

### **USE OF PROCEEDS**

Except as otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities offered by this prospectus for general corporate purposes, which may include working capital, capital expenditures, research and development expenditures, regulatory affairs expenditures, clinical trial expenditures, acquisitions of new technologies and investments, and the repayment, refinancing, redemption or repurchase of future indebtedness or capital stock. Additional information on the use of net proceeds from the sale of securities offered by this prospectus may be set forth in the prospectus supplement relating to that offering.

## DESCRIPTION OF CAPITAL STOCK

Our authorized capital stock currently consists of 200,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, \$0.01 par value per share.

The following summary of certain provisions of our common and preferred stock does not purport to be complete. You should refer to our Amended and Restated Certificate of Incorporation, amendments thereto, and our By laws, as amended, all of which are filed with the SEC. The summary below is also qualified by provisions of applicable law.

### Common Stock

Holders of common stock are entitled to one vote per share on matters on which our stockholders vote. There are no cumulative voting rights. Holders of common stock are entitled to receive dividends, if declared by our board of directors, out of funds that we may legally use to pay dividends. If we liquidate or dissolve, holders of common stock are entitled to share ratably in our assets once our debts and any liquidation preference owed to any then-outstanding preferred stockholders are paid. All shares of common stock that are outstanding as of the date of this prospectus are fully-paid and non-assessable.

### Preferred Stock

We are currently authorized to issue 5,000,000 shares of preferred stock, none of which are currently outstanding.

Our board of directors has the authority to designate any or all shares of preferred stock in one or more series and to fix the rights of each series. Prior to issuance of shares of each series, our Board of Directors will adopt resolutions and file a certificate of designation fixing for each series the designations, powers, preferences, conversion and other rights, voting powers, qualifications, limitations as to dividends, restrictions and terms and conditions of redemption. The preferred stock will, when issued, be fully paid and nonassessable and will not have, or be subject to, any preemptive or similar rights.

If we sell preferred stock, the prospectus supplement relating to the series of preferred stock offered by that supplement will describe the specific terms of those securities, including:

1. the title and stated value of that preferred stock;
2. the number of shares of that preferred stock offered, the liquidation preference per share and the offering price of that preferred stock;
3. the dividend rate(s), period(s) and/or payment date(s) or method(s) of calculation thereof applicable to that preferred stock;
4. whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends on that preferred stock will accumulate;
5. the voting rights applicable to that preferred stock;
6. the procedures for any auction and remarketing, if any, for that preferred stock;
7. the provisions for a sinking fund, if any, for that preferred stock;
8. the provisions for redemption, if applicable, of that preferred stock;
9. any listing of that preferred stock on any securities exchange;
10. the terms and conditions, if applicable, upon which that preferred stock will be convertible into shares of the Common Stock, including the conversion price (or manner of calculation of the conversion price) and conversion period;
11. a discussion of federal income tax considerations applicable to that preferred stock;
12. any limitations on issuance of any series of preferred stock ranking senior to or on a parity with that series of preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs; and
13. any other specific terms, preferences, rights, limitations or restrictions of that preferred stock.

We believe the power to issue preferred stock will provide our board of directors with flexibility in connection with certain possible corporate transactions. The issuance of preferred stock, however, could adversely affect the voting power of holders of our common stock, restrict their rights to receive payment upon liquidation, and have the effect of delaying, deferring, or preventing a change in control.

## Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

## DESCRIPTION OF WARRANTS

The following description of our warrants for the purchase of our common stock, preferred stock and/or debt securities in this prospectus contains the general terms and provisions of the warrants. The particular terms of any offering of warrants will be described in a prospectus supplement relating to such offering. The statements below describing the warrants are subject to and qualified by the applicable provisions of our certificate of incorporation, bylaws and the relevant provisions of the laws of the State of Delaware.

### General

We may issue warrants for the purchase of our common stock, preferred stock and/or debt securities. We may issue warrants independently or together with any of our securities, and warrants also may be attached to our securities or independent of them. We may issue series of warrants under a separate warrant agreement between us and a specified warrant agent described in the prospectus supplement. The warrant agent will act solely as our agent in connection with the warrants and will not assume any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants.

### Terms

A prospectus supplement will describe the specific terms of any warrants that we issue or offer, including:

- the title of the warrants;
- the aggregate number of warrants;
- the price or prices at which the warrants will be issued;
- the currencies in which the price or prices of the warrants may be payable;
- the designation, amount and terms of our capital stock or debt securities purchasable upon exercise of the warrants;
- the designation and terms of our other securities, if any, that may be issued in connection with the warrants, and the number of warrants issued with each corresponding security;
- if applicable, the date that the warrants and the securities purchasable upon exercise of the warrants will be separately transferable;
- the prices and currencies for which the securities purchasable upon exercise of the warrants may be purchased;

- the date that the warrants may first be exercised;
- the date that the warrants expire;
- the minimum or maximum amount of warrants that may be exercised at any one time;
- information with respect to book-entry procedures, if any;
- a discussion of certain federal income tax considerations; and
- any other material terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

### **Exercise of Warrants**

Each warrant will entitle the holder to purchase for cash the principal amount of debt securities or shares of preferred stock or common stock at the applicable exercise price set forth in, or determined as described in, the applicable prospectus supplement. Warrants may be exercised at any time up to the close of business on the expiration date set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Warrants may be exercised by delivering to the corporation trust office of the warrant agent or any other officer indicated in the applicable prospectus supplement (a) the warrant certificate properly completed and duly executed and (b) payment of the amount due upon exercise. As soon as practicable following exercise, we will forward the debt securities or shares of preferred stock or common stock purchasable upon exercise. If less than all of the warrants represented by a warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants.

### **DESCRIPTION OF DEBT SECURITIES**

We anticipate that any debt securities which we offer by this prospectus will be issued under an indenture between us and a trustee to be identified in the prospectus supplement. If a proposed debt transaction is not exempt under the Trust Indenture Act of 1939, as amended (the "Trust Indenture Act"), the terms of the debt securities will include those stated in the indenture and those made part of the indenture by reference to the Trust Indenture Act, as in effect on the date of the indenture. If a proposed transaction is exempt under the Trust Indenture Act, we may not use an indenture (and, thus a trustee) or, if we use an indenture, it may not fully comply with the requirements of the Trust Indenture Act. The following description summarizes only the material provisions of the indenture. Accordingly, you should read the form of indenture, a copy of which has been filed as an exhibit to the registration statement of which this prospectus forms a part, because it, and not this description, defines your rights as holders of our debt securities. The following description also provides general information that will be contained in any debt instrument we may use if we do not use an indenture. You should also read the applicable prospectus supplement for additional information and the specific terms of the debt securities.

## General

We may, at our option, issue debt securities in one or more series from time to time. "Debt securities" may include senior debt, senior subordinated debt or subordinated debt. The particular terms of the debt securities offered by any prospectus supplement, and the extent, if any, to which such general provisions do not apply to the debt securities will be described in the prospectus supplement relating to such debt securities. The following summaries set forth certain general terms and provisions of the indenture and the debt securities. The prospectus supplement relating to a series of debt securities being offered will contain the following terms, if applicable:

- the title and ranking;
- the aggregate principal amount and any limit on such amount;
- the price at which such debt securities will be issued;
- the date on which the debt securities mature;
- the fixed or variable rate at which the debt securities will bear interest, or the method by which such rate shall be determined;
- the timing, place and manner of making principal, interest and any premium payments on the debt securities, and, if applicable, where such debt securities may be surrendered for registration of transfer or exchange;
- the date or dates, if any, after which the debt securities may be converted or exchanged into or for shares of our common stock, preferred stock or another company's securities or properties or cash and the terms of any such conversion or exchange;
  - any redemption or early repayment provisions;
  - any sinking fund or similar provisions;
  - the authorized denominations;
  - any applicable subordination provisions;
  - any guarantees of such securities by our subsidiaries or others;
- the currency in which we will pay the principal, interest and any premium payments on such debt securities;
- whether the amount of payments of principal of (and premium, if any) or interest, if any, on the debt securities may be determined with reference to an index, formula or other method and the manner in which such amounts shall be determined;
- the time period within which, the manner in which and the terms and conditions upon which the purchaser of the securities can select the payment currency;
  - the provisions, if any, granting special rights to the holders of debt securities upon certain events;

- any additions to or changes in the events of default or covenants of Hemispherx with respect to the debt securities and any change in the right of the trustee or the holders to declare the principal, premium and interest with respect to such securities to be due and payable;
- whether and under what circumstances we will pay any additional amounts on such debt securities for any tax, assessment or governmental charge and, if so, whether we will have the option to redeem such debt securities instead of paying such amounts;
- the form (registered and/or bearer securities), any restrictions applicable to the offer, sale or delivery of bearer securities and the terms, if any, upon which bearer securities may be exchanged for registered securities and vice versa;
  - the date of any bearer securities or any global security, if other than the date of original issuance of the first security of the series to be issued;
    - the person to whom and manner in which any interest shall be payable;
  - whether such securities will be issued in whole or in part in the form of one or more global securities;
    - the identity of the depositary for global securities;
- whether a temporary security is to be issued with respect to such series and whether any interest payable prior to the issuance of definitive securities of the series will be credited to the account of the persons entitled thereto;
- the terms upon which beneficial interests in a temporary global security may be exchanged in whole or in part for beneficial interests in a definitive global security or for individual definitive securities and the terms upon which such exchanges may be made;
  - the securities exchange(s), if any, on which the securities will be listed;
  - whether any underwriter(s) will act as market maker(s) for the securities;
    - the form (certificated or book-entry);
- the form and/or terms of certificates, documents or conditions which may be necessary, if any, for the debt securities to be issuable in final form; and
  - additional terms not inconsistent with the provisions of the indenture.

One or more series of debt securities may be sold at a substantial discount below their stated principal amount bearing no interest or interest at a rate below the market rate at the time of issuance. One or more series of debt securities may be variable rate debt securities that may be exchanged for fixed rate debt securities. In such cases, all material United States federal income tax and other considerations applicable to any such series will be described in the applicable prospectus supplement. You should consult with your own tax advisor before making a decision to purchase any debt security.

We will comply with Section 14(e) under the Exchange Act, to the extent applicable, and any other tender offer rules under the Exchange Act, which may then be applicable, in connection with any obligation of Hemispherx to purchase debt securities at the option of the holders thereof. Any such obligation applicable to a series of debt securities will be described in the applicable prospectus supplement.

### **Exchange, Registration, Transfer and Payment**

We expect payment of principal, premium, if any, and any interest on the debt securities to be payable, and the exchange and the transfer of debt securities will be registrable, at the office of the trustee or at any other office or agency we maintain for such purpose. We expect to issue debt securities in denominations of U.S. \$1,000 or integral multiples thereof. No service charge will be made for any registration of transfer or exchange of the debt securities, but we may require a payment to cover any tax or other governmental charges payable in connection therewith.

### **Global Debt Securities**

Unless we indicate otherwise in the applicable prospectus supplement, the following provisions will apply to all debt securities.

The debt securities of a series may be issued in whole or in part in the form of one or more global securities that will be deposited with a depository that we will identify in a prospectus supplement. Each global security will be deposited with the depository and will bear a legend regarding any related restrictions or other matters as may be provided for pursuant to the applicable indenture.

Unless a prospectus supplement states otherwise, no global security may be transferred to, or registered or exchanged for debt securities registered in the name of, any person or entity other than the depository, unless: