

HEMISPHERX BIOPHARMA INC

Form POS AM

April 24, 2008

As filed with the Securities and Exchange Commission on April 24, 2008

Registration No. 333-136187

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

POST EFFECTIVE
AMENDMENT NO. 2 TO
FORM S-1
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)

1617 JFK Boulevard
Philadelphia, Pennsylvania 19103
(215) 988-0080
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

William A. Carter, M.D., Chief Executive Officer
Hemispherx Biopharma, Inc.
1617 JFK Boulevard
Philadelphia, Pennsylvania 19103
(215) 988-0080
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications to:
Richard Feiner, Esq.
Silverman Sclar Shin & Byrne PLLC
381 Park Avenue South, Suite 1601
New York, New York, 10016

Edgar Filing: HEMISPHERX BIOPHARMA INC - Form POS AM

(212) 779-8600

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

If 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"), 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. o

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 statement number of the earlier effective registration statement for the same offering. o

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

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 o Accelerated filer x
Non-accelerated filer o Smaller Reporting Company o.

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 under Registration Statement Nos. 333-117178, 333-108645, 333-111135, 333-113796 and 333-130008.

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 April 24, 2008

HEMISPHERX BIOPHARMA, INC.

8,564,225 Shares of Common Stock

The Offering:

This prospectus relates to the sale of up to 8,564,225 shares of our common stock that may be offered and sold from time to time by selling stockholders and the persons to whom such selling stockholders may transfer their shares, consisting of: (1) 1,255,877 shares of our common stock issuable to Fusion Capital Fund II, LLC ("Fusion Capital") under a common stock purchase agreement; (2) 5,594,104 shares of common stock issuable upon exercise of outstanding warrants; (3) 135% of 3,615,514 shares of common stock issuable upon the exercise of outstanding warrants related to our former 2003 and 2004 7% Senior Convertible Debentures ("Debenture Warrants"); and (4) 448,814 shares of outstanding common stock issued to Fusion Capital. We will not receive any of the proceeds from the sale of these shares by the selling stockholders, but we will receive proceeds from sales of shares to Fusion Capital and the cash exercise of warrants, if any.

Our common stock is listed on the American Stock Exchange under the symbol HEB. The reported last sale price on the American Stock Exchange on April 18, 2008 was \$0.68.

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

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

Fusion Capital is an "underwriter" within the meaning of the Securities Act of 1933. Other selling stockholders may be deemed to be an "underwriter" within the meaning of the Securities Act of 1933.

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

The date of this prospectus is April __, 2008

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement (which includes this prospectus) on Form S-1 (File No. 333-136187) under the Securities Act of 1933, as amended, with respect to the common stock the selling stockholders are offering by this prospectus. This prospectus does not contain all of the information included in the registration statement and the exhibits and schedules to the registration statement. For further information about us and our securities, you should refer to the registration statement and the exhibits filed with the registration statement. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of that contract or document filed as an exhibit to the Registration Statement.

We are subject to the information requirements of the Securities Exchange Act of 1934 and file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov or through our website at www.hemispherx.net. Information contained on our website is not considered to be a part of, nor incorporated by reference in, this prospectus. You may also read and copy any document we file with the SEC at its Public Reference Room at 100 F Street, NE, Washington, D.C. 20549.

You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Room of the SEC at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to "incorporate by reference" the information that we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus, and you should review that information in order to understand the nature of any investment by you in our common stock. Information contained in this prospectus automatically updates and supersedes previously filed information. We are incorporating by reference the following documents:

- (a) Our annual report on Form 10-K for our fiscal year ended December 31, 2007, SEC File No. 1-13441.
- (b) Our current report on Form 8-K, SEC File No. 1-13441 filed with the SEC on March 10, 2008.
- (c) Our proxy statement on schedule 14A for our 2007 annual meeting, SEC File No. 1-13441.

- (d) A description of our common stock contained in our registration statement on Form S-1, SEC File No. 333-117178, 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.
- (e) All of our filings pursuant to Sections 13(a) or 15(d) under the Securities Exchange Act of 1934, as amended, since the date of the filing of our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 through the date of this prospectus.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the reports or documents that we have incorporated by reference in this prospectus, at no cost. To obtain any such documents please write or telephone us at the following address: Hemispherx Biopharma, Inc., 1617 JFK Boulevard, Philadelphia, Pennsylvania 19103, telephone number 215-988-0080. In addition, these documents may be accessed at our website at www.hemispherx.net via a link to the SEC's website. Information contained on our website is not considered to be a part of, nor incorporated by reference in, this prospectus.

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

PROSPECTUS SUMMARY

The following is a brief summary of certain information contained elsewhere in this prospectus or incorporated in this prospectus by reference. This summary is not intended to be a complete description of the matters covered in this prospectus and is qualified in its entirety by reference to the more detailed information contained or incorporated by reference in this prospectus. You are urged to read this prospectus in its entirety, including all materials incorporated in this prospectus by reference.

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

About Hemispherx

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”). An NDA for treatment of CFS was filed on October 10, 2007. On December 3, 2007 a refusal to file (RTF) letter was received because the application was deemed “not substantially complete”. A written response was developed and submitted to the FDA addressing 14 pre-clinical and clinical questions. We are currently in the process of submitting amendments to the NDA filing that we believe address certain of these questions. Ampligen represents the first drug in class of RNA (nucleic acid) molecules to apply for NDA review.

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.

Fusion Capital Transactions

On April 12, 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC, (“Fusion Capital”), pursuant to which, Fusion Capital has agreed, under certain conditions, to purchase from us on each trading day \$100,000 of our common stock up to an aggregate of \$50,000,000 through August 1, 2008, subject to earlier termination at our discretion. At our option, we may elect to sell less of our common stock to Fusion Capital than the daily amount and we may increase the daily amount as the market price of our stock increases. The purchase price of the shares of common stock is equal to a price based upon the future market price of the common stock without any fixed discount to the market price. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than \$1.00. As of the date hereof, Fusion is not permitted to purchase shares under the common stock purchase agreement because the price of our common stock is less than \$1.00.

Through April 18, 2008, we have sold to Fusion Capital an aggregate of 10,682,032 shares under the common stock purchase agreement for aggregate gross proceeds of approximately \$19,739,000. In addition, we have issued 448,814 Commitment Shares. Fusion Capital is offering for sale herein up to 1,704,691 shares of our common stock consisting of 448,814 shares currently owned by Fusion Capital (Commitment Shares) and 1,255,877 shares (inclusive of an additional 194,688 Commitment Shares) issuable under the common stock purchase agreement. We will realize much less than the maximum \$50,000,000 proceeds from the sale of stock under the Purchase Agreement (please see “*Selling Stockholders; The Fusion Transaction; Commitment Shares Issued to Fusion Capital*” for a description of the Commitment Shares).

The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the common stock purchase agreement. For more detailed information, please see “*The Fusion Transaction*” in “*Selling Stockholders*” below.

Securities Offered

Common stock to be offered
by the selling stockholders 8,564,225 Shares consisting of:

- 1,255,877 shares of our common stock issuable to Fusion Capital pursuant to a common stock purchase agreement (inclusive of 194,688 Commitment Shares);
- 5,594,104 shares of common stock issuable upon exercise of other outstanding warrants;
- 135% of 3,615,514 shares of common stock issuable upon the exercise of outstanding warrants related to our former 2003 and 2004 7% Senior Convertible Debentures; and
- 448,814 outstanding shares of common stock owned by Fusion Capital.

Common stock outstanding
prior to this offering 73,975,265 Shares

Use of Proceeds We will not receive any of the proceeds from the sale of the shares of common stock because they are being offered by the selling stockholders and we are not offering any shares for sale under this prospectus, but we may receive proceeds from the exercise of warrants held by certain of the selling stockholders. In addition, if the price of our common stock reaches \$1.00 per share, we may receive gross proceeds from the sale of up to 1,255,877 shares of our common stock to Fusion Capital under the common stock purchase agreement. We will apply such proceeds, if any, for general corporate operating purposes. See "Use of Proceeds."

American Stock Exchange symbol HEB

RISK FACTORS

Special Note Regarding Forward-Looking Statements

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

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

The following cautionary statements identify important factors that could cause our actual 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 3, 2007 we received a refusal to file (“RTF”) letter from the FDA because the application was deemed “not substantially complete”. We submitted a written response to the FDA addressing 14 pre-clinical and clinical questions. Ampligen represents the first drug in class of RNA (nucleic acid) molecules to apply for NDA review. We are currently in the process of submitting amendments to the NDA filing that we believe address certain of these questions. We can provide no guidance as to the tentative date at which the filing of the NDA will be accepted or, if accepted, when or if the NDA will be approved. The timing of the FDA review process of the NDA is subject to the control of the FDA and could result in one of the following events: 1) approval to market Ampligen® for use in treating ME/CFS patients; 2) require more research, development, and clinical work; 3) approval to market as well as conduct more testing; or 4) reject our NDA application.

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 December 31, 2007, our accumulated deficit was approximately \$185,190,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

We may require additional financing which may not be available.

The development of our products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of December 31, 2007, we had approximately \$15,415,000 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 18 months.

In April 2006, we entered into a common stock purchase agreement with Fusion Capital pursuant to which Fusion Capital has agreed, under certain conditions and with certain limitations, to purchase on each trading day \$100,000 of our common stock up to an aggregate of \$50,000,000 until August 1, 2008 (see “The Fusion Transaction” in Selling Stockholders” below).

We only have the right to receive up to \$100,000 per trading day under the agreement with Fusion Capital unless our stock price exceeds \$1.90 by at least \$0.10, in which case the daily amount may be increased under certain conditions as the price of our common stock increases. 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. We have registered an aggregate of 13,201,840 shares purchasable by Fusion Capital pursuant to the common stock purchase agreement (inclusive of up to 643,502 additional Commitment Shares) and, through April 18, 2008, we have sold to Fusion Capital an aggregate of 10,682,032 shares under the common stock purchase agreement for aggregate gross proceeds of approximately \$19,739,000. Assuming a purchase price of \$1.00 per share, the lowest price at which Fusion is obligated to purchase shares from us (the closing sale price of the common stock on April 18, 2008 was \$0.68) and the purchase by Fusion Capital of the remaining 1,061,189 shares (not including the remaining 194,688 Commitment Shares), total gross proceeds to us from the remaining shares would only be approximately \$1,061,000 (\$20,800,000 in the aggregate under the common stock purchase agreement).

Unless and until the market price for our common stock increases to at least \$1.00, no additional shares will be sold to Fusion Capital under the agreement. We will realize much less than the maximum \$50,000,000 proceeds from the sale of stock under the Purchase Agreement.

Assuming no material additional financing 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