HEMISPHERX BIOPHARMA INC Form POS AM May 08, 2007

As filed with the Securities and Exchange Commission on May 8, 2007

Registration No. 333-136187

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

POST EFFECTIVE
AMENDMENT NO. 1
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)

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

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

Copies of all communications to:
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Silverman Sclar Shin & Byrne PLLC
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New York, New York, 10016
(212) 779-8600
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Approximate date of proposed sale to the public: From time to time or at one time after the effective date of this Registration Statement.

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

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

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.

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

Subject to Completion
Preliminary Prospectus Dated May 8, 2007

HEMISPHERX BIOPHARMA, INC.

13,243,283 Shares of Common Stock

## The Offering:

This prospectus relates to the sale of up to 13,243,283 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) 2,575,069 shares of our common stock issuable to Fusion Capital Fund II, LLC ("Fusion Capital") under a common stock purchase agreement; (2) 135% of 2,081,262 shares of common stock issuable upon the conversion, redemption or other payments relating to our outstanding October 2003, January 2004 and July 2004 7% Senior Convertible Debentures Due June 30, 2007 ("Debentures") and as payment of interest thereon and 135% of 3,615,514 shares of common stock issuable upon the exercise of related outstanding warrants ("Debenture Warrants"); (3) outstanding 1,978,590 shares of common stock issuable upon exercise of other warrants; and (4) outstanding 998,976 shares of common stock (including 855,318 issued to Fusion Capital) to be sold by certain of the selling stockholders. We will not receive any of the proceeds from the sale of these shares by the selling stockholders, but we will receive proceeds from the cash exercise of warrants, if any.

Our common stock is listed on the American Stock Exchange under the symbol HEB. The reported last sale price on the American Stock Exchange on May 7, 2007 was \$1.61.

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 May , 2007

### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file at the Securities and Exchange Commission's public reference rooms at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the public reference rooms. Our Securities and Exchange Commission filings are also available to the public from the Securities and Exchange Commission's website at "http://www.sec.gov." Such filings are also available through a link at our 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.

We have filed with the Securities and Exchange Commission a registration statement (which contains this prospectus) on Form S-1 under the Securities Act of 1933. The registration statement relates to the securities offered by the selling stockholders. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Please refer to the registration statement and its exhibits and schedules for further information with respect to us, the common stock being offered in this prospectus. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of that contract or document filed as an exhibit to the Registration Statement. You may read and obtain a copy of the registration statement and its exhibits and schedules from the SEC, as described in the preceding paragraph.

#### INFORMATION INCORPORATED BY REFERENCE

The Commission allows us to "incorporate by reference" the information that we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of the 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, 2006, SEC File No. 1-13441.
- (b) A description of our common stock contained in our registration statement on Form S-1, SEC File No. 33-93314.
- (c) 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, 2006 through the date of this prospectus.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address: Hemispherx Biopharma, Inc., 1617 JFK Boulevard, Philadelphia, Pennsylvania 19103, telephone number 215-988-0080. In addition, these documents may be accessed at our website at "http://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, and the selling stockholders have not, authorized anyone else to provide you with different information. The selling stockholders will not make offers to these shares in any state where the offer is not permitted. You should not assume that the information in this prospectus or incorporated by reference or in 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, exhibits and documents from which information is incorporated by reference 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 and marketing of new drug entities based on natural immune system enhancing technologies for the treatment of viral and immune based acute and chronic disorders. We were founded in the early 1970s, as a contract researcher 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 acute and chronic diseases. We own a U.S. Food and Drug Administration ("FDA") approved GMP (good manufacturing practice) manufacturing facility in New Jersey. Our flagship products include Ampligen® and Alferon N Injection®.

Ampligen® is an experimental drug currently undergoing clinical development for the treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome ("ME/CFS" or "CFS") and HIV, and clinical testing for treatment/prevention of avian and seasonal influenza. We have completed Phase III clinical trials using Ampligen® to treat ME/CFS patients and are currently in the process of preparing and filing a New Drug Application ("NDA") with the FDA.

Alferon N Injection® is the registered trademark for our injectable formulation of natural alpha interferon, which is approved by the FDA for the treatment of genital warts. Alferon N Injection® is also in clinical development for treating Multiple Sclerosis and West Nile Virus ("WNV").

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ 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 over a period of approximately 25 months, 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.

We initially registered 12,386,723 shares under the Fusion Capital common stock purchase agreement. The shares offered herein by Fusion Capital represent the balance of the 12,386,723 shares initially registered. Through May 7, 2007, we have sold to Fusion Capital an aggregate of 9,375,390 shares under the common stock purchase agreement for aggregate gross proceeds of \$17,789,128. In addition, we have issued 436,264 Commitment Shares. Fusion Capital is offering for sale herein up to 3,430,387 shares of our common stock consisting of 855,318 shares currently owned by Fusion Capital (inclusive of 436,264 Commitment Shares) and 2,575,069 shares (inclusive of an additional 207,238 Commitment Shares) issuable under the common stock purchase agreement (please see "Selling Stockholders; The Fusion Transaction; Commitment Shares Issued to Fusion Capital" for a description of the Commitment Shares).

Under the rules of the American Stock Exchange, in the event that we elect to sell more than 12,386,723 shares to Fusion Capital, we were required to seek stockholder approval. This approval was obtained on September 20, 2006. We also will be required to file a new registration statement and have it declared effective by the SEC in the event we elect to sell to Fusion Capital more than the 2,575,069 registered herein.

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*" below.

#### Securities Offered

Common stock to be offered by the selling 13,243,283 Shares consisting of: stockholders

- ·2,575,069 shares of our common stock issuable to Fusion Capital pursuant to a common stock purchase agreement;
- ·135% of 2,081,262 shares of common stock issuable upon the conversion, redemption or other payments relating to our outstanding October 2003, January 2004 and July 2004 7% Senior Convertible Debentures Due June 30, 2007 (collectively, the "Debentures") and as payment of interest thereon;
- ·135% of 3,615,514 shares of common stock issuable upon the exercise of related outstanding warrants ("Debenture Warrants");
- · 1,978,590 shares of common stock issuable upon exercise of other outstanding warrants; and ·998,976 outstanding shares of common stock (including 855,318 owned by Fusion Capital and 143,658 owned by other selling stockholders.

Common stock outstanding as of May 7, 2007

72,309,424 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, we may receive up to \$32,210,872 in gross proceeds from the sale of our common stock to Fusion Capital under the common stock purchase agreement. We will apply such proceeds, if any, to extend our New Brunswick facility for the production of Ampligen® and Alferon N Injection®, Research and Development and 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 result to differ materially from those projected in the forward-looking statements made in this prospectus. Among the key factors that have a direct bearing on our results of operations are:

#### **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.

We are in the registration process for an NDA with the FDA for approval to use Ampligen in the treatment of Chronic Fatigue Syndrome. We can provide no guidance as to the tentative date at which the compilation and filing of the NDA will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the time required for our New Brunswick staff/facilities to interface with Hollister-Stier to assure compliance with manufacturing regulatory standards. Also, 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. Given these variables, we are unable to project when material net cash inflows are expected to commence from the sale of Ampligen®.

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 such as multiple sclerosis and cancer.

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

All of our drugs and associated technologies, other than Alferon N Injection®, are investigational and must receive prior regulatory approval by appropriate regulatory authorities for general use and are currently legally available only through clinical trials with specified disorders. At present, Alferon N Injection® is only approved for the 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. In this regard, ISI, the company from which we obtained our rights to Alferon N Injection®, conducted clinical trials related to use of Alferon N Injection® for treatment of HIV and Hepatitis C. In both instances, the FDA determined that additional studies were necessary in order to fully evaluate the efficacy of Alferon N Injection® in the treatment of HIV and Hepatitis C diseases. We have no immediate plans to conduct these additional studies at this time.

Our products, including Ampligen®, 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 ("EMEA") in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen® 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 in the United States, we cannot assure you that additional clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials. If Ampligen® 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 flu. There are a number of strains and strains mutate. No assurance can be given that a 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, 2007, our accumulated deficit was approximately \$172,151,000. 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 March 31, 2007, we had approximately \$24,600,000 in cash and cash equivalents and short-term investments. These funds should be sufficient to meet our operating cash requirements, including debt service, for at least the next 18 months.

On April 12, 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 over a 25 month period (see "The Fusion Transaction" in Selling Stockholders" below).

We only have the right to receive \$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 shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than \$1.00. We have registered herein and in a prior registration statement 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 May 7, 2007, we have sold to Fusion Capital an aggregate of 9,375,390 shares under the common stock purchase agreement for aggregate gross proceeds of \$17,789,128. Assuming a purchase price of \$1.61 per share (the closing sale price of the common stock on May 7, 2007) and the purchase by Fusion Capital of the remaining 2,367,831 shares (after deducting the remaining 207,238 Commitment Shares) registered herein, total gross proceeds to us from the remaining shares would only be \$3,812,208 (\$21,601,336 in the aggregate under the common stock purchase agreement). Accordingly, depending upon the future market price of our common stock, we may realize less than the maximum \$50,000,000 proceeds from the sale of stock under the Purchase Agreement.

In the event we elect to issue additional shares to Fusion Capital, we will be required to file a new registration statement and have it declared effective by the Securities and Exchange Commission. In addition, Fusion Capital cannot purchase more than 27,386,723 shares, inclusive of Commitment Shares under the common stock purchase agreement. Accordingly, depending upon the future market price of our common stock, we may realize less than the maximum \$50,000,000 proceeds from the sale of stock under the Purchase Agreement.

The extent to which we rely on Fusion Capital as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources.

If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive 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 another source of funding in order to satisfy our working capital needs. Even if we are able to access the full \$50,000,000 under the common stock purchase agreement with Fusion Capital, we may need to raise additional funds through additional equity or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes including the commercializing of Ampligen® products. There can be no assurances that we will raise adequate funds which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

## 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 drug product which are carried out according to standard operating procedure manuals. We have been issued certain patents including those on the use of Ampligen® 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 AmpligenO 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.

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

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

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

There are no long-term agreements with suppliers of required materials. If we are unable to obtain the required raw materials, we may be required to scale back our operations or stop manufacturing Alferon N Injection® 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® raw materials in order to obtain polymers on a more consistent manufacturing basis. The establishment of an Ampligen® raw materials production line within our own facilities, while having obvious advantages with respect to regulatory compliance (other parts of our 43,000 sq. ft. wholly owned FDA approved facility are already in compliance for the manufacture of Alferon N Injection®), may delay certain steps in the commercialization process, specifically, our Ampligen® NDA Registration process with the FDA.

If we are unable to obtain or manufacture the required raw materials, we may be required to scale back our operations or stop manufacturing. The costs and availability of products and materials we need for the production of Ampligen® 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 third party suppliers 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 facili-ties. 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 HIV diseases 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®. Many 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 received FDA approval for 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, VeregenTM, 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. In the United States, three recombinant forms of beta interferon have been approved for the treatment of relapsing-remitting multiple sclerosis. There can be no assurance that, if we are able to obtain regulatory approval of Alferon N Injection® 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 slowing the infusion rate. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, transient visual disturbances, slow or irregular heart rate, decreases in platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills, fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months. One or more of the potential side effects might deter usage of Ampligen® 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 appro-priate 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 Dr. William A. Carter's services could hurt our chances for success.

Our success is dependent on the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen®, 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 April 30, 2007, the price of our common stock has ranged from \$1.54 to \$3.45 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

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

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

We have registered 13,201,840 shares herein and in a prior registration statement for sale by Fusion Capital, and may, in the future, register additional shares for sale by Fusion Capital under the common stock purchase agreement. As of May 7, 2007, approximately 1,121,953 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act, 396,669 of which have been registered in prior registration statements. Also, we have registered 9,812,896 shares issuable (i) upon conversion of approximately 135% of Debentures that we issued in 2003 and 2004; (ii) as payment of 135% of the interest on all of the Debentures; (iii) upon exercise of 135% of certain Warrants; and (iv) 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 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.

The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by Fusion Capital and other shares registered for selling stockholders could cause the price of our common stock to decline.

The sale by Fusion Capital and other selling stockholders of our common stock will increase the number of our publicly traded shares, which could depress the market price of our common stock. Moreover, the mere prospect of sales by Fusion Capital and other selling stockholders as contemplated in this prospectus could depress the market price for our common stock. The issuance of 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.

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

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November 2002, we adopted a stockholder rights plan and, under the Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one unit of preferred stock for \$30.00. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Dr. Carter, our chief executive officer, who already beneficially owns 8.0% 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 revenues in Europe, Canada and in the United States.

#### SELLING STOCKHOLDERS

We have registered all 13,243,283 shares of common stock covered by this prospectus on behalf of the selling stockholders named in the table below. We have registered the shares to permit the selling stockholders and their respective transferees, assignees or other successors-in-interest that receive their shares from a selling stockholder to sell the shares, from time to time, when they deem appropriate.

The table below identifies the selling stockholders who will be offering shares and other information regarding the beneficial ownership of the common stock held by each of the selling stockholders as of May 7, 2007. For the Debenture holders (the second and third stockholders listed below), the second column lists the number of shares of common stock beneficially owned by each selling stockholder, based on each selling stockholder's ownership of shares of common stock, Debentures and Debenture Warrants, and assumes the conversion of all the Debentures, the payment of all interest in stock and the exercise of all Debenture Warrants. Because the conversion price of the Debentures and the exercise price of the warrants are subject to adjustment for anti-dilution protection, the interest on the Debentures may be paid in cash or common stock, and the value attributed to any shares issued to the investors as interest (the "Interest Shares") depends on the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date, the numbers listed in the second column may change. For the other selling stockholders, the second column lists the number of shares of common stock beneficially owned by the selling stockholder as of the above date, based on each selling stockholder's ownership of shares of common stock, and, except as set forth in the relevant footnotes, does not assume the conversion of any of the Debentures, the exercise of any warrants or the payment of any interest on the Debentures in the form of common stock rather than cash.

The third column lists each selling stockholder's portion, based on agreements with us, of the 13,243,283 shares of common stock being offered by this prospectus. With regard to the Debenture holders, the number of shares being offered by this prospectus was determined in accordance with the terms of the registration rights agreements with them, in which we agreed to register the resale of 135% of (w) the number of shares of common stock issuable upon conversion of the Debentures, plus (x) the number of shares of common stock issuable upon exercise of the Debenture Warrants, plus (y) an estimate of the number of Interest Shares that may be issued to the selling stockholders as interest payments on the Debentures and assuming interest is paid exclusively in Interest Shares over the full term of the Debentures, rather than in cash. As we stated above, the number of shares that will actually be issued may be more or less than the 13,243,283 shares being offered by this prospectus.

Fusion Capital may not purchase shares of our common stock under the common stock purchase agreement if Fusion Capital, together with its affiliates, would beneficially own more than 9.9% of our common stock outstanding at the time of the purchase by Fusion Capital. Under the terms of the Debentures and the Debenture Warrants, no selling stockholder who owns any of these securities may convert any of their Debentures or exercise any of the foregoing Warrants to the extent that the conversion or exercise would cause the selling stockholder, together with its affiliates, to beneficially own more than 4.99% of the shares of our then outstanding common stock following such conversion or exercise. For purposes of making this determination, shares of common stock issuable upon conversion of those Debentures which have not been converted and upon exercise of the Warrants which have not been exercised are excluded. The number of shares offered in the third column does not reflect this limitation.

Unless otherwise indicated in the footnotes below, we believe that the persons and entities named in the table have sole voting and investment power with respect to all shares beneficially owned.

Any selling stockholder may sell all, some or none of its respective shares in this offering. See "Plan of Distribution" below.

None of the selling stockholder has had any position, office or other material relationship with us or any of our affiliates within the past three years, other than as disclosed in the footnotes to the table or elsewhere below.

|                                     | Common Stock<br>Owned Prior | No. of Shares | Common Stock<br>Owned After |
|-------------------------------------|-----------------------------|---------------|-----------------------------|
| Selling Stockholder                 | To Offering                 | Being Offered | The Offering                |
| Fusion Capital Fund II, LLC         | 855,318(1)(2)               | 3,430,387     | -                           |
| Portside Growth & Opportunity Fund  | 4,092,877 (3)               | 4,092,877     | -                           |
| Leonardo L.P.                       | 3,886,233 (4)               | 3,886,233     | -                           |
| Mid South Capital, LLC              | 55,000 (5)                  | 55,000        | -                           |
| Windward Capital Advisors, LLC      | 182,292 (6)                 | 182,292       | -                           |
| HefCap Holdings, LLC                | 212,292 (7)                 | 212,292       | -                           |
| Baxter Capital Advisors, Inc.       | 30,000 (8)                  | 30,000        | -                           |
| Christopher Chipman                 | 30,000 (9)                  | 30,000        | -                           |
| JMBL, LTD                           | 75,000 (10)                 | 75,000        | -                           |
| William Mason                       | 131,066 (11)                | 41,666        | 89,400                      |
| W. Barry McDonald                   | 131,067 (11)                | 41,667        | 89,400                      |
| Wayne Pambianchi                    | 131,067 (11)                | 41,667        | 89,400                      |
| Gordon Ramseier                     | 131,066 (11)                | 41,666        | 89,400                      |
| Daniel Tripodi                      | 131,067 (11)                | 41,667        | 89,400                      |
| Michael Burrows                     | 690,000 (12)                | 150,000       | 540,000                     |
| UBS O'Connor LLC                    | 30,000 (13)                 | 30,000        | -                           |
| Kingsbridge Capital Ltd.            | 28,846 (14)                 | 28,846        | -                           |
| Fenmore Holdings                    | 36,058 (15)                 | 36,058        | -                           |
| Smithfield Fiduciary, LLC           | 72,115 (16)                 | 72,115        | -                           |
| Spectra Investments, LLC            | 36,058 (17)                 | 36,058        | -                           |
| Gemini Master Fund, Ltd.            | 7,211 (18)                  | 7,211         | -                           |
| Provident Premier Master Fund, Ltd. | 36,058 (19)                 | 36,058        |                             |
| Vision Opportunity Fund             | 188,461 (20)                | 188,461       | -                           |

| JMG Capital Partners, LP        | 37,116 (21)  | 37,116  | - |
|---------------------------------|--------------|---------|---|
| JMG Triton Off shore Fund, Ltd. | 72,116 (22)  | 72,116  | - |
| Winton Capital Holdings, Ltd.   | 60,000 (23)  | 60,000  | - |
| Iroquois Capital, LP            | 57,692 (24)  | 57,692  | - |
| Jefferies & Company, Inc.       | 150,480 (25) | 150,480 | - |
| Global Fluency                  | 6,900 (26)   | 6,900   | - |
| Sage Healthcare Advisors        | 10,000 (27)  | 10,000  | - |
| Paul Griffin                    | 61,758       | 61,758  | - |

- (1) Steven G. Martin and Joshua B. Scheinfeld, the principals of Fusion Capital, are deemed to be beneficial owners of all of the shares of common stock owned by Fusion Capital. Messrs. Martin and Scheinfeld have shared voting and investment power over the Fusion Capital shares being offered under this prospectus.
- (2) We originally registered 12,386,723 shares in connection with the Fusion Capital common stock purchase agreement. We have sold 9,375,390 shares to Fusion Capital and issued 436,264 Commitment Shares. Accordingly Fusion Capital may acquire up to an additional 2,367,831 shares and up to 207,238 additional Commitment Shares under the common stock purchase agreement in addition to the 855,318 shares (including the 436,264 Commitment Shares) owned by Fusion Capital.
- (3) Includes (i) up to 1,015,724 shares of common stock issuable upon conversion of the Debentures, (ii) up to 107,104 shares of common stock issuable upon exercise of the Debenture Warrants; (iii) up to 650,000 shares of common stock issuable upon exercise of Warrants that expire in May 2009, (iv) up to 650,000 shares of common stock issuable upon exercise of Warrants that expire in June 2009 and (v) up to 395,257 shares of common stock issuable upon exercise of Warrants that expire in July 2009, and (vi) up to 288,462 shares issuable upon exercise of warrants issued in the August 5, 2004 Private Placement. Ramius Capital Group, LLC ("Ramius Capital") is the investment adviser of Portside Growth & Opportunity Fund ("Portside") and consequently has voting control and investment discretion over securities held by Portside. Ramius Capital disclaims beneficial ownership of the shares held by Portside. Peter A. Cohen, Morgan B. Stark, Thomas W. Strauss and Jeffrey M. Solomon are the sole managing members of C4S& Co., LLC, the sole managing member of Ramius Capital. As a result, Messrs. Cohen, Stark, Strauss and Solomon may be considered beneficial owners of any shares deemed to be beneficially owned by Ramius Capital. Messrs. Cohen, Stark, Strauss and Solomon disclaim beneficial ownership of these shares.
- (4) Represents (i) up to 1,065,538 shares of common stock issuable upon conversion of the Debentures, (ii) up to 117,896 shares of common stock issuable upon exercise of the Debenture Warrants; (iii) up to 1,300,000 shares of common stock issuable upon exercise of Warrants that expire in May 2009, and (iv) up to 395,257 shares of common stock issuable upon exercise of Warrants that expire in July 2009. Angelo, Gordon & Co., L.P. ("Angelo, Gordon") is the sole director of the general partner of Leonardo, L.P. ("Leonardo") and consequently has voting control and investment discretion over securities held by Leonardo. Angelo, Gordon disclaims beneficial ownership of the shares held by Leonardo. Mr. John M. Angelo, the Chief Executive Officer of Angelo, Gordon, and Mr. Michael L. Gordon, the Chief Operating Officer of Angelo, Gordon, are the sole general partners of AG Partners, L.P., the sole general partner of Angelo, Gordon. As a result, Messrs. Angelo and Gordon may be considered beneficial owners of any shares deemed to be beneficially owned by Angelo, Gordon. Messrs. Angelo and Gordon disclaim beneficial ownership of these shares.

- (5) Represents up to 25,000 shares of common stock issuable upon exercise of warrants at \$3.00 per share and 30,000 shares of common stock issuance upon the exercise of warrants at \$3.04 per share. Mark Hill and Jack Magerson are the principals of Mid South Capital and are therefore considered the beneficial owner of these securities.
- (6) H. David Coherd is the sole member of Windward Capital Advisors, LLC. Accordingly, the shares beneficially owned by Windward Capital are deemed to be beneficially owned by this selling stockholder. Shares owned and offered include up to 182,292 shares of common stock issuable upon exercise of warrants of which (i) 33,750 are exercisable at a price of \$2.57 per share, (ii) 91,667 are exercisable at a price of \$2.50 per share, (iii) 16,875 are exercisable at a price if \$2.57 per share, and (iv) 15,000 are exercisable at a price of \$3.04 per share, and (v) 25,000 are exercisable at a price of \$4.07 per share.
- (7) Robert Rosenstein is the sole member of Hefcap Holdings, LLC. Accordingly, the shares beneficially owned by Hefcap Holdings are deemed to be beneficially owned by this selling stockholder. In addition, shares owned and offered include up to 212,292 shares of common stock issuable upon exercise of warrants of which (i) 33,750 are exercisable at a price of \$2.57 per share, (ii) 91,667 are exercisable at a price of \$2.50 per share, (iii) 16,875 are exercisable at a price if \$2.57 per share, (iv) 45,000 are exercisable at a price of \$3.04 per share, and (v) 25,000 are exercisable at a price of \$4.07 per share.
- (8) Peter Baxter is the president of Baxter Capital Advisors, Inc. Shares owned and offered include up to 30,000 shares of common stock issuable upon exercise of warrants of which (i) 11,250 are exercisable at a price of \$2.57 per share, (ii) 8,750 are exercisable at a price if \$2.42 per share, and (iii) 10,000 are exercisable at a price of \$3.04 per share.
- (9) Represents (i) 5,000 shares issuable upon exercise of warrants exercisable at \$3.91 per shares expiring on February 28, 2009, (ii) 5,000 shares issuable upon exercise of warrants exercisable at \$4.20 per shares expiring on January 31, 2009, (iii) 5,000 shares issuable upon the exercise of warrants at \$3.51 per share expiring March 31, 2009, (iv) 5,000 shares issuable upon the exercise of warrants at \$2.70 expiring January 1, 2011, (v) 5,000 shares issuable upon the exercise of warrants at \$3.60 expiring April 1, 2011, and (vi) 5,000 shares issuable upon the exercise of warrants at \$2.54 expiring July 1, 2011. Mr. Chipman provides us with financial and accounting consulting services.

- (10) Jeffrey M. Busch, the principal of JMBL LLC, is deemed to be the beneficial owner of all shares of common stock owned by JMBL LLC. Mr. Busch has voting and investment power over the JMBL LLC shares being offered under this prospectus.
- (11)Both columns include shares issuable upon the exercise of outstanding options exercisable at \$1.55 per share expiring February 14, 2015. The first column also includes 89,400 shares owned by The Sage Group. The principals of The Sage Group are Wayne Pambianchi, Daniel Tripodi, W. Barry McDonald, Gordon Ramseier and R. Douglas Hulse. The foregoing securities were issued to The Sage Group and its principals for services provided to us. Mr. Hulse was our President from March 2005 to November 2007.
- (12) Consists of shares issuable upon exercise of 150,000 options issued in 2005 to purchase common stock at \$2.00 per share expiring September 23, 2015. Mr. Burrows is a former member of the Board of Directors ad serves as an advisor to the Company from time to time. Also includes 540,000 shares of common stock of which Mr. Burrows is the beneficial owner.
- (13) Shares offered and owned includes 30,000 shares issuable upon exercise of warrants issued in the Private Placement. The shares are beneficially owned by O'Connor PIPES Corporate Strategies Master Ltd. UBS O'Connor LLC is the investment manager for O'Connor PIPES Corporate Strategies Master Ltd. UBS O'Connor LLC is a wholly owned subsidiary of UBS AG, which is traded on the NYSE.
- (14) Shares offered and owned includes 28,846 shares issuable upon exercise of warrants issued in the Private Placement. The selling stockholder has identified Adam Gurney, as a natural person with voting and investment control over shares of our common stock beneficially owned by the selling stockholder.
- (15) Shares offered and owned includes 36,058 shares issuable upon exercise of warrants issued in the Private Placement. The selling stockholder has identified Mark Nordlicht, as a natural person with voting and investment control over shares of our common stock beneficially owned by the selling stockholder. Mr. Nordlicht disclaims beneficial ownership of the securities held by Fennmore.
- (16) Shares offered and owned includes 72,115 shares issuable upon exercise of warrants issued in the Private Placement. Highbridge Capital Management, LLC is the trading manager of Smithfield Fiduciary LLC and consequently has voting control and investment discretion over securities held by Smithfield. Glenn Dubin and Henry Swieca control Highbridge. Each of Highbridge, Glenn Dubin and Henry Swieca disclaims beneficial ownership of the securities held by Smithfield.
- (17) Shares offered and owned includes 36,058 shares issuable upon exercise of warrants issued in the Private Placement. The selling stockholder has identified Greg Porges, as a natural person with voting and investment control over shares of our common stock beneficially owned by the selling stockholder. Mr. Porges disclaims beneficial ownership of the securities held by Spectra.

- (18) Shares offered and owned includes 7,211 shares issuable upon exercise of warrants issued in the Private Placement. Shares listed as owned and offered excludes shares beneficially owned by Provident Premier Master Fund, Ltd. The Investment Manager of Gemini Master Fund, Ltd. is Gemini Investment Strategies, LLC. The Managing Members of Gemini Investment Strategies, LLC are Messrs. Steven W. Winters and Mr. Richard S. Yakomin. As such, Messrs. Winters and Yakomin may be deemed beneficial owners of the shares. Messrs. Winters and Yakomin, however, disclaim beneficial ownership of such shares.
- (19) Shares offered and owned includes 36,058 shares issuable upon exercise of warrants issued in the Private Placement. Shares listed as owned and offered excludes shares beneficially owned by Gemini Master Fund, Ltd. The Investment Advisor to Provident Premier Master Fund, Ltd. is Gemini Investment Strategies, LLC. The Managing Members of Gemini Investment Strategies, LLC are Messrs. Steven W. Winters and Mr. Richard S. Yakomin. As such, Messrs. Winters and Yakomin may be deemed beneficial owners of the shares. Messrs. Winters and Yakomin, however, disclaim beneficial ownership of such shares.

Address Change? Mark Box Indicate changes below:

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Date

Signature(s) in Box (Please sign exactly as your name appears to the left. When shares are held by joint tenants, both should sign. When signing as executor, administrator, attorney, trustee or guardian, please give full title as such. If a corporation, please sign in full corporate name by president or other authorized officer. If a partnership, please sign in partnership name by an authorized person.)