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HEMISPHERX BIOPHARMA INC
Form 424B3
August 08, 2006

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Registration Nos. 333-136187, 333-108645, 333-111135,
333-113796, 333-117178 and 333-130008

HEMISPHERX BIOPHARMA, INC.

23,807,453 Shares of Common Stock

The Offering:

This prospectus relates to the sale of up to 23,807,453 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) 12,064,972 shares of our common stock issuable to Fusion Capital Fund II, LLC ("Fusion Capital") under a common stock purchase agreement; (2) 135% of 2,149,232 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 2,302,590 shares of common stock issuable upon exercise of other warrants; and (5) outstanding 1,657,485 shares of common stock (including 321,751 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 August 4, 2006 was \$2.18.

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

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criminal offense.

The date of this prospectus is August 7, 2006

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/A-2 for our fiscal year ended December 31, 2005, SEC File No. 1-13441.
- (b) Our annual report on Form 10-K/A for our fiscal year ended December 31, 2005, SEC File No. 1-13441.
- (c) Our quarterly report on Form 10-Q for the quarterly period ended March 31, 2006, SEC File No. 1-13441.

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- (d) Our definitive proxy statement on schedule 14A for our annual meeting of stockholders to be held on September 20, 2006, SEC File No. 1-13441.

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- (e) Our current reports on Form 8-K filed on January 3, 2006; April 3, 2006 (amended April 11, 2006); April 7, 2006; April 12, 2006; April 13, 2006 and May 12, 2006; SEC File No. 1-13441.
- (f) A description of our common stock contained in our registration statement on Form S-1, SEC File No. 33-93314.
- (g) 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/A-2 for the fiscal year ended December 31, 2005 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 approved GMP (good manufacturing practice) manufacturing facility in New Jersey.

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Our flagship products include Ampligen(R) and Alferon N Injection(R). Ampligen(R) is an experimental drug currently undergoing clinical development for the treatment of: Myalgic Encephalomyelitis/Chronic Fatigue Syndrome and HIV, and pre-clinical testing for possible treatment of avian and seasonal influenza viruses.

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

Our principal executive offices are located at One Penn Center, 1617 JFK Boulevard, Philadelphia, Pennsylvania 19103, and its 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 million 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 will be 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

Fusion Capital is offering for sale herein up to 12,386,723 shares of our common stock. However, in the event that we decide to issue more than 12,386,723, i.e. greater than 19.99% of our outstanding shares of common stock as of the date of the agreement, we would first seek stockholder approval in order to be in compliance with American Stock Exchange rules. In the event we elect to issue more than 12,386,723 shares to Fusion Capital under the common stock purchase agreement, we also will be required to file a new registration statement and have it declared effective by the SEC. 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.

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Securities Offered

Common stock to be offered
by the selling stockholders 23,807,453 Shares consisting of:

- o 12,064,972 shares of our common stock issuable to Fusion Capital pursuant to a common stock purchase agreement;
- o 135% of 2,149,232 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;

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- o 135% of 3,615,514 shares of common stock issuable upon the exercise of related outstanding warrants ("Debenture Warrants");
- o 2,302,590 shares of common stock issuable upon exercise of other outstanding warrants; and
- o 1,657,485 outstanding shares of common stock (including 1,136,868 owned by Fusion Capital and 520,617 owned by other selling stockholders.

Common stock outstanding
prior to this offering 62,581,122 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 \$50 million in 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(R) and Alferon N Injection(R), Research and Development and for general corporate purposes. See "Use of Proceeds."

American Stock Exchange
symbol HEB

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RISK FACTORS

Special Note Regarding Forward-Looking Statements

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

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

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

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The clinical development of the experimental therapeutic, Ampligen(R) for CFS was initiated approximately 16 years ago. To date federal health agencies have yet to reach a consensus regarding various aspects of ME/CFS, including parameters of "promising therapies" for ME/CFS and which aspects of ME/CFS are anticipated to be "serious or life-threatening".

Over its developmental history, Ampligen(R) has received various designations, including Orphan Drug Product Certification (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports (AHRQ, Agency Health Research Quality). However to date, the FDA has determined it has yet to receive sufficient information to support the potential of Ampligen(R) to treat a serious or life threatening aspect of ME/CFS. The definition of the "seriousness of a condition", according to Guidance for Industry documents published in July 2004 is "a matter of judgment, but generally based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one". The FDA has recently requested a "complete and audited report of the Amp 516 study to determine whether Ampligen(R) has a clinically meaningful benefit on a serious or life threatening aspect of ME/CFS in order to evaluate whether the Amp 516 study results do or do not support a "fast track designation". The FDA has also invited us to include a schedule for completion of all ME/CFS studies as well as a proposed schedule for our NDA submission. Because we believe our ME/CFS studies are complete, we requested a pre-NDA meeting to obtain advice on preparing and submitting our NDA, which may eliminate the need for Fast Track

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Designation. This meeting has been scheduled for August 2, 2006. Meanwhile, we will continue with our existing ongoing efforts to prepare a complete and audited report of our various studies, including the well-controlled Amp 516 study. We are using our best efforts to complete the requisite reports including the hiring of new staff and various recognized expert medical/regulatory consultants, but can provide no assurance as to whether the outcome of this large data collection and filing process (approximately 750 patients, treated more than 45,000 times) will be favorable or unfavorable, specifically with respect to the FDA's perspective. Also, we can provide no guidance as to the tentative date at which the compilation and filing of such data will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the ability of Hollister-Stier facilities to interface with our own New Brunswick staff/facilities to meet the manufacturing regulatory standards.

Alferon N Injection(R). Although Alferon N Injection(R) is approved for marketing in the United States for the 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.

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

All of our drugs and associated technologies, other than Alferon N Injection(R), are investigational and must receive prior regulatory approval by appropriate regulatory authorities for general use and are currently legally available only through clinical trials with specified disorders. At present, Alferon N Injection(R) is only approved for the intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection(R) for other indications will require regulatory approval. In this regard, ISI, the company from which we obtained our rights to Alferon N Injection(R), conducted clinical trials related to use of Alferon N Injection(R) for treatment of HIV and Hepatitis C. In both instances, the FDA determined that additional studies were necessary in order to fully evaluate the efficacy of Alferon N Injection(R) in the treatment of HIV and Hepatitis C diseases. We have no immediate plans to conduct these additional studies at this time.

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

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clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials. If Ampligen(R) or one of our other products does not receive regulatory approval in the U.S. or elsewhere, our operations most likely will be materially adversely affected.

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

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

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In addition, Ampligen(R) 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(R) will be effective on any strains that might infect humans.

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

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses, as we pursued our clinical trial effort and expanded our efforts in Europe. As of March 31, 2006 our accumulated deficit was approximately \$153,572,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

We may require additional financing which may not be available.

The development of our products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of June 30, 2006, we had approximately \$21,500,000 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 12 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 \$50.0 million over a 25 month period (see "The Fusion Transaction" in Selling Stockholders" below).

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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, 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. Since we initially registered herein 12,386,723 shares purchasable by Fusion Capital pursuant to the common stock purchase agreement (inclusive of up to 643,502 additional Commitment Shares), the selling price of our common stock to Fusion Capital will have to average at least about \$4.26 per share for us to receive the maximum proceeds of \$50.0 million without registering additional shares of common stock. Assuming a purchase price of \$2.18 per share (the closing sale price of the common stock on August 4, 2006) and the purchase by Fusion Capital of the full 12,386,723 shares (inclusive of up to 643,502 additional Commitment Shares) under the common stock purchase agreement, proceeds to us would only be \$25,600,222 unless we choose to register more than 12,386,723 shares, which we have the right, but not the obligation, to do. In the event we elect to issue additional shares to Fusion Capital, we will be required to (i) file a new registration statement and have it declared effective by the Securities and Exchange Commission and (2) seek stockholder approval in order to be in compliance with the American Stock Exchange Market rules. 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.

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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(R) and/or increase sales of Alferon N Injection(R) or our other products, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full \$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(R) products. There can be no assurances that we will raise adequate funds which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

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

We need to preserve and acquire enforceable patents covering the use of Ampligen(R) for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen(R) for such disease. We obtained all rights to Alferon N Injection(R), and we plan to preserve and acquire enforceable patents covering its use for existing and potentially new diseases. Our success depends, in large part, on our ability to preserve and obtain patent protection for our products and to obtain and preserve our trade secrets and expertise. Certain of

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our know-how and technology is not patentable, particularly the procedures for the manufacture of our drug product which are carried out according to standard operating procedure manuals. We have been issued certain patents including those on the use of Ampligen(R) and Ampligen(R) in combination with certain other drugs for the treatment of HIV. We also have been issued patents on the use of Ampligen(R) in combination with certain other drugs for the treatment of chronic Hepatitis B virus, chronic Hepatitis C virus, and a patent which affords protection on the use of Ampligen(R) in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of Ampligen(R) as a sole treatment for any of the cancers, which we have sought to target. With regard to Alferon N Injection(R), we have acquired from ISI its patents for natural alpha interferon produced from human peripheral blood leukocytes and its production process 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.

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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 products in order to generate significant revenues and become profitable. As a result, any revenues received by us will be dependent on the efforts of third parties, and there is no assurance that these efforts will be successful. Our agreement with Accredo offers the potential to provide some marketing and distribution capacity in the United States while agreements with Biovail Corporation and Laboratorios Del Dr. Esteve S.A. may provide a sales force in Canada, Spain and Portugal. We also had an agreement with Bioclones (Proprietary), Ltd ("Bioclones") that covered South America, Africa, United Kingdom, Australia and New Zealand. However, we deem this marketing arrangement with Bioclones void due to the numerous and long standing failures of performance by Bioclones. In addition, in December 2004, we initiated a lawsuit in Federal Court identifying a conspiratorial group seeking to illegally manipulate our stock for purposes of bringing about the hostile takeover of Hemispherx. This conspiratorial group includes Bioclones.

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

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

A number of essential materials are used in the production of Alferon N Injection(R), including human white blood cells. We do not have long-term agreements for the supply of any of such materials. There can be no assurance we can enter into long-term supply agreements covering essential materials on commercially reasonable terms, if at all.

There are a limited number of manufacturers in the United States available to provide the polymers for use in manufacturing Ampligen(R). At present, we do not have any agreements with third parties for the supply of any of these polymers. We are establishing relevant manufacturing operations within our New Brunswick, New Jersey facility for the production of Ampligen(R) raw materials in order to obtain polymers on a more consistent manufacturing basis. The establishment of an Ampligen(R) raw materials production line within our own facilities, while having obvious advantages with respect to regulatory

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

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

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

Small changes in methods of manufacturing, including commercial scale-up, may affect the chemical structure of Ampligen(R) and other RNA drugs, as well as their safety and efficacy, and can, among other things, require new clinical studies and affect orphan drug status, particularly, market exclusivity rights, if any, under the Orphan Drug Act. The transition from limited production of pre-clinical and clinical research quantities to production of commercial quantities of our products will involve distinct management and technical challenges and will require additional management and technical personnel and capital to the extent such manufacturing is not handled by third parties. There can be no assurance that our manufacturing will be successful or that any given product will be determined to be safe and effective, capable of being manufactured economically in commercial quantities or successfully marketed.

We have limited manufacturing experience and capacity.

Ampligen(R) has been only produced in limited quantities for use in our clinical trials and we are dependent upon third party suppliers for 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.

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

We have never produced Ampligen(R) or any other products in large commercial quantities. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen(R) or enter into third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Also, each production lot of Alferon N Injection(R) is subject to FDA review and approval prior to releasing the lots to be sold. This review and approval process could take considerable time, which would delay our having product in inventory to sell.

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

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

Our products may be subject to substantial competition.

Ampligen(R). Competitors may be developing technologies that are, or in the future may be, the basis for competitive products. Some of these potential products may have an entirely different approach or means of accomplishing similar therapeutic effects to products being developed by us. These competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments may offer competition to our products. Furthermore, many of our competitors have significantly greater experience than us in pre-clinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, HPB or other regulatory product approvals more rapidly than us. There are no drugs approved for commercial sale with respect to treating ME/CF5 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(R) on the immune system, we cannot assure that we will be able to compete.

ALFERON N Injection(R). Many potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product

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

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

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

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

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

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

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

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

Our success is dependent on the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen(R), and his knowledge of our overall activities, including patents and clinical trials. The loss of Dr. Carter's services could have a material adverse effect on our operations and chances for success. We have secured key man life insurance in the amount of \$2,000,000 on the life of Dr. Carter and we have an employment agreement with Dr. Carter that, as amended, runs until 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.

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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

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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

We reported material weaknesses in our internal control over financial reporting that, if not remedied, could adversely affect our internal controls.

We assessed the effectiveness of our internal control over financial reporting as of December 31, 2005. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control--Integrated Framework (COSO). Based on this assessment, our management identified the following material weaknesses as of December 31, 2005. A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

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1. Financial Statement Close and Reporting Process - We did not maintain effective controls over the financial statement close and reporting process because we lacked a complement of personnel able to devote sufficient time and adequate financial reporting expertise commensurate with quarterly and year-end financial statement close requirements, which include the financial statement preparation and disclosures. Additionally, we had inadequate policies and procedures providing for a detailed comprehensive review of the underlying information supporting the amounts including in our annual and interim consolidation financial statements and disclosures.
2. We did not maintain effective controls over the initial recording of our convertible debentures that contained beneficial conversion features (including incorrect recording of investment banking fees incurred and subsequent conversion price resets) and the accounting for warrants and options issued to non-employees. Our interpretation and application of EITF No. 00-27, FASB Statement 133, EITF 98-5 and EITF 00-19 was not correct at the time the convertible debentures were initially recorded (2003 through July 2004), and our interpretation and application of FASB statement No. 123 was not correct in recording certain warrant and option issuances to non-employees. These control deficiencies resulted in the restatement of the 2004 and 2003 annual consolidated financial statements as well as to the unaudited consolidated interim financial statements for each of the three years in the period ended December 31, 2005.

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The result of applying the proper accounting treatment increased our net loss applicable to common stockholders by \$0.01, from \$0.42 per share to \$0.43 per share, for the year ended December 31, 2003 and decreased our net loss applicable to common stockholders by \$0.07, from \$0.53 per share to \$0.46 per share, for the year ended December 31, 2004.

Although the recording of the convertible debentures occurred during the periods from March 2003 through July 2004, and we have not issued any debentures since July 2004, we have taken and plan to take, during 2006, additional steps to remediate these internal control weaknesses. In March 2006, we increased the time allocated by our financial consultant with regards to remediating these disclosed internal control weaknesses and we will spend additional time monitoring our internal controls on an on-going basis. In addition, we have subscribed to CCH's "Accounting Research Manager," a recognized on-line service in order to maintain up-to-date accounting guidance to enhance internal control over both financial reporting and disclosure requirements. In addition, we have established policies and procedures to include a detailed comprehensive review of the underlying information supporting the amounts included within our consolidated financial statements and disclosures including to assist in ensuring: 1) clerical accuracy within our financial statements and disclosures, 2) financial statement groupings within our financial statements are accurate, 3) support utilized in preparation of the consolidated statement of cash flows is accurate, and 4) equity transactions during the reporting period are complete and accurate. We also engaged an additional accounting consultant in April 2006 to assist in initiating the implementation of these policies and procedures on a going forward basis. Notwithstanding the foregoing, and the measures we have taken and any future measures we may take to remediate the reported internal control weaknesses, we may not be able to maintain effective internal controls over financial reporting in the future. In addition, deficiencies in our internal controls may be discovered in the future. Any failure to remediate the reported material weaknesses, or to implement new or improved controls, or difficulties encountered in their implementation, could harm our operating results, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Any such failure also could affect the ability of our management to certify in our Forms 10-K and 10-Q that our internal controls are effective when it provides an assessment of our internal control over financial reporting, and could affect the results of our independent registered public accounting firm's related attestation report regarding our management's assessment. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our securities.

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

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

- o announcements of the results of clinical trials by us or our competitors;
- o adverse reactions to products;
- o governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory

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

Our common stock is listed for quotation on the American Stock Exchange. For the 12-month period ended June 30, 2006, the price of our common stock has ranged from \$1.45 to \$3.99 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.

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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 12,386,723 shares herein for sale by Fusion Capital and 333,658 shares by others, and may, in the future, register additional shares for sale by Fusion under the common stock purchase agreement. As of August 4, 2006, approximately 2,341,007 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act, 815,117 of which have been registered in prior registration statements. Also, we have registered 10,084,996 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

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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 resales 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 25 months. 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.

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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

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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 9.3% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at \$.01 per Right under certain circumstances.

We have a limited number of authorized shares that are not issued or reserved for issuance. If we do not increase our authorized shares, our ability to raise capital may be hindered.

Our Certificate of Incorporation currently authorizes the issuance of 100,000,000 common shares and 5,000,000 Preferred Shares. As of August 4, 2006, we had 62,581,122 common shares outstanding and 35,637,410 common shares reserved for future issuance under our existing stock option plan and outstanding options, warrants, convertible debentures, and the 2006 Purchase Agreement with Fusion, leaving only 1,781,478 common shares available for future use. In April 2006, our Board of Directors adopted a resolution proposing that our Certificate of Incorporation be amended to increase the authorized number of common shares to 200,000,000 subject to stockholder approval of such amendment. If stockholders do not approve the amendment to our Certificate of Incorporation at our next Annual Stockholders Meeting, it could harm our business by preventing us from utilizing the daily purchase amounts available under the 2006 Purchase Agreement in full, raising capital from the issuance of our common stock or delaying the payment of services via issuances of our common stock.

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

SELLING STOCKHOLDERS

We have registered all 23,807,453 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 resell the shares, from time to time,

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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 August 4, 2006. 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.

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The third column lists each selling stockholder's portion, based on agreements with us, of the 23,807,453 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 23,807,453 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.

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

Selling Stockholder	Common Stock Owned Prior To Offering	No. of Shares Being Offered	Common Stock Owned After The Offering
Fusion Capital Fund II, LLC	1,136,868 (1) (2)	13,201,840	--
Portside Growth & Opportunity Fund	4,136,967 (3)	4,136,967	--
Leonardo L.P.	3,933,901 (4)	3,933,901	--
Mid South Capital, LLC	25,000 (5)	25,000	--
Windward Capital Advisors, LLC	212,292 (6)	212,292	--
HefCap Holdings, LLC	212,292 (7)	212,292	--
Baxter Capital Advisors, Inc.	30,000 (8)	30,000	--
CEOCast, Inc.	20,000 (9)	20,000	--
Christopher Chipman	30,000 (10)	30,000	--
Fried Epstein & Rettig LLP	5,000 (11)	5,000	--
Business Asia Consultants, Inc.	17,959 (12)	17,959	--
JMBL, LTD	75,000 (13)	75,000	--
The Investor Relations Group	84,000 (14)	84,000	--
William Mason	131,066 (15)	41,666	89,400
W. Barry McDonald	131,067 (15)	41,667	89,400
Wayne Pambianchi	131,067 (15)	41,667	89,400
Gordon Ramseier	131,066 (15)	41,666	89,400
Daniel Tripodi	131,067 (15)	41,667	89,400
Michael Burrows	690,000 (16)	150,000	540,000
UBS O'Connor LLC	30,000 (17)	30,000	--
Kingsbridge Capital Ltd.	28,846 (18)	28,846	--
Fenmore Holdings	36,058 (19)	36,058	--
Smithfield Fiduciary, LLC	72,115 (20)	72,115	--
Spectra Investments, LLC	36,058 (21)	36,058	--
Gemini Master Fund, Ltd.	7,211 (22)	7,211	--
Provident Premier Master Fund, Ltd.	360,058 (23)	360,058	--
Asset Managers International	188,461 (24)	188,461	--
JMG Capital Partners, LP	37,116 (25)	37,116	--
JMG Triton Off shore Fund, Ltd.	72,116 (26)	72,116	--
Winton Capital Holdings, Ltd.	60,000 (27)	60,000	--
Iroquois Capital, LP	57,692 (28)	57,692	--
Jefferies & Company, Inc.	150,480 (29)	150,480	--
Global Fluency	6,900 (30)	6,900	--
Sage Healthcare Advisors	10,000 (31)	10,000	--
Stem Cell Innovations, Inc.	250,000 (32)	250,000	--
Paul Griffin	61,758	61,758	--

(1) As of the date hereof, 321,751 shares of our common stock have been acquired by Fusion Capital under the common stock purchase agreement and Fusion Capital owns an additional 815,117 shares that it purchased pursuant to the prior common stock purchase agreement. Fusion Capital may acquire up to an additional 12,064,972 shares under the common stock purchase agreement, inclusive of additional Commitment Shares.

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- (2) 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.
- (3) Includes (i) up to 1,048,384 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 1,100,848 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 owned by Mid South Capital which are exercisable at a price of \$3.00 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 212,292 shares of common stock issuable upon

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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) 30,000 are exercisable at a price of \$3.04 per share, and (v) 15,000 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) Messrs. Ken Sgro and Rachel Glicksman share voting control and investment discretion over the shares. CEOCast provides investor relations consulting services to us.
- (10) 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.
- (11) Represents shares issued to Fried Epstein & Rettig LLP, a law firm, for legal services provided to us. The three named partners share voting control and investment discretion over the shares.
- (12) Business Asia Consultants, Inc. provides consulting services related to obtaining distribution channels in China. It is owned by Lawrence Kronick.

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- (13) 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.
- (14) Dian Griesel is the owner of the Investor Relations Group and is deemed to be the beneficial owner of all common stock owned by the Investors Relations Group.
- (15) 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.

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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 is our President.

- (16) 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 and 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.
- (17) 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.
- (18) 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.
- (19) 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.
- (20) Shares offered and owned includes 72,115 shares issuable upon exercise of warrants issued in the Private Placement. Highbridge Capital Management, LLC is the trading manager of Smithfield Fiduciary LLC and consequently has voting control and investment discretion over securities held by Smithfield. Glenn Dubin and Henry Swieca control Highbridge. Each of Highbridge, Glenn Dubin and Henry Swieca disclaims beneficial ownership of the securities held by Smithfield.

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- (21) 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.
- (22) 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.
- (23) Shares offered and owned includes 360,058 shares issuable upon exercise of warrants issued in the Private Placement. Shares listed as owned and

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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.

- (24) Shares offered and owned includes 188,461 shares issuable upon exercise of warrants issued in the Private Placement. The selling stockholder has identified Adam Benowitz, as a natural person with voting and investment control over shares of our common stock beneficially owned by the selling stockholder. Mr. Benowitz disclaims beneficial ownership of the securities held by Asset Managers International.
- (25) Shares offered and owned includes 37,116 shares issuable upon exercise of warrants issued in the Private Placement. Shares listed as owned and offered excludes shares beneficially owned by JMG Triton Offshore Fund, Ltd. JMG Capital Partners, L.P. ("JMG Partners") is a California limited partnership. Its general partner is JMG Capital Management, LLC (the "Manager"), a Delaware limited liability company and an investment adviser registered with the Securities and Exchange Commission. The Manager has voting and dispositive power over JMG Partners' investments, including the Registrable Securities. The equity interests of the Manager are owned by JMG Capital Management, Inc., ("JMG Capital") a Delaware corporation, and Asset Alliance Holding Corp., a Delaware corporation. Jonathan M. Glaser is the Executive Officer and Director of JMG Capital and has sole investment discretion over JMG Partners' portfolio holdings.

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- (26) Shares offered and owned includes 72,116 shares issuable upon exercise of warrants issued in the Private Placement. Shares listed as owned and offered excludes shares beneficially owned by JMG Capital Partners, L.P. JMG Triton Offshore Fund, Ltd. (The "Fund") is an international business company under the laws of the British Virgin Islands. The Fund's investment manager is Pacific Assets Management LLC, a Delaware limited liability company (the "Manager"). The Manager is an investment adviser registered with the Securities and Exchange Commission and has voting and dispositive power over the Fund's investments, including the Registrable Securities. The equity interests of the Manager are owned by Pacific Capital Management, Inc., a Delaware company ("the Pacific") and Asset Alliance Holding Corp., a Delaware company. The equity interests of Pacific are owned by Messrs. Roger Richter, Jonathan M. Glaser and Daniel A. David and Messrs. Glaser and Richter have sole investment discretion over the fund's portfolio holdings.
- (27) Shares offered and owned includes 60,000 shares issuable upon exercise of warrants issued in the Private Placement. The selling stockholder has identified Marc Belzberg, as a natural person with voting and investment control over shares of our common stock beneficially owned by the selling stockholder.
- (28) Shares offered and owned includes 57,692 shares issuable upon exercise of warrants issued in the Private Placement. The selling stockholder has identified Joshua Silverman, as a natural person with voting and investment control over shares of our common stock beneficially owned by the selling stockholder. Mr. Silverman disclaims beneficial ownership of the shares held by Iroquois Capital LP.

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- (29) Represents 150,480 shares issuable upon exercise of immediately exercisable warrants. Jefferies acted as the sole placement agent in the financing and is a registered broker-dealer. Based upon representations made to us by Jefferies, the warrant to purchase common stock were acquired in the ordinary course of its business for its own account for investment purposes only and not with a view to, or for, distributing the warrant or the shares of common stock issuable upon exercise thereof. Jefferies does not have any agreements, plans or understandings, directly or indirectly, with any person or entity to distribute the warrant to purchase common stock or the shares of common stock issuable upon exercise of the warrant.
- (30) Donovan Neale-May is the owner of Global Fluency and is considered to be the beneficial owner of all common stock owned by Global Fluency.
- (31) Reflects 10,000 warrants to purchase common stock at \$2.46 per share expiring December 8, 2010.
- (32) Stem Cell Innovations, Inc. was formerly known as Interferon Sciences, Inc. James H. Kelly, the Chief Executive Officer of Stem Cell Innovations, Inc., is a natural person with voting and investment control over shares of our common stock beneficially owned by Stem Cell Innovations.

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The Fusion Transaction

General

On April 12, 2006 we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC, pursuant to which Fusion Capital has agreed, under certain conditions, to purchase on each trading day \$100,000 of our common stock up to an aggregate of \$50.0 million over a period of approximately 25 months, subject to earlier termination at our discretion. The purchase price of the shares of common stock will be equal to a price based upon the future market price of the common stock. 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.

The shares being offered by Fusion Capital herein include up to 12,386,723 shares of our common stock issued and issuable pursuant to the common stock purchase agreement. In the event we elect to issue more than 12,386,723 shares, we will be required to: (i) file a new registration statement and have it declared effective by the SEC and (ii) seek and obtain stockholder approval in order to be in compliance with American Stock Exchange rules. In addition, Fusion Capital cannot purchase more than 26,743,221 shares, exclusive of Commitment Shares under the common stock purchase agreement. 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.

Purchase Of Shares Under The Common Stock Purchase Agreement

Under the common stock purchase agreement, on each trading day Fusion Capital is obligated to purchase a specified dollar amount of our common stock. Subject to our right to suspend such purchases at any time, and our right to terminate the agreement with Fusion Capital at any time, each as described below, Fusion Capital shall purchase on each trading day during the term of the

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agreement \$100,000 of our common stock. This daily purchase amount may be decreased by us at any time. We also have the right to increase the daily purchase amount at any time, provided however, we may not increase the daily purchase amount above \$100,000 unless our stock price exceeds \$1.90 per share by at least \$0.10 per share for five consecutive trading days.

The purchase price per share is equal to the lesser of:

- o the lowest sale price of our common stock on the purchase date; or
- o the average of the three lowest closing sale prices of our common stock during the twelve consecutive trading days prior to the date of a purchase by Fusion Capital.

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The purchase price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction. 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. Fusion Capital has the right at any time to sell any shares purchased under the common stock purchase agreement which would allow it to avoid the 9.9% limitation. Therefore, we do not believe that Fusion Capital will ever reach the 9.9% limitation.

The following table sets forth the amount of proceeds we would receive from Fusion Capital from the sale of shares of our common stock offered by this prospectus at varying purchase prices. It is for illustrative purposes only. Actual results will differ because it assumes that purchases will be made at a constant price.

Assumed Average Purchase Price	Number of Shares to be Issued if Full Purchase (1)	Percentage of Shares Outstanding After Giving Effect to the Issuance to Fusion Capital (2)	Proceeds from the Sale of Shares to Fusion Capital Under the Common Stock Purchase Agreement
\$1.00	11,743,221	16.5%	\$11,743,221
\$2.00	11,743,221	16.5%	\$23,486,442
\$2.18 (3)	11,743,221	16.5%	\$25,600,222
\$3.00	11,743,221	16.5%	\$35,229,663
\$4.00	11,743,221	16.5%	\$46,972,884
\$4.26	11,743,221	16.5%	\$50,000,000
\$5.00	10,000,000	13.7%	\$50,000,000

(1) Excludes Commitment Shares issued and to be issued to Fusion Capital (see "Commitment Shares Issued to Fusion Capital" below).

(2) Based on 62,581,122 shares outstanding as of August 4, 2006 which includes the issuance to Fusion Capital of 321,751 shares as a partial commitment fee. Also includes the balance of Commitment Shares to be issued and the number of shares issuable at the corresponding assumed purchase price set forth in the adjacent column.

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(3) Closing sale price of our common stock on August 4, 2006.

In connection with entering into the agreement, we authorized the sale to Fusion Capital of up to 12,386,723 shares of our common stock and issued to Fusion Capital 321,751 Commitment Shares. We estimate that we will issue no more than 12,064,972 shares to Fusion Capital under the common stock purchase agreement (inclusive of additional Commitment Shares), all of which are included in this offering. We have the right to terminate the agreement without any payment or liability to Fusion Capital at any time, including in the event that all 12,064,972 shares are sold to Fusion Capital under the common stock purchase agreement. In the event we elect to issue more than the 12,386,723 shares offered hereby, we will be required to: (i) file a new registration statement and have it declared effective by the SEC and (ii) seek and obtain stockholder approval in order to be in compliance with American Stock Exchange rules. In this regard, at our 2005 Annual Meeting of Stockholders scheduled for September 2006, we are seeking stockholder approval of the issuance of more than 12,386,723 shares under the Purchase Agreement. Notwithstanding the foregoing, Fusion Capital cannot purchase more than 27,386,723, inclusive of Commitment Shares under the common stock purchase agreement.

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Minimum Purchase Price

Under the common stock purchase agreement, we have set a minimum purchase price ("floor price") of \$1.00. Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock in the event that the purchase price would be less than the floor price.

Our Right To Suspend Purchases

We have the unconditional right to suspend purchases at any time for any reason effective upon one trading day's notice. Any suspension would remain in effect until our revocation of the suspension.

Our Right To Increase and Decrease the Amount to be Purchased

Under the common stock purchase agreement, Fusion Capital has agreed to purchase on each trading day during a period of approximately 25 months, \$100,000 of our common stock up to an aggregate of \$50.0 million. We have the unconditional right to decrease the daily amount to be purchased by Fusion Capital at any time for any reason effective upon one trading day's notice.

In our discretion, we may elect to sell more of our common stock to Fusion Capital than the minimum daily amount. First, in respect of the daily purchase amount, we have the right to increase the daily purchase amount as the market price of our common stock increases. Specifically, for every \$0.10 increase in Threshold Price (as defined below) above \$1.90, we have the right to increase the daily purchase amount by up to an additional \$10,000. For example, if the Threshold Price is \$2.20 we would have the right to increase the daily purchase amount by up to \$30,000 to an aggregate of \$130,000. The "Threshold Price" is the lowest sale price of our common stock during the five trading days immediately preceding our notice to Fusion Capital to increase the daily purchase amount. If at any time during any trading day the sale price of our common stock is below the Threshold Price, the applicable increase in the daily purchase amount will be void.

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In addition to the daily purchase amount, we may elect to require Fusion Capital to purchase on any single trading day our shares in an amount up to \$250,000, provided that our share price is above \$1.50 during the five trading days prior thereto. The price at which such shares would be purchased will be the lower of the lowest Sale Price of our common stock on the trading day that Fusion Capital receives such purchase notice from us, or the lowest Purchase Price (as defined above) during the previous ten trading days prior to the date that such purchase notice was received by Fusion Capital. We may increase this amount as follows:

Share Price	Increased Daily Amount
\$3.00	\$ 500,000
\$5.00	\$1,000,000
\$8.00	\$2,000,000

We may deliver multiple purchase notices; however at least five trading days must have passed since the most recent non-daily purchase was completed.

Events of Default

Generally, Fusion Capital may terminate the common stock purchase agreement without any liability or payment to us upon the occurrence of any of the following events of default:

- o the effectiveness of the registration statement of which this prospectus is a part lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Fusion Capital for sale of our common stock offered hereby and such lapse or unavailability continues for a period of ten consecutive trading days or for more than an aggregate of 30 trading days in any 365-day period;
 - o suspension by our principal market of our common stock from trading for a period of three consecutive trading days;
 - o the de-listing of our common stock from the American Stock Exchange, our principal market, provided our common stock is not immediately thereafter trading on the Nasdaq National Market, the Nasdaq SmallCap Market or the New York Stock Exchange or the OTC Bulletin Board;
 - o the transfer agent's failure for five trading days to issue to Fusion Capital shares of our common stock which Fusion Capital is entitled to under the common stock purchase agreement;
 - o any material breach of the representations or warranties or covenants contained in the common stock purchase agreement or any related agreements which has or which could have a material adverse affect on us subject to a cure period of ten trading days;
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- o any participation or threatened participation in insolvency or bankruptcy proceedings by or against us;

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- o a material adverse change in our business, properties, operations, financial condition or results of operations; or
- o the issuance of an aggregate of 12,386,723 shares to Fusion Capital under our agreement and, prior to Fusion Capital's determination to terminate the agreement, we fail to obtain the requisite stockholder approval.

Our Termination Rights

We have the unconditional right at any time for any reason to give notice to Fusion Capital terminating the common stock purchase agreement. Such notice shall be effective one trading day after Fusion Capital receives such notice.

Effect of Performance of the Common Stock Purchase Agreement on Our Stockholders

All shares registered in this offering will be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 25 months from the date of this prospectus. The sale of a significant amount of shares registered in this offering at any given time could cause the trading price of our common stock to decline and to be highly volatile. Fusion Capital may ultimately purchase all of the 12,386,723 shares of common stock registered in this offering, and it may sell some, none or all of the shares of common stock it acquires upon purchase. Therefore, the purchases under the common stock purchase agreement may result in substantial dilution to the interests of other holders of our common stock. However, we have the right at any time for any reason to: (1) reduce the daily purchase amount, (2) suspend purchases of the common stock by Fusion Capital and (3) terminate the common stock purchase agreement.

No Short-Selling or Hedging by Fusion Capital

Fusion Capital has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the common stock purchase agreement.

Commitment Shares Issued to Fusion Capital

Under the terms of the common stock purchase agreement Fusion Capital has received 321,751 shares of our common stock as a partial commitment fee and is entitled to receive up to an additional 321,751 commitment shares (collectively, the "Commitment Shares"). These additional commitment shares will be issued in an amount equal to the product of (x) 321,751 and (y) the Purchase Amount Fraction. The "Purchase Amount Fraction" means a fraction, the numerator of which is the purchase price at which the shares are being purchased by Fusion Capital and the denominator of which is \$50,000,000. Unless an event of default occurs these shares must be held by Fusion Capital until 25 months from the date of the common stock purchase agreement or the date the common stock purchase agreement is terminated or in the event that we cannot commence sales of stock to Fusion Capital prior to August 31, 2006.

No Variable Priced Financings

Until the termination of the common stock purchase agreement, we have agreed not to issue, or enter into any agreement with respect to the issuance of, any variable priced equity or variable priced equity-like securities unless

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we have obtained Fusion Capital's prior written consent.

Repurchase of Royalty Rights from Stem Cell Innovations, Inc. (formerly, Interferon Sciences, Inc.)

On July 26, 2006 we entered into an agreement with Stem Cell Innovations, Inc. ("SCI") to acquire its royalty interest in the sale of products containing natural interferon ("Interferon Products") in exchange for 250,000 shares of our common stock. We originally acquired the rights to manufacture and market Alferon N Injections(R) and related interferon products from SCI (then known as Interferon Sciences, Inc.) in 2003 subject to the terms of a 6% royalty on sales of Interferon Products. Upon execution of this agreement, we terminated this royalty interest. Pursuant to our agreement with SCI, we have registered herein the 250,000 shares issued to SCI for public resale.

BUSINESS

Our Annual Report on Form 10-K/A and Form 10-K/A-2 for the fiscal year ended December 31, 2005, and our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2006, incorporated by reference into this Prospectus, contain information about us, including audited financial statements for our fiscal year ended December 31, 2005 and unaudited financial statements for our fiscal quarter ended March 31, 2006. Please refer to these reports for additional information.

PLAN OF DISTRIBUTION

Selling Stockholders other than Fusion Capital

The following Plan of distribution relates to all selling stockholders other than Fusion Capital.

The common stock offered by this prospectus is being offered by the selling stockholders. The selling stockholders may sell their shares of common stock from time to time in various ways and at various prices. The shares may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions that may involve crosses or block transactions. Some of the methods by which the selling stockholders may sell the shares include:

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- o on any national securities exchange or quotation service on which the shares may be listed or quoted at the time of sale;
- o in the over-the-counter market;
- o in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- o through the writing of options, whether such options are listed on an options exchange or otherwise;
- o ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- o privately negotiated transactions;

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- o block trades in which the broker or dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- o purchases by a broker or dealer as principal and resale by that broker or dealer for the selling stockholder's account under this prospectus;
- o sales under Rule 144 rather than by using this prospectus;
- o through the settlement of short sales;
- o a combination of any of these methods of sale; or
- o any other legally permitted method.

In connection with sales of the shares or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares in the course of hedging in positions they assume. The selling stockholders may also sell shares short and deliver shares to close out short positions, provided that the selling stockholders may not close out short positions entered into prior to the effective date of the registration statement of which this prospectus is a part with any shares included in this prospectus. The selling stockholders may also pledge their shares as collateral for a margin loan under their customer agreements with their brokers. If there is a default by the selling stockholders, the brokers may offer and sell the pledged shares from time to time under this prospectus or an amendment to this prospectus under Rule 424(b)(3) or other applicable provisions of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

Brokers or dealers may receive commissions or discounts from the selling stockholders (or, if the broker-dealer acts as agent for the purchaser of the shares, from that purchaser) in amounts to be negotiated. These commissions may exceed those customary in the types of transactions involved.

We cannot estimate at the present time the amount of commissions or discounts, if any, that will be paid by the selling stockholders in connection with sales of the shares.

The selling stockholders and any broker-dealers or agents that participate with the selling stockholders in sales of the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In that event, any commissions received by the broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of the shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of shares by the selling stockholders. In addition, each of the selling stockholders who is a registered broker-dealer or is affiliated with a registered broker-dealer has advised us that:

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- o it purchased the shares in the ordinary course of business; and
- o at the time of the purchase of the shares to be resold, it had no agreements or understandings, directly or indirectly, with any person to

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distribute the shares.

Under the securities laws of certain states, the shares may be sold in those states only through registered or licensed broker-dealers. In addition, the shares may not be sold unless they have been registered or qualified for sale in the relevant state or unless they qualify for an exemption from registration or qualification.

We do not know whether any selling stockholder will sell any or all of the shares registered by the registration statement of which this prospectus forms a part.

We have agreed to pay all fees and expenses incident to the registration of the shares, including certain fees and disbursements of counsel to certain of the selling stockholders. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Certain of the selling stockholders have also agreed to indemnify us, our directors, officers, agents and representatives against certain liabilities, including certain liabilities under the Securities Act.

The selling stockholders and other persons participating in the distribution of the shares offered under this prospectus are subject to the applicable requirements of Regulation M promulgated under the Exchange Act in connection with sales of the shares. With certain exceptions, Regulation M precludes the selling stockholders, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this Prospectus.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus is a part effective until all the shares registered under the registration statement have been resold.

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This offering will terminate on the date that all shares offered by this Prospectus have been sold by the selling stockholders.

Fusion Capital

The following Plan of distribution relates to all selling stockholders other than Fusion Capital.

The common stock offered by Fusion Capital may be sold or distributed from time to time by Fusion Capital only for cash directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock may be effected in one or more of the following methods:

- o ordinary brokers' transactions;

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- o transactions involving cross or block trades;
- o through brokers, dealers or underwriters who may act solely as agents;
- o "at the market" into an existing market for the common stock;
- o in other ways not involving market makers or established trading markets, including direct sales to purchasers or sales effected through agents;
- o in privately negotiated transactions;
- o any combination of the foregoing methods of sale; and
- o any other method permitted pursuant to applicable law.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions.

Fusion Capital is an "underwriter" within the meaning of the Securities Act of 1933. Any broker-dealers or agents that are involved in selling the shares for the selling stockholders may be deemed to be "underwriters" within the meaning of the Securities Act of 1933 in connection with such sales.

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Neither we nor the selling stockholder can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between the selling stockholder, any other stockholder, broker, dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this Prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholder, and any other required information.

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have also agreed to indemnify Fusion Capital and related persons against specified liabilities, including liabilities under the Securities Act of 1933.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

Fusion Capital and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the

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common stock purchase agreement.

We have advised Fusion Capital that while it is engaged in a distribution of the shares included in this Prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling stockholders, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this Prospectus.

This offering will terminate on the date that all shares offered by this Prospectus have been sold by the selling stockholders.

USE OF PROCEEDS

We will not receive any proceeds from the sale of the shares of common stock offered by the selling stockholders. However, we may receive up to \$50.0 million in proceeds from the sale of our common stock to Fusion Capital under the common stock purchase agreement and we may receive additional proceeds from the exercise of warrants. We intend to use such proceeds to extend our New Brunswick facility for the production of Ampligen(R) and Alferon N Injection(R), Research and Development and for general corporate purposes.

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SEC POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the company pursuant to the foregoing provisions, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

LEGAL MATTERS

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

EXPERTS

The financial statements and schedule and management's report on the effectiveness of internal control over financial reporting incorporated by reference in this Prospectus and in the Registration Statement have been audited by BDO Seidman, LLP, an independent registered public accounting firm, to the extent and for the periods set forth in their reports incorporated herein by reference, and are included in reliance upon such reports given upon the authority of said firm as experts in auditing and accounting.

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No dealer, salesman or any other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell these securities and it is not a solicitation of an offer to buy these securities in any state where the offer or sale is not permitted. The information contained in this Prospectus is current only as of this date.

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23,807,453 SHARES OF
COMMON STOCK

HEMISPHERX BIOPHARMA, INC.

PROSPECTUS

August 7, 2006
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