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HEMISPHERX BIOPHARMA INC

Form 424B3

August 04, 2005

Filed Pursuant to Rule 424(b) (3)
Registration Number 333--126804

HEMISPHERX BIOPHARMA, INC.

10,845,597 Shares of Common Stock

The Offering:

This prospectus relates to the sale of up to 10,795,597 shares of our common stock by Fusion Capital Fund II, LLC and up to 50,000 shares of our common stock by JMBL LLC. We will not receive proceeds from the sale of our shares by the selling stockholders.

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 July 19, 2005 was \$1.75.

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 4 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.

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

The date of this prospectus is August 3, 2005

PROSPECTUS SUMMARY

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a "shelf" registration statement. The selling stockholders may from time to time sell their shares of

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our common stock in one or more transactions. This prospectus provides you with a general description of the common stock being offered. You should read this prospectus, including all documents incorporated herein by reference, together with additional information described under the heading "Where You Can Find More Information."

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

About Hemispherx

We are a biopharmaceutical company engaged in the clinical development, manufacture, marketing and distribution of new drug entities based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. We were founded in the early 1970s, as a contract researcher for the National Institutes of Health. After almost 30 years, we have established a strong foundation of laboratory, pre-clinical, and clinical data with respect to the development of nucleic acids to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of chronic diseases. We own a U.S. Food and Drug Administration ("FDA") approved GMP (good manufacturing practice) manufacturing facility in New Jersey, and our corporate offices are in Philadelphia, PA.

Our flagship products include Ampligen and Alferon. Ampligen is an experimental drug undergoing clinical trials for the treatment of: Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), HIV, and HIV/Hepatitis C co-infection. In August 2004, we completed a Phase III clinical trial treating over 230 ME/CFS patients with Ampligen and are in the process of preparing a new drug application to be filed with the FDA. Alferon N Injection is the registered trademark for our injectable formulation of Natural Alpha Interferon, which is approved by the FDA for the treatment of genital warts. Alferon N is also in clinical development for treating Hepatitis C ("HEP-C"), Multiple Sclerosis, Human Immunodeficiency Virus (HIV), West Nile Virus ("WNV") and Severe Acute Respiratory Syndrome (SARS).

We have over 140 patents worldwide with 10 additional patents pending comprising our core intellectual property, a fully commercialized product (Alferon), and a GMP certified manufacturing facility.

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

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

Our principal executive offices are located at One Penn Center, 1617

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JFK Boulevard, Philadelphia, Pennsylvania 19103, and its telephone number is 215-988-0080.

Securities Offered

On July 8, 2005, 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 \$40,000 of our common stock up to an aggregate of \$20.0 million over approximately a 25 month period, subject to earlier termination at our discretion. In our discretion, 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 up to 10,795,597 shares of our common stock. However, in the event that we decide to issue more than 10,113,278, 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. Assuming Fusion Capital purchases all \$20.0 million of common stock, we estimate that the maximum number of shares we will sell to Fusion Capital under the common stock purchase agreement will be 10,000,000 shares (exclusive of the 785,597 shares issued and to be issued to Fusion Capital as the commitment fee and 10,000 shares issued to Fusion Capital as a partial expense reimbursement). In the event we elect to issue more than 10,795,597 shares offered hereby, we 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. The other selling stockholder, JMBL LLC, is offering for sale up to 50,000 shares of our common stock.

As of July 8, 2005, there were 50,984,488 shares outstanding, including the 402,798 shares that we have issued to Fusion Capital and 50,000 shares offered by JMBL LLC, but excluding 10,392,799 shares offered by Fusion Capital pursuant to this prospectus which it has not yet purchased from us. If all of shares offered by this prospectus were issued and outstanding as of the date hereof, the number of shares offered by this prospectus would represent 21.3 % of the total common stock outstanding as of July 8, 2005.

We are also registering for sale any additional shares of common stock which may become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration, which results in an increase in the number of outstanding shares of our common stock.

RISK FACTORS

Special Note Regarding Forward-Looking Statements

Certain statements in this prospectus constitute "forwarding-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1995 (collectively, the "Reform Act"). Certain, but not necessarily all, of such forward-looking statements can be identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should," or "anticipates" or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. All statements other than statements of historical fact, included in this

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prospectus regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note that statements regarding potential drugs, their potential therapeutic effect, the possibility of obtaining regulatory approval, our ability to manufacture and sell any products, market acceptance or our ability to earn a profit from sales or licenses of any drugs or our ability to discover new drugs in the future are all forward-looking in nature.

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

The following cautionary statements identify important factors that could cause our actual result to differ materially from those projected in the forward-looking statements made in this prospectus. Among the key factors that have a direct bearing on our results of operations are:

Risks Associated With Our Business

No assurance of successful product development

Ampligen(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.

ALFERON N Injection(R). Although ALFERON N Injection(R) is approved for marketing in the United States for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older; to date it has not been approved for other indications. We face many of the risks discussed above, with regard to developing this product for use to treat other ailments such as multiple sclerosis and cancer.

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

All of our drugs and associated technologies other than ALFERON N Injection(R) are investigational and must receive prior regulatory approval by appropriate regulatory authorities for general use and are currently legally available only through clinical trials with specified disorders. At present, ALFERON N Injection(R) is only approved for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of ALFERON N Injection(R) for other indications will require regulatory approval. In this regard, ISI, the company from which we obtained our rights to ALFERON N Injection(R), conducted clinical trials related to use of

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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 obligation or 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 European Medical Evaluation Agency ("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 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.

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, 2005 our accumulated deficit was approximately \$141,000,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

We may require additional financing which may not be available.

The development of our products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of March 31, 2005, we had approximately \$14,407,000 in cash and cash equivalents and short-term investments. These funds should be sufficient to meet our operating cash requirements including debt service for the near term. However, we may need to raise additional funds through additional equity or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes including the commercializing of Ampligen(R) products. There can be no assurances that we will raise adequate funds which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

We only have the right to receive \$40,000 per trading day under the agreement with Fusion Capital unless our stock price equals or exceeds \$2.00, in which case the daily amount may be increased under certain conditions as the

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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 10,000,000 shares purchasable by Fusion Capital pursuant to the common stock purchase agreement, the selling price of our common stock to Fusion Capital will have to average at least \$2.00 per share for us to receive the maximum proceeds of \$20.0 million without registering additional shares of common stock. Assuming a purchase price of \$1.75 per share (the closing sale price of the common stock on July 19, 2005) and the purchase by Fusion Capital of the full 10,000,000 shares under the common stock purchase agreement, proceeds to us would only be \$17,500,000 unless we choose to register more than 10,000,000 shares, which we have the right, but not the obligation, to do. Subject to approval by our board of directors, we have the right but not the obligation to issue more than 10,000,000 shares to Fusion Capital. In the event we elect to issue more than 10,000,000 shares offered hereby, we will be required to file a new registration statement and have it declared effective by the Securities and Exchange Commission. In the event that we decide to issue more than 10,113,278 (19.99% of our outstanding shares of common stock as of the date of our agreement), we would first be required to seek shareholder approval in order to be in compliance with the American Stock Exchange Market rules.

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

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

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

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will not seek and obtain patents regarding the use of similar products in combination with various other agents, for a particular target indication prior to our doing such. If we cannot protect our patents covering the use of our products for a particular disease, or obtain additional patents, we may not be able to successfully market our products.

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

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

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

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

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

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

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

We have limited marketing and sales capability. We are dependent upon existing and, possibly future, marketing agreements and third party distribution agreements for our 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

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marketing and distribution capacity in the United States while agreements with Bioclones (Proprietary), Ltd, Biovail Corporation and Laboratorios Del Dr. Esteve S.A. may provide a sales force in South America, Africa, United Kingdom, Australia and New Zealand, Canada, Spain and Portugal. On December 27, 2004, we initiated a lawsuit in Federal Court identifying a conspiratorial group seeking to illegally manipulate our stock for purposes of bringing about the hostile takeover of Hemispherx. This conspiratorial group includes Bioclones and the potential legal action may adversely effect our agreement with Bioclones and the potential for marketing and distribution capacity in South America, Africa, United Kingdom, Australia and New Zealand.

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

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

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

At present, we do not have any agreements with third parties for the supply of any polymers for use in manufacturing Ampligen. We have consolidated relevant manufacturing operations into our New Brunswick, New Jersey facility for the production of Ampligen raw materials. This consolidation and transfer of manufacturing operations has been implemented as an inspection of the Ribotech facility in South Africa, our previous supplier of Ampligen(R) raw materials, indicated that it did not, at present, meet the necessary GMP standards for a fully certified commercial process. The transfer of Ampligen(R) raw materials manufacture to our own facilities, while having obvious advantages with respect to regulatory compliance (other parts of the 43,000 sq. ft. wholly owned facility are already in compliance for Alferon N manufacture), may delay certain steps in the commercialization process, specifically a targeted NDA filing.

If we are unable to obtain 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 may affect the chemical structure of Ampligen(R) and other RNA drugs, as well as their safety and efficacy. Changes in methods of manufacture, including commercial scale-up may affect the chemical structure of Ampligen(R) and can, among other things, require new clinical studies and affect orphan drug status, particularly, market

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exclusivity rights, if any, under the Orphan Drug Act. The transition from limited production of pre-clinical and clinical research quantities to production of commercial quantities of our products will involve distinct management and technical challenges and will require additional management and technical personnel and capital to the extent such manufacturing is not handled by third parties. There can be no assurance that our manufacturing will be successful or that any given product will be determined to be safe and effective, capable of being manufactured economically in commercial quantities or successfully marketed.

We have limited manufacturing experience and capacity.

Ampligen(R) has been only produced in limited quantities for use in our clinical trials and we are dependent upon third party suppliers for key components of our products and for substantially all of the production process. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a material adverse affect on us. Also, to be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. To the extent we are involved in the production process, our current facilities are not adequate for the production of our proposed products for large-scale commercialization, and we currently do not have adequate personnel to conduct commercial-scale manufacturing. We intend to utilize third-party facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. We will need to comply with regulatory requirements for such facilities, including those of the FDA and HPB pertaining to current Good Manufacturing Practices ("cGMP") regulations. There can be no assurance that such facilities can be used, built, or acquired on commercially acceptable terms, or that such facilities, if used, built, or acquired, will be adequate for our long-term needs.

In connection with settling various manufacturing infractions previously noted by the FDA, Schering-Plough ("Schering") entered into a "Consent Decree" with the FDA whereby, among other things, it agreed to discontinue various contract (third party) manufacturing activities at various facilities including its San Juan, Puerto Rico, plant. Ampligen(R) (which was not involved in any of the cited infractions) was produced at this Puerto Rico plant from year 2000-2004. Operating under instructions from the Consent Decree, Schering has advised us that it would no longer manufacture Ampligen(R) in this facility beyond 2004 and would assist us in an orderly transfer of said activities to other non Schering facilities. Accordingly, we have entered into a Confidentiality Agreement with Mayne Pharma Pty, Ltd ("Mayne") to lead to reinitiation and expansion of its Ampligen(R) manufacturing program. Senior management at Mayne's Mulgrave operations in Australia recently informed us that they are ceasing to continue with all development activities associated with potential contract customers and all other contract business will be progressively scaled down over the next couple of years. Therefore, Mayne's Mulgrave facility in Australia will no longer be a possibility for manufacturing. We have obtained two proposals from manufacturers in the US and expect to obtain at least two more for the manufacturing of Ampligen. We want to qualify at least two GMP facilities in order to maintain a minimum of two independent production sites. If we are unable to engage a contract manufacturer in a timely manner, our plans to file an NDA for Ampligen(R) and, eventually, to market and sell Ampligen(R) will be delayed.

The purified drug concentrate utilized in the formulation of ALFERON N Injection(R) is manufactured in our New Brunswick, New Jersey facility and ALFERON N Injection(R) was formulated and packaged at a production facility formerly owned and operated by Abbott Laboratories located in Kansas. Abbott Labs has sold the facility to Hospira and we are currently in discussions with two other production facilities for this work. We currently have 12,000 vials at Hospira in purified drug concentrate form. Hospira will complete the labeling

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and packaging of this lot. We have identified four new potential contract manufacturers and obtained proposals for the future formulation and packaging of Alferon. If we are unable to secure a new facility within a reasonable period of time to formulate and package ALFERON N Injection(R) at an acceptable cost, our ability to sell ALFERON N Injection(R) and to generate profits therefrom will be adversely affected.

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

We have never produced Ampligen(R) or any other products in large commercial quantities. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen(R) or enter into third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Also, each production lots 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. Alferon N Injection(R) presently has a shelf life of 18 months after having been bottled. Studies were completed in 2004 to possibly extend the shelf life to 24 months. We filed our annual report with the FDA in December 2004 informing them of the extension of shelf-life for Alferon N Injection(R). We filed the request with the FDA in May 2005 requesting approval to relabel the first 2,000 vials with an extended shelf-life of 24 months. We anticipate a response from the FDA by the end of June 2005. The FDA responded to our relabeling request of Alferon N Injection(R) in June 2005. After reviewing the information submitted, the FDA determined the submission as a "Prior Approval Supplement". Under this designation, the FDA has six months, as of May 2005, to approve the request to relabel Alferon N Injection(R) with the extended shelf-life. We further anticipate a response from the FDA by November 2005.

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/CFS

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in the United States. The dominant competitors with drugs to treat HIV diseases include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs, Glaxo Smithkline, Merck and Schering-Plough Corp. These potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Although we believe our principal advantage is the unique mechanism of action of Ampligen(R) on the immune system, we cannot assure that we will be able to compete.

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

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

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confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills, fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months. One or more of the potential side effects might deter usage of Ampligen(R) in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

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

We may be subject to product liability claims from the use of Ampligen(R) 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 and/or Alferon N Injection product liability claims. A successful product liability claim against us in excess of Ampligen's \$1,000,000 in insurance coverage; \$3,000,000 in aggregate, or in excess of Alferon'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 May 8, 2008. However, Dr. Carter has the right to terminate his employment upon not less than 30 days prior written notice. The loss of Dr. Carter or other personnel, or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

Uncertainty of health care reimbursement for our products.

Our ability to successfully commercialize our products will depend, in part, on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and from time to time legislation is proposed, which, if adopted, could further restrict the prices charged by and/or amounts reimbursable to manufacturers of pharmaceutical products. We cannot predict

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what, if any, legislation will ultimately be adopted or the impact of such legislation on us. There can be no assurance that third party insurance companies will allow us to charge and receive payments for products sufficient to realize an appropriate return on our investment in product development.

There are risks of liabilities associated with handling and disposing of hazardous materials.

Our business involves the controlled use of hazardous materials, carcinogenic chemicals, flammable solvents and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with the standards prescribed by applicable regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident or the failure to comply with applicable regulations, we could be held liable for any damages that result, and any such liability could be significant. We do not maintain insurance coverage against such liabilities.

Risks Associated With and Investment in Our Common Stock

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

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

- o announcements of the results of clinical trials by us or our competitors;
- o adverse reactions to products;
- o governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- o changes in U.S. or foreign regulatory policy during the period of product development;
- 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, 2005, the price of our common stock has ranged from \$1.25 to \$3.54 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

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sell their shares in the public market at prevailing prices and a more active market may never develop.

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

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

We have registered 10,795,597 shares herein for sale by Fusion Capital and 50,000 shares for sale by JMBL LLC. As of July 18, 2005, approximately 657,072 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act of 1933, 179,323 of which are registered in prior registration statements. In addition, we have registered 8,989,720 shares issuable (i) upon conversion of approximately 135% of Debentures that we issued in 2003 and 2004; (ii) as payment of 135% of the interest on all of the Debentures; (iii) upon exercise of 135% of certain warrants; and (iv) upon exercise of certain other warrants. Registration of the shares permits the sale of the shares in the open market or in privately negotiated transactions without compliance with the requirements of Rule 144. To the extent the exercise price of the warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the conversion price and exercise price of these securities are adjusted pursuant to anti-dilution protection, the securities could be exercisable or convertible for even more shares of common stock. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock. Sales of substantial amounts of our common stock in the public market could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

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

The sale by the selling stockholders of our common stock as contemplated by this prospectus 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 the selling stockholders as contemplated by 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 in this offering are freely tradable. Fusion Capital may sell none, some or all of the shares of common stock purchased from us at any time. We expect that the shares offered by this prospectus will be sold over a period of in excess of 25 months from the date of this prospectus. 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 under this offering, or anticipation of such sales, could make it

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more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November 2002, we adopted a stockholder rights plan and, under the Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one unit of preferred stock for \$30.00. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Dr. Carter, our chief executive officer, who already beneficially owns 10.9% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at \$.01 per Right under certain circumstances.

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

The following table provides information regarding the selling stockholders and the number of shares of common stock they are offering.

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. The information regarding shares beneficially owned after the offering assumes the sale of all shares offered by each of the selling stockholders. The percentage ownership data is based on

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50,984,488 shares of our common stock issued and outstanding as of July 8, 2005.

Neither of the selling stockholder has had any position, office or other material relationship with us or any of our affiliates within the past three years, other than as a stockholder, unless otherwise disclosed in the footnotes.

| Selling Stockholder | Common Stock Owned Prior To Offering | No. of Shares Being Offered |
|-------------------------------------|--|--------------------------------|
| Fusion Capital Fund II, LLC (1) (2) | 402,798 | 10,795,597 |
| JMBL LLC (3) | 50,000 | 50,000 |

- (1) As of the date hereof, 402,798 shares of our common stock have been acquired by Fusion Capital under the common stock purchase agreement. Fusion Capital may acquire up to an additional 10,000,000 shares under the common stock purchase agreement, plus 392,799 shares as an additional commitment fee. 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.
- (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) 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.

The Fusion Transaction

General

On July 8, 2005 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 \$40,000 of our common stock up to an aggregate of \$20.0 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.

Fusion Capital is offering for sale up to 10,795,597 shares of our

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common stock, which includes up to 10,000,000 shares of our common stock that we authorized for sale to Fusion Capital pursuant to the common stock purchase agreement for a maximum proceeds of \$20.0 million. Assuming Fusion Capital purchases all \$20.0 million of our common stock, we estimate that the maximum number of shares we will sell to Fusion Capital under the common stock purchase agreement will be 10,000,000 shares (exclusive of the 785,597 shares issued and to be issued to Fusion Capital as the commitment fee and 10,000 shares issued to Fusion Capital as a partial expense reimbursement). In the event we elect to issue more than 10,795,597 shares offered hereby, we will be required to file a new registration statement and have it declared effective by the SEC. In the event that we decide to issue more than 10,113,278, i.e. greater than 19.99% of our outstanding shares of common stock as of the date of the agreement, we would first be required to seek stockholder approval in order to be in compliance with American Stock Exchange rules. 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 agreement \$40,000 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 \$40,000 unless our stock price is above \$2.00 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.

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.

| Number of Shares | Percentage of Shares Outstanding | Proceeds from the Sale of Shares to Fusion Capital Under |
|------------------|----------------------------------|--|
|------------------|----------------------------------|--|

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| Assumed Average Purchase Price | to be issued if Full Purchase | After Giving Effect to the Issuance to Fusion Capital(1) | the Common Stock Purchase Agreement |
|-----------------------------------|-------------------------------------|---|---|
| \$1.00 | 10,000,000 | 16.3 % | \$ 10,000,000 |
| \$1.75 (2) | 10,000,000 | 16.3 % | \$ 17,500,000 |
| \$2.00 | 10,000,000 | 16.3 % | \$ 20,000,000 |
| \$3.00 | 6,666,667 | 11.5 % | \$ 20,000,000 |
| \$4.00 | 5,000,000 | 8.9 % | \$ 20,000,000 |

(1) Based on 50,984,488 shares outstanding as of July 8, 2005 which includes the issuance to Fusion Capital of 10,000 shares of common stock as partial expense reimbursement and 392,798 shares as a partial commitment fee. Also includes the balance of commitment fee shares to be issued (see "Commitment Shares Issued to Fusion Capital" below) and the number of shares issuable at the corresponding assumed purchase price set forth in the adjacent column.

(2) Closing sale price of our common stock on July 19, 2005.

In connection with entering into the agreement, we authorized the sale to Fusion Capital of up to 10,000,000 shares of our common stock. We estimate that we will issue no more than 10,000,000 shares to Fusion Capital under the common stock purchase agreement (exclusive of the 785,597 shares issued and to be issued to Fusion Capital as the commitment fee and 10,000 shares issued to Fusion Capital as a partial expense reimbursement), 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 10,000,000 shares are sold to Fusion Capital under the common stock purchase agreement. In the event we elect to issue more than the 10,795,597 shares offered hereby, we will be required to file a new registration statement and have it declared effective by the SEC. In the event that we decide to issue more than 10,113,278, i.e. greater than 19.99% of our outstanding shares of common stock as of the date of the agreement, we would first be required to seek stockholder approval in order to be in compliance with American Stock Exchange rules.

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, \$40,000 of our common stock or an aggregate of \$20.0 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.

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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 \$0.15 increase in Threshold Price (as defined below) above \$1.85, we have the right to increase the daily purchase amount by up to an additional \$10,000. For example, if the Threshold Price is \$2.15 we would have the right to increase the daily purchase amount by up to an aggregate of \$60,000. 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.

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 \$2.00 during the five trading days prior thereto. The price at which such shares would be purchased will be 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 to \$500,000 if our share price is above \$4.00 during the five trading days prior to our delivery of the purchase notice to Fusion Capital. We may deliver multiple purchase notices; however at least ten 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 of 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 (10) consecutive trading days or for more than an aggregate of thirty (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 (5) 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 (10) trading days;
- o any participation or threatened participation in insolvency or bankruptcy proceedings by or against us;
- o a material adverse change in our business, properties, operations, financial condition or results of operations; or

o

the issuance of an aggregate of 10,113,278 shares to Fusion Capital under our agreement and 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 10,000,000 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 392,798 shares of our common stock as a partial commitment fee and is entitled to receive up to an additional 392,799 commitment shares. These additional commitment shares will be issued in an amount equal to the product of (x) 392,799 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 \$20,000,000. 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 October 31, 2005.

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 we have obtained Fusion Capital's prior written consent.

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Participations Rights

For a period of 20 months from July 8, 2005, the date of the common stock purchase agreement, we have granted to Fusion Capital the right to participate in the purchase of any New Securities (as defined below) that we may, from time to time, propose to issue and sell in connection with any financing transaction to a third party. In particular, Fusion Capital can purchase up to 20% of such New Securities at the same price and on the same terms as such other investor. "New Securities" means any shares of our Common Stock, preferred stock or any other equity securities or securities convertible or exchangeable for such equity securities, provided, however, that New Securities does not include, (i) shares of Common Stock issuable upon conversion or exercise of any securities outstanding as of the date of the common stock purchase agreement, (ii) shares, options or warrants for Common Stock granted to our officers, directors and employees pursuant to stock option plans approved by our board of directors, (iii) shares of common stock issued by us pursuant to our 2004 Equity Incentive Plan and shares of common stock issuable upon exercise of options and rights issued pursuant to this plan, (iv) shares of Common Stock issued pursuant to the program authorized in 2003 to pay vendors for services rendered, (v) shares of Common Stock or securities convertible or exchangeable for Common Stock issued pursuant to the acquisition of another company by consolidation, merger, or purchase of all or substantially all of the assets of such company or (vi) shares of Common Stock or securities convertible or exchangeable into shares of Common Stock issued in connection with a strategic transaction involving us and issued to an entity or an affiliate of such entity that is engaged in the same or substantially related business as we are. Fusion Capital's participation rights shall not prohibit or limit us from selling any securities so long as we make the same offer to Fusion Capital.

PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by the selling stockholders. The common stock may be sold or distributed from time to time by the selling stockholders 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 offered by this Prospectus may be effected in one or more of the following methods:

- o ordinary brokers' transactions;
- 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

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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 stockholders 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. JMBL LLC and 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..

Neither we nor the selling stockholders can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between the selling stockholders, 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 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 \$20.0 million in proceeds from the sale of our common stock to Fusion Capital under the common

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stock purchase agreement. We intend to use such proceeds to extend our New Brunswick facility for the production of Ampligen(R) and Alferon N injections and for general corporate purposes.

WHERE YOU CAN FIND MORE INFORMATION

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

We have filed with the Securities and Exchange Commission a registration statement (which contains this prospectus) on Form S-3 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 and the Warrants. 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 considered to be part of this prospectus, and later information that we file with the Commission will automatically update and supercede this information. We incorporate by reference the following documents and any future filing made with the Commission under Sections 13(a), 14 or 15(d) of the Securities Exchange Act of 1934 until we and the selling stockholders sell all the securities included in this prospectus:

- (a) Our annual report on Form 10-K for our fiscal year ended December 31, 2004, SEC File No. 1-13441.
- (b) Our quarterly report on Form 10-Q for the quarterly period ended March 31, 2005, SEC File No. 1-13441.
- (c) Our proxy statement on schedule 14A for our 2005 annual meeting, SEC File No. 1-13441.
- (d) Our current report on Form 8-K dated July 11, 2005, SEC File No. 1-13441.
- (e) A description of our common stock contained in our registration statement on Form S-1, SEC File No. 33-93314, and any amendment or report filed for the purpose of updating this description filed subsequent to the date of this prospectus and prior to the termination of this offering.

You 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.

You should rely only on the information incorporated by reference or

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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. We and 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 any supplement is accurate as of any date other than the date on the front of those documents.

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

Our financial statements incorporated by reference in this Prospectus which are included in our Annual Report on Form 10-K for the year ended December 31, 2004 have been audited by BDO Seidman, LLP, an independent registered public accounting firm, to the extent and for the periods set forth in their report, and are included in reliance upon such report given upon the authority of said firm as experts in auditing and accounting.

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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10,845,597 SHARES OF
COMMON STOCK

HEMISPHERX BIOPHARMA, INC.

PROSPECTUS

August 3, 2005
