

GENETRONICS BIOMEDICAL CORP

Form 424B3

October 20, 2004

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As filed pursuant to Rule 424(b)(3)  
under the Securities Act of 1933  
Registration No. 333-118187

PROSPECTUS

## 320,066 Shares

### Common Stock

This prospectus relates to 320,066 shares of common stock of Genetronics Biomedical Corporation that may be sold from time to time by the selling stockholders named on page 17 of this prospectus. We will not receive any proceeds from the sales by the selling stockholders.

Our common stock is traded on the American Stock Exchange under the symbol "GEB." On August 12, 2004, the last reported sale price for our common stock on the American Stock Exchange was \$0.83 per share.

The securities offered by this prospectus involve a high degree of risk. See "Risk Factors" beginning on page 7.

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

This prospectus is dated October 19, 2004

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**You should rely only on the information contained or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with information different from that contained or incorporated by reference into this prospectus. No dealer, salesperson or 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 representation. You should assume that the information contained in this prospectus or any prospectus supplement is accurate only as of the date on the front of the document and that any information contained in any document we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any prospectus supplement or any sale of a security. These documents are not an offer to sell or a solicitation of an offer to buy these shares of common stock in any circumstances under which the offer or solicitation is unlawful.**

## Prospectus Summary

*This summary highlights some information from this prospectus, and it may not contain all of the information that is important to you. You should read the following summary together with the more detailed information regarding our company and the shares being sold in this offering, including "Risk Factors" and our consolidated financial statements and related notes, included elsewhere in, or incorporated by reference into, this prospectus.*

## Our Company

We are a San Diego-based biomedical company whose technology platform is based on medical devices that use Electroporation Therapy (EPT) to deliver drugs and genes into cells. We are developing and commercializing novel medical therapies to address a number of critical unmet treatment needs using EPT. Our MedPulser System is in late stage development in the United States for the treatment of head and neck cancer. This system delivers electrical pulses to tumors injected with the generic drug bleomycin. The unique feature of the system, which uses a generator together with disposable needle applicators, is the preservation of healthy tissue at the margins of the tumor. We believe this may afford distinct advantages over surgery in preserving function and improving the quality of life for cancer patients who would otherwise face significant morbidity associated with cancer surgery. We believe that the planned commercial launch of our CE certified MedPulser System in Europe in 2005 represents an important milestone for us. We have also been developing devices for the delivery of DNA for DNA vaccinations and gene therapy. We believe that through our research efforts and those of our corporate partners, that we will soon execute the first clinical study involving the use of EPT with DNA involving human patients. We believe that our compelling asset base of intellectual property and scientific and engineering accomplishments, combined with clinical results position us as a leader in EPT.

The primary front line treatment of solid tumors involves surgical resection and/or radiation to debulk and control tumor growth prior to initiating systemic therapy with chemotherapeutic agents. Because surgeons often cannot distinguish the border, or margins, between healthy and diseased tissue, they will often resect an area outside of the obvious tumor mass. This can result in the loss of function and appearance of the surrounding tissues and organs, reducing the patient's quality of life. Examples include the loss of speech from resection of tumors on the tongue and larynx or loss of erectile function from resection of the prostate. Recent advances in non-surgical forms of tumor ablation, such as cryoablation, microwave or high frequency radio ablation therapy, fail to meet clinical needs in preserving normal healthy tissue. Given the desire for improved outcomes in the surgical resection of a large number of solid tumors such as head and neck, cutaneous, pancreatic, breast and prostate cancer, we believe that there will be significant demand for its technology from surgical oncologists.

We believe that attempts to pioneer new therapies based on DNA have been hampered by the use of viral vectors to deliver DNA. In addition to safety issues, viral vectors are difficult and expensive to manufacture. Because electroporation has proven efficient and safe in animal experiments, we are developing a MedPulser DNA Delivery System. By engineering different applicators, we can deliver DNA to the muscle, skin or vasculature. This should facilitate attempts to use DNA for therapies ranging from vaccination to gene therapy of single or multiple gene defects, including cancer and vascular diseases. As with our oncology program, we believe that our efforts in DNA delivery position us as a leader in the field.

We were organized as Genetronics Biomedical Ltd., a British Columbia corporation and reincorporated in Delaware on June 15, 2001, at which time we changed our name to Genetronics Biomedical Corporation. All of our business activities are conducted through Genetronics, Inc., a California corporation.

All periods presented in the consolidated financial statements and notes thereto that appear in the documents incorporated herein by reference have been restated to financial statements prepared in accordance with accounting principles generally accepted in the United States. ALL DOLLAR AMOUNTS SET FORTH IN THIS PROSPECTUS AND IN THE DOCUMENTS INCORPORATED HEREIN BY REFERENCE ARE STATED IN UNITED STATES DOLLARS, EXCEPT WHERE OTHERWISE INDICATED.

Our principal executive offices are located at 11199 Sorrento Valley Road, San Diego, California 92121, and our telephone number is (858) 597-6006.

### Recent Developments

On January 20, 2004, we announced that we have been granted two new U.S. patents. The first patent includes claims to novel, less severe methods for delivering an agent, such as a drug or polynucleotide, into a cell. We believe that this patent enhances the intellectual property for the oncology, gene therapy and DNA vaccine applications of electroporation. The second patent includes claims to methods for reducing changes in target muscle tissue from the application of an electric field, the key elements including electric pulsing parameters. We believe this patent has applicability in the field of gene therapy and DNA vaccines.

On February 4, 2004, we announced that we have entered into an agreement with RMR Technologies, LLC ("RMR"), to permit us to commercialize RMR's electroporation methods and devices on a worldwide exclusive basis. This extends a long-standing relationship with University of South Florida scientists and RMR founders Drs. Richard Heller, Mark Jaroszeski, and Richard Gilbert, dating back to the co-development of our CE marked MedPulser technology for the treatment of solid malignant tumors including head and neck cancers.

During the first quarter of 2004, we initiated two Phase III head and neck clinical trials, which will include sites in the United States and Europe. On February 23, 2004, we announced that we have completed the Special Protocol Assessment review process with the FDA for the two Phase III pivotal studies to evaluate the use of our MedPulser® Electroporation Therapy System as a treatment for recurrent and second primary squamous cell carcinomas of the head and neck (SCCHN). Three Institutional Review Boards (IRBs) in the U.S. have approved the two protocols to date, and we have initiated patient enrollment. These trials compare EPT to surgery using a primary endpoint of function preservation and secondary endpoints of local tumor control, disease-free survival and overall survival. Shifting from a primary endpoint of survival to a quality of life outcome allows us to carry out clinical trials that we expect may be faster, less costly and have a higher likelihood of success. As a result, our previously announced Phase III head and neck trials focusing on survival as a primary endpoint have been discontinued.

On March 1, 2004, we announced that we have begun treating patients with primary or recurrent squamous cell carcinoma of the head and neck (SCCHN) in a post European regulatory approval clinical study. The clinical study is designed to support the commercialization of our MedPulser® Electroporation System in the European Union (EU). The European clinical study will facilitate adoption of the technology by thought leaders and allow us to apply for reimbursement. Prior clinical trials established the safety and performance of the MedPulser® System for the treatment of SCCHN, leading to approval for sale in the EU based on achieving the CE Mark.

On March 9, 2004, we announced the selection of Quintiles Transnational Corp., a leading global pharmaceutical services organization, as the clinical research organization (CRO) for our clinical trials in the U.S. and Europe for the treatment of head and neck cancer.

On May 21, 2004, we issued a press release announcing that we had raised an aggregate of \$10.9 million after completing the sale of our Series C Cumulative Convertible Preferred Stock to

certain institutional and accredited investors. The Series C Preferred Stock is convertible into shares of our common stock at \$1.70 per share. Each investor received warrants to purchase shares of our common stock in an amount equal to 35% of the number of shares of common stock underlying the Series C Preferred Stock at a per share exercise price of \$2.20.

On May 24, 2004, we issued a press release announcing that we had entered into a collaboration and licensing agreement with Merck & Co., Inc. to develop and commercialize our MedPulser® DNA Delivery System, which will be used with Merck's DNA vaccine programs. Under the terms of the agreement, Merck receives the right to use our proprietary technology initially for two specific antigens with an option to extend the agreement to additional antigens. We will receive an upfront payment as well as milestone payments linked to the successful development of a product.

On June 7, 2004, we issued a press release announcing that the U.S. Food and Drug Administration has granted us a fast track designation for our MedPulser Electroporation System clinical development program for patients with head and neck cancer. We are currently conducting two Phase III pivotal studies comparing the MedPulser System in combination with the cancer drug, bleomycin, versus surgical resection in patients with recurrent or second primary squamous cell carcinoma head and neck cancer. The fast track designation is intended to facilitate development and expedite the review of new therapies that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs so that an approved product can reach the market expeditiously.

On June 22, 2004, we issued a press release announcing that we have been granted two U.S. patents. U.S. Patent No. 6,748,265, which is entitled "Electrode apparatus and method for the delivery of drugs and genes into tissue," advances our trans-surface drug and gene delivery technology and provides additional proprietary rights for an apparatus and method to deliver genes, drugs, and other molecules through tissue surfaces, including skin, for therapeutic or cosmetic purposes. U.S. Patent No. 6,746,441, which is entitled "Flow-through electroporation system for ex vivo gene therapy," advances our patent portfolio in the field of ex vivo therapies and includes claims allowing for the introduction of molecules into cells by electroporation, either in a continuous-flow or batch mode, with a variable electric field orientation.

On July 21, 2004, we issued a press release announcing that we have been granted U.S. Patent No. 6,763,264, entitled, "Method of Treatment Using Electroporation Mediated Delivery of Drugs and Genes." This patent adds to our portfolio of claimed methods for carrying out electroporation in patient tissues. Specifically, it claims methods for in vivo delivery of a recombinant expression vector (DNA) or a pharmaceutical agent into tissue cells, and a method for the therapeutic application of electroporation to a patient to introduce macromolecules.

On August 1, 2004, we issued a press release announcing that a study assessing the clinical utility of an electroporation-mediated method for delivering DNA in humans without anesthesia showed that this method was safe and tolerable. The results of the Investigational Review Board (IRB)-approved pilot study, which measured pain response in healthy volunteers using an electrical pulse suitable for DNA delivery using our MedPulser® DNA Delivery System, support electroporation as a potentially attractive DNA delivery method for potential use in humans to treat serious or life-threatening diseases.

#### **Special Note on Forward Looking Statements**

This prospectus and the documents and information incorporated by reference in this prospectus, such as from Item 1. "Business" and Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2003, include "forward-looking statements" within the meaning of section 27A of the Securities Act of 1933, as amended and section 21E of the Securities Exchange Act of 1934, as

amended. Forward-looking statements include the information concerning our possible or assumed future operating results, business strategies, financing plans, competitive position, industry environment, the anticipated impact on our business and financial results of recent and future acquisitions, the effects of competition, our ability to produce new products in a cost-effective manner and estimates relating to our industry. Forward-looking statements may be identified by the use of words like "believes," "intends," "expects," "may," "will," "should" or "anticipates," or the negative equivalents of those words or comparable terminology, and by discussions of strategies that involve risks and uncertainties.

Actual results may differ materially from those expressed or implied by forward-looking statements for a number of reasons, including those appearing elsewhere in this prospectus under the heading "Risk Factors." In addition, we base forward-looking statements on assumptions about future events, which may not prove to be accurate. In light of these risks, uncertainties and assumptions, you should be aware that the forward-looking events described in this prospectus and the documents incorporated by reference in this prospectus may not occur.

## RISK FACTORS

*You should carefully consider and evaluate all of the information contained or incorporated by reference in this prospectus, including the following risk factors, before deciding to invest in our notes. Any of these risks could materially and adversely affect our business, financial condition and results of operations, which in turn could adversely affect the price of the notes and our common stock.*

### **WE WILL HAVE A NEED FOR SIGNIFICANT FUNDS IN THE FUTURE AND THERE IS NO GUARANTEE THAT WE WILL BE ABLE TO OBTAIN THE FUNDS WE NEED.**

As discussed, we have operated at a loss, and expect that to continue for some time in the future. Our plans for continuing clinical trials, conducting research, furthering development and, eventually, marketing our human-use equipment will involve substantial costs. The extent of these costs will depend on many factors, including some of the following:

The progress and breadth of preclinical testing and the size of our drug delivery programs, all of which directly influence cost;

The costs involved in complying with the regulatory process to get our human-use products approved, including the number, size, and timing of necessary clinical trials and costs associated with the current assembly and review of existing clinical and pre-clinical information;

The costs involved in patenting our technologies and defending them;

Changes in our existing research and development relationships and our ability to enter into new agreements;

The cost of manufacturing our human-use equipment; and

Competition for our products and our ability, and that of our partners, to commercialize our products.

We plan to fund operations by several means. We will attempt to enter into contracts with partners that will fund either general operating expenses or specific programs or projects. Some funding also may be received through government grants. We cannot promise that we will enter into any such contracts or receive such grants or, if we do, that our partners and the grants will provide enough funding to meet our needs.

In the past, we have raised funds by public and private sale of our stock, and we are likely to do this in the future to raise needed funds. Sale of our stock to new private or public investors usually results in existing stockholders becoming "diluted". The greater the number of shares sold, the greater the dilution. A high degree of dilution can make it difficult for the price of our stock to rise rapidly, among other things. Dilution also lessens a stockholder's voting power.

We cannot assure you that we will be able to raise capital needed to fund operations, or that we will be able to raise capital under terms that are favorable to us.

### **IF WE DO NOT HAVE ENOUGH CAPITAL TO FUND OPERATIONS, THEN WE WILL HAVE TO CUT COSTS.**

If we are not able to raise needed money under acceptable terms, then we will have to take measures to cut costs, such as:

Delay, scale back or discontinue one or more of our drug or gene delivery programs or other aspects of operations, including laying off some personnel or stopping or delaying clinical trials;

Sell or license some of our technologies that we would not otherwise give up if we were in a better financial position;





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Sell or license some of our technologies under terms that are a lot less favorable than they otherwise might have been if we were in a better financial position; and

Consider merging with another company or positioning ourselves to be acquired by another company.

If it became necessary to take one or more of the above-listed actions, then we may have a lower valuation, which probably would be reflected in our stock price.

### **IF WE ARE NOT SUCCESSFUL DEVELOPING OUR CURRENT PRODUCTS, OUR BUSINESS MODEL MAY CHANGE AS OUR PRIORITIES AND OPPORTUNITIES CHANGE. OUR BUSINESS MAY NEVER DEVELOP TO BE PROFITABLE OR SUSTAINABLE.**

There are many products and programs that to us seem promising and that we could pursue. However, with limited resources, we may decide to change priorities and shift programs away from those that we had been pursuing for the purpose of exploiting our core technology of electroporation. The choices we may make will be dependent upon numerous factors, which we cannot predict. We cannot assure you that our business model, as it currently exists or as it may evolve, will enable us to become profitable or to sustain operations.

### **IF WE DO NOT SUCCESSFULLY COMMERCIALIZE PRODUCTS, THEN OUR BUSINESS WILL SUFFER.**

We have received various regulatory approvals, which apply to Europe for our equipment for use in treating solid tumors, the products related to such regulatory approval have not yet been commercialized. In addition, we have not yet received any regulatory approvals to sell our clinical products in the United States and further clinical trials are still necessary before we can seek regulatory approval to sell our products in the United States for treating solid tumors. We cannot assure you that we will successfully develop any products. If we fail to develop or successfully commercialize any products, then our business will suffer. Additionally, much of the commercialization efforts for our products must be carried forward by a licensing partner. We may not be able to obtain such a partner.

### **PRE-CLINICAL AND CLINICAL TRIALS OF HUMAN-USE EQUIPMENT ARE UNPREDICTABLE. IF WE EXPERIENCE UNSUCCESSFUL TRIAL RESULTS OUR BUSINESS WILL SUFFER.**

Before any of our human-use equipment can be sold, the Food and Drug Administration (FDA) or applicable foreign regulatory authorities must determine that the equipment meets specified criteria for use in the indications for which approval is requested. The FDA will make this determination based on the results from our pre-clinical testing and clinical trials.

Clinical trials are unpredictable, especially human-use trials. Results achieved in early stage clinical trials may not be repeated in later stage trials, or in trials with more patients. When early positive results were not repeated in later stage trials, pharmaceutical and biotechnology companies have suffered significant setbacks. Not only are commercialization timelines pushed back, but some companies, particularly smaller biotechnology companies with limited cash reserves, have gone out of business after releasing news of unsuccessful clinical trial results.

If we experience unexpected, inconsistent or disappointing results in connection with a clinical or pre-clinical trial our business will suffer. If any of the following events arise during our clinical trials or data review, then we would expect this to have a serious negative effect on our company and your investment:

The electroporation-mediated delivery of drugs or other agents may be found to be ineffective or to cause harmful side effects, including death;

Our clinical trials may take longer than anticipated, for any of a number of reasons including a scarcity of subjects that meet the physiological or pathological criteria for entry into the study, a scarcity of subjects that are willing to participate through the end of the trial, or data and document review;

The reported clinical data may change over time as a result of the continuing evaluation of patients or the current assembly and review of existing clinical and pre-clinical information;

Data from various sites participating in the clinical trials may be incomplete or unreliable, which could result in the need to repeat the trial or abandon the project; and

The FDA and other regulatory authorities may interpret our data differently than we do, which may delay or deny approval.

Clinical trials are generally quite expensive. A delay in our trials, for whatever reason, will probably require us to spend additional funds to keep the product(s) moving through the regulatory process. If we do not have or cannot raise the needed funds, then the testing of our human-use products could be shelved. In the event the clinical trials are not successful, we will have to determine whether to put more money into the program to address its deficiencies or whether to abandon the clinical development programs for the products in the tested indications. Loss of the human-use product line would be a significant setback for our company.

Because there are so many variables inherent in clinical trials, we cannot predict whether any of our future regulatory applications to conduct clinical trials will be approved by the FDA or other regulatory authorities, whether our clinical trials will commence or proceed as planned, and whether the trials will ultimately be deemed to be successful. To date, our experience has been that submission and approval of clinical protocols has taken longer than desired or expected.

**OUR BUSINESS IS HIGHLY DEPENDENT ON RECEIVING APPROVALS FROM VARIOUS UNITED STATES AND INTERNATIONAL GOVERNMENT AGENCIES AND WILL BE DRAMATICALLY AFFECTED IF APPROVAL TO MANUFACTURE AND SELL OUR HUMAN-USE EQUIPMENT IS NOT GRANTED OR IS NOT GRANTED IN A TIMELY MANNER.**

The production and marketing of our human-use equipment and the ongoing research, development, preclinical testing, and clinical trial activities are subject to extensive regulation. Numerous governmental agencies in the US and internationally, including the FDA, must review our applications and decide whether to grant approval. All of our human-use equipment must go through an approval process, in some instances for each indication for which we want to label it for use (such as use for dermatology, use for transfer of a certain gene to a certain tissue, or use for administering a certain drug to a certain tumor type in a patient having certain characteristics). These regulatory processes are extensive and involve substantial costs and time.

We have limited experience in, and limited resources available for, regulatory activities. Failure to comply with applicable regulations can, among other things, result in non-approval, suspensions of regulatory approvals, fines, product seizures and recalls, operating restrictions, injunctions and criminal prosecution.

Any of the following events can occur and, if any did occur, any one could have a material adverse effect on our business, financial conditions and results of operations:

As mentioned earlier, clinical trials may not yield sufficiently conclusive results for regulatory agencies to approve the use of our products;

There can be delays, sometimes long, in obtaining approval for our human-use devices, and indeed, we have experienced such delays in obtaining FDA approval of our clinical protocols;

The rules and regulations governing human-use equipment such as ours can change during the review process, which can result in the need to spend time and money for further testing or review;

If approval for commercialization is granted, it is possible the authorized use will be more limited than we believe is necessary for commercial success, or that approval may be conditioned on completion of further clinical trials or other activities; and

Once granted, approval can be withdrawn, or limited, if previously unknown problems arise with our human-use product or data arising from its use.

**WE RELY ON COLLABORATIVE AND LICENSING RELATIONSHIPS TO FUND A PORTION OF OUR RESEARCH AND DEVELOPMENT EXPENSES. IF WE ARE UNABLE TO MAINTAIN OR EXPAND EXISTING RELATIONSHIPS, OR INITIATE NEW RELATIONSHIPS, WE WILL HAVE TO DEFER OR CURTAIL RESEARCH AND DEVELOPMENT ACTIVITIES IN ONE OR MORE AREAS.**

Our partners and collaborators fund a portion of our research and development expenses and assist us in the research and development of our human-use equipment. These collaborations and partnerships can help pay the salaries and other overhead expenses related to research. In the past, we encountered operational difficulties after the termination of an agreement by a former partner. Because this partnership was terminated, we did not receive significant milestone payments which we had expected and were forced to delay some clinical trials as well as some product development.

Our clinical trials to date have used our equipment with the anti-cancer drug bleomycin. We do not currently intend to package bleomycin together with the equipment for sale, but if it should be necessary or desirable to do this, we would need a reliable source of the drug. At this time we do not have a fixed source of bleomycin for inclusion with equipment or alone. If it becomes necessary or desirable to include bleomycin in our package we would have to form a relationship with another provider of this generic drug before any product could be launched.

We also rely on scientific collaborators at companies and universities to further our research and test our equipment. In most cases, we lend our equipment to a collaborator, teach him or her how to use it, and together design experiments to test the equipment in one of the collaborator's fields of expertise. We aim to secure agreements that restrict collaborators' rights to use the equipment outside of the agreed upon research, and outline the rights each of us will have in any results or inventions arising from the work.

Nevertheless, there is always risk that:

Our equipment will be used in ways we did not authorize, which can lead to liability and unwanted competition;

We may determine that our technology has been improperly assigned to us or a collaborator may claim rights to certain of our technology, which may require us to pay license fees or milestone payments and, if commercial sales of the underlying product is achieved, royalties;

We may lose rights to inventions made by our collaborators in the field of our business, which can lead to expensive legal fights and unwanted competition;

Our collaborators may not keep our confidential information to themselves, which can lead to loss of our right to seek patent protection and loss of trade secrets, and expensive legal fights; and

Collaborative associations can damage a company's reputation if they go awry and thus, by association or otherwise, the scientific or medical community may develop a negative view of us.

We cannot guarantee that any of the results from these collaborations will be fruitful. We also cannot tell you that we will be able to continue to collaborate with individuals and institutions that will further our work, or that we will be able to do so under terms that are not too restrictive. If we are not able to maintain or develop new collaborative relationships, then it is likely the research pace will slow down and it will take longer to identify and commercialize new products, or new indications for our existing products.

**WE COULD BE SUBSTANTIALLY DAMAGED IF PHYSICIANS AND HOSPITALS PERFORMING OUR CLINICAL TRIALS DO NOT ADHERE TO PROTOCOLS OR PROMISES MADE IN CLINICAL TRIAL AGREEMENTS.**

We work and have worked with a number of hospitals to perform clinical trials, primarily in oncology. We depend on these hospitals to recruit patients for the trials, to perform the trials according to our protocols, and to report the results in a thorough, accurate and consistent fashion. Although we have agreements with these hospitals, which govern what each party is to do with respect to the protocol, patient safety, and avoidance of conflict of interest, there are risks that the terms of the contracts will not be followed, such as the following:

*Risk of Deviations from Protocol.* The hospitals or the physicians working at the hospitals may not perform the trial correctly. Deviations from protocol may make the clinical data not useful and the trial could be essentially worthless.

*Risk of Improper Conflict of Interest.* Physicians working on protocols may have an improper economic interest in our company, or other conflict of interest. When a physician has a personal stake in the success of the trial, such as can be inferred if the physician owns stock, or rights to purchase stock, of the trial sponsor, it can create suspicion that the trial results were improperly influenced by the physician's interest in economic gain. Not only can this put the clinical trial results at risk, but it can also do serious damage to a company's reputation.

*Risks Involving Patient Safety and Consent.* Physicians and hospitals may fail to secure formal written consent as instructed or report adverse effects that arise during the trial in the proper manner, which could put patients at unnecessary risk. Physicians and hospital staff may fail to observe proper safety measures such as the mishandling of used medical needles, which may result in the transmission of infectious and deadly diseases, such as HIV and AIDS. This increases our liability, affects the data, and can damage our reputation.

If any of these events were to occur, then it could have a material adverse effect on our ability to receive regulatory authorization to sell our human-use equipment, not to mention on our reputation. Negative events that arise in the performance of clinical trials sponsored by biotechnology companies of our size and with limited cash reserves similar to ours have resulted in companies going out of business. While these risks are ever present, to date our contracted physicians and clinics have been successful in collecting significant data regarding the clinical protocols under which they have operated, and we are unaware of any conflicts of interest or improprieties regarding our protocols.

**WE RELY HEAVILY ON OUR PATENTS AND PROPRIETARY RIGHTS TO ATTRACT PARTNERSHIPS AND MAINTAIN MARKET POSITION.**

Another factor that will influence our success is the strength of our patent portfolio. Patents give the patent holder the right to prevent others from using its patented technology. If someone infringes upon the patented material of a patent holder, then the patent holder has the right to initiate legal proceedings against that person to protect the patented material. These proceedings, however, can be lengthy and costly. We are in the process of performing an ongoing review of our patent portfolio to confirm that our key technologies are adequately protected. If we determine that any of our patents

require either additional disclosures or revisions to existing information, we may ask that such patents be reexamined or reissued, as applicable, by the United States patent office.

The patenting process, enforcement of issued patents, and defense against claims of infringement are inherently risky. Because we rely heavily on patent protection, for us the risks are significant and include the following:

*Risk of Inadequate Patent Protection for Product.* The United States or foreign patent offices may not grant patents of meaningful scope based on the applications we have already filed and those we intend to file. If we do not have patents that adequately protect our human-use equipment and indications for its use, then we will not be competitive.

*Risk That Important Patents Will Be Judged Invalid.* Some of the issued patents we now own or license may be determined to be invalid. If we have to defend the validity of any of our patents, the costs of such defense could be substantial, and there is no guarantee of a successful outcome. In the event an important patent related to our drug delivery technology is found to be invalid, we may lose competitive position and may not be able to receive royalties for products covered in part or whole by that patent under license agreements.

*Risk of Being Charged With Infringement.* Although we and our partners try to avoid infringement, there is the risk that we will use a patented technology owned by another person and/or be charged with infringement. Defending or indemnifying a third party against a charge of infringement can involve lengthy and costly legal actions, and there can be no guarantee of a successful outcome. Biotechnology companies of roughly our size and financial position have gone out of business after fighting and losing an infringement battle. If we or our partners were prevented from using or selling our human-use equipment, then our business would be seriously affected.

*Freedom to Operate Risks.* We are aware that patents related to electrically assisted drug delivery have been granted to, and patent applications filed by, our potential competitors. We or our partners have taken licenses to some of these patents, and will consider taking additional licenses in the future. Nevertheless, the competitive nature of our field of business and the fact that others have sought patent protection for technologies similar to ours make these significant risks.

In addition to patents, we also rely on trade secrets and proprietary know-how. We try to protect this information with appropriate confidentiality and inventions agreements with our employees, scientific advisors, consultants, and collaborators. We cannot assure you that these agreements will not be breached, that we will be able to do much to protect ourselves if they are breached, or that our trade secrets will not otherwise become known or be independently discovered by competitors. If any of these events occurs, then we run the risk of losing control over valuable company information, which could negatively affect our competitive position.

#### **WE RUN THE RISK THAT OUR TECHNOLOGY WILL BECOME OBSOLETE OR LOSE ITS COMPETITIVE ADVANTAGE.**

The drug delivery business is very competitive, fast moving and intense, and expected to be increasingly so in the future. Other companies and research institutions are developing drug delivery systems that, if not similar in type to our systems, are designed to address the same patient or subject population. Therefore, we cannot promise you that our products will be the best, the safest, the first to market, or the most economical to make or use. If competitors' products are better than ours, for whatever reason, then we could make less money from sales and our products risk becoming obsolete.

There are many reasons why a competitor might be more successful than us, including:

*Financial Resources.* Some competitors have greater financial resources and can afford more technical and development setbacks than we can.

*Greater Experience.* Some competitors have been in the drug delivery business longer than we have. They have greater experience than us in critical areas like clinical testing, obtaining regulatory approval, and sales and marketing. This experience or their name recognition may give them a competitive advantage over us.

*Superior Patent Position.* Some competitors may have a better patent position protecting their technology than we have or will have to protect our technology. If we cannot use our patents to prevent others from copying our technology or developing similar technology, or if we cannot obtain a critical license to another's patent that we need to make and use our equipment, then we would expect our competitive position to lessen. However, we feel that our patent position adequately protects our technology portfolio.

*Faster to Market.* Some companies with competitive technologies may move through stages of development, approval, and marketing faster than us. If a competitor receives FDA approval before us, then it will be authorized to sell its products before we can sell ours. Because the first company "to market" often has a significant advantage over late-comers, a second place position could result in less than anticipated sales.

*Reimbursement Allowed.* In the United States, third party payers, such as Medicare, may reimburse physicians and hospitals for competitors' products but not for our human-use products. This would significantly affect our ability to sell our human-use products in the United States and would have a serious effect on revenues and our business as a whole. Outside of the United States, reimbursement and funding policies vary widely.

**OUR ABILITY TO ACHIEVE SIGNIFICANT REVENUE FROM SALES OR LEASES OF HUMAN-USE EQUIPMENT WILL DEPEND ON ESTABLISHING EFFECTIVE SALES, MARKETING AND DISTRIBUTION CAPABILITIES OR RELATIONSHIPS AND WE LACK SUBSTANTIAL EXPERIENCE IN THESE AREAS.**

We have no experience in sales, marketing and distribution of clinical and human-use products. If we want to be direct distributors of the human-use products, then we must develop a marketing and sales force. This would involve substantial costs, training, and time. Alternatively, we may decide to rely on a company with a large distribution system and a large direct sales force to undertake the majority of these activities on our behalf. This route could result in less profit for us, but may permit us to reach market faster. In any event, we may not be able to undertake this effort on our own, or contract with another to do this at a reasonable cost. Regardless of the route we take, we may not be able to successfully commercialize any product.

**THE MARKET FOR OUR STOCK IS VOLATILE, WHICH COULD ADVERSELY AFFECT AN INVESTMENT IN OUR STOCK.**

Our share price and volume are highly volatile. This is not unusual for biomedical companies of our size, age, and with a discrete market niche. It also is common for the trading volume and price of biotechnology stocks to be unrelated to a company's operations, i.e. to go up or down on positive news and to go up or down on no news. Our stock has exhibited this type of behavior in the past, and may well exhibit it in the future. The historically low trading volume of our stock, in relation to many other biomedical companies of about our size, makes it more likely that a severe fluctuation in volume, either up or down, will affect the stock price.

Some factors that we would expect to depress the price of our stock include:

Adverse clinical trial results;

Our inability to obtain additional capital;

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Announcement that the FDA denied our request to approve our human-use product for commercialization in the United States, or similar denial by other regulatory bodies which make independent decisions outside the United States. To date, Europe is the only foreign jurisdiction in which we have sought approval for commercialization;

Announcement of legal actions brought by or filed against us for patent or other matters, especially if we do not win such actions;

Cancellation of important corporate partnerships or agreements;

Public concern as to the safety or efficacy of our human-use products including public perceptions regarding gene therapy in general;

Stockholders' decisions, for whatever reasons, to sell large amounts of our stock;

Adverse research and development results;

Declining working capital to fund operations, or other signs of apparent financial uncertainty; and

Significant advances made by competitors that are perceived to limit our market position.

Additionally, our clinical trials are open ended and therefore there is a risk information regarding the success of our clinical trials maybe be obtained by the public prior to a formal announcement by the Company.

### **ECONOMIC, POLITICAL, MILITARY OR OTHER EVENTS IN THE UNITED STATES OR IN OTHER COUNTRIES COULD INTERFERE WITH OUR SUCCESS OR OPERATIONS AND HARM OUR BUSINESS**

The September 11, 2001 terrorist attacks disrupted commerce throughout the United States and other parts of the world. The continued threat of similar attacks throughout the world and the military action taken by the United States and other nations in Iraq or other countries may cause significant disruption to commerce throughout the world. To the extent that such disruptions further slow the global economy, our business and results of operations could be materially adversely affected. We are unable to predict whether the threat of new attacks or the responses thereto will result in any long-term commercial disruptions or if such activities or responses will have a long-term material adverse effect on our business, results of operations or financial condition.

### **OUR DEPENDENCE UPON NON-MARKETED PRODUCTS, LACK OF EXPERIENCE IN MANUFACTURING AND MARKETING HUMAN-USE PRODUCTS, AND OUR CONTINUING DEFICIT MAY RESULT IN EVEN FURTHER FLUCTUATIONS IN OUR TRADING VOLUME AND SHARE PRICE.**

Successful approval, marketing, and sales of our human-use equipment are critical to the financial future of our company. Our human-use products are not yet approved for sale in the United States and some other jurisdictions and we may never obtain those approvals. Even if we do obtain approvals to sell our human-use products in the United States, those sales may not be as large or timely as we expect. These uncertainties may cause our operating results to fluctuate dramatically in the next several years. We believe that quarter-to-quarter or annual comparisons of our operating results are not a good indication of our future performance. Nevertheless, these fluctuations may cause us to perform below the expectations of the public market analysts and investors. If this happens, the price of our common shares would likely fall.

**THERE IS A RISK OF PRODUCT LIABILITY WITH HUMAN-USE EQUIPMENT**

The testing, marketing and sale of human-use products expose us to significant and unpredictable risks of equipment product liability claims. These claims may arise from patients, clinical trial volunteers, consumers, physicians, hospitals, companies, institutions, researchers or others using, selling, or buying our equipment. Product liability risks are inherent in our business and will exist even after the products are approved for sale. If and when our human-use equipment is commercialized, we run the risk that use (or misuse) of the equipment will result in personal injury. The chance of such an occurrence will increase after a product type is on the market.

We possess liability insurance in connection with ongoing business and products, and we will purchase additional policies if such policies are determined by management to be necessary. The insurance we purchase may not provide adequate coverage in the event a claim is made, however, and we may be required to pay claims directly. If we did have to make payment against a claim, then it would impact our financial ability to perform the research, development, and sales activities we have planned.

If and when our human-use equipment is commercialized, there is always the risk of product defects. Product defects can lead to loss of future sales, decrease in market acceptance, damage to our brand or reputation, and product returns and warranty costs. These events can occur whether the defect resides in a component we purchased from a third party or whether it was due to our design and/or manufacture. We expect that our sales agreements will contain provisions designed to limit our exposure to product liability claims. However, we do not know whether these limitations are enforceable in the countries in which the sale is made. Any product liability or other claim brought against us, if successful and of sufficient magnitude, could negatively impact our financial performance, even if we have insurance.

**WE CANNOT BE CERTAIN THAT WE WILL BE ABLE TO MANUFACTURE OUR HUMAN-USE EQUIPMENT IN SUFFICIENT VOLUMES AT COMMERCIALY REASONABLE RATES.**

Our manufacturing facilities for human-use products will be subject to quality systems regulations, international quality standards and other regulatory requirements, including pre-approval inspection for the human-use equipment and periodic post-approval inspections for all human-use products. While we have undergone and passed a quality systems review from an international body, we have never undergone a quality systems inspection by the FDA. We may not be able to pass an FDA inspection when it occurs. If our facilities are not up to the FDA standards in sufficient time, prior to United States launch of product, then it will result in a delay or termination of our ability to produce the human-use equipment in our facility. Any delay in production will have a negative effect on our business. There are no immediate dates set forth for launch of our products in the United States. We plan on launching these products once we successfully perform a Phase III clinical study, obtain the requisite regulatory approval, and engage a partner who has the financial resources and marketing capacity to bring our products to market.

Our products must be manufactured in sufficient commercial quantities, in compliance with regulatory requirements, and at an acceptable cost to be attractive to purchasers. We rely on third parties to manufacture and assemble most aspects of our equipment.

Disruption of the manufacture of our products, for whatever reason, could delay or interrupt our ability to manufacture or deliver our products to customers on a timely basis. This would be expected to affect revenues and may affect our long-term reputation, as well. In the event we provide product of inferior quality, we run the risk of product liability claims and warranty obligations, which will negatively affect our financial performance.



**WE DEPEND ON THE CONTINUED EMPLOYMENT OF QUALIFIED PERSONNEL.**

Our success is highly dependent on the people who work for us. If we cannot attract and retain top talent to work in our company, then our business will suffer. Our staff may not decide to stay with our company, and we may not be able to replace departing employees or build departments with qualified individuals.

We have an employment agreement in place for Avtar Dhillon, our President and Chief Executive Officer. If Mr. Dhillon leaves us, that might pose significant risks to our continued development and progress. Our progress may also be curtailed if Dietmar Rabussay, Ph.D., our Vice President of Research and Development, were to leave us.

**WE MAY NOT MEET ENVIRONMENTAL GUIDELINES AND AS A RESULT COULD BE SUBJECT TO CIVIL AND CRIMINAL PENALTIES.**

Like all companies in our line of work, we are subject to a variety of governmental regulations relating to the use, storage, discharge and disposal of hazardous substances. Our safety procedures for handling, storage and disposal of such materials are designed to comply with applicable laws and regulations. Nevertheless, if we are found to not comply with environmental regulations, or if we are involved with contamination or injury from these materials, then we may be subject to civil and criminal penalties. This would have a negative impact on our reputation, our finances, and could result in a slowdown, or even complete cessation of our business.

**OUR FACILITIES ARE LOCATED NEAR KNOWN EARTHQUAKE FAULT ZONES, AND THE OCCURRENCE OF AN EARTHQUAKE OR OTHER CATASTROPHIC DISASTER COULD CAUSE DAMAGE TO OUR FACILITIES AND EQUIPMENT.**

Our facilities are located near known earthquake fault zones and are vulnerable to damage from earthquakes. We are also vulnerable to damage from other types of disasters, including fire, floods, power loss, communications failures and similar events. If any disaster were to occur, our ability to operate our business at our facilities would be seriously impaired. In addition, the unique nature of our research activities could cause significant delays in our programs and make it difficult for us to recover from a disaster. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions. Accordingly, an earthquake or other disaster could materially and adversely harm our ability to conduct business.

**Additional or Updated Risk Factors**

Prior to making an investment decision with respect to the common stock offered hereby, prospective investors should also carefully consider any specific factors set forth under a caption "risk factors" in the applicable prospectus supplement, together with all of the other information appearing in this prospectus or the prospectus supplement or incorporated by reference into this prospectus.

**Use of Proceeds**

We will not receive any proceeds from the sale by any selling stockholder of the 320,066 shares of our common stock being offered in this prospectus.

**Selling Stockholders**

We originally sold and issued to the selling stockholders (i) shares of Series A preferred stock that are convertible into shares of our common stock, (ii) shares of Series B preferred stock that are convertible into shares of our common stock, (iii) shares of Series C preferred stock that are convertible into shares of our common stock, and (iv) warrants to purchase shares of our common

stock, pursuant to transactions exempt from registration under the Securities Act of 1933. As holders of Series A preferred stock, Series B preferred stock and/or Series C preferred stock, the selling stockholders are entitled to receive certain periodic common stock dividends as set forth in greater detail in the certificate of designations, rights and preferences of the Series A preferred stock, the certificate of designations, rights and preferences of the Series B preferred stock and/or the certificate of designations, rights and preferences of the Series C preferred stock, respectively. The shares of common stock that are being registered to permit public sales thereof represent shares of common stock that the selling stockholders received as dividends on December 31, 2003, March 31, 2004 and/or June 30, 2004, and the selling stockholders may offer the shares for resale from time to time pursuant to this prospectus.

The following table sets forth certain information regarding the selling stockholders and the shares offered by them in this prospectus. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission, or SEC. In computing the number of shares beneficially owned by a selling stockholder and the percentage of ownership of that selling stockholder, shares of common stock underlying shares of convertible preferred stock, options or warrants held by that selling stockholder that are convertible or exercisable, as the case may be, within 60 days of July 31, 2004 are included. Those shares, however, are not deemed outstanding for the purpose of computing the percentage ownership of any other selling stockholder. Each selling stockholder's percentage of ownership in the following table is based upon 70,544,794 shares of common stock outstanding as of July 31, 2004.

None of the selling stockholders within the past three years has had any material relationship with us or any of our affiliates. The term "selling stockholders" also includes any transferees, pledges, donees, or other successors in interest to the selling stockholders named in the table below. To our knowledge, subject to applicable community property laws, each person named in the table has sole voting and investment power with respect to the shares of common stock set forth opposite such person's name.

<b>Selling Stockholder</b>	<b>Number of Shares of Common stock Beneficially Owned Prior to Offering</b>	<b>Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering</b>	<b>Number of Shares of Common Stock Registered for Sale Hereby</b>	<b>Number of Shares of Common Stock Beneficially Owned After Completion of the Offering(1)</b>	<b>Percentage of Shares of Common Stock Beneficially Owned After Completion of the Offering(1)</b>
Alpha Capital	200,100(2)	*	1,571	198,529(2)	*
Aran Asset Management SA	2,761,716(3)	3.91%	1,687	2,760,029(3)	3.91%
B.C. Equities Inc.	121,178(4)	*	657	120,521(4)	*
BayStar Capital II, LP	3,648,667(5)	4.95%	34,687	3,650,489(41)	4.95%
Brian Noble	354,160(6)	*	1,079	353,081(6)	*
Bridges and Pipes LLC	200,100(7)	*	1,571	198,529(7)	*
Catalyst Capital LLC	354,039(8)	*	958	353,081(8)	*
Crescent International Ltd	21,910	*	3,325	18,585	*
David Israel	33,900	*	567	33,333	*
East Hudson Inc. (BVI)	280,128(9)	*	1,975	278,153(9)	*
Ellis International Ltd. Inc.	285	*	285		*
Finter Bank Zurich	806,501(10)	1.14%	555	805,946(10)	1.14%
Gamma Opportunity Capital Partners, LP	1,168	*	1,168		*
Haywood Securities ITF Bernard Leroux	237,937(11)	*	3,292	234,645(11)	*

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Haywood Securities ITF Colin Paul Sabiston	119,617(12)	*	1,645	117,972(12)	*
Haywood Securities ITF Glenariff Investments Ltd.	118,966(13)	*	1,645	117,321(13)	*
John W. Mellors	18,158	*	63	18,095	*
JR Jay Public Investments, LLC	2,210	*	2,210		*
Kenneth S. Pilot	20,340	*	340	20,000	*
Kinetic Capital "TNT" Limited	280,140(14)	*	2,199	277,941(14)	*
Kinetic Capital Limited Partnership	3,409,246(15)	4.72%	24,704	3,384,542(15)	4.68%
Mike Fitzmaurice	118,966(16)	*	1,645	117,321(16)	*
Nesbitt Burns ITF Account 402 200 9122	616,098	*	727	615,371	*
North Sound Legacy Fund LLC	102,076(17)	*	1,036	101,040(17)	*
North Sound Legacy Institutional Fund LLC	866,649(18)	1.22%	8,431	858,218(18)	1.21%
North Sound Legacy International Ltd.	1,614,098(19)	2.27%	8,996	1,605,102(19)	2.26%
Otape Investments LLC	173,382	*	1,800	171,582	*
Park Place Columbia Limited	805,321(20)	1.14%	5,097	800,224(20)	1.13%
Park Place Galileo Ltd.	405,094	*	3,983	401,111	*
Paul Scharfer	277,007	*	2,721	274,286	*
Pharmaceutical Medical Tech Fund	400,200(21)	*	3,142	397,058(21)	*
ProMed Offshore Fund, Ltd.	108,926(22)	*	246	108,680(22)	*
ProMed Partners, L.P.	748,025(23)	1.06%	1,150	746,875(23)	1.05%
Qfinance, Inc.	3,669,866(24)	4.95%	56,260	3,672,796(42)	4.95%
RAM Capital Group, LLC	713,816(25)	1.00%	9,881	703,935(25)	*
Rennes Fondation	629,021(26)	*	2,521	626,500(26)	*
SCO Capital Partners LLC	3,381,528(27)	4.58%	32,610	3,348,918(27)	4.53%
SDS Capital Group SPC, Ltd.	2,416,909(28)	3.32%	12,570	2,404,339(28)	3.30%
SDS Merchant Fund, LP	327,584	*	13,792	313,792	*
Shekhar K. Basu	503,572(29)	*	4,939	498,633(29)	*
SRG Capital, LLC	160,080(30)	*	1,257	158,823(30)	*
Stonestreet LP	400,200(31)	*	3,142	397,058(31)	*
The Chloe H. Rouhandeh Trust	194,143(32)	*	2,963	191,180(32)	*
The Conus Fund L.P.	2,128,850(33)	3.00%	28,986	2,099,864(33)	2.89%
The Conus Fund Offshore Ltd.	332,746(34)	*	4,280	328,466(34)	*
The Conus Fund QP, L.P.	331,276(35)	*	4,610	326,666(35)	*

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The Sophie C. Rouhandeh Trust	194,143(36)	*	2,963	191,180(36)	*
The Steven H. Rouhandeh 1999 Family Trust	194,143(37)	*	2,963	191,180(37)	*
William Kane Mahon	77,012(38)	*	188	76,824(38)	*
Xmark Fund, LP	864,608(39)	1.21%	5,464	859,144(39)	1.20%
Xmark Fund, Ltd.	957,671(40)	1.34%	5,220	952,451(40)	1.33%

\*

Less than 1 percent.

(1)

Represents the amount of shares that will be held by the selling stockholders after completion of this offering based on the assumption that all shares registered for sale hereby will be sold. However, the selling stockholders may offer all, some or none of the shares pursuant to this prospectus, and to our knowledge there are currently no agreements, arrangements or understanding with respect to the sale of any of the shares that may be held by the selling stockholders after completion of this offering.

(2)

Includes 147,058 shares underlying Series C Preferred Stock and 51,471 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.

(3)

Includes 133,333 shares underlying warrants that are exercisable within 60 days.

(4)

Includes 33,333 shares underlying Series A Preferred Stock and 13,333 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.

(5)

BayStar Capital II, LP ("BayStar") holds (a) 483,014 shares of our common stock, (b) warrants to purchase up to 1,703,361 shares of our common stock that are exercisable within 60 days and (c) Series C Preferred Stock that is convertible into 1,764,705 shares of our common stock within 60 days. The terms of the Preferred Stock and warrants owned by BayStar provide that the number of shares of our common stock that may be acquired by BayStar upon conversion of the Preferred Stock and/or exercise of the warrants is limited to the extent necessary to ensure that, following such exercise, the number of shares of our common stock then beneficially owned by BayStar and any other persons or entities whose beneficial ownership of common stock would be aggregated with BayStar for purposes of the Exchange Act, does not exceed 4.95% of the total number of shares of our common stock then outstanding. The voting rights of the Preferred Stock are similarly limited such that BayStar will not have voting power with respect to such shares of Preferred Stock to the extent that such voting power would exceed 4.95%. By written notice to us, BayStar may waive these provisions, but any such waiver will not be effective until the 61st day after such notice is delivered to us (any such waiver will apply only to BayStar and not to any other holder of warrants or Preferred Stock). Subject to the limitations described above, BayStar beneficially owns 3,165,653 shares of our common stock underlying warrants and Preferred Stock that are exercisable or convertible, respectively, within 60 days.

(6)

Includes 93,333 shares underlying warrants that are exercisable within 60 days.

(7)

Includes 147,058 shares underlying Series C Preferred Stock and 51,471 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.

(8)

Includes 100,000 shares underlying warrants that are exercisable within 60 days.

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- (9) Includes 100,000 shares underlying Series A Preferred Stock and 40,000 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (10) Includes 166,666 shares underlying warrants that are exercisable within 60 days.
- (11) Includes 166,666 shares underlying Series A Preferred Stock and 66,666 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (12) Includes 83,333 shares underlying Series A Preferred Stock and 33,333 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (13) Includes 83,333 shares underlying Series A Preferred Stock and 33,333 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (14) Includes 205,882 shares underlying Series C Preferred Stock and 72,058 shares underlying warrants that are convertible or exercisable, as the case may be, within 60 days.
- (15) Includes 1,250,000 shares underlying Series A Preferred Stock and 500,000 shares underlying warrants that are convertible or exercisable, as the case may be, within 60 days.
- (16) Includes 83,333 shares underlying Series A Preferred Stock and 33,333 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (17) Includes 54,286 shares underlying warrants that are exercisable within 60 days.
- (18) Includes 488,571 shares underlying warrants that are exercisable within 60 days.
- (19) Includes 542,857 shares underlying warrants that are exercisable within 60 days.
- (20) Includes 216,667 shares underlying Series A Preferred Stock, 76,470 shares underlying Series C Preferred Stock and 113,432 shares underlying warrants that are convertible or exercisable, as the case may be, within 60 days.
- (21) Includes 294,117 shares underlying Series C Preferred Stock and 102,941 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (22) Includes 54,286 shares underlying warrants that are exercisable within 60 days.
- (23) Includes 253,333 shares underlying warrants that are exercisable within 60 days.
- (24) Qfinance, Inc. ("QFinance") holds (a) 75,935 shares of our common stock, (b) warrants to purchase up to 1,129,200 shares of our common stock that are exercisable within 60 days, (c) Series A Preferred Stock that is convertible into 833,333 shares of our common stock within 60 days, (d) Series B Preferred Stock that is convertible into 1,428,571 shares of our common stock within 60 days and (e) Series C Preferred Stock that is convertible into 641,254 shares of our common stock within 60 days. The terms of the Preferred Stock and warrants owned by QFinance provide that the number of shares of our common stock that may be acquired by QFinance upon conversion of the Preferred Stock and/or exercise of the warrants is limited to the extent necessary to ensure that, following such exercise, the number of shares of our common stock then beneficially owned by QFinance and any other persons or entities whose

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beneficial ownership of common stock would be aggregated with QFinance for purposes of the Exchange Act, does not exceed 4.95% of the total number of shares of our common stock then outstanding. The voting rights of the Preferred Stock are similarly limited such that QFinance will not have voting power with respect to such shares of Preferred Stock to the extent that such voting power would exceed 4.95%. By written notice to us, QFinance may waive these provisions, but any such waiver will not be effective until the 61st day after such notice is delivered to us (any such waiver will apply only to QFinance and not to any other holder of warrants or Preferred Stock). Subject to the limitations described above, QFinance beneficially owns 3,593,931 shares of our common stock

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underlying warrants and Preferred Stock that are exercisable or convertible, respectively, within 60 days.

- (25) Includes 500,000 shares underlying Series A Preferred Stock and 33,333 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (26) Includes 236,000 shares underlying Series C Preferred Stock and 82,600 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (27) Includes 550,000 shares underlying Series A Preferred Stock, 942,857 shares underlying Series B Preferred Stock, and 1,843,074 shares underlying warrants that are convertible or exercisable, as the case may be, within 60 days.
- (28) Includes 1,176,470 shares underlying Series C Preferred Stock and 1,135,575 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (29) Includes 83,333 shares underlying Series A Preferred Stock, 142,857 shares underlying Series B Preferred Stock and 90,476 shares underlying warrants that are convertible or exercisable, as the case may be, within 60 days.
- (30) Includes 117,647 shares underlying Series C Preferred Stock and 41,176 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (31) Includes 294,117 shares underlying Series C Preferred Stock and 102,941 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (32) Includes 50,000 shares underlying Series A Preferred Stock, 85,714 shares underlying Series B Preferred Stock, and 54,286 shares underlying warrants that are convertible or exercisable, as the case may be, within 60 days.
- (33) Includes 1,466,666 shares underlying Series A Preferred Stock and 586,666 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (34) Includes 216,666 shares underlying Series A Preferred Stock and 86,666 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (35) Includes 233,333 shares underlying Series A Preferred Stock and 93,333 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (36) Includes 50,000 shares underlying Series A Preferred Stock, 85,714 shares underlying Series B Preferred Stock, and 54,286 shares underlying warrants that are convertible or exercisable, as the case may be, within 60 days.
- (37) Includes 50,000 shares underlying Series A Preferred Stock, 85,714 shares underlying Series B Preferred Stock, and 54,286 shares underlying warrants that are convertible or exercisable, as the case may be, within 60 days.
- (38) Includes 17,647 shares underlying Series C Preferred Stock and 6,176 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.
- (39) Includes 511,400 shares underlying Series C Preferred Stock and 341,847 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.

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(40) Includes 488,600 shares underlying Series C Preferred Stock and 460,534 shares underlying warrants that are convertible or exercisable, respectively, within 60 days.

(41) After completion of this offering based on the assumption that all shares registered for sale hereby will be sold, BayStar Capital II, LP ("BayStar") would hold (a) 448,027 shares of our common stock, (b) warrants to purchase up to 1,703,361 shares of our common stock that are exercisable



within 60 days and (c) Series C Preferred Stock that is convertible into 1,764,705 shares of our common stock within 60 days. The terms of the Preferred Stock and warrants owned by BayStar provide that the number of shares of our common stock that may be acquired by BayStar upon conversion of the Preferred Stock and/or exercise of the warrants is limited to the extent necessary to ensure that, following such exercise, the number of shares of our common stock then beneficially owned by BayStar and any other persons or entities whose beneficial ownership of common stock would be aggregated with BayStar for purposes of the Exchange Act, does not exceed 4.95% of the total number of shares of our common stock then outstanding. The voting rights of the Preferred Stock are similarly limited such that BayStar will not have voting power with respect to such shares of Preferred Stock to the extent that such voting power would exceed 4.95%. By written notice to us, BayStar may waive these provisions, but any such waiver will not be effective until the 61st day after such notice is delivered to us (any such waiver will apply only to BayStar and not to any other holder of warrants or Preferred Stock). After completion of this offering and subject to the limitations described above, BayStar beneficially would own 3,202,462 shares of our common stock underlying warrants and Preferred Stock that are exercisable or convertible, respectively, within 60 days.

(42)

After completion of this offering based on the assumption that all shares registered for sale hereby will be sold, QFinance, Inc. ("QFinance") would hold (a) 19,675 shares of our common stock, (b) warrants to purchase up to 1,129,200 shares of our common stock that are exercisable within 60 days, (c) Series A Preferred Stock that is convertible into 833,333 shares of our common stock within 60 days, (d) Series B Preferred Stock that is convertible into 1,428,571 shares of our common stock within 60 days and (e) Series C Preferred Stock that is convertible into 641,254 shares of our common stock within 60 days. The terms of the Preferred Stock and warrants owned by QFinance provide that the number of shares of our common stock that may be acquired by QFinance upon conversion of the Preferred Stock and/or exercise of the warrants is limited to the extent necessary to ensure that, following such exercise, the number of shares of our common stock then beneficially owned by QFinance and any other persons or entities whose beneficial ownership of common stock would be aggregated with QFinance for purposes of the Exchange Act, does not exceed 4.95% of the total number of shares of our common stock then outstanding. The voting rights of the Preferred Stock are similarly limited such that QFinance will not have voting power with respect to such shares of Preferred Stock to the extent that such voting power would exceed 4.95%. By written notice to us, QFinance may waive these provisions, but any such waiver will not be effective until the 61st day after such notice is delivered to us (any such waiver will apply only to QFinance and not to any other holder of warrants or Preferred Stock). After completion of this offering and subject to the limitations described above, QFinance beneficially would own 3,653,121 shares of our common stock underlying warrants and Preferred Stock that are exercisable or convertible, respectively, within 60 days.

#### **Plan of Distribution**

We are registering the shares of common stock on behalf of the selling security holders. Sales of shares may be made by selling security holders, including their respective donees, transferees, pledgees or other successors-in-interest directly to purchasers or to or through underwriters, broker-dealers or through agents. Sales may be made from time to time on the American Stock Exchange, any other exchange upon which our shares may trade in the future, in the over-the-counter market or otherwise, at market prices prevailing at the time of sale, at prices related to market prices, or at negotiated or fixed prices. The shares may be sold by one or more of, or a combination of, the following:

a block trade in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction (including crosses in which the same broker acts as agent for both sides of the transaction);

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purchases by a broker-dealer as principal and resale by such broker-dealer, including resales for its account, pursuant to this prospectus;

ordinary brokerage transactions and transactions in which the broker solicits purchases;

through options, swaps or derivatives;

in privately negotiated transactions;

in making short sales or in transactions to cover short sales; and

put or call option transactions relating to the shares.

The selling security holders may effect these transactions by selling shares directly to purchasers or to or through broker-dealers, which may act as agents or principals. These broker-dealers may receive compensation in the form of discounts, concessions or commissions from the selling security holders and/or the purchasers of shares for whom such broker-dealers may act as agents or to whom they sell as principals, or both (which compensation as to a particular broker-dealer might be in excess of customary commissions). The selling security holders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities.

The selling security holders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with those transactions, the broker-dealers or other financial institutions may engage in short sales of the shares or of securities convertible into or exchangeable for the shares in the course of hedging positions they assume with the selling security holders. The selling security holders may also enter into options or other transactions with broker-dealers or other financial institutions which require the delivery of shares offered by this prospectus to those broker-dealers or other financial institutions. The broker-dealer or other financial institution may then resell the shares pursuant to this prospectus (as amended or supplemented, if required by applicable law, to reflect those transactions).

The selling security holders and any broker-dealers that act in connection with the sale of shares may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act of 1933, and any commissions received by broker-dealers or any profit on the resale of the shares sold by them while acting as principals may be deemed to be underwriting discounts or commissions under the Securities Act. The selling security holders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares against liabilities, including liabilities arising under the Securities Act. We have agreed to indemnify each of the selling security holders and each selling security holder has agreed, severally and not jointly, to indemnify us against some liabilities in connection with the offering of the shares, including liabilities arising under the Securities Act.

The selling security holders will be subject to the prospectus delivery requirements of the Securities Act. We have informed the selling security holders that the anti-manipulative provisions of Regulation M promulgated under the Securities Exchange Act of 1934 may apply to their sales in the market.

Selling security holders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided they meet the criteria and conform to the requirements of Rule 144.

Upon being notified by a selling security holder that a material arrangement has been entered into with a broker-dealer for the sale of shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file a supplement to this prospectus, if required pursuant to Rule 424(b) under the Securities Act, disclosing:

the name of each such selling security holder and of the participating broker-dealer(s);

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the number of shares involved;

the initial price at which the shares were sold;

the commissions paid or discounts or concessions allowed to the broker-dealer(s), where applicable;

that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus; and

other facts material to the transactions.

In addition, if required under applicable law or the rules or regulations of the Commission, we will file a supplement to this prospectus when a selling security holder notifies us that a donee or pledgee intends to sell more than 500 shares of common stock.

We are paying all expenses and fees in connection with the registration of the shares. The selling security holders will bear all brokerage or underwriting discounts or commissions paid to broker-dealers in connection with the sale of the shares.

### **Legal Matters**

The validity of the issuance of the shares offered in this prospectus will be passed upon for us by Kirkpatrick & Lockhart, LLP, Los Angeles, California.

### **Experts**

Ernst & Young LLP, independent registered public accounting firm, have audited our consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2003, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

### **Where You Can Find More Information**

We file annual, quarterly and special reports, along with other information with the SEC. You may read and copy any document we file at the public reference facilities maintained by the SEC at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our common stock is traded on The American Stock Exchange. You may inspect reports and other information concerning us at the offices of the American Stock Exchange, Inc., 86 Trinity Place, New York, New York 10006. These filings and other information may also be inspected without charge at a Web site maintained by the SEC. The address of the site is <http://www.sec.gov>.

### **Incorporation of Certain Documents by Reference**

This prospectus is part of a registration statement filed with the SEC. The SEC allows us to "incorporate by reference" into this prospectus 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 information that we file later with the SEC will automatically update and supersede this information. The following documents were filed with the SEC pursuant to the Exchange Act and are incorporated by reference and made a part of this prospectus:

our Annual Report on Form 10-K for the year ended December 31, 2003;



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our Current Report on Form 8-K filed with the SEC on May 27, 2004;

our definitive proxy statement filed with the SEC on April 28, 2004;

our preliminary proxy statement filed with the SEC on July 30, 2004; and

the description of our capital stock contained in our registration statement on Form 8-A filed with the SEC on December 4, 1998, including any amendment or report filed for the purpose of updating such description.

The documents listed above and all documents that we file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 subsequent to the date of this initial registration statement and prior to effectiveness of this registration statement, or prior to the filing of a post-effective amendment that indicates that all securities offered herein have been sold or which deregisters all securities remaining unsold, shall be deemed to be incorporated by reference into this prospectus and to be a part hereto from the date of filing such documents.

Any statement contained in a document that is incorporated by reference will be modified or superseded for all purposes to the extent that a statement contained in this prospectus, or in any other document that is subsequently filed with the SEC and incorporated by reference, modifies or is contrary to that previous statement. Any statement so modified or superseded will not be deemed a part of this prospectus except as so modified and superseded.

We will provide without charge to each person to whom this prospectus is delivered, upon oral or written request, a copy of any or all of the foregoing documents incorporated herein by reference (other than exhibits to such documents unless such exhibits are specifically incorporated by reference into the information that this prospectus incorporates). Written or telephone requests should be directed to Shareholder Relations at Genetronics Biomedical Corporation, 11199 Sorrento Valley Road, San Diego, CA 92121-1334, telephone number (858) 597-6006. These reports are also available on our web site, the address of which is <http://www.genetronics.com>.

You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. The selling stockholders will not make an offer of 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 of those documents.

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