

GENETRONICS BIOMEDICAL CORP
Form S-3
March 28, 2005

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As Filed with the Securities and Exchange Commission on March 28, 2005

Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

GENETRONICS BIOMEDICAL CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

3841
(Primary Standard Industrial
Classification Code Number)
11494 Sorrento Valley Road
San Diego, California 92121-1318
Telephone (858) 597-6006
Facsimile (858) 597-0451

33-0969592
(I.R.S. Employer
Identification Number)

(Address including zip code and telephone number, including area code, of registrant's principal executive offices)

Avtar Dhillon
Chief Executive Officer and President
11494 Sorrento Valley Road
San Diego, California 92121
Telephone (858) 597-6006
Facsimile (858) 597-0451

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

Copies to

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

If the only securities being registered on this Form are to be offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, \$.001 par value(3)	56,648(1)	\$3.87(2)	\$219,228(2)	
Common Stock, \$.001 par value(3)	1,540,123(1)	\$3.87(2)	\$5,960,276(2)	
Common Stock, \$.001 par value(4)	508,240(1)	\$3.87(2)	\$1,966,889(2)	
Common Stock, \$.001 par value(4)	50,000(1)	\$3.87(2)	\$193,500(2)	
Common Stock, \$.001 par value(5)	1,966,292(1)	\$3.87(2)	\$7,609,550(2)	
Total Registration Fee				\$1,877

- (1) In accordance with Rule 416(a), the Registrant is also registering hereunder an indeterminate number of shares that may be issued and resold to prevent dilution resulting from stock splits, stock dividends or similar transactions.
- (2) The price of \$3.87, the average of the high and low prices of the Registrant's common stock on the American Stock Exchange on March 22, 2005 is set forth solely for the purpose of computing the registration fee pursuant to Rule 457(c).
- (3) Represents shares of the Registrant's common stock being registered for resale that have been issued to the selling stockholders named in the prospectus or a prospectus supplement.
- (4) Represents shares of the Registrant's common stock that have been or may be acquired upon the exercise of warrants issued to the selling stockholders.
- (5) Represents shares of the Registrant's common stock that have been or may be acquired by the selling stockholders upon the conversion of 1,966,292 shares of Series D preferred stock that have been issued, assuming a conversion rate equal to one share of common stock per share of Series D preferred stock.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registration shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement relating to these securities that has been filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, Dated March 28, 2005

PROSPECTUS

4,121,303 Shares

Common Stock

This prospectus relates to 4,121,303 shares of common stock of Genetronics Biomedical Corporation that may be sold from time to time by the selling stockholders named in 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 March 24, 2005, the last reported sale price for our common stock on the American Stock Exchange was \$3.92 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 March 28, 2005.

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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 diseases with critical unmet treatment needs using EPT. Our MedPulser Electroporation Therapy System is in Phase III clinical trials in the United States for the treatment of recurrent head and neck cancer. In addition, we are currently conducting a pre-marketing study to support the commercialization of the MedPulser Electroporation Therapy System in Europe. The Genetronics' 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 Electroporation Therapy System in Europe in 2006 represents an important milestone for us.

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 determine 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 or 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 our technology from surgical oncologists.

As part of our MedPulser Electroporation Therapy System product line, we have also been developing devices for the delivery of DNA for DNA vaccinations and gene therapy. We were the first company to initiate a clinical study involving the use of EPT with DNA involving human patients. This was done in collaboration with investigators at the Moffit Regional Cancer Center in Tampa, Florida in December 2004. This FDA-approved investigation involves electroporating melanomas with DNA-encoded cytokines in an attempt to stimulate immunity against the patient's tumor. In 2004, we also extended our license with Vical to include a worldwide exclusive license for the use of electroporation together with Vical's "naked" DNA technology for their development of an HIV DNA vaccine. We also executed a major licensing deal with milestone and royalty payments with Merck for the development of proprietary DNA vaccines for cancer and infectious disease using electroporation. In addition, in January 2005, we acquired Inovio AS, a Norwegian company, to expand Genetronics' patent portfolio in the area of intramuscular electroporation. We believe our compelling asset base of intellectual property and scientific and engineering accomplishments, combined with clinical results, position us as a leader in EPT.

We believe that attempts to pioneer new therapies based on DNA have been hampered by the side effects associated with the use of viral vectors for DNA delivery. In addition to safety issues, viral vectors are difficult and expensive to manufacture. Because electroporation has proven efficient and safe in animal experiments, we have been developing MedPulser DNA Delivery Systems for different target tissues. By engineering different applicators and choosing appropriate electroporation parameters, we can deliver DNA to the muscle, tumor tissue, 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.

Our principal executive offices are located at 11494 Sorrento Valley Road, San Diego, California 92121-1318, and our telephone number is (858) 597-6006.

Recent Developments

In March 2005, we announced the initiation of a Phase I clinical trial to treat pancreatic cancer using our MedPulser Electroporation Therapy System. The FDA has granted us orphan designation for this indication. The primary endpoint of this FDA-approved study is to determine the safety profile of the MedPulser Electroporation Therapy System in conjunction with intralesionally-injected bleomycin for the treatment of unresectable or incurable locally advanced pancreatic cancer.

In January 2005, we announced the acquisition of Inovio AS, a Norwegian company dedicated to intramuscular electroporation, in a stock purchase transaction for \$3.0 million in cash and \$7.0 million in Series D Preferred Stock. Inovio AS holds several patents for the use of intramuscular electroporation for gene therapy, supports a number of clinical studies and is the recipient of a significant appropriation from the U.S. Department of Defense to develop electroporation devices. We believe that the acquisition represents a consolidation within the industry that will serve to strengthen our position as a leader in EPT.

In January 2005, we completed a private placement to accredited investors whereby we sold 1,540,123 shares of our common stock at a purchase price of \$4.05 per share and issued warrants to purchase 508,240 shares of our common stock at an exercise price of \$5.50 per share, which resulted in aggregate cash proceeds of \$3.03 million (assuming no exercise of the warrants). A portion of this private placement involved investors who converted \$3.2 million of their previous investment in our Series C Preferred Stock into 790,123 shares of the common stock issued as part of this private placement with no associated cash proceeds to us.

In December 2004, we announced the initiation of a clinical study at the Moffitt Regional Cancer Center to treat melanomas injected with a cytokine gene followed by electroporation. This study is a first for the combined use of DNA with electroporation in humans and highlights our pioneering efforts with DNA and that of our other partners Vical and Merck. If successful, we have rights to the proprietary method being used at Moffitt (which is held by RMR Technologies and licensed to us) and could subsequently enter into a licensing deal with a partner for the treatment of melanoma.

In October 2004, we announced the extension of our licensing deal with Vical to include the development of HIV DNA vaccines using electroporation. This expands the existing license to include HIV and increases the milestone and royalty payments we would receive from the successful development of this vaccine by Vical or its future partners.

In August 2004, we announced that we had been awarded a grant by the National Institutes of Health to conduct research in the field of vascular gene therapy. The \$100,000 Phase I grant entitled "Ex vivo venous gene delivery by pulsed electric fields," was awarded through the Small Business Innovative Research ("SBIR") program and may be followed, upon evaluation, by a Phase II award of up to \$1.0 million. Vascular diseases are the number one cause of death in the U.S and other

industrialized countries. Vascular transplants, a frequently used method to treat these diseases, unfortunately suffer from a high failure rate, resulting in a significant unmet treatment need. The SBIR grant will support our research aimed at making vascular transplants more effective and longer lasting.

In May 2004, we closed a private preferred share placement and raised an aggregate of \$10.9 million through the sale of our Series C Cumulative Convertible Preferred Stock to institutional and accredited investors. All proceeds from the sale of the Series C Preferred Stock were received as of December 31, 2004.

In May 2004, we announced a significant licensing deal with Merck for the development of Merck's DNA cancer and infectious disease vaccines. The terms of the agreement include milestone and royalty payments for successful completion of the clinical development of the vaccines by Merck. Merck will also reimburse us for the co-development of a proprietary electroporation system for the delivery of the Merck DNA vaccines. In addition, Merck and Genetronics will execute a supply and licensing agreement according to a timeline mutually agreed upon by the companies.

In March 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 EU for the treatment of head and neck cancer.

In March 2004, we announced that we have begun treating patients with new and recurrent primary 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 Therapy System in the 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 Electroporation Therapy System for the treatment of SCCHN, leading to approval for sale in the EU based on achieving the CE Mark.

During the first quarter of 2004, we initiated two Phase III head and neck clinical trials in the U.S. and EU. In February 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 SCCHN. Several Institutional Review Boards ("IRB") 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.

In February 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 Electroporation Therapy System for the treatment of solid malignant tumors including head and neck cancers.

In January 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.

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, 2004, 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 the following factors regarding information included in this Registration Statement. The risks and uncertainties described below are not the only ones the Company faces. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, financial condition and operating results could be materially adversely affected.

IF WE ARE UNABLE TO DEVELOP COMMERCIALY SUCCESSFUL PRODUCTS, INCLUDING OUR MEDPULSER ELECTROPORATION THERAPY SYSTEM IN VARIOUS MARKETS FOR MULTIPLE INDICATIONS, PARTICULARLY FOR THE TREATMENT OF HEAD AND NECK CANCER, OUR BUSINESS WILL BE HARMED AND WE MAY BE FORCED TO CURTAIL OR CEASE OPERATIONS.

Our ability to achieve and sustain operating profitability depends on our ability to successfully commercialize our MedPulser Electroporation Therapy System in various markets for use in treating solid tumors, particularly for the treatment of head and neck cancer, and other indications, which depends in large part on our ability to commence, execute and complete clinical programs and obtain regulatory approvals for our MedPulser Electroporation Therapy System. In particular, our ability to achieve and sustain profitability will depend in large part on our ability to commercialize our MedPulser Electroporation Therapy System for the treatment of head and neck cancer in Europe and the United States. We have received various regulatory approvals, which apply to Europe for our MedPulser Electroporation Therapy System for use in treating solid tumors; the products related to such regulatory approval have not yet been commercialized. 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 we will receive approval for our MedPulser Electroporation Therapy System for the treatment of head and neck cancer or other types of cancer or indications in the United States or in other countries or, if approved, that we will achieve significant level of sales. If we fail to commercialize our products, we may be forced to curtail or cease operations.

We will be starting additional clinical studies in different indications, such as breast and pancreas, and are also in the pre-clinical stages of research and development with new product candidates using our electroporation technology. These new indications and product candidates will require significant costs to advance through the development stages. If such product candidates are advanced through clinical trials, the results of such trials may not gain FDA approval. Even if approved, our products may not be commercially successful. If we fail to develop and commercialize our products, we may be forced to curtail or cease operations.

We cannot assure you that we will successfully develop any products. If we fail to develop or successfully commercialize any products, we may be forced to curtail or cease operations. 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.

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.

Developing a new drug and conducting clinical trials is expensive. Our product development efforts may not lead to commercial products, either because our product candidates fail to be found safe or effective in clinical trials or because we lack the necessary financial or other resources or relationships to pursue our programs through commercialization. Our capital and future revenues may not be sufficient to support the expenses of our operations, the development of commercial infrastructure and the conduct of our clinical trials and pre-clinical research.

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As discussed, we have operated at a loss in the past, 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. We expect we will fund our operations until the second half of 2006 with our current working capital. The extent of these costs will depend on many factors, including some of the following:

The progress and breadth of pre-clinical testing and the size or complexity of our clinical trials and drug delivery programs, all of which directly influence cost;

Higher than expected 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;

Higher than expected costs involved in patenting our technologies and defending them and pursuing our intellectual property strategy;

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

Changes in or terminations of our existing collaboration and licensing arrangements;

Faster than expected rate of progress and cost of our research and development and clinical trial activities;

Decrease in the amount and timing of milestone payments we receive from collaborators;

Higher than expected costs of preparing an application for FDA approval of our MedPulser Electroporation Therapy System;

Higher than expected costs of developing the processes and systems to support FDA approval of our MedPulser Electroporation Therapy System;

An increase in our timetable and costs for the development of marketing operations and other activities related to the commercialization of our MedPulser Electroporation Therapy System and our other product candidates;

A change in the degree of success in our Phase III clinical trial of MedPulser Electroporation Therapy System and in our other clinical trials;

Higher than expected costs to further develop and scale up our manufacturing capability of 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 oncology 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;

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 may be reflected in our stock price.

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 FDA or applicable foreign regulatory authorities must determine that the equipment meets specified criteria for use in the indications for which approval is requested, including obtaining appropriate regulatory approvals. Satisfaction of regulatory requirements typically takes many years, and involves compliance with requirements covering research and development, testing, manufacturing, quality control, labeling and promotion of drugs for human use. To obtain regulatory approvals, we must, among other requirements, complete clinical trials demonstrating our product candidates are safe and effective for a particular cancer type or other disease. Regulatory approval of a new drug is never guaranteed. The FDA will make this determination based on the results from our pre-clinical testing and clinical trials and has substantial discretion in the approval process. Despite the time and experience exerted, failure can occur at any stage, and we could encounter problems causing us to abandon clinical trials.

We have completed Phase II clinical trials and are conducting two Phase III clinical trials of our lead product candidate, the MedPulser Electroporation Therapy System, for the treatment of recurrent head and neck cancer. In addition, we are conducting two Phase IV (or Pre-Marketing) clinical trials of our MedPulser Electroporation Therapy System for the treatment of primary and recurrent head and neck cancer and are starting a Phase I clinical trial of our MedPulser Electroporation Therapy System for the treatment of breast and pancreas cancers. Current or future clinical trials may demonstrate the MedPulser Electroporation Therapy System is neither safe nor effective.

Any delays or difficulties we encounter in our pre-clinical research and clinical trials, in particular the Phase III clinical trials of our MedPulser Electroporation Therapy System for the treatment of recurrent head and neck cancer, may delay or preclude regulatory approval. Our product development costs will increase if we experience delays in testing or regulatory approvals or if we need to perform more or larger clinical trials than planned. Any delay or preclusion could also delay or preclude the commercialization of our MedPulser Electroporation Therapy System or any other product candidates.

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.

We cannot be certain the results we observed in our pre-clinical testing will be confirmed in clinical trials or the results of any of our clinical trials will support FDA approval. If we experience unexpected, inconsistent or disappointing results in connection with a clinical or pre-clinical trial our business will suffer.

In addition, any of our clinical trials for our treatment may be delayed or halted at any time for various reasons, including:

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

Pre-clinical and clinical data can be interpreted in many different ways, and the FDA and other regulatory authorities may interpret our data differently than we do, which could halt or delay our clinical trials or prevent regulatory approval.

If any of the above 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.

Despite the FDA's designation of our MedPulser Electroporation Therapy System as a Fast Track product, we may encounter delays in the regulatory approval process due to additional information requirements from the FDA, unintentional omissions in our PMA for our MedPulser Electroporation Therapy System, or other delays in the FDA's review process. We may encounter delays or rejections in the regulatory approval process because of additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

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, pre-clinical testing, and clinical trial activities are subject to extensive regulation. Numerous governmental agencies in the U.S. 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 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.

EVEN IF OUR PRODUCTS ARE APPROVED BY REGULATORY AUTHORITIES, IF WE FAIL TO COMPLY WITH ON-GOING REGULATORY REQUIREMENTS, OR IF WE EXPERIENCE UNANTICIPATED PROBLEMS WITH OUR PRODUCTS, THESE PRODUCTS COULD BE SUBJECT TO RESTRICTIONS OR WITHDRAWAL FROM THE MARKET.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or certain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, including unanticipated adverse events of unanticipated severity or frequency, manufacturer or manufacturing processes or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures or detention, injunctions or the imposition of civil or criminal penalties.

FAILURE TO COMPLY WITH FOREIGN REGULATORY REQUIREMENTS GOVERNING HUMAN CLINICAL TRIALS AND MARKETING APPROVAL FOR OUR HUMAN-USE EQUIPMENT COULD PREVENT US FROM SELLING OUR PRODUCTS IN FOREIGN MARKETS, WHICH MAY ADVERSELY AFFECT OUR OPERATING RESULTS AND FINANCIAL CONDITIONS.

For marketing our MedPulser Electroporation Therapy System outside the United States, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country and may require additional testing. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approval on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. Failure to comply with these regulatory requirements or to obtain required approvals could impair our ability to develop

these markets and could have a material adverse effect on our results of operations and financial condition.

IF WE CANNOT MAINTAIN OUR EXISTING CORPORATE AND ACADEMIC ARRANGEMENTS AND ENTER INTO NEW ARRANGEMENTS, WE MAY BE UNABLE TO DEVELOP PRODUCTS EFFECTIVELY, OR AT ALL.

Our strategy for the research, development and commercialization of our product candidates may result in our entering into contractual arrangements with corporate collaborators, academic institutions and others. We have entered into sponsored research, license and/or collaborative arrangements with several entities, including Merck, Vical, Valentis, the U.S. Navy, Chiron and the University of South Florida, as well as numerous other institutions that conduct clinical trials work or perform pre-clinical research for us. Our success depends upon our collaborative partners performing their responsibilities under these arrangements and complying with the regulations and requirements governing clinical trials. We cannot control the amount and timing of resources our collaborative partners devote to our research and testing programs or product candidates, or their compliance with regulatory requirements which can vary because of factors unrelated to such programs or product candidates. These relationships may in some cases be terminated at the discretion of our collaborative partners with only limited notice to us. We may not be able to maintain our existing arrangements, enter into new arrangements or negotiate current or new arrangements on acceptable terms, if at all. Some of our collaborative partners may also be researching competing technologies independently from us to treat the diseases targeted by our collaborative programs.

IF WE ARE NOT ABLE TO CREATE EFFECTIVE COLLABORATIVE MARKETING RELATIONSHIPS, WE MAY BE UNABLE TO MARKET OUR MEDPULSER ELECTROPORATION THERAPY SYSTEM SUCCESSFULLY OR IN A COST-EFFECTIVE MANNER.

To effectively market our products, we will need to develop sales, marketing and distribution capabilities. In order to develop or otherwise obtain these capabilities, we may have to enter into marketing, distribution or other similar arrangements with third parties in order to sell, market and distribute our products successfully. To the extent we enter into any such arrangements with third parties, our product revenues are likely to be lower than if we directly marketed and sold our products, and any revenues we receive will depend upon the efforts of such third parties. We have no experience in marketing or selling pharmaceutical products and we currently have no sales, marketing or distribution capability. We may be unable to develop sufficient sales, marketing and distribution capabilities to commercialize our products successfully.

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 successful. 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 overly 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 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 and Trademark 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 Patent and Trademark Office 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 risks significant.

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.

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.

SERIOUS AND UNEXPECTED SIDE EFFECTS ATTRIBUTABLE TO GENE THERAPY MAY RESULT IN GOVERNMENTAL AUTHORITIES IMPOSING ADDITIONAL REGULATORY REQUIREMENTS OR A NEGATIVE PUBLIC PERCEPTION OF OUR PRODUCTS.

The MedPulser DNA Delivery System and any of our other Gene Therapy or DNA Vaccine product candidates under development could be broadly described as gene therapies. A number of clinical trials are being conducted by other pharmaceutical companies involving gene therapy, including compounds similar to, or competitive with, our product candidates. The announcement of adverse results from these clinical trials, such as serious unwanted and unexpected side effects attributable to treatment, or any response by the FDA to such clinical trials, may impede the timing of our clinical trials, delay or prevent us from obtaining regulatory approval or negatively influence public perception of our product candidates, which could harm our business and results of operations and depress the value of our stock.

The U.S. Senate has held hearings concerning the adequacy of regulatory oversight of gene therapy clinical trials, as well as the adequacy of research subject education and protection in clinical research in general, and to determine whether additional legislation is required to protect volunteers and patients who participate in such clinical trials. The Recombinant DNA Advisory Committee, or RAC, which acts as an advisory body to the National Institutes of Health, has expanded its public role in evaluating important public and ethical issues in gene therapy clinical trials. Implementation of any additional review and reporting procedures or other additional regulatory measures could increase the costs of or prolong our product development efforts or clinical trials.

We report to the FDA and other regulatory agencies serious adverse events, including those we believe may be reasonably related to the treatments administered in our clinical trials. Such serious adverse events, whether treatment-related or not, could result in negative public perception of our treatments and require additional regulatory review or measures, which could increase the cost of or prolong our clinical trials.

The FDA has not approved any gene therapy product or gene-induced product for sale in the United States. The commercial success of our products will depend in part on public acceptance of the use of gene therapy products or gene-induced products, which are a new type of disease treatment for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy products or gene-induced products are unsafe, and these treatment methodologies may not gain the acceptance of the public or the medical community. Negative public reaction to gene therapy products or gene-induced products could also result in greater government regulation and stricter clinical trial oversight.

WE CANNOT PREDICT THE SAFETY PROFILE OF THE USE OF OUR MEDPULSER ELECTROPORATION SYSTEM WHEN USED IN COMBINATION WITH OTHER THERAPIES.

Our trials involve the use of our MedPulser Electroporation System in combination with bleomycin, an anti-cancer drug. While the data we have evaluated to date suggest the MedPulser

Electroporation Therapy System does not increase the adverse effects of other therapies, we cannot predict if this outcome will continue to be true or whether possible adverse side effects not directly attributable to the other drugs will compromise the safety profile of our MedPulser Electroporation Therapy System when used in certain combination therapies or if used off-label with other drugs by physicians.

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 U.S., 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 U.S. and would have a serious effect on revenues and our business as a whole. Outside of the U.S., reimbursement and funding policies vary widely.

ANY ACQUISITION WE MIGHT MAKE MAY BE COSTLY AND DIFFICULT TO INTEGRATE, MAY DIVERT MANAGEMENT RESOURCES OR DILUTE STOCKHOLDER VALUE.

We have considered and made strategic acquisitions in the past, including Inovio AS in January 2005, and, in the future, may acquire or make investments in complementary companies, products or technologies. As part of our business strategy, we may acquire assets or businesses principally relating to or complementary to our current operations, and we have in the past evaluated and discussed such opportunities with interested parties. Any acquisitions we undertake will be

accompanied by the risks commonly encountered in business acquisitions. These risks include, among other things:

Potential exposure to unknown liabilities of acquired companies;

The difficulty and expense of assimilating the operations and personnel of acquired businesses;

Diversion of management time and attention and other resources;

Loss of key employees and customers as a result of changes in management;

Incurrence of amortization expenses related to intangible assets or large impairment charges; and

Possible dilution to our stockholders.

In addition, geographic distances may make the integration of businesses more difficult. We may not be successful in overcoming these risks or any other problems encountered in connection with any acquisitions.

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

We have limited 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 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;

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, the EU 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 that information regarding the success of our clinical trials maybe be obtained by the public prior to a formal announcement by us.

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 audit 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 found not to be 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.

IF WE LOSE KEY PERSONNEL OR ARE UNABLE TO ATTRACT AND RETAIN ADDITIONAL, HIGHLY SKILLED PERSONNEL REQUIRED TO DEVELOP OUR PRODUCTS OR OBTAIN NEW COLLABORATIONS, OUR BUSINESS MAY SUFFER.

We depend, to a significant extent, on the efforts of our key employees, including senior management and senior scientific, clinical, regulatory and other personnel. The development of new therapeutic products requires expertise from a number of different disciplines, some of which is not widely available. We depend upon our scientific staff to discover new product candidates and to develop and conduct pre-clinical studies of those new potential products. Our clinical and regulatory staff is responsible for the design and execution of clinical trials in accordance with FDA requirements

and for the advancement of our product candidates toward FDA approval. Our manufacturing staff is responsible for designing and conducting our manufacturing processes in accordance with the FDA's Quality System Regulations. The quality and reputation of our scientific, clinical, regulatory and manufacturing staff, especially the senior staff, and their success in performing their responsibilities, are a basis on which we attract potential funding sources and collaborators. In addition, our Chief Executive Officer and Chief Financial Officer and other executive officers are involved in a broad range of critical activities, including providing strategic and operational guidance. The loss of these individuals, or our inability to retain or recruit other key management and scientific, clinical, regulatory, manufacturing and other personnel, may delay or prevent us from achieving our business objectives. We face intense competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations.

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 and 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.

WE ARE EXPOSED TO POTENTIAL RISKS FROM RECENT LEGISLATION REQUIRING COMPANIES TO EVALUATE INTERNAL CONTROLS UNDER SECTION 404 OF THE SARBANES-OXLEY ACT OF 2002.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"), the Securities and Exchange Commission adopted rules requiring public companies to include a report of management on our internal controls over financial reporting in our annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal controls over financial reporting. In addition, our independent auditor must attest to and report on management's assessment of the effectiveness of our internal controls over financial reporting. This requirement first applied to our 2004 Annual Report on Form 10-K.

How companies are implementing these new requirements including internal control reforms, if any, to comply with Section 404's requirements, and how independent auditors are applying these new requirements and testing companies' internal controls, remains subject to uncertainty. The requirements of Section 404 are ongoing and apply to future years. We expect that our internal controls will continue to evolve as our business activities change. During the course of management's and our independent

auditor's review of our internal controls over financial reporting as of December 31, 2004, we did identify two significant control deficiencies that did not rise to the level of material weaknesses, as defined by the Public Company Accounting Oversight Board (PCAOB). Although we will continue to diligently and vigorously review our internal controls over financial reporting in order to ensure compliance with the Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met.

If, during any year, our independent auditor is not satisfied with our internal controls over financial reporting or the level at which these controls are documented, designed, operated, tested or assessed, or if the independent auditor interprets the requirements, rules or regulations differently than we do, then our independent auditor may decline to attest to management's assessment or may issue a report that is qualified. This could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively impact the market price of our stock.

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 4,121,303 shares of our common stock being offered in this prospectus.

Selling Stockholders

We originally sold and issued to the selling stockholders (i) shares of our common stock, (ii) shares of Series A preferred stock that are convertible into shares of our common stock, (iii) shares of Series B preferred stock that are convertible into shares of our common stock, (iv) shares of Series C preferred stock that are convertible into shares of our common stock, (v) shares of Series D preferred stock that are convertible into shares of our common stock, and/or (vi) warrants to purchase shares of our common stock, pursuant to transactions exempt from registration under the Securities Act of 1933, as amended.

Holder of Series A preferred stock, Series B preferred stock and/or Series C preferred stock 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. Holders of Series A preferred stock, Series B preferred stock and/or Series C preferred stock received shares of common stock as dividends on September 30, 2004 and/or December 31, 2004.

In January 2005, we consummated the acquisition of Inovio AS ("Inovio"), a Norwegian company. Under the terms of the transaction, we acquired the entire share capital of Inovio for an aggregate purchase price of \$10.0 million; \$3.0 million of the purchase price consisted of cash and \$7.0 million consisted of shares of Series D Convertible Preferred Stock, par value \$0.001 per share (the "Series D preferred stock"). We issued 1,966,292 shares of the Series D preferred stock in the transaction to certain shareholders of Inovio, all of whom were foreign persons outside the United States, based on the average closing price of our common stock as reported on the American Stock Exchange during the 30 trading day period immediately preceding the closing. The shares of Series D preferred stock are convertible to shares of our common stock on a one-for-one basis.

In January 2005, we completed a private placement to accredited investors whereby we sold 1,540,123 shares of our common stock at a purchase price of \$4.05 per share and issued warrants to purchase 508,240 shares of our common stock at an exercise price of \$5.50 per share, which resulted in aggregate cash proceeds of \$3.03 million (assuming no exercise of the warrants). A portion of this private placement involved investors who converted \$3.2 million of their previous investment in our Series C preferred stock into 790,123 shares of the common stock issued as part of this private placement with no associated cash proceeds to us.

In connection with the signing of the lease for our new corporate headquarters, we issued a warrant to purchase 50,000 shares of our common stock at \$5.00 per share to the landlord of this leased facility in December 2004.

The shares of common stock being registered hereby are (i) shares underlying the Series D preferred stock, (ii) shares underlying warrants exercisable to purchase shares of common stock, (iii) shares received as dividends, and/or (iv) shares of common stock, acquired pursuant to the transactions described above. The shares of common stock are being registered to permit public sales of the shares, 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 March 8, 2005 are included. Those shares, however, are not deemed outstanding for the purpose of computing the

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percentage ownership of any other selling stockholder. Each selling stockholder's percentage of ownership in the following table is based upon 19,999,625 shares of common stock outstanding as of March 8, 2005.

With the exception of Avtar Dhillon, a director and our Chief Executive Officer and President, Peter Kies, our Chief Financial Officer, Bernard Hertel, our Manager of Investor Relations, Brook Riggins, our former Vice President of Finance and Corporate Communications, Dietmar P. Rabussay, our Vice President of Research & Development, Eugene Larson, a director, George McHugh, our Vice President of Operations, Jacob Mathiesen, our Executive Director of Gene Delivery, Paul Goldfarb, our Consulting Medical Director, Punit Dhillon, our Director of Finance and Corporate Communications, James Heppell, our Chairman of the Board of Directors, Riaz Bandali, a director, Robert Goodenow, our Vice President of Corporate Development, Simon Benito, a director, Tazdin Esmail, a director, Felix Theeuwes, a director, the selling stockholders listed below do not have, and have not had for the past three years, any position or office with, been employed by, or otherwise had a material relationship with us. 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.

Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Number of Shares of Common Stock Beneficially Owned After Completion of the Offering(1)	Percentage of Shares of Common Stock Beneficially Owned After Completion of the Offering(1)
Alpha Capital	50,774(2)	*	1,166	49,608	*
Arlin Miller Multiples	13,170(3)	*	13,170		*
Selvaag Invest AS	314,757(4)	1.55%	314,757		*
Avtar S. Dhillon	483,106(5)	2.37%	185	482,921	2.36%
B.C. Equities Inc.	11,851(6)	*	185	11,666	*
BayStar Capital II, LP	1,002,715(7)	4.95%	985,185	357,655	1.76%
Bernard Hertel	54,661(8)	*	46	54,615	*
Brook Riggins	45,192(9)	*			