INOVIO BIOMEDICAL CORP
Form S-3
January 27, 2006

As Filed with the Securities and Exchange Commission on January 27, 2006 **Registration No. 333-**

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

INOVIO BIOMEDICAL CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Delaware	**3841**	**33-0969592**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

11494 Sorrento Valley Road
San Diego, California 92121
Telephone (858) 597-6006
Facsimile (858) 597-0119

(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

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(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. o

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. ý

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

If this form is a post-effective amendment filed pursuant to 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. o

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

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 (2)	Amount of Registration Fee
Common Stock, $.001 par value (3)	13,782,127	$2.225	$30,665,233	$3,281.18

(1) The shares of common stock being registered hereunder are being registered for resale by the selling stockholders named in the prospectus or a prospectus supplement (the selling stockholders) and includes 3,737,053 shares issuable upon exercise of outstanding warrants. 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) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(c) based on the average of the high and low prices of Registrant s common stock on the American Stock Exchange on January 24, 2006.

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 January 27, 2006

PROSPECTUS

13,782,127 Shares

Common Stock

This prospectus relates to 13,782,127 shares of common stock of Inovio Biomedical Corporation that may be sold from time to time by the selling stockholders named in this prospectus beginning on page 26. Of these shares, 10,045,074 shares are issued and outstanding and 3,737,053 shares are issuable upon exercise of outstanding warrants. We originally issued the shares and warrants in private transactions. The selling stockholders may offer their shares through public or private transactions, on or off the American Stock Exchange, at prevailing market prices, or at privately negotiated prices. For details of how the selling stockholders may offer their Inovio common stock, please see the section of this prospectus called Plan of Distribution beginning on page 36. We will not receive any proceeds from the sales of shares by the selling stockholders.

Our common stock is traded on the American Stock Exchange under the symbol INO. On January 26, 2006, the last reported sale price for our common stock on the American Stock Exchange was $2.36 per share.

The securities offered by this prospectus involve a high degree of risk. See Risk Factors beginning on page 8.

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 ,2006

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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.

ABOUT INOVIO

We are a San Diego-based biomedical company whose technology platform is based on medical devices that use electroporation therapy, or EPT, to deliver drugs and genes into cells. We are developing and seeking to commercialize 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 our Medpulser® Electroporation Therapy System in Europe. Inovio s system delivers electrical pulses to tumors injected with the generic drug bleomycin. The distinctive 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 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.

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 remove, or 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. Cryoablation is a technique that freezes cancer cells with liquid nitrogen. Radio ablation uses radio frequency energy to heat tissue to a high enough temperature to ablate it, or cause cell death. 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 may 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. To our knowledge, 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 our 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, i.e., certain genetically engineered viruses used as carriers or vectors to deliver DNA to the cell. 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.

We incurred a net loss attributable to common stockholders of $14.8 million for the nine months ended September 30, 2005, and had working capital of $2.4 million and an accumulated deficit of $102.7 million as of September 30, 2005. In December 2005, we successfully raised gross cash proceeds of approximately $15.8 million (including $2.4 million due from one of the investors as part of a funding commitment made, and promissory note delivered, to us in January 2005) through the sale of our common stock and warrants (see Recent Developments below). Net cash proceeds from this sale were approximately $14.8 million. However, despite our receipt of these funds, our ability to continue as a going concern is dependent upon our ability to obtain additional capital and to achieve profitable operations. We will continue to rely on outside sources of financing to meet our capital needs for 2007 and beyond. The outcome of whether we will ever be able to achieve profitable operations or continue to obtain additional capital cannot be predicted at this time. Further, there can be no assurance, assuming we successfully raise additional funds, that we will achieve positive cash flow or successfully commercialize our products. If we are not able to secure additional funding, we will be required to scale back our research and development programs, preclinical studies and clinical trials, and general and administrative activities and may not be able to continue in business. Including the cash proceeds received from our December 2005, January 2005, May 2004 and July 2003 financings discussed below, various licensing payments, the exercise of employee stock options and investor warrants, we believe we have sufficient funds to fund our operations for at least the next 12 months.

Our principal executive offices are located at 11494 Sorrento Valley Road, San Diego, California 92121-1318, and our telephone number is (858) 597-6006. Our website address is www.inovio.com. Effective March 31, 2005, we changed our name from Genetronics Biomedical Corporation to Inovio Biomedical Corporation and effective April 4, 2005, our American Stock Exchange ticker symbol changed from «GEB» to «INO.»

Recent Developments

In January 2006, we announced that we have been granted two new U.S. patents relating to the use of electroporation to deliver useful therapeutic agents in humans. The first patent includes claims for in vivo electroporation of muscle tissue. We believe this patent enhances the intellectual property for *in vivo* applications of electroporation and expands the coverage of our primary patents directed at basic electroporation methodologies that are important in the multiple Phase I clinical studies being conducted by our strategic partners. The second patent includes claims methods for the use of electroporation to deliver DNA and other nucleic acids into skin for the purpose of DNA vaccination and gene therapy. We believe DNA electroporation of the skin expands the delivery methods toward the development of next generation DNA vaccines and gene therapeutics in an area we are actively partnering

In December 2005, we completed a private placement of an aggregate of approximately $15.8 million in gross cash proceeds through the sale of our common stock to institutional and accredited investors, which included Merck & Co. Inc. and Vical Inc., two of our strategic partners. Net cash proceeds from this sale were approximately $14.8 million. The common stock was priced at $2.40 per share, which represented a premium to the closing price on December 15, 2005. In addition, we issued to the investors five-year warrants to purchase 35% of the number of shares of common stock they acquired in the offering at an exercise price of approximately $2.93 per share, a 25% premium to the closing price on December 15, 2005. In addition to the securities sold for cash in the private placement, we also issued shares of common stock and warrants on the same terms as the corresponding securities that were sold for cash to certain holders of our outstanding Cumulative Convertible Preferred Stock in exchange for their Preferred Stock pursuant to existing participation rights applicable to our new equity financings and to certain holders of our outstanding common stock in

exchange for our common stock. Gross cash proceeds from this funding included $2.4 million due from an investor, as part of their funding commitment made, and promissory note delivered, to us in January 2005. As a result of the use by these existing holders of our Preferred Stock and Common Stock to acquire our shares and warrants in this private placement, we expect to report a non-cash imputed dividend charge that we estimate will be approximately $8.3 million in our consolidated statement of operations for the year ended December 31, 2005. This imputed dividend charge will be calculated using guidance contained in Emerging Issues Task Force (EITF) Issue No. 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments. Our estimate regarding the range of the non-cash imputed dividend charge to be recorded for the year ended December 31, 2005 is a forward looking statement. The actual charge may be more or less depending on any adjustments we make as a result of the audit of our financial statements for the year ended December 31, 2005 by our independent registered public accounting firm.

In October 2005, we announced the initiation of a Phase I clinical trial to treat locally recurrent cancer after a mastectomy or partial mastectomy using Inovio s Selective Electrochemical Tumor Ablation, or SECTA, therapy. This study is designed to demonstrate that Inovio s innovative SECTA therapy, which provides discriminating selectivity in killing cancerous cells, can preserve surrounding healthy tissue when treating solid tumors while providing equivalency to surgery in terms of local tumor control. As an alternative to mastectomy for managing recurrences after prior breast conserving therapy, SECTA could potentially provide important quality of life benefits to breast cancer patients. This FDA-approved study is a multi-center, open label, single treatment arm trial and may enroll up to 24 patients with locally recurrent or metastatic in-breast carcinoma after partial mastectomy (lumptectomy) or cutaneous or sub-cutaneous recurrent or metastatic carcinoma of the breast or chest wall following mastectomy. The primary endpoint of this study is to assess the safety profile of Inovio s electroporation-based SECTA therapy in conjunction with bleomycin injected into a lesion. Secondary endpoints include an assessment of histopathology and objective tumor response through 24 weeks.

In October 2005, we announced that we have been granted a new patent for transdermal applications (i.e., applications to the skin) of our technology. This patent claims an apparatus that uses electroporation to deliver a therapeutic agent to and through the skin for medical applications, such as for delivering drugs or agents for cosmetic purposes. This patent expands Inovio s protected intellectual property to a handheld electroporation device that can be battery powered and offers a variety of electrode configurations.

In September 2005, we announced that we had been awarded an appropriation of approximately $1 million by the United States Department of Defense for the development of its gene delivery electroporation technology for application to vaccinations against infectious diseases, including potential bioterrorism agents. The United States Congress appropriated the funding in the Defense Appropriations Bill for 2005. The appropriation is a continuation of the first United States Army grant received by Inovio AS in Norway last year. The Inovio gene delivery system is a proprietary process for genetic immunization. It utilizes intramuscular electroporation of DNA, encoding selected antigens to induce immune responses. Compared to conventional vaccines, DNA vaccines delivered using electroporation appear to afford several important advantages in enhancing the onset and level of immunity generated, which may be critical in attempting to address threats posed by pandemics or bioterrorism. Numerous genes can be isolated from potential infectious organisms, sequenced, and then synthesized for vaccination of the population or military in order to induce a protective immune response. We expect to recognize the majority of the revenue from this grant beginning in 2006.

In July 2005, we announced along with our partner Vical Inc. the initiation of a human Phase 1 study of an investigational method of delivering interleukin-2 (IL-2), a potent immune system stimulant, for patients with recurrent metastatic melanoma. Intravenous delivery of IL-2 protein is approved as a treatment for metastatic melanoma, but frequently causes severe systemic toxicities. The novel treatment

approach being studied in this trial involves direct injection into a tumor lesion of plasmid DNA, or pDNA, encoding IL-2 followed by electroporation, the local application of electrical pulses designed to enhance the uptake of the pDNA into tumor cells. The pDNA is designed to cause cells within the tumor to produce high levels of IL-2 protein locally and stimulate the immune system to attack the tumor without the associated systemic toxicities. The protocol for this trial contemplates that treatments will be administered once a week in two four-week cycles, with each cycle followed by a four-week observation period. The initial dose-escalation phase of the trial will enroll up to three patients each at doses of 0.5 mg, 1.5 mg and 5 mg delivered to a single tumor lesion per patient, with a final group receiving 5 mg in each of three tumor lesions per patient. Up to 17 additional patients will be treated at the highest tolerated dose. The primary endpoint in the trial is safety. Secondary efficacy endpoints will also be monitored.

In July 2005, we received a $2 million milestone payment from Merck & Co., Inc. resulting from the achievement of a clinical milestone by Merck for a plasmid-based vaccine using Inovio s MedPulser® DNA Delivery System. The milestone relates to Inovio s license and collaboration agreement with Merck that was initiated in May 2004 for the development of certain DNA vaccines. Further development of the product may lead to additional milestone payments and royalties to Inovio. Inovio received this milestone payment for its contribution to the collaboration, which has demonstrated the high level of gene delivery and expression that is thought to be necessary for the induction of a therapeutic immune response. Merck has funded all clinical development costs of this product to date.

In May 2005, Merck exercised an option for a non-exclusive license for an additional antigen to be used with Inovio s MedPulser® DNA Delivery System, which is being developed for use with certain of Merck s DNA vaccine research programs. This option was also created under our 2004 license and research collaboration agreement with Merck and brings the total number of antigens licensed by Merck so far to three. A limited number of additional options for further target antigens remain available for Merck to license under our 2004 license and research collaboration agreement with Merck. We received the option fee of $500,000, which is characterized as a license payment in our financial statements, in June 2005, and along with other license payments received from Merck in 2004 and 2005, will be amortized over the remaining minimum term of our agreement with Merck.

In April 2005, we announced the initiation of a Phase I/II clinical trial undertaken in collaboration with the University of Southampton of Inovio s DNA delivery technology. This trial has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom and will investigate Inovio s DNA delivery technology to deliver a therapeutic plasmid-based DNA vaccine to skeletal muscles with the aim of treating recurrent prostate cancer. The trial is sponsored and led by the University of Southampton, to investigate whether its DNA vaccine can stimulate patients to develop immune responses against prostate cancer and whether use of Inovio s electroporation system enhances this response. In this Phase I/II open-label study, plasmid DNA encoding a prostate tumor antigen is delivered directly to skeletal muscles in patients with recurrent prostate cancer either by simple injection or using Inovio s proprietary DNA delivery system. This technology, which has been shown in preclinical studies to induce antigen production and generation of an immune response against the tumor antigen, uses electroporation to enable the entry and uptake of plasmid DNA into the muscle cells.

In March 2005, we announced that we have been granted a patent for a vascular application of our technology. The patent was granted for the invention that brief electrical pulses of relatively high field strength applied to blood vessels cause a widening of the inner diameter, or lumen, of the treated vessels. This allows for enhanced blood flow while lowering local blood pressure. We believe this procedure may have the potential to be applied beneficially to patients who suffer from partially or totally blocked arteries or veins, either by administering electrical field pulses by themselves or in conjunction with angioplasty.

In March 2005, we announced the initiation of a Phase I clinical trial to treat pancreatic cancer using our Medpulser® Elecroporation Therapy System. The FDA has granted us orphan designation for this indication. The primary endpoint of this study is to determine the safety profile of the Medpulser® electroporation therapy in conjunction with intralesionally-injected (i.e., tumor injected) bleomycin for the treatment of unresectable (i.e., unable to be removed by surgery) locally advanced pancreatic cancer. The secondary endpoints are to assess objective tumor response, patient pain, and weight loss over 24 weeks following electroporation therapy. Our aim is to complete enrollment of up to 12 patients by the end of the second quarter of 2006.

SPECIAL NOTE ON FORWARD LOOKING STATEMENTS

This prospectus and the documents and information incorporated by reference in this prospectus, such as under the heading About Inovio in this prospectus and 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 wor 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 COMMERCIALLY 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 any of our 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 have started additional clinical studies for 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 medical device 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 revenue 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.

Our plans for continuing clinical trials, conducting research, furthering development and, eventually, marketing our human-use equipment will involve substantial costs. The extent of our 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 then 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 then 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 changes in scope and cost of our research and development and clinical trial activities;

An increase or 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 then 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.

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 may be obtained by the public prior to a formal announcement by us. These factors, as well as the other factors described in this Report, could significantly affect the price of our stock.

WE HAVE A HISTORY OF LOSSES, WE EXPECT TO CONTINUE TO INCUR LOSSES AND WE MAY NOT ACHIEVE OR MAINTAIN PROFITABILITY

As of September 30, 2005, we had an accumulated deficit of $102.7 million. We have operated at a loss since 1994, and we expect this to continue for some time. The amount of the accumulated deficit will continue to increase, as it will be expensive to continue clinical, research and development efforts. If these activities are successful and if we receive approval from the FDA to market equipment, then even more funding will be required to market and sell the equipment. We are evaluating potential partnerships as an additional way to fund operations. We will continue to rely on outside sources of financing to meet our capital needs beyond next year. The outcome of these matters cannot be predicted at this time.

Further, there can be no assurance, assuming we successfully raise additional funds, that we will achieve positive cash flow. If we are not able to secure additional funding, we will be required to further scale back our research and development programs, preclinical studies and clinical trials, general, and administrative activities and may not be able to continue in business. Including the cash proceeds received

from the January 2005, May 2004 and July 2003 financings, various licensing payments, the exercise of employee stock options and investor warrants, we believe we have sufficient funds to fund operations for at least the next 12 months.

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 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.

A SMALL NUMBER OF LICENSING PARTNERS ACCOUNT FOR A SUBSTANTIAL PORTION OF OUR REVENUES AND OUR RESULTS OF OPERATIONS AND FINANCIAL CONDITION COULD SUFFER IF WE LOSE THESE LICENSING PARTNERS OR FAIL TO ADD ADDITIONAL LICENSING PARTNERS IN THE FUTURE.

We derive a significant portion of our revenue from a limited number of licensing partners in each period. Accordingly, if we fail to sign additional future contracts with major licensing partners, if a licensing contract is delayed or deferred, or if an existing licensing contract expires or is cancelled and we fail to replace the contract with new business, our revenue could be adversely affected. Until commercialization of our Medpulser® Electroporation Therapy System, we expect that a limited number of licensing partners will continue to account for a substantial portion of our revenue in each quarter in the foreseeable future. During the nine months ended September 30, 2005, one licensing partner, Merck, accounted for approximately 78% or $3.6 million of our consolidated revenue.

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 and second primary head and neck cancers. In addition, we are conducting two Phase IV (or Pre-Marketing) clinical trials of our Medpulser® Electroporation Therapy System for the treatment of new and recurrent head and neck cancers and new and recurrent primary skin cancers, and have started 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.

The patients admitted to our oncology clinical trials conducted in the United States and Europe are experiencing late stage cancer and are in a diminished physical state prior to entering our studies and thus these patients can experience serious adverse events (SAEs) whether due to our technology or other procedures. To date, there have been seven SAEs that were at least possibly related to our technology that resulted in death, a life-threatening experience, and hospitalization or prolongation of existing hospitalization. All seven of these serious adverse events were reported to the FDA. The SAEs were excessive bleeding in the tumor bed, edema of larynx, sudden death (suspected heart failure), weight loss, sudden death (cause unknown), obstruction of the airway, and death (suspected internal bleeding). Because our studies are controlled and ongoing, we cannot assure you that these or other serious adverse events will not delay or prevent approval of our product by the FDA.

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, such FDA designation is independent of the FDA s Priority Review and Accelerated Approval designations and 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.

A majority of our operating expenses relate to our clinical trials. 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:

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;

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