

GENETRONICS BIOMEDICAL CORP

Form S-3/A

February 25, 2002

**Table of Contents**

As filed with the Securities And Exchange Commission on February 25, 2002

Registration No. 333-76738

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**AMENDMENT NO. 1  
TO FORM S-3**

**REGISTRATION STATEMENT  
Under  
THE SECURITIES ACT OF 1933**

**GENETRONICS BIOMEDICAL CORPORATION**

(Exact Name of Registrant as Specified in Its Charter)

---

**Delaware** **33-0969592**  
(State or Other Jurisdiction) (IRS Employer Identification Number)  
of Incorporation or Organization)

**11199 Sorrento Valley Road  
San Diego, CA 92121-1334  
(858) 597-6006**  
(Address, Including Zip Code, and Telephone Number, Including  
Area Code, of Registrant's Principal Executive Offices)

---

**Avtar Dhillon  
President, Chief Executive Officer  
11199 Sorrento Valley Road  
San Diego, CA 92121-1334  
(858) 597-6006**  
(Name, Address, Including Zip Code, and Telephone Number, Including  
Area Code, of Agent for Service)

---

**Copies to:**

**Douglas J. Rein, Esq.  
Gray Cary Ware & Freidenrich LLP  
4365 Executive Drive, Suite 1100  
San Diego, CA 92121-2133  
Telephone: (858) 677-1400  
Facsimile: (858) 677-1477**

---

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



**Table of Contents**

If the only securities being registered on this Form are being 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.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, 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.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant 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.**

---

---

---

**Table of Contents**

**PROSPECTUS**

**GENETRONICS BIOMEDICAL CORPORATION  
9,289,990 SHARES OF COMMON STOCK**

The selling stockholders of Genetronics Biomedical Corporation listed on Pages 19 and 20 of this prospectus may offer and resell up to 9,289,990 shares of Genetronics Biomedical Corporation common stock under this prospectus. All of the shares offered hereunder are to be sold by the selling stockholders; we will not receive any proceeds from this offering.

Our common stock is traded on the American Stock Exchange and the Toronto Stock Exchange under the symbol GEB. The address of our principal executive offices is: 11199 Sorrento Valley Road, San Diego, California 92121-1334. Our telephone number is (858) 597-6006. On February 22, 2002, the last sale price of our common stock as reported on the American Stock Exchange was \$0.63.

**The information in the prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement 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.**

**This investment involves a high degree of risk. You should purchase shares only if you can afford a complete loss of your investment**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense**

**See Risk Factors beginning on Page 6 for a discussion of certain factors that should be considered by prospective purchasers of shares of our common stock.**

You should not assume that the information in this prospectus is accurate as of any date other than the date below.

The date of this prospectus is February 25, 2002.

---

**TABLE OF CONTENTS**

SUMMARY INFORMATION

RISK FACTORS

WHERE YOU CAN FIND MORE INFORMATION

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

SELLING STOCKHOLDERS

PLAN OF DISTRIBUTION

USE OF PROCEEDS

LEGAL MATTERS

EXPERTS

PART II

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

ITEM 16. EXHIBITS

ITEM 17. UNDERTAKINGS

SIGNATURES

INDEX TO EXHIBITS

EXHIBIT 5.1

EXHIBIT 21.1

EXHIBIT 23.1

EXHIBIT 23.2

EXHIBIT 99.1

---

**Table of Contents**

**Table of Contents**

	<b>Page</b>
Summary Information	5
Risk Factors	
6	
Where You Can Find More Information	
19	
Incorporation of Certain Documents by Reference	
19	
Selling Stockholders	
20	
Plan of Distribution	
22	
Use of Proceeds	
23	
Legal Matters	
23	
Experts	
23	

---

You should rely only on the information contained or incorporated by reference in this prospectus. No one has been authorized to provide you with different information.

---

**Table of Contents**

**SUMMARY INFORMATION**

You should read this summary together with the more detailed information and/or financial statements and notes appearing elsewhere in this prospectus and in the documents incorporated into this prospectus by reference. You should carefully consider, among other things, the matters set forth in Risk Factors. ALL DOLLAR AMOUNTS SET FORTH IN THE PROSPECTUS ARE STATED IN UNITED STATES DOLLARS, EXCEPT WHERE OTHERWISE INDICATED.

We are a drug and gene delivery company specializing in developing technology and hardware focused on electroporation. Electroporation is the application of brief, controlled pulsed electric fields to cells, which cause tiny pores to temporarily open in the cell membrane. Immediately after electroporation, the cell membrane is more permeable to drugs and other agents. The use of electroporation along with these other agents is called electroporation therapy.

We operate through two divisions: (i) the Drug and Gene Delivery Division, through which we are developing drug and gene delivery systems based on electroporation to be used in the treatment of disease and, (ii) the BTX Instrument Division, which develops, manufactures, and sells electroporation equipment to the research laboratory market.

The Drug and Gene Delivery Division focuses on the development of human-use equipment that is designed to allow physicians to use electroporation therapy to achieve more efficient and cost-effective delivery of drugs or genes to patients with a variety of illnesses, including cancer. Our proprietary electroporation drug and gene delivery system, the MedPulser® system, has been used with bleomycin, a chemotherapeutic agent, in clinical trials conducted in the United States, Australia, Europe and Canada for treatment of head and neck cancer, as well as melanoma, liver, pancreatic, basal cell and Kaposi sarcoma cancers.

The BTX Instrument Division is a leader in the development and marketing of electroporation instruments and supplies, with more than 2,000 customers in universities, companies, and research institutions worldwide. The BTX Instrument Division produces an extensive line of electroporation instruments and accessories, including electroporation and cell fusion instruments, a monitoring device, and an assortment of electrodes and accessories. These instruments and accessories are used for research purposes only and are not used directly upon human subjects. Electroporation in research is commonly used for the transformation and transfection of all cell types, as well as for general molecular delivery at the cellular level. Transformation is a process by which the genetic material carried by an individual cell is altered by the incorporation of exogenous DNA into its genome. Transfection is the uptake, incorporation, and expression of exogenous DNA by eukaryotic cells.

We currently sell instrumentation and accessories in all states and territories of the United States and in over 47 foreign countries. The main distributors of our products in North America are VWR Scientific Products Corporation and Fisher Scientific Company, two of the largest laboratory products suppliers in the United States. In addition, the BTX Instrument Division distributes instruments and supplies through Intermountain Scientific Corporation, which has 23 field sales specialists in the United States. The BTX Instrument Division has over 45 international distributors in 36 countries, of which Merck Eurolab Holding GmbH is the main distributor in Europe.

All our business activities are conducted through Genetronics, Inc., a California corporation. Our common shares trade on the Toronto Stock Exchange and on the American Stock Exchange under the symbol GEB. A more complete description of our business and its recent activities can be found in the documents described in WHERE YOU CAN FIND MORE INFORMATION on Page 18.



**Table of Contents**

**RISK FACTORS**

In addition to the other information in this prospectus or incorporated in this prospectus by reference, you should consider carefully the following factors in evaluating our business before purchasing the common stock offered by this prospectus. If any of the following risks actually occur, our business or results of operations could be seriously harmed. In that case, the trading price of our common shares could decline, and you may lose part or all of your investment. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.

This prospectus, including the information incorporated by reference, contains forward-looking statements made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Actual results could differ materially from those projected in the forward-looking statements as a result of the risk factors set forth beginning on this page and others detailed from time to time in our periodic reports filed with the SEC.

***We Have Operated At A Loss And We Expect To Continue To Accumulate A Deficit; There Is A Doubt About Our Ability To Continue As A Going Concern .***

As of December 31, 2001, we had a deficit of \$47,361,720. We have operated at a loss since 1994, and we expect this to continue for some time. The amount of our accumulated deficit will continue to grow, as it will be expensive to continue our clinical, research, and development efforts. If these activities are successful, and if we receive approval from the FDA to market human-use equipment, then even more money will be required to market and sell the equipment.

Most of the cash we have received during the fiscal year beginning April 1, 2001 came from the sale and distribution of special warrants in November of 2001 and sales of BTX research-use equipment. Other funds came from collaborative research arrangements, interest income on our investments and the exercise of stock options. We do not expect to receive enough money from these sources to completely pay for future activities. There is substantial doubt about our ability to continue as a going concern due to our historical negative cash flow and because we do not have access to sufficient committed capital to meet our projected operating needs for at least the next twelve months.

***We Will Have A Need For Significant Amounts Of Money In The Future And There Is No Guarantee That We Will Be Able To Obtain The Amounts We Need.***

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

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

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

The costs involved in patenting our technologies and defending them;

**Table of Contents**

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

The cost of manufacturing our human-use and research-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 money to meet our needs.

In the past, we have raised funds by public and private sale of our stock, and we may 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 money needed to fund operations, or that we will be able to raise money under terms that are favorable to us.

***If We Do Not Have Enough Money To Fund Operations, Then We Will Have To Cut Costs.***

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

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

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

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

***If We Are Not Successful Developing Our Current Products, Our Business Model May Change As Our Priorities and Opportunities Change; And 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

**Table of Contents**

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. For example, we recently had to make a decision to forego commercial marketing opportunities in Europe given our financial condition.

***If We Do Not Successfully Commercialize Products From Our Drug and Gene Delivery Division, Then Our Business Will Suffer.***

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

***Pre-Clinical And Clinical Trials Of Human-Use Equipment Are Unpredictable; If We Experience Unsuccessful Trial Results Our Business Will Suffer.***

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

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

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

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

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

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

**Table of Contents**

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

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

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

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

***Our Business Is Highly Dependent On Receiving Approvals From Various United States And International Government Agencies And Will Be Dramatically Affected If Approval To Manufacture And Sell Our Human-Use Equipment Is Not Granted.***

The production and marketing of our human-use equipment and the ongoing research, development, preclinical testing, and clinical trial activities are subject to extensive regulation. Numerous governmental agencies in the US and internationally, including the FDA, must review our applications and decide whether to grant approval. All of our human-use equipment must go through an approval process, in some instances for each indication in 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 us:

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;

Currently, our clinical protocol for Phase III Clinical Trials is being reviewed by the FDA. While we anticipate ultimate approval of this protocol (perhaps with some modifications), we will not know for certain until the FDA responds. We are unable, due to the complexities of completing Phases III clinical trials, to estimate the length of time involved in obtaining approval of this protocol from the FDA. Failure to receive permission to enter Phase III Clinical Trials could be devastating to our efforts to raise further funding for our work;

**Table of Contents**

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

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

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

***We Rely Heavily On Collaborative And Licensing Relationships, And Will Be Negatively Affected If We Cannot Maintain Or Expand Existing Relationships, And Initiate New Ones.***

We rely and will continue to rely on partners and collaborators to fund a portion of our research and development expenses and to assist us in the research and development of our human-use equipment. Currently, two-thirds of our research and development expenses are funded by our partners and collaborators. Specifically, such collaborations and partnerships can provide the financial resources necessary to pay the salaries and other overhead expenses related to research. Some of our research efforts are funded by such partnerships. Our largest partner at this time is Valentis, Inc. In November 2001, we entered into a non-exclusive license with Valentis, whereby Valentis obtained rights to use our electroporation technology in the development of certain Genemedicine products. The Valentis arrangement calls for an upfront payment followed by milestone payments as well as a supply agreement between the two companies. In the past, we encountered operational difficulties after the termination of a similar agreement by a former partner, Ethicon, Inc., a Johnson & Johnson company. 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. In order to obtain the funding necessary for these projects we pursued other licensing and development arrangements as well as private equity investments. Furthermore, the termination of this partnership damaged our reputation in the biotechnology community. While termination of, or any significant change in, any of our material collaborative relationships could adversely impact our business, the termination of the Ethicon partnership was the most significant to date. The Valentis partnership is not of the same size and scope as the Ethicon partnership and termination of the Valentis partnership would not, in and of itself, cause us to cease operations due to financial concerns. Termination of the Valentis partnership, however, would present operational difficulties as we would be required to reallocate existing and anticipated resources among various potential uses. We would likely have to defer or curtail our development activities in one or more areas because potential revenues available under the terms of the relationship would go unrealized.

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. In 1998, we signed a supply agreement with Abbott Laboratories under which Abbott would sell us bleomycin for inclusion in our package. If it becomes necessary or desirable to include bleomycin in our package, and this relationship with Abbott should be terminated, then 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 universities and companies 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.

**Table of Contents**

Nevertheless, there is always risk that:

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

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

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

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

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

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

***We Could Be Substantially Damaged If Physicians And Hospitals Performing Our Clinical Trials Do Not Adhere To Protocols Or Promises Made In Clinical Trial Agreements.***

Our company also works and has 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.

For instance:

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

**Table of Contents**

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. This increases our liability, affects the data, and can damage our reputation.

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

***We Rely Heavily On Our Patents And Proprietary Rights To Attract Partnerships And Maintain Market Position.***

Another factor that will influence our success is the strength of our patent portfolio. Patents give the patent holder the right to prevent others from using its patented technology. If someone infringes upon the patented material of a patent holder, then the patent holder has the right to initiate legal proceedings against that person to protect the patented material. These proceedings, however, can be lengthy and costly. We are in the process of performing an ongoing review of our patent portfolio to confirm that our key technologies are adequately protected. If we determine that any of our patents require either additional disclosures or revisions to existing information, we may ask that such patents be reexamined or reissued, as applicable, by the United States patent office.

The patenting process, enforcement of issued patents, and defense against claims of infringement are inherently risky. Because our Drug and Gene Delivery Division relies heavily on patent protection, for us, the risks are significant and include the following:

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

**Risk 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 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 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

**Table of Contents**

and losing an infringement battle. If we 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, makes these significant risks.

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

***We Run The Risk That Our Technology Will Become Obsolete Or Lose Its Competitive Advantage.***

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

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

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

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

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

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



**Table of Contents**

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

Despite these competitive threats, we feel that our position in electroporation therapy is very competitive in that we have extensive clinical trials behind us, we are attempting to get approval for our Phase III clinical protocol, and we believe that the state of our technology development is equal to, and in some cases superior to, that of our competitors. Specifically, we believe that our methodologies for drug and gene delivery are quite competitive in that our proprietary needle arrays allow for more efficacious delivery of drug and genes to targeted areas.

***Our Ability To Achieve Significant Revenue From Sales Or Leases Of Human-Use Equipment Will Depend On Establishing Effective Sales, Marketing And Distribution Capabilities Or Relationships And We Lack Substantial Experience In These Areas.***

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

***The Market For Our Stock Is Volatile, Which Could Adversely Affect An Investment In Our Stock.***

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

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

Adverse clinical trial results;

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

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

Cancellation of important corporate partnerships or agreements;

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

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

A decreasing cash-on-hand balance to fund operations, or other signs of apparent financial uncertainty; and

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

**Table of Contents**

***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.

***Our BTX Instrument Division Markets Only To The Electroporation Product Niche Markets And Relies On Distribution Relationships For Sales.***

The BTX Instrument Division currently markets only electroporation equipment to the research market. If our research-use equipment loses its competitive position, because the BTX Instrument Division does not have any other product line on which to rely, our sales would likely decline. Therefore, if we do not develop and introduce new products directed to research-use electroporation, at a reasonable price, then we will lose pace with our competitors. We may not have the necessary funds for our BTX Instrument Division to stay competitive and that division may not ultimately succeed.

The research-use equipment is sold through United States and international distributors. Approximately 42% of BTX instrument sales during the nine months ended December 31, 2001 were in the United States and Europe through our distribution relationships with Fisher Scientific Products Corporation, VWR Scientific Products Corporation and Merck Eurolab Holding GmSH (both VWR and Merck Eurolab are members of the Merck Group). This accounted for roughly 41% of our total revenue during this period. We rely heavily on our relationship with VWR and Merck Eurolab to sell our product in the United States and Europe. We may not be able to maintain or replace our current distribution relationship with VWR, Merck Eurolab or other distributors, or establish sales, marketing and distribution capabilities of our own. If we cannot develop or maintain distribution relationships for major markets such as the United States, Europe and Japan, then the BTX Instrument Division may suffer declining sales, which would have an effect on our financial performance.

***There Is A Risk Of Product Liability With Human-Use Equipment And Research-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

**Table of Contents**

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, and with respect to the research-use equipment that is currently marketed by our BTX Instrument Division, 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.

With respect to our research-use equipment, 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. Our sales agreements typically 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 And Research-Use Equipment In Sufficient Volumes At Commercially Reasonable Rates.***

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.

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

***Our BTX Instrument Division Must Manage The Risks Of International Operations.***

Our BTX Instrument Division sells a significant amount of its research-use equipment in foreign countries, particularly in the Pacific Rim. In the nine months ended December 31, 2001, 37% of BTX's revenues were from BTX sales into foreign countries. Like any company having foreign sales, BTX's sales are influenced by many factors outside of our control.

**Table of Contents**

For instance, the following factors can negatively influence BTX's sales or profitability in foreign markets:

We are subject to foreign regulatory requirements, foreign tariffs and other trade barriers that may change without sufficient notice;

Our expenses related to international sales and marketing, including money spent to control and manage distributors, may increase to a significant extent due to political and/or economic factors out of our control;

We are subject to various export restrictions and may not be able to obtain export licenses when needed;

Some of the foreign countries in which we do business suffer from political and economic instability;

Some of the foreign currencies in which we do business fluctuate significantly;

We may have difficulty collecting accounts receivables or enforcing other legal rights; and

We are subject to the Foreign Corrupt Practices Act, which may place us at a competitive disadvantage to foreign companies that do not have to adhere to this statute.

***We Depend On The Continued Employment Of Qualified Personnel.***

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

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

***We May Not Meet Environmental Guidelines, And As A Result Could Be Subject To Civil And Criminal Penalties.***

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

**Table of Contents**

***A Majority Of Our Directors Are Canadian Citizens And Service And Enforcement Of Legal Process Upon Them May Be Difficult.***

A majority of our directors are residents of Canada and most, if not all, of these persons' assets are located outside of the United States. It may be difficult for a stockholder in the United States to effect service or realize anything from a judgment against these Canadian residents as a result of any possible civil liability resulting from the violation of United States federal securities laws. We currently have five directors, four of whom are Canadian citizens.

***Our Actual Results Could Differ Materially From Those Anticipated In Our Forward-Looking Statements.***

Any statements in this prospectus about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as believe, anticipate, should, intend, plan, will, expects, estimates, projects, positioned, strategy, outlook and similar expressions. These statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from the results expressed in the statements. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus. The following cautionary statements identify important factors that could cause our actual results to differ materially from those projected in the forward-looking statements made in this prospectus. Among the key factors that have a direct impact on our results of operations are:

the risks and other factors described under the caption "Risk Factors" in this prospectus;

general economic and business conditions;

industry trends;

our assumptions about customer acceptance, overall market penetration and competition from providers of alternative products and services;

our actual funding requirements; and

availability, terms and deployment of capital.

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

**Table of Contents**

**WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and special reports, along with other information with the SEC. You may read and copy any document we file at the public reference facilities maintained by the SEC at 450 Fifth Street, N.W., Washington, D.C. 20549 and at the Regional Offices of the SEC at Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661; and at 75 Park Place, New York, New York 10007. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our common stock is traded on The American Stock Exchange and the Toronto Stock Exchange. You may inspect reports and other information concerning us at the offices of the American Stock Exchange, Inc., 86 Trinity Place, New York, New York 10006. These filings and other information may also be inspected without charge at a Web site maintained by the SEC. The address of the site is <http://www.sec.gov>.

**INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

The following documents we filed with the SEC pursuant to the Exchange Act are incorporated by reference and made a part of this prospectus:

Our Annual Report on Form 10-K for the fiscal year ended March 31, 2001 (as amended by Amendment No. 1 to Form 10-K/A filed on January 11, 2002 and Amendment No. 2 to Form 10-K/A filed on February 25, 2002).

Our Quarterly Reports on Form 10-Q for the quarters ended June 30, 2001 and September 30, 2001.

Our Form 8-K filed June 19, 2001.

Our Form 8-K filed December 3, 2001.

Our form 8-K filed February 22, 2002.

This prospectus is part of a registration statement filed with the SEC. The SEC allows us to incorporate by reference into this prospectus the information that we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We are incorporating by reference the documents listed above and any future filings that we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 prior to the sale of all the shares covered by this prospectus.

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

You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. The

**Table of Contents**

selling stockholders will not make an offer of these shares in any state where the offer is not permitted. You should not assume that the information in this prospectus or any supplement is accurate as of any date other than the date of those documents.

**SELLING STOCKHOLDERS**

The table below sets forth certain information regarding the selling stockholders as of February 22, 2002. The shares are being registered to permit public sales of the shares, and the selling stockholders may offer the shares for resale from time to time. See Plan of Distribution. The selling stockholders may offer all, some or none of the common stock listed below.

With the exception of Avtar Dhillon, our President and Chief Executive Officer, none of the selling stockholders has, or in the past three years has had, any position or office with, been employed by, or otherwise had a material relationship with us.

Canaccord Capital (Europe) Limited is an affiliate of Canaccord Capital Corporation, a registered broker-dealer. Canaccord Capital (Europe) Limited purchased the securities listed below in the ordinary course of business and has no agreements or understandings to distribute these securities.

The table below sets forth the names of the selling stockholders and the number of shares owned, directly and beneficially, by such stockholders. If all of the shares are sold pursuant to this prospectus then the selling stockholders will sell 9,289,990 shares of our common stock or 19% of the common stock outstanding.

Selling Stockholder (1)	Number of Shares of Common Stock Held  Prior to the Offering	Number of Shares of Common Stock  Registered for Sale  Hereby (2)	Number of Shares of Common Stock Beneficially Owned After Completion of the Offering	Percentage of  Common Stock Outstanding (3)
Aegean Trust Company Limited	45,000	45,000		*
Aran Asset Management SA	2,148,700	1,905,000	243,700	*
Aton Ventures Fund Limited	150,000	150,000		*
Banque de Luxembourg	615,000	300,000	315,000	*
Banque SCS Alliance SA	150,000	150,000		*
Bogart Delafield Ferrier, LLC	100,000	100,000		*
Brewin Nominees Limited	337,500	337,500		*
Canaccord Capital (Europe) Limited	649,548	621,249	28,299	*
Clariden Investments Ltd.	45,000	45,000		*
Smallcap World Fund, Inc.	2,810,000	360,000	2,450,000	6.7%
Dexamemos Developpement	105,000	60,000	45,000	*

**Table of Contents**

Selling Stockholder (1)	Number of Shares of Common Stock Held Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby (2)	Number of Shares of Common Stock Beneficially Owned After Completion of the Offering	Percentage of Common Stock Outstanding (3)
Doltech Worldwide Limited	200,000	200,000	*	
LaMont Asset Management SA	300,000	300,000	*	
Northern Rivers Innovation Fund, LP	315,000	315,000	*	
Park Place Galileo Ltd.	667,500	667,500	*	
Peter M. Brown	454,575	454,575	*	
SKN Holdings Limited	1,500,000	1,500,000	*	
Michael W. Reynolds	715,000	375,000	340,000	*