GENETRONICS BIOMEDICAL LTD
Form 10-K405
May 18, 2001

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934
FOR THE FISCAL YEAR ENDED MARCH 31, 2001

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NO. 0-29608
GENETRONICS BIOMEDICAL LTD.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

BRITISH COLUMBIA, CANADA (State or other jurisdiction of incorporation or organization)	33-0024450 (I.R.S. Employer Identification No. for Genetronics, Inc.)
11199 SORRENTO VALLEY ROAD SAN DIEGO, CALIFORNIA (Address of principal executive offices)	92121-1334 (Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (858)597-6006

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT: NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:

COMMON STOCK, NO PAR VALUE

(Title of Class)

Indicate by check mark whether the Company (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

The number of shares outstanding of the Registrant's Common Stock, no par value, was 33,756,718 as of May 10, 2001. The aggregate market value of the voting stock (which consists solely of shares of Common Stock) held by

non-affiliates of the Company as of May 10, 2001 was approximately $43,999,300, based on $1.48, the closing price on that date of Common Stock on the American Stock Exchange. *

DOCUMENTS INCORPORATED BY REFERENCE

Certain exhibits filed with the Registrant's prior registration statements, Forms 10-K, 10-Q, and 8-K are incorporated herein by reference into Part IV of this report.

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* Excludes 4,027,461 shares of Common Stock held by directors and officers, and shareholders whose beneficial ownership exceeds 10% of the shares outstanding on May 10, 2001. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Company, or that such person is controlled by or under common control with the Company.

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THIS ANNUAL REPORT ON FORM 10-K CONTAINS FORWARD-LOOKING STATEMENTS THAT INVOLVE RISKS AND UNCERTAINTIES. SUCH STATEMENTS INCLUDE, BUT ARE NOT LIMITED TO, STATEMENTS CONTAINING THE WORDS "BELIEVES," "ANTICIPATES," "EXPECTS," "ESTIMATES" AND WORDS OF SIMILAR IMPORTANCE. THE COMPANY'S ACTUAL RESULTS COULD DIFFER MATERIALLY FROM ANY FORWARD-LOOKING STATEMENTS, WHICH REFLECT MANAGEMENT'S OPINIONS ONLY AS OF THE DATE OF THIS REPORT, AS A RESULT OF SUCH RISKS AND UNCERTAINTIES. THE COMPANY UNDERTAKES NO OBLIGATION TO REVISE OR PUBLICLY RELEASE THE RESULTS OF ANY REVISIONS TO THESE FORWARD-LOOKING STATEMENTS. FACTORS THAT COULD CAUSE OR CONTRIBUTE TO SUCH DIFFERENCES INCLUDE, BUT ARE NOT LIMITED TO, THOSE FOUND IN THIS ANNUAL REPORT ON FORM 10-K IN PART I, ITEM 1 UNDER THE CAPTION "CERTAIN RISK FACTORS RELATED TO THE COMPANY'S BUSINESS," IN PART II, ITEM 7 UNDER THE CAPTION "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS" AND ADDITIONAL FACTORS DISCUSSED ELSEWHERE IN THIS ANNUAL REPORT AND IN OTHER DOCUMENTS THE COMPANY FILES FROM TIME TO TIME WITH THE SECURITIES AND EXCHANGE COMMISSION, INCLUDING ITS QUARTERLY REPORTS ON FORM 10-Q. READERS ARE CAUTIONED NOT TO PLACE UNDUE RELIANCE ON ANY FORWARD-LOOKING STATEMENTS.

PLEASE NOTE THAT UNLESS OTHERWISE INDICATED, ALL REFERENCE TO MONEY IS STATED IN UNITED STATES DOLLARS.

On May 10, 2001, the Interbank rate of exchange for converting Canadian dollars into United States dollars equalled 1.5390 Canadian dollars for one (1) United States dollar. The following table presents a history of the exchange rates of Canadian dollars into one (1) United States dollar for the five most recent fiscal years of our company.

TWELVE MONTHS ENDED	TWELVE MONTHS ENDED	TWELVE MONTHS ENDED	THIRTEEN MONTHS ENDED	TWELVE MONTHS ENDED

FISCAL PERIODS ENDED	MARCH 31, 2001	MARCH 31, 2000	MARCH 31, 1999	MARCH 31, 1998	FEB. 28, 1997
Period End	1.5767	1.4494	1.5104	1.4218	1.3556
Average	1.5038	1.4661	1.5031	1.3994	1.3556
Period's High	1.5791	1.4878	1.5845	1.4686	1.3752
Period's Low	1.4470	1.4524	1.4144	1.3594	1.3381

PART I

ITEM 1. BUSINESS

OVERVIEW

We were incorporated in British Columbia, Canada on August 8, 1979 under the name of Concord Energy Corp. We changed our name to United Safety Technology Inc. on February 17, 1988, to Consolidated United Safety Technology Inc. on January 3, 1990, and then to Genetronics Biomedical Ltd., on September 29, 1994. We carry on our business through our operating subsidiary Genetronics, Inc., a California corporation. Genetronics, Inc. was incorporated in California on June 29, 1983. Genetronics, Inc. had a subsidiary called Genetronics S.A., which was incorporated in France on January 30, 1998. Genetronics S.A. was formed primarily to manage clinical trials that were being conducted in France. Effective May 2000, the Company closed the operations of Genetronics S.A. and subsequently sold its investment for nominal consideration to Geser S.A., a company owned by Genetronics S.A.'s former General Manager. All our business activities are conducted through Genetronics, Inc. Unless otherwise indicated, all references to Genetronics or the Company refer to Genetronics Biomedical, Ltd. and Genetronics, Inc. on a consolidated basis.

We have called an Extraordinary General Meeting of our shareholders for May 22, 2001 to consider the continuation of the Company from British Columbia, Canada into Delaware, U.S.A. This continuation is subject to the approval of the shareholders and subsequent to their approval, is subject to the approval of our Board of Directors.

We are a San Diego-based 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. In the lab, researchers use electroporation to introduce

genes, drugs, and other compounds into cells and experimental animals. This is a common and well-known procedure and more than 4,000 scientific papers have been published describing results achieved using electroporation.

While widely used in the research arena, electroporation is a relatively new technology in the therapeutic arena. One of the major difficulties in many forms of drug or gene therapy is that the pharmaceutical agent or gene is often not able to penetrate the relatively impermeable walls of cells. The pores produced by electroporation permit entry of such agents into cells to a much greater extent than if the drug or gene was administered without electroporation. When electroporation is used in conjunction with drugs, genes, or other therapeutic agents, it is referred to as Electroporation Therapy ("EPT"). We operate through our 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 for in vitro and for in vivo animal experimentation.

The Drug and Gene Delivery Division focuses on the development of human-use equipment that is designed to allow physicians to use EPT 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 Genetronics MedPulser(R) 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.

DRUG AND GENE DELIVERY DIVISION

OVERVIEW

Through our Drug and Gene Delivery Division, we are developing drug and gene delivery systems based on the technology of electroporation to be used in combination with drugs or genes in the treatment of disease. There are many diseases where improved drug delivery is important. Our Drug and Gene Delivery Division has identified five potential areas of application for our electroporation technology -- oncology, gene therapy, dermatology, cardiology and transdermal drug delivery. At present, the primary areas of our focus are oncology and gene therapy.

Our Drug and Gene Delivery Division's most advanced product candidates treat solid malignant tumors such as squamous cell carcinoma, melanoma, and adenocarcinoma in the areas of application of oncology and dermatology. We have completed Phase II clinical trials in the United States of EPT and bleomycin in the treatment of head and neck cancer and melanoma. Initial results from the clinical trials carried out in Europe have allowed us to obtain a CE Mark certification qualifying the MedPulser(R) system for sale in Europe with respect to the treatment of head and neck cancer and melanoma using EPT and bleomycin. We intend to initiate the marketing of the MedPulser System in Europe in 2001.

We intend to develop and pursue other appropriate targets using the MedPulser System to deliver bleomycin or other chemotherapeutic agents. Such studies will begin as Phase I or Phase II clinical trials. Phase I clinical trials are early stage trials in human subjects, used to test a drug or delivery system for safety. Phase II clinical trials assess the effectiveness of a treatment, as well as adding to safety data. Phase III clinical trials evaluate the comparative safety and efficacy of a drug or delivery system and the data from these trials are used by regulatory agencies to approve or reject a product licensing application.

Our drug delivery system, including the MedPulser(R) instrument and the disposable applicators, are subject to various regulatory requirements depending on the country of sale. The Drug and Gene Delivery Division MedPulser(R) system has been awarded ISO 9001, EN46001 and ISO 13485 registration, as well as CE mark certification in Europe.

MARKET

Our Drug and Gene Delivery Division is expected to enter the commercial market with equipment to be used in the treatment of cancer (oncology). Cancer is a life threatening disease affecting millions of people worldwide. The World Health Organization reports that cancer will remain one of the leading causes of death worldwide for years to come. In the United States, approximately 13 million new cases were diagnosed between 1990 and 1999. To further illustrate

the market potential for EPT, solid tumor cancers, the first target for EPT, constitute the majority of all cancers. The majority of cancer victims is over age 65 and is supported by government-funded programs. In the United States the costs of cancer, including mortality, morbidity and direct medical costs, exceed $107 billion per year: some $37 billion for direct medical costs (total of all health expenditures); at least $11 billion for indirect morbidity costs (cost of lost productivity due to illness); and over $59 billion for indirect mortality costs.

There is still very much that scientists do not know about cancer; consequently, there are significant unmet needs in the treatment of cancer. The oncology business unit within the Drug and Gene Delivery Division has initially targeted those indications for which current treatment modalities result in a poor quality of life and very high mortality rates. Specialized applicators are being designed which will allow EPT to treat other solid tumor cancers with minimally invasive procedures.

In the United States, the cumulative dollar value of treatments and technologies commonly used in the curative and palliative management of cancer exceeded $8 billion in 1999 and is expected to continue growing at a rate of approximately 12% annually. Our analyses project that EPT could be applicable to over 4,000,000 cancer patients.

TREATMENT OF TUMORS

Equipment made by our BTX Instrument Division has been used by our investigators and in other laboratories to screen drugs for their effectiveness in killing tumor cells in test tubes and to study the drugs' mode of action. Our scientists, and outside researchers, also have studied the combination of electroporation and various agents to destroy tumors in animals and humans.

In most of the clinical protocols, the site of the tumor is anesthetized and the chemotherapeutic agent of choice (bleomycin) is injected directly into the tumor. The therapeutic agent is allowed to diffuse throughout the tumor, which can take one to several minutes depending on the size, type and location of the tumor. Once the drug is distributed in the tumor, the electrical field is applied by the MedPulser(R) system so as to create a greater permeability in the cells walls to allow the chemotherapeutic agent to enter the cells.

The entire procedure can be completed in 20 minutes or less and typically needs to be done only once. The dosage of drug used in the published results is based on tumor volume, and is typically a small fraction (1/3 to as little as 1/50) of the dosage that would be used systemically. As a result of the lower dosage administered locally, side effects have been minimal. Tumor death with sloughing and ulceration were common reactions following EPT. No episodes of injury to normal (non-tumor) tissue adjacent to the tumors have been observed.

MEDPULSER(R) SYSTEM

The MedPulser(R) system is an electroporation system designed for the clinical application of EPT. The technology is intended to treat various malignant and non-malignant tumors by locally applying a controlled electric field to targeted tumor tissues previously injected with a chemotherapeutic agent. The controlled short duration electric field pulses temporarily increase the cellular membrane permeability of the tumor cell membrane allowing the therapeutic agent to more easily enter the tumor cells and kill them.

The system has two components: (1) a medical instrument which creates the electric field (the MedPulser(R) instrument); and (2) a single use, sterile, disposable electrode applicator. The electrodes may be needles, plates, or other configurations, depending on the geometry of the tumor and its location.

The instrument was designed for ease of use, such that minimal user input is needed to apply the therapy. Based on the size and anatomical location of the tumor to be treated, a physician selects the most appropriate electrode applicator. The chosen applicator is then connected to the MedPulser(R) instrument, and it is the connection of applicator to instrument that automatically configures the therapy parameters for that particular applicator size and shape. Currently, several different electrode applicator configurations are available. The applicators vary in needle length, needle gauge, electrode needle spacing, tip angle and handle configuration so as to allow the physician to access a greater range of tumors.

New models of electrode applicators will be considered in the future to address customer needs. The system is designed such that the installed base of MedPulser(R) generator instruments allows for a wide variety of new electrode applicator configurations. Also, the system incorporates other features to minimize the possibility of applicator reuse as well as prevent the use of competitive applicators with the MedPulser(R) instrument. The commercial version MedPulser(R) system has been certified by an independent test laboratory as meeting strict international product standards. Our drug delivery device, including the MedPulser(R) system and the disposable electrode applicators, are subject to various regulatory requirements, depending on the country of sale.

In the United States, EPT utilizing the MedPulser(R) system and bleomycin drug is currently regulated as a combination drug-device system. We will be required to obtain both drug labelling and device approvals from the United States Food and Drug Administration ("FDA"). Clinical trials (Phase I, II and III) to support drug indication labelling require filing an Investigational New Drug Application ("IND"), followed by submission of a United States New Drug Application, and submission of a device Pre-Market Approval or 510(k), for marketing approval.

In most of the rest of the world, we anticipate that the MedPulser(R) system will be regulated as a device. In Europe, the device comes under the Medical Device Directive 93/42/EEC ("MDD") and marketing requires CE mark certification of conformity to the quality system, production and clinical investigation essential requirements of the directive. We have obtained CE mark certification for electroporation devices, which allows us to sell and use the MedPulser(R) electroporation system for the treatment of solid tumors with bleomycin in Europe.

MEDICAL DEVICE MANUFACTURING

Our Drug and Gene Delivery Division must comply with a variety of regulations to manufacture our products for sale around the world. In Europe, we must comply with MDD. Our Drug and Gene Delivery Division has demonstrated the quality system is in place by securing ISO 9001

approval. It demonstrated compliance with international medical device standards with EN 46001 and ISO 13485 recognition. These all occurred in January 1999. In March 1999, the CE Mark was obtained for the MedPulser(R) electroporation system. To sell in the United States, we will need to be in compliance with FDA current Good Manufacturing Practices (GMP).

We employ modern manufacturing practices, which include outsourcing of significant custom assemblies used in the manufacture of the MedPulser(R) instrument. The instrument final assembly, testing and quality control functions are performed in a physically distinct area of the company where the appropriate controls are employed. We outsource the manufacture of the disposable electrode applicators to a GMP/ISO9002 compliant contract manufacturer.

CLINICAL STUDIES

North America Trials

In late 1997 the FDA gave us clearance to initiate multi-center Phase II clinical trials in the United States utilizing the MedPulser(R) electroporation system in combination with intralesional bleomycin to treat squamous cell carcinoma of the head and neck in patients who failed conventional therapies. We obtained IND clearance from the Canadian Health Protection Branch to initiate similar clinical trials in Canada. Two protocols were initiated. One cross-over-controlled study evaluated the effectiveness of the bleomycin-EPT treatment in tumors that failed an initial bleomycin-alone treatment. The second study was a single arm study which evaluated the effect of the bleomycin-EPT treatment as an initial therapy of the study tumors.

Twenty-five patients were enrolled in the controlled study and 25 patients were enrolled into the single arm bleomycin-EPT trial. The results based on the primary endpoint for response (50% or greater reduction in tumor size) are provided in the table below.

			RESPONSE(1)(2)	
CLINICAL TRIAL	PATIENTS	TUMORS	RESPONDING TUMORS	NON-RESPONDING TUMORS
North America Phase I/II	8	8	6(75)%	2(25)%
North America Phase II 01 Study -- Bleomycin only	25	37	1(3)%	36(97)%
North America Phase II 01 Study	17	20	11(55)%	9(45)%
North America Phase II 02 Study	25	31	18(58)%	13(42)%
European Study	12	18	10(56)%	8(44)%

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(1) Four tumors could not be evaluated

(2) Control Group patients received only drug, no electric field

The two Phase II protocols involved a total of 42 tumors treated with bleomycin and EPT. Tumors treated in the trial include squamous cell carcinoma of the face, oral cavity, pharynx, larynx and sinus. The size of tumors treated ranged from less than one cubic centimeter to more than 132 cubic centimeters. In the crossover controlled Phase II study, patients initially received only the drug. Patients who did not respond to drug alone were then treated with the complete system of drug and electric field. Of the 37 tumors on 25 patients treated only with drug, only one demonstrated a clinical response. Seventeen of these patients, having 20 lesions, were subsequently treated with bleomycin and EPT and 55% achieved a clinical response. In the open-label Phase II study, all patients received full EPT as their initial treatment. Among the 25 patients (31

tumors) so treated, 58% achieved a clinical response.

A limited, well-controlled Phase III trial for palliative treatment of head and neck cancer in patients who failed conventional therapy may be sufficient to support NDA submission for this indication. Treatment of other diseases will involve expanded Phase II and Phase III trials pending successful outcome of the initial Phase I/II studies.

International Trials

In late 1997 and early 1998, we received ethics committee approval from multiple Consulting Committees for the Protection of Humans in Biomedical Research (CCPPRB) to initiate clinical trials in France in patients with pancreatic cancer, metastatic cancer in the liver, head and neck cancer, melanoma and Kaposi's sarcoma. These trials were initiated to demonstrate the MedPulser(R) system device's safety and performance in treating a variety of solid tumors in support of CE mark certification in accordance with the essential requirements of MDD. Results from the patients with head and neck cancer are reported under North America Trials above. We achieved CE mark certification in March 1999 from notified body TUV Product Service GMBH.

Current Developments

On October 6, 1998, we entered into a comprehensive License and Development Agreement and a Supply Agreement with Ethicon, Inc., a Johnson & Johnson company, involving our proprietary drug delivery system for EPT treatment of cancer. In August 5, 1999, these agreements were assigned to Ethicon Endo-Surgery, Inc., another Johnson & Johnson company. Ethicon, Inc. and Ethicon Endo-Surgery, Inc. are referred to as Ethicon in this filing. On July 26, 2000, we received written notice from Ethicon Endo-Surgery, Inc. that it had elected to exercise its discretionary right to terminate, without cause, the License and Development Agreement and the Supply Agreement. All rights for the development and distribution of Genetronics proprietary electroporation drug delivery system for the treatment of cancer were returned to Genetronics.

In September 2000, we executed an exclusive license agreement with the University of South Florida Research Foundation, Inc. ("USF") that granted to us the worldwide license to USF's rights in certain patents and patent applications generally related to needle electrodes. Genetronics and USF jointly developed these electrodes. The needle electrodes are components of Genetronics' electroporations systems and are used to deliver electric pulses to cells and tissues during the process of electroporation. Pulsed electric fields generated during the electroporation process cause a temporary but significant increase in the permeability of human cells. This makes it easier for drugs and genes to enter cells, a key element for successful cancer or gene therapy treatment. In April 2001, we initiated a limited release of the MedPulser(R) Electroporation Therapy System, to key head and neck surgeons in several countries through a European Access Program (EAP). We have initiated a marketing evaluation of the technology, under the EAP, with a select group of thought leaders at premier cancer centers in Austria, the United Kingdom, Germany, the Netherlands, Switzerland, and the Czech Republic. Genetronics has a CE Mark certification qualifying the MedPulser(R) system for sale in Europe for the treatment of solid tumors. The lead indication for the planned launch of the MedPulser(R) Electroporation Therapy System is the treatment of head and neck cancers and the initiation of the EAP represents the beginning of the commercialization phase of our EPT program for head and neck cancer in Europe. We believe we have sufficient current resources to initiate a variety of activities directed toward the MedPulser(R) system launch and marketing in Europe, and for initiation of a

Phase III clinical study in the United States. In April 2001, we completed a review of our existing clinical and regulatory information related to the Electroporation Drug Delivery System and submitted the results of this review to the FDA. The responses are described above under "Clinical Studies--North America Trials." The response rate determined pursuant to the review is consistent with previous data disclosed by us.

Research and Development Summary

We perform an ongoing review of our patent portfolio to confirm that our technologies are adequately protected. Each year we review our patent portfolio and write-off all abandoned patents.

Our Drug and Gene Delivery Division has, in the past, focused its research primarily in the areas of oncology, gene therapy, vascular therapy, transdermal delivery and dermatology. At present, the primary areas of focus are oncology and gene therapy.

The following table summarizes the programs of the Drug and Gene Delivery Division, the primary indications for each product and the current status of development. "Developmental" means the program is at the planning stage, protocols are being developed, and little if any animal work has commenced. "Preclinical data" means the program is at the stage where results from animal studies have been obtained. "Clinical Trials" means that human data is available. "Tolerance study" means a pilot clinical study to determine patient tolerance of electrical pulses at therapeutic dose.

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SUMMARY TABLE

		STAGE OF APPROVAL	
PROGRAMS	DEVELOPMENT STATUS	UNITED STATES & CANADA	
DERMATOLOGY			
Basal Cell Cancer	Clinical Trials	Two pilot studies completed	N/A
Genital Warts	Developmental	N/A	N/A
ONCOLOGY			
Head and Neck Cancer	Clinical Trials	Phase II Clinical Trials	CE 900
Melanoma	Clinical Trials	N/A	CE 900
Metastatic Liver Cancer	Clinical Trials	N/A	CE 900
Peripheral Sarcoma	Preclinical data	N/A	CE 900
Breast Cancer	Preclinical data	N/A	CE 900
Prostate Cancer	Preclinical data	N/A	CE 900
Glioma	Preclinical data	N/A	CE 900
GENE THERAPY			
In vivo Gene Transfer -- blood protein encoding genes	Preclinical data	N/A	N/A

In vivo Gene Transfer -- DNA vaccines	Preclinical data	N/A	N/A
In vivo Gene Transfer anti-inflammatory protein encoding genes	Preclinical data	N/A	N/A
In vivo Gene Transfer vascular protein encoding genes	Preclinical data	N/A	N/A
VASCULAR THERAPY			
Coronary Artery Disease, Marker genes & drugs	Preclinical data	N/A	N/A
Vascular Disease, Heparin delivery (anti-restenosis)	Preclinical data	N/A	N/A
TRANSDERMAL DELIVERY			
PGE-1 delivery for Erectile dysfunction	Tolerance Study	One Device Tolerance Study completed	N/A
Calcitonin (osteoporosis)	Preclinical data	N/A	N/A
Vitamin C	Preclinical data	N/A	N/A

"N/A" means not applicable.

GENE THERAPY

Gene therapy, in classical terms, involves the introduction of new genetic information into cells (transfection) for therapeutic purposes. Somatic cells of the body are transfected with a specific functioning gene to compensate for a genetic defect that results in a deficiency of a specific protein factor. In this context, one goal of gene therapy is to convert target cells or tissues into "protein factories" for the production and secretion of a normal protein locally or into the circulation. Many vexing genetic illnesses, including those currently treated by regular injection of a missing protein, can potentially be "cured" by supplying the functional gene to a sufficient number of cells under conditions which allow these cells to produce a therapeutically effective dose of the gene product.

Currently, single-gene recessive genetic disorders are the most accessible targets for correction by gene therapy, but ultimately polygenic and acquired diseases can and will be treated by using genes as pharmaceutical agents. In principle, any aspect of metabolism can be manipulated by modifying gene function, and it is this application of gene therapy that has enormous potential, extending far beyond the treatment of rare genetic diseases. For example, the ability to influence cellular metabolism by introducing specific genes has led to extensive investigation into the use of gene therapy for cancer treatment. By adding a tumor suppressor gene to certain types of cancers, the uncontrolled growth of those cells potentially could be brought under normal regulation. Likewise, transfecting tumor cells with genes capable of inducing programmed cell death can result in tumor ablation.

The methods of introducing genes have two specific approaches. Gene therapy can be performed either ex vivo or in vivo. Ex vivo gene therapy is the transfection of cells outside the body. Typically, a small amount of tissue is removed from the patient and the cells within that tissue are put into culture. The genetically modified cells, typically blood, bone marrow or others, are then returned to the patient, usually by blood transfusion or direct engraftment. In

vivo gene therapy is the introduction of genetic information directly into cells in the patient's body. Theoretically, any tissue or cell type in the body can be used, and the choice is dependent on the specific goals of treatment and indications being treated. For internal tissue targets, a gene may be transfused through the blood stream to the organ or site of action, or it may be injected at the desired site, which is then electroporated to allow the gene to pass through the cell membrane.

Genes can also be applied topically or by injection to skin and then transferred into the cells of the skin by electroporation. Skin gene delivery by electroporation for gene therapy is currently being investigated at Genetronics as a safe, effective and cost-competitive approach. The skin is also a target for DNA vaccination. "Vaccinating" skin with DNA that encodes a specific antigen present in infectious agents or in tumor cells can produce beneficial immunological responses. Genes can also be used to directly fight cancer. The thymidine kinase gene, in conjunction with the prodrug ganciclovir, produces a potent antitumor effect based on drug toxicity and programmed cell killing via a bystander effect. Animal trials treating glioblastomas using this strategy have shown substantial success.

To make gene therapy a reality, many obstacles have to be overcome, including the safe, efficient delivery of the intact DNA construct into the host cells. The instrumentation we use for high-efficiency in vivo gene transfer is derived from the instrumentation developed for intratumoral and transdermal drug delivery. We believe electroporation will become the method of choice for DNA delivery to cells in many applications of gene therapy.

Because of the broad applicability of this technology, we have adopted the strategy of co-developing or licensing our technology exclusively or non-exclusively for specific genes or specific medical indications. In most cases, we contribute proprietary technology, expertise and instrumentation to optimize the delivery technology for particular applications. A partner company provides its proprietary DNA constructs, may conduct the pre-clinical research and clinical trials, and may introduce the new treatment and products to the marketplace. Genetronics and the partner company would share in the commercial success of the project. We have actively sought partners to develop this exciting technology to its full potential. On November 8, 1999, we entered into an 18-month research and option agreement with Boehringer Ingelheim International GmbH (Boehringer Ingelheim) related to the development of our electroporation technology for use in particular gene therapy applications. While the research results were successful Boehringer Ingelheim decided not to pursue that subject field and declined to exercise the option to license. On June 9, 2000, we announced that research studies using our electroporation systems were presented at a major international gene therapy conference. Additionally, in collaborations with Chiron Corporation and Valentis, Inc., our technology was shown to effectively deliver a variety of genes and DNA vaccines to skin and muscle of animals, including non-human primates.

BTX INSTRUMENT DIVISION

OVERVIEW

Our company, through our BTX Instrument Division, began developing and manufacturing electroporation equipment for the research laboratory market in 1983 and sold our first product in 1985. BTX was founded to develop and manufacture high quality scientific instrumentation that can be used by research scientists to perform various types of electroporation and electrofusion experiments. Electroporation in research is commonly used for transformation and transfection of all cell types, as well as for general molecular delivery at the cellular level. Electrofusion is the fusing together of two or more cells to form hybrid cells. Transformation is a process by which the genetic material carried by an individual cell is altered by incorporation of exogenous DNA into

its genome. Transfection is the uptake, incorporation, and expression of exogenous DNA by eukaryotic cells.

The BTX Instrument Division is the second largest developer and marketer of electroporation instruments and supplies, with more than 2,000 customers in universities, companies, and research institutions worldwide. Our BTX Instrument Division sells its electroporation/electro cell fusion instrumentation and accessories to customers located in all states and territories of the United States and in over 47 foreign countries. The majority of our products are sold to customers in the United States, Europe and East Asia. The BTX Instrument Division currently produces an extensive line of electroporation instruments and accessories, including electroporation and electro cell fusion instruments, a monitoring device, and an assortment of electrodes and accessories.

PRODUCTS

BTX developed the square wave generator and graphic pulse analyzer for in vivo gene delivery and nuclear transfer research, fields that are rapidly increasing in scientific and medical interest. BTX also has developed the most versatile electro cell fusion system on the market, the only commercial large volume flow-through electroporation system, and offers an extensive collection of in situ and high throughput screening electroporation applicators.

BTX focused its efforts in recent years on product development and promotion of a new line of products for developing sophisticated applications. We released the ECM(TM) 830 in December 1998. It is a sophisticated square wave electroporation system with a menu driven digital user interface. In August 1999 we introduced the ECM 630, an Exponential Decay Wave Electroporation system that utilizes a Precision Pulse Technology, the new BTX

Platform technology, and an all-new digital user interface. During the fiscal years ended March 31, 2001 and 2000, publications outlined the utilization of BTX equipment in newly developing animal in vivo gene delivery research. In the support of this research, we expanded our in vivo electrode offering and continue to emphasize the development of novel applicators.

The BTX Instrument Division's product line includes two exponential decay wave generators, one square wave generator, one electro cell fusion instrument and a graphic wave display monitor. In addition, this Division markets over 43 different types of electrodes and related accessories, as well as the standard disposable electroporation cuvettes, containers for holding liquid samples.

Exponential decay generators have been traditionally used for the electroporation of all cell types. Square wave generators have shown the greatest utility in the electroporation of mammalian and plant cells, as well as for animal in vivo applications. The Electro Cell Fusion System is used by researchers for embryo manipulation, hybridoma and quadroma formation, as well as for all cell fusion techniques, including applications involving adoptive immunotherapy.

While we, through our BTX Instrument Division, sell devices purportedly used by others for non-human embryo cloning, we do not ourself conduct embryo cloning. All of our BTX Instrument Division instruments sold to the research market carry the label "not for human use." We are not aware of any regulations or industry guidelines limiting the use of our instrumentation in the animal research market. We comply with all National Institutes of Health guidelines on

cloning and gene therapy. We also comply with all Federal and State regulations regarding the restrictions on research imposed on federally funded grants.

The BTX Instrument Division supplies three cuvette models, as do our competitors, plus some 43 additional specialized chambers electrodes, and accessories for electroporation. BTX in situ electrodes (e.g., Petri Pulser(TM) electrodes) position us to expand the electroporation market for adherent cell transfection applications, while high throughput screening electrodes and large volume production systems (e.g., 96-Well Coaxial Electrode, ElectroFlowPorator(TM) system), respectively, provide the BTX Instrument Division with an entry into the large volume and multi-sample processing arenas used by the major pharmaceutical and biotech companies conducting drug research.

The BTX Instrument Division meets regulatory requirements necessary to provide instrumentation to the research market for in vivo and in vitro animal experimentation. The BTX Instrument Division does not market equipment for use in humans, and, therefore, is not required to receive marketing approval from the FDA.

DISTRIBUTION

The main distributors of our BTX Instrument Division products in North America are VWR Scientific Products Corporation and Fisher Scientific Company, the two largest laboratory products suppliers in the United States. Both VWR and Fisher have over 250 representatives dedicated to the biological sciences in North America. Both VWR and Fisher have dedicated Life Science Programs in which BTX participates. The Fischer Scientific distribution agreement was signed in December 2000 and it is anticipated that they will become a main distributor in the fiscal year ended March 31, 2002. In addition, the BTX Instrument Division distributes instruments and supplies through Intermountain Scientific Corporation, which has 20 field sales specialists in the United States. The BTX Instrument Division has over 45 international distributors in 47 countries, of which Merck Eurolab Holding GmbH is the biggest distributor in Europe. VWR Scientific Products Corporation and Merck Eurolab Holding GmbH are both members of the Merck Group. The BTX Instrument Division supports its distributors with advertising, exhibit exposure and lead generation.

ADVERTISING

The BTX Instrument Division advertises in major national and international scientific journals such as Science, Nature, Genetic Engineering News, and BioTechniques. The Division also attends and displays our products at about one scientific conference per month such as American Association for Cancer Research, American Society for Gene Therapy, and Neuroscience meeting. On a quarterly basis the BTX Instrument Division utilizes direct mail to an identified mailing list for specific product promotion. The BTX Instrument Division works closely with distribution partners in joint marketing campaigns and other value-added suppliers in co-marketing efforts.

COMPETITION

The main competitors of our BTX Instrument Division in the research marketplace are BioRad Laboratories, Eppendorf Scientific, Inc. and Hybaid Corporation. There are other companies entering and departing this market on a regular basis. The majority of these companies have other molecular biology product lines besides electroporation, while electroporation and electrofusion is the only business of the BTX Instrument Division. Most competing manufacturers concentrate on the exponential decay wave system and do not compete in the square wave market at this time. In the past 12 months, the competition in the marketing of electroporation cuvettes has increased, leading to the development of BTX-supplied private label products for both VWR and Fisher Scientific.

STRATEGIC PARTNERS

LICENSE AND DEVELOPMENT AGREEMENTS

On October 6, 1998, we entered into a comprehensive License and Development Agreement and a Supply Agreement with Ethicon, Inc., a Johnson & Johnson company, involving the use of our MedPulser(R) system for Electroporation Therapy in the treatment of solid tumor cancer. In addition, Johnson & Johnson Development Corporation purchased $6 million of shares of common stock of our company at a price of $2.68 per share, pursuant to the October 6, 1998 Stock Purchase Agreement. On August 5, 1999, we announced that Ethicon, Inc. had assigned the License and Development Agreement and Supply Agreement to Ethicon Endo-Surgery, Inc., another Johnson & Johnson company. On July 26, 2000, we received written notice from Ethicon Endo-Surgery, Inc. that it had elected to exercise its discretionary right to terminate, without cause, the License and Development Agreement and the Supply Agreement. As a result, all rights for the development and distribution of Genetronics proprietary electroporation drug delivery system for the treatment of cancer were returned to Genetronics.

On September 20, 2000, the University of South Florida Research Foundation, Inc. ("USF") granted to Genetronics, Inc. and Genetronics Biomedical Limited an exclusive, worldwide license to its rights in certain patents and patent applications generally related to needle electrodes. Genetronics and USF jointly developed these electrodes. The needle electrodes are components of Genetronics electroporation systems and are used to deliver electric pulses to cells and tissues during the process of electroporation. Pulsed electric fields generated during the electroporation process cause a temporary but significant increase in the permeability of human cells. This makes it easier for drugs and genes to enter cells, a key element for successful cancer or gene therapy treatment. The terms of the exclusive license include a royalty to be paid to USF based on net sales or products under the license. At March 31, 2001, no royalty had accrued as the Company had not yet generated any sales from this product. In addition, Genetronics has issued a total of 150,000 common shares and a total of 600,000 warrants of which 300,000 will vest subject to the achievement of certain milestones in Genetronics Biomedical Ltd. to USF and its designees, Drs. Heller, Jaroszeski, and Gilbert.

COLLABORATIVE RESEARCH AGREEMENTS

On November 8, 1999, we entered into an 18-month research and option agreement with Boehringer Ingelheim to develop our electroporation technology for use in a particular gene therapy application. Under the terms of the agreement, we will develop hardware and perform preclinical research relating to DNA delivery for cancer DNA vaccination. While the research results were successful Boehringer Ingelheim decided not to pursue that subject field and declined to exercise the option to license. On August 28, 2000, we announced that we had entered into a collaborative agreement with Johnson & Johnson Research Pty Ltd., a wholly owned subsidiary of Johnson & Johnson, located in Eveleigh, Australia, to explore the feasibility of using electroporation, Genetronics platform technology, to deliver nucleic acid materials into tumors in vivo.

Sales and Revenue

The following table provides the amount of net product sales, interest income, and revenue from grant funding and research and development agreements

generated by us for the past three fiscal years. Segmented financial information is contained in Note 16 of the Consolidated Financial Statements that begin on Page F-1. The following table sets forth our selected consolidated financial data for the periods indicated, derived from audited consolidated financial statements prepared in accordance with accounting principles generally accepted in Canada which conform to accounting principles generally accepted in the United States, except as described in Note 19 to the consolidated financial statements.

PERIOD ENDED:	MARCH 31, 2001 12 MONTHS	MARCH 31, 2000 12 MONTHS
PRODUCT SALES		
United States	$ 2,890,875	$ 2,905,065
Rest of World	1,562,064	1,229,371
INTEREST INCOME		
United States	431,729	497,586
Canada	11,900	58,607
GRANT FUNDING		
United States	101,086	334,901
REVENUES UNDER COLLABORATIVE RESEARCH AND DEVELOPMENT ARRANGEMENTS		
Germany	411,616	91,335
United States	48,095	100,000
LICENSE FEE AND MILESTONE PAYMENTS		
United States	83,333	416,667

We, like many biomedical companies, devote a substantial portion of our annual budget to research and development. For the year ended March 31, 1999, research and development expenses totaled $8,086,959; for the year ended March 31, 2000, they totaled $6,977,220 and for the year ended March 31, 2001, they totaled $6,436,377. These amounts far exceed revenues from research arrangements and contribute substantially to our losses. We anticipate a reduction in losses when we market products developed by our Drug and Gene Delivery Division. The launch of the first such products in Europe is anticipated to be in 2001, and will most likely be followed by launch in the United States subject to FDA approval at a later date.

INTELLECTUAL PROPERTY

As of April 21, 2001, we had 36 issued United States patents, 48 issued and granted foreign patents, 3 allowed United States patent applications, an additional 18 pending United States applications, and additional pending foreign patent applications.

We have registered on the Principal Register of the United States Patent and Trademark Office the following trademarks: BTX (Mark), BTX (Logo), ELECTRONIC GENETICS, MANIPULATOR, OPTIMIZOR, HUMAN IN SQUARE (Design), ENHANCER, and MEDPULSER. The following United States trademark applications are pending: COSMETRONICS and GENETRODES. We have registered the BTX and MEDPULSER trademarks in Canada, and have applied to trademark GENETRONICS in Canada. We have a European Community Trade Mark registration for GENETRONICS, BTX and for

MEDPULSER. We have registered the MEDPULSER and BTX marks in Japan. We have registered the BTX mark in South Korea and have registered the GENETRONICS mark in the United Kingdom. We are not aware of any claims of infringement or other challenges to our right to use our marks.

EMPLOYEES

As of May 10, 2001, we employed 66 people on a full-time basis. Of the total, 21 were in product research and development, 10 in sales, marketing and support, 11 in manufacturing, and 24 in finance and administration. Our success is dependent on our ability to attract and retain qualified employees. Competition for employees is intense in the biomedical industry. None of our employees is subject to collective bargaining agreements.

CERTAIN RISK FACTORS RELATED TO THE COMPANY'S BUSINESS

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 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 other aspects of our core technology of electroporation. The choices we may make will be dependent upon numerous factors, which we cannot predict. We cannot assure you that our business model, as it currently exists or as it may evolve, will enable us to become profitable or to sustain operations.

IF WE DO NOT SUCCESSFULLY COMMERCIALIZE PRODUCTS 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 that 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 product 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.

UNPREDICTABILITY OF CONDUCTING PRE-CLINICAL AND CLINICAL TRIALS OF OUR HUMAN-USE EQUIPMENT.

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. The FDA will make this determination based on the results from our pre-clinical testing and clinical trials.

Clinical trials are unpredictable. 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.

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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 delivery of drugs or other agents by electroporation 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 to the end of the trial, or data and document review;

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

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

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

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

Because there are so many variables inherent in clinical trials, we cannot predict whether any of our future regulatory applications to conduct clinical trials will be approved by the FDA or other regulatory authorities, whether our clinical trials will commence or proceed as planned, and whether the trials will ultimately be deemed to be successful.

OUR BUSINESS IS HIGHLY DEPENDENT ON RECEIVING APPROVALS FROM VARIOUS UNITED STATES AND INTERNATIONAL GOVERNMENT AGENCIES AND CAN 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 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 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.

Our company has 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:

-- There can be delays, sometimes long, in obtaining approval for our human-use devices;

-- 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 some of our research and development expenses and to assist us in the research and development of our human-use equipment. Our largest partner had been Ethicon Endo-Surgery, Inc., a Johnson & Johnson company. On July 26, 2000, we received written notice from Ethicon Endo-Surgery, Inc. that it had elected to exercise its discretionary right to terminate, without cause, our License and Development Agreement and our Supply Agreement. If we are unable to enter into a relationship with a new partner for the Electroporation Drug Delivery System, our business could be adversely impacted. Moreover, loss of or any significant change in any of our material collaborative relationships could adversely impact our business.

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.

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 commercialise 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 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.

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-- 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.

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 keep others out of its patented territory. If someone practices within the patented territory of a patent holder, then the patent holder has the right to charge that person with infringement and begin legal proceedings, which can be lengthy and costly. We perform an ongoing review of our patent portfolio to confirm that our key technologies are adequately protected. If necessary, we may ask that one or more of our patents be re-examined or reissued 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, then it will require a lot of time and money to do so, 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, with no guarantee of a successful outcome. Biotechnology companies of roughly our size and financial position have gone out of business after fighting and losing an infringement battle. If we 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, along with some of 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 will make less money from sales and our products risk becoming obsolete.

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

-- More Money. Some competitors have significantly more money than we do. They can afford more technical and development setbacks than we can, and can devote more resources in an effort to improve development times or pursue alternate approaches.

-- 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.

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

-- Reimbursement Allowed. In the United States, third party

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

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

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 a lot of money, 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.

WE HAVE OPERATED AT A LOSS AND WE EXPECT TO CONTINUE TO ACCUMULATE A DEFICIT.

As of March 31, 2001, we had a deficit of $38,238,798. 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 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 received during the year ended March 31, 2001 was from proceeds from issuance of common shares and from sales of BTX research-use equipment. Other funds came from interest income on our investments, revenue under collaborative research and development agreements, Small Business Innovative Research (SBIR) grants, and milestone payments. We do not expect to receive enough money from these sources to completely pay for future activities.

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 cost signficant amounts of money. 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;

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

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.

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 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 products, 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 shares of common stock 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 39% of BTX instrument sales during the twelve months ended March 31, 2001 were through our distribution relationships with the Merck Group, which includes Merck Eurolab Holding GmbH and VWR Scientific Products Corporation. This accounted for about 31% of our total revenue. We rely heavily on our relationships with VWR and Fisher Scientific Company to sell our product in the United States and on Merck Eurolab Holding GmbH to sell our product in Europe. We may not be able to maintain or replace our current distribution relationship with the Merck Group, Fisher, 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 and Europe, 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 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 purchased liability insurance in connection with the ongoing oncology clinical trials, and we would expect to purchase additional policies for any additional clinical trial. The insurance we purchase may not provide adequate coverage in the event a claim is made, 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.

OUR BTX INSTRUMENT DIVISION MUST MANAGE THE RISKS OF INTERNATIONAL OPERATIONS.

Our BTX Instrument Division sells a significant amount of its research-use equipment to customers outside of the United States. In the year ended March 31, 2001, 35% of BTX's revenues were from BTX sales into non-U.S. countries. Like any company having foreign sales, BTX's sales are influenced by many factors outside of our control.

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 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.

THE MAJORITY OF OUR DIRECTORS ARE CANADIAN CITIZENS AND SERVICE AND ENFORCEMENT OF LEGAL PROCESS UPON THEM MAY BE DIFFICULT.

The 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.

OUR ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE ANTICIPATED IN OUR FORWARD-LOOKING STATEMENTS.

This report contains forward-looking statements, including statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance, especially as they relate to our product development plans and expectation of clinical trial progress and results. These statements are often, but not always, made through the use of words or phrases such as "believe," "anticipate," "may," "could," "believe," "predict," "potential," "continue," "should," "intend," "plan," "will," "expects," "estimates," "projects," "positioned," "strategy," "outlook" and similar expressions. Accordingly, 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 report. 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 report. 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 annual report;

-- 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.

ITEM 2. PROPERTIES

We own no real property and have no plans to acquire any real property in the future. We currently lease a facility of 24,931 square feet at our headquarters in San Diego. This facility provides adequate space for our current research, manufacturing, sales and administrative operations. The current lease runs through December 31, 2004.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings with respect to us, our subsidiaries, or any of our material properties.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matter was submitted during the fourth quarter of the fiscal year covered by this report to a vote of security holders, through the solicitation of proxies or otherwise.

PART II

ITEM 5. MARKET FOR COMPANY'S COMMON EQUITY AND RELATED SHAREHOLDER MATTERS

MARKET PRICE OF AND DIVIDENDS ON THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

The principal trading markets for the common shares of Genetronics Biomedical Ltd. are the American Stock Exchange (AMEX) and the Toronto Stock Exchange (TSE). Trading began on the AMEX on December 8, 1998. The Company's common shares have also traded on the former Vancouver Stock Exchange (VSE),

however the Company voluntarily de-listed from that exchange on March 6, 1998. The table below sets forth the quarterly high and low sales prices of the Company's common shares in the two most recent fiscal years.

	TORONTO STOCK EXCHANGE CDN$		AMERICAN STOCK EXCHANGE US$	
YEAR ENDED MARCH 31, 2001	HIGH	LOW	HIGH	LOW
First Quarter	9.00	4.50	6.19	3.00
Second Quarter	5.00	1.80	3.25	1.25
Third Quarter	2.45	1.20	1.75	0.75
Fourth Quarter	2.40	1.10	1.55	0.75

	TORONTO STOCK EXCHANGE CDN$		AMERICAN STOCK EXCHANGE US$	
YEAR ENDED MARCH 31, 2000	HIGH	LOW	HIGH	LOW
First Quarter	5.70	4.10	3.875	3.81
Second Quarter	5.70	3.40	3.873	2.31
Third Quarter	5.15	4.00	3.500	2.69
Fourth Quarter	17.40	4.50	11.94	3.00

On May 10, 2001, the closing price of the Company's common shares was CDN$2.30 on the TSE and US1.48 on the AMEX. As of May 10, 2001, there were approximately 187 registered shareholders of record. In addition, approximately 10,014,550 of the Company's common shares or 30% of the total 33,756,718 issued and outstanding common shares on May 10, 2001, were held among 161 registered United States record holders.

Dividends

We have never paid any cash dividends on our common stock and do not expect to pay any cash dividends in the foreseeable future.

RECENT SALES OF UNREGISTERED SECURITIES

In the fiscal year ending March 31, 2001, the Company issued a total of 180,500 shares of its common stock pursuant to the exercise of agent's warrants for a total consideration of $597,455.

On September 20, 2001, we entered into an exclusive license agreement with the University of South Florida Research Foundation, Inc. ("USF"). Pursuant to the above license agreement, we issued 150,000 common shares and warrants to purchase 600,000 common shares at a purchase price of $2.25 per share until September 14, 2010 to USF and its designees. These shares were issued in a private transaction exempt from registration pursuant to section 4(2) of the Securities Act.

On January 17, 2001, we completed a public offering in Canada, through Canaccord Capital Corporation, of 6,267,500 common shares at a price of CDN $1.35 per share for gross proceeds of CDN $ 8,461,125 (US $5,640,750) less expenses of CDN $1,102,877 (US $734,368). We also issued to Canaccord 50,000

common shares as compensation for corporate finance services and 500,000 compensation warrants exercisable at CDN $1.35 per share at any time until January 16, 2002. A total of 1,000,000 of these shares were issued to two institutional investors in the United States pursuant to the exemption from registration provided by Section 4(2) of the Securities Act and Rule 506 of Regulation D. The remainder were exempt from registration under Regulation S as an offering conducted on a designated offshore securities market.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following table sets forth our selected consolidated financial data for the periods indicated, derived from audited consolidated financial statements prepared in accordance with accounting principles generally accepted in Canada which conform to accounting principles generally accepted in

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the United States, except as described in Note 19 to the consolidated financial statements. The data set forth below should be read in conjunction with our Consolidated Financial Statements and the Notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" set forth below. Effective January 23, 1998, our Board of Directors approved the change of our fiscal year-end from February 28 to March 31.

The following summarizes certain selected consolidated financial information prepared in accordance with Canadian generally accepted accounting principles, except where noted, with respect to our company and is qualified in its entirety by reference to our Consolidated Financial Statements and the Notes thereto prepared in accordance with Canadian generally accepted accounting principles. All amounts are shown in United States dollars.

FISCAL PERIODS ENDED	TWELVE MONTHS ENDED MARCH 31, 2001	TWELVE MONTHS ENDED MARCH 31, 2000	TWELVE MONTHS ENDED MARCH 31, 1999	THIRT MONT END MARC 19
Net Sales	4,452,939	4,134,436	3,434,105	3,09
License Fee and milestone payments	83,333	416,667	4,500,000	
Interest Income	443,629	556,193	300,911	42
Revenues Under Collaborative Research and Development Arrangements and Government grants	560,797	526,236	387,183	13
Net Loss for Period				
Canadian GAAP(1)	(8,640,355)	(9,599,942)	(6,603,837)	(7,59
United States GAAP(2)	(8,866,355)	(10,703,830)	(7,150,537)	(7,90
Net Loss per Common Share				
Canadian GAAP	(0.31)	(0.43)	(0.33)	
United States GAAP(2)	(0.32)	(0.48)	(0.35)	
Total Assets				
Canadian GAAP	11,484,114	14,012,304	9,807,644	9,24
United States GAAP(2)	11,486,266	14,012,304	9,807,644	9,24
Long Term Liabilities	117,463	118,384	164,276	9
Dividends per Share	0	0	0	

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(1) GAAP means Generally Accepted Accounting Principles.

(2) Refer to footnote 19 of the audited consolidated financial statements for the year ended March 31, 2001.

The following is a summary of the results of operations in accordance with accounting principles generally accepted in the United States for fiscal year ended March 31, 2001:(1)

	First Quarter Ended June 30, 2000		Second Quarter Ended Sept. 30, 2000		Thi
	Previously Reported	As Restated	Previously Reported	As Restated	Previ Repo
License fee and milestone payments	--	58,823	83,333	142,156	
Net income/(loss) before cumulative effect of change in accounting principle	(2,007,171)	(1,948,348)	(2,107,320)	(2,048,497)	(2,2
Cumulative effect of a change in accounting principle	--	(3,647,059)	--	--	
Net income/(loss)	(2,007,171)	(5,595,407)	(2,107,320)	(2,048,497)	(2,2
AMOUNTS PER COMMON SHARE:					
Income/(loss) before cumulative effect of change in accounting principle	(0.08)	(0.08)	(0.08)	(0.08)	

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Cumulative effect of a change in accounting principle	--	(0.15)	--	--	
Net loss	(0.08)	(0.23)	(0.08)	(0.08)	
Weighted average # shares	23,629,490	23,629,490	27,272,642	27,272,642	27,2

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(1) During the fourth quarter ended March 31, 2001, the Company changed its method of accounting for revenue recognition in accordance with Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements. Pursuant to Financial Accounting Standards Board Statement No. 3, Reporting Accounting Changes in Interim Financial Statements, effective April 1, 2000, the Company recorded the cumulative effect of the accounting change

and accordingly, the quarterly information for the first three quarters of fiscal year ended March 31, 2001 which had been previously reported has been restated. No restatement for the fiscal year ended March 31, 2000 was necessary.

The following is a summary of the results of operations in accordance with accounting principles generally accepted in the United States for fiscal year ended March 31, 2000:

	First Quarter Ended June 30, 1999	Second Quarter Ended Sept. 30, 1999	Third Quar Dec. 31
License fee and milestone payments	--	333,334	83
Net income/(loss) before cumulative effect of change in accounting principle	(3,046,771)	(3,031,514)	(2,000
Cumulative effect of a change in accounting principle	--	--	
Net income/(loss)	(3,046,771)	(3,031,514)	(2,000
AMOUNTS PER COMMON SHARE:			
Income/(loss) before cumulative effect of change in accounting principle	(0.14)	(0.14)	(
Cumulative effect of a change in accounting principle	--	--	
Net loss	(0.14)	(0.14)	(
Weighted average # shares	21,673,079	(22,017,670)	22,212

The following is a summary of the results of operations in accordance with accounting principles generally accepted in Canada for fiscal year ended March 31, 2001:

	First Quarter Ended June 30, 2000	Second Quarter Ended Sept. 30, 2000	Third Quar Dec. 31
License fee and milestone payments	--	83,333	
Net income/(loss) before cumulative effect of change in accounting principle	(1,907,280)	(1,902,886)	(2,160
Cumulative effect of a change in accounting principle	--	--	

Net income/(loss)	(1,907,280)	(1,902,886)	(2,160
AMOUNTS PER COMMON SHARE:			
Income/(loss) before cumulative effect of change in accounting principle	(0.08)	(0.07)	(
Cumulative effect of a change in accounting principle	--	--	
Net loss	(0.08)	(0.07)	(
Weighted average # shares	23,629,490	27,272,642	27,289

The following is a summary of the results of operations in accordance with accounting principles generally accepted in Canada for fiscal year ended March 31, 2000:

	First Quarter Ended June 30, 1999	Second Quarter Ended Sept. 30, 1999	Third Quar Dec. 31
License fee and milestone payments	--	333,334	83
Net income/(loss) before cumulative effect of change in accounting principle	(2,944,228)	(2,243,919)	(1,986

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Cumulative effect of a change in accounting principle	--	--	
Net income/(loss)	(2,944,228)	(2,243,919)	(1,986
AMOUNTS PER COMMON SHARE:			
Income/(loss) before cumulative effect of change in accounting principle	(0.14)	(0.10)	(
Cumulative effect of a change in accounting principle	--	--	
Net loss	(0.14)	(0.10)	(
Weighted average # shares	21,673,079	22,017,670	22,212

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS

OF OPERATIONS (All figures in U.S. Dollars unless noted otherwise.)

The following discussion should be read in conjunction with the Consolidated Financial Statements and the Notes thereto prepared in accordance with Canadian GAAP contained elsewhere in this Form 10-K. A reconciliation of amounts presented in accordance with U.S. GAAP is detailed in note 19 to the audited consolidated financial statements for the year ended March 31, 2001.

The following discussion and analysis explains trends in our financial condition and results of operations for the years ended March 31, 2001, March 31, 2000 and March 31, 1999. This discussion and analysis of the results of operations and financial condition of our Company should be read in conjunction with the Consolidated Financial statements and the Notes thereto included elsewhere in this Form 10-K. The consolidated financial statements have been prepared by management in accordance with Canadian generally accepted accounting principles, which conform to United States generally accepted accounting principles, except as described in Note 19 to the Consolidated Financial Statements.

OVERVIEW

Through its Drug and Gene Delivery Division, the Company is engaged in developing drug and gene delivery systems based on electroporation to be used in the site-specific treatment of disease. Through its BTX Instrument Division, the Company develops, manufactures, and sells electroporation equipment to the research laboratory market for non-human use.

In the past the Company's revenues primarily reflected product sales to the research market through the BTX Instrument Division, research grants through the Drug and Gene Delivery Division, and revenues from collaborative research and development arrangements. From October 1998 to August 2000 the Company received up-front licensing fees and milestone payments from Ethicon, Inc. and Ethicon Endo-Surgery, Inc.

The Company plans to seek a new licensing partner for the Electroporation Drug Delivery System. The Company will not receive any milestone or licensing payments for development or sale of the products until a new agreement is in place with a new partner and the Company achieves the milestones specified in the new agreement or product sales commence under the new agreement. The Company believes it has sufficient current resources to initiate activities directed toward product launch and marketing in Europe, and for initiation of a Phase III clinical study in the United States.

Until it achieves the commercialization of clinical products, the Company expects revenues to continue to be attributable to product sales to the research market, grants, collaborative research arrangements, and interest income.

Due to the expenses incurred in the development of the drug and gene delivery systems, the Company has been unprofitable in the last five years. As of March 31, 2001, the Company has incurred a cumulative deficit of $38,238,798. The Company expects to continue to incur substantial operating losses in the future due to continued spending on research and development programs, the funding of preclinical studies, clinical trials and regulatory activities and the costs of manufacturing and administrative activities.

RESULTS OF OPERATIONS

YEAR ENDED MARCH 31, 2001 COMPARED TO YEAR ENDED MARCH 31, 2000

REVENUES

The BTX Instrument Division produced net sales of $4,452,939 for the twelve months ended March 31, 2001, compared with net sales of $3,827,537, for the twelve months ended March 31, 2000, which meant an increase of $625,402, or 16.3%. The primary factor contributing to this increase was the result of higher sales through the Company's main distributors, VWR Scientific and Merck Eurolab, both members of the Merck Group. Merck Eurolab was added as a distributor in April of 2000. Also, in December 2000 the Company signed a non-exclusive distributorship agreement with Fisher Scientific Company to further promote sales to the United States.

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Non-U.S. sales increased by $332,693, or 27%, from $1,229,371 for the twelve months ended March 31, 2000 to $1,562,064 for the twelve months ended March 31, 2001. Export sales as a percentage of total sales by the BTX Instrument Division increased slightly from 32% in the twelve months ended March 31, 2000 to 35% in the twelve months ended March 31, 2001. The increase is mainly attributable to the addition of Merck Eurolab as a distributor to promote sales to Europe.

Total sales for the Company increased only by 8% since in the Drug Delivery Division no product for clinical trials was shipped in the year ended March 31, 2001 as opposed to shipments in the previous year. That is mainly attributable to the fact that the Phase II clinical trials were winding down and that in July 2000 the Company received notice from Ethicon that it had elected to exercise its discretionary right to terminate the License and Development Agreement and Supply Agreement.

Revenues from government grants funding decreased from $334,901 for the year ended March 31, 2000 to $101,086 for the year ended March 31, 2001. The reason for the decrease in grant revenues was that activities for grants awarded in previous years in the Oncology field and Gene Therapy field were winding down in the year ended March 31, 2001 and all active grants had expired by December 31, 2000. No new grants have been awarded as of the time of this filing. Revenues from grant funding may fluctuate from period to period based on the level of grant funding awarded and the level of research activity related to the grants awarded.

During the year ended March 31, 2001 the Drug and Gene Delivery Division recorded revenues under collaborative research and development arrangements in the amount of $459,711 as a result of collaborative research agreements to develop electroporation technology for use in particular gene therapy applications. This represents a significant increase over the same period of the previous year since the Company did not enter into these research agreements until the end of calendar 1999.

In August 2000, the Company received from Ethicon a final milestone payment in the amount of $83,333 in accordance with the above mentioned terminated License and Development Agreement.

Interest income for the year ended March 31, 2001 in the amount of $443,629 decreased by $112,564, or 25%, compared to the interest income for the year ended March 31, 2000 in the amount of $556,193. The decrease in interest income was attributable to the cash used in operating activities which resulted in decreased levels of interest bearing financial instruments.

COST OF SALES

Cost of sales for the BTX Instrument Division increased by $143,146, or 8%, from $1,781,972, for the twelve months ended March 31, 2000 to $1,925,118 for the twelve months ended March 31, 2001. The increase was primarily a result

of the 16.5% increase in net sales.

GROSS PROFIT AND GROSS MARGIN

Primarily due to the higher sales, the gross profit for the BTX Instrument Division for the twelve months ended March 31, 2001 in the amount of $2,527,821, increased by $482,256, or 24%, compared with $2,045,565 for the twelve months ended March 31, 2000.

The gross profit margin for BTX products increased slightly from 53% for the twelve months ended March 31, 2000 to 57% for the twelve months ended March 31, 2001. The 4% increase is mainly attributable to a change in product mix in favor of products with a higher profit margin due to the successful implementation of a niche market strategy in developing a market for the ECM 830 and ECM 2001.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses which include advertising, promotion and selling expenses, increased by $121,895, or 2%, from $5,610,830 for the twelve months ended March 31, 2000 to $5,732,725 for the twelve months ended March 31, 2001. While selling expenses for the year ended March 31, 2001 remained relatively constant compared to the previous year, general and administrative expenses increased slightly. The increase was primarily due to legal expenses incurred in the year ended March 31, 2001 for a review of our patent portfolio by a third party as well as legal expenses incurred for the planned continuation of the Company into the U.S. The increased legal expenses more than offset a decrease of other administrative expenses due to the closing of Genetronics SA as well as a decrease of outside consulting services.

RESEARCH AND DEVELOPMENT/CLINICAL TRIALS

Research and development costs decreased by $540,843, or 8%, from $6,977,220 for the twelve months ended March 31, 2000 to $6,436,377 for the twelve months ended March 31, 2001.

The expenses in the twelve months ended March 31, 2001, decreased over the previous year, primarily in the clinical and regulatory areas as a result of the delay of initiation of pivotal and other clinical trials in the U.S. These lower expenses more than offset higher expenses in the Gene Therapy area due to the increased focus on this field and higher engineering expenses in the BTX Instrument Division. The higher BTX Instrument engineering expenses were primarily related to an increase in the effective headcount and skill level of personnel assigned to a project to improve manufacturability and engineering design of the overall BTX product line.

NET INCOME/LOSS (NET INCOME/LOSS OF REPORTABLE SEGMENTS DOES NOT INCLUDE UNALLOCATED ITEMS SUCH AS INTEREST INCOME AND EXPENSE AND GENERAL AND ADMINISTRATIVE COSTS)

The BTX Instrument Division reported a net income in the amount of $670,903 for the twelve months ended March 31, 2001 compared to a net income in the amount of $332,657 for the twelve months ended March 31, 2000. The $338,246 increase was attributable to the 16.5% increase in net sales, which more than offset the higher operating expenses.

The Drug and Gene Delivery Division reported a net loss in the amount of $5,166,428 for the twelve months ended March 31, 2001 compared to a net loss in the amount of $6,073,667 for the twelve months ended March 31, 2000, a decrease

of $907,239. The decrease is a result of lower operating expenditures in the year ended March 31, 2001, which did not include -- as opposed to the previous year -- any restructuring charges. The lower operating expenses more than offset the decrease in revenues for the Drug Delivery Division, which were a result of lower revenues from grant funding and milestone payments.

For the twelve months ended March 31, 2001 the Company recorded a total net loss of $8,640,355 compared with a total net loss of $9,599,942 for the twelve months ended March 31, 2000, which meant a decrease of $959,587, or 10%. The higher loss in the previous year was mainly attributable to the one-time restructuring charges in the amount of $ 597,183 and the higher research and development expenses.

YEAR ENDED MARCH 31,2000 COMPARED TO YEAR ENDED MARCH 31, 1999

REVENUES

The BTX Instrument Division produced net sales of $3,827,537 for the twelve months ended March 31, 2000, compared with net sales of $3,434,105 for the twelve months ended March 31, 1999, which meant an increase of $393,432, or 11%. The primary factor contributing to this increase was the result of higher sales through domestic distributors, which increased by 31% over the previous year due to the successful implementation of the dedicated life sciences program at VWR.

Non-U.S. sales were basically flat. They decreased by $30,370, or 2%, from $1,259,741 for the twelve months ended March 31, 1999 to $1,229,371 for the twelve months ended March 31, 2000. As a result of the increased sales to domestic distributors non-U.S. sales as a percentage of total sales by the BTX Instrument Division decreased from 37% in the twelve months ended March 31, 1999 to 32% in the twelve months ended March 31, 2000.

In August of 1999 we introduced the ECM 630, an Exponential Decay Wave Electroporation system, which utilizes a Precision Pulse Technology, the new BTX Platform technology, and an all-ne