



RENEWAL ANNUAL INFORMATION FORM

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BIONICHE LIFE SCIENCES INC.

INTRODUCTION

Vetrepharm Inc. was incorporated in May, 1979 under the *Business Corporations Act* (Ontario) (the "OBCA"). In February, 1992, it segregated its animal health and human health businesses with the amalgamation of two of its wholly-owned subsidiaries, Bioniche Inc. and Caneire (Canada) Inc. with Almark Capital Ltd. to form Bioniche Inc. Following the amalgamation, Vetrepharm Inc.'s human health business was carried on by Bioniche Inc., a publicly traded company and the animal health business was carried on through privately held subsidiaries.

In 1996, Vetrepharm Inc. transferred its animal health business to Vetrepharm Animal Health Inc., a wholly-owned subsidiary at the time. Vetrepharm Inc. amalgamated with its parent, Vetrepharm Investments Holdings Inc., pursuant to articles of amalgamation dated July 1, 1998 under the OBCA and on July 2, 1998, by articles of amendment, changed its name to Renaissance Life Sciences Inc.

On September 1, 1999, Renaissance Life Sciences Inc., Bioniche Inc. and Vetrepharm Animal Health Inc. amalgamated to form Bioniche Life Sciences Inc. pursuant to articles of arrangement issued under the Canada *Business Corporations Act*.

On July 1, 2002, the Company's animal health business changed its name from Vetrepharm to Bioniche Animal Health. Accordingly, Vetrepharm Canada Inc. changed its name to Bioniche Animal Health Canada Inc., Vetrepharm Research, Inc. changed its name to Bioniche Animal Health USA, Inc., Vetrepharm Teoranta changed its name to Bioniche Animal Health Europe Limited and Vetrepharm (A/Asia) Pty. Ltd. changed its name to Bioniche Animal Health (A/Asia) Pty. Ltd.

Bioniche Therapeutics Inc. was wound up on March 1, 2002 and all of its assets were transferred to Vetrepharm Research Inc., which subsequently changed its name to Bioniche Therapeutics Limited on July 1, 2002. This subsidiary now holds all of the Company's research activities on both the animal and human health businesses.

The Company's registered and principal office is located at 231 Dundas Street East, Box 1570, Belleville, Ontario.

In this Annual Information Form, unless the context otherwise requires, Bioniche Life Sciences Inc., along with all of its subsidiaries where the context requires, is referred to as "Bioniche" or the "Company".

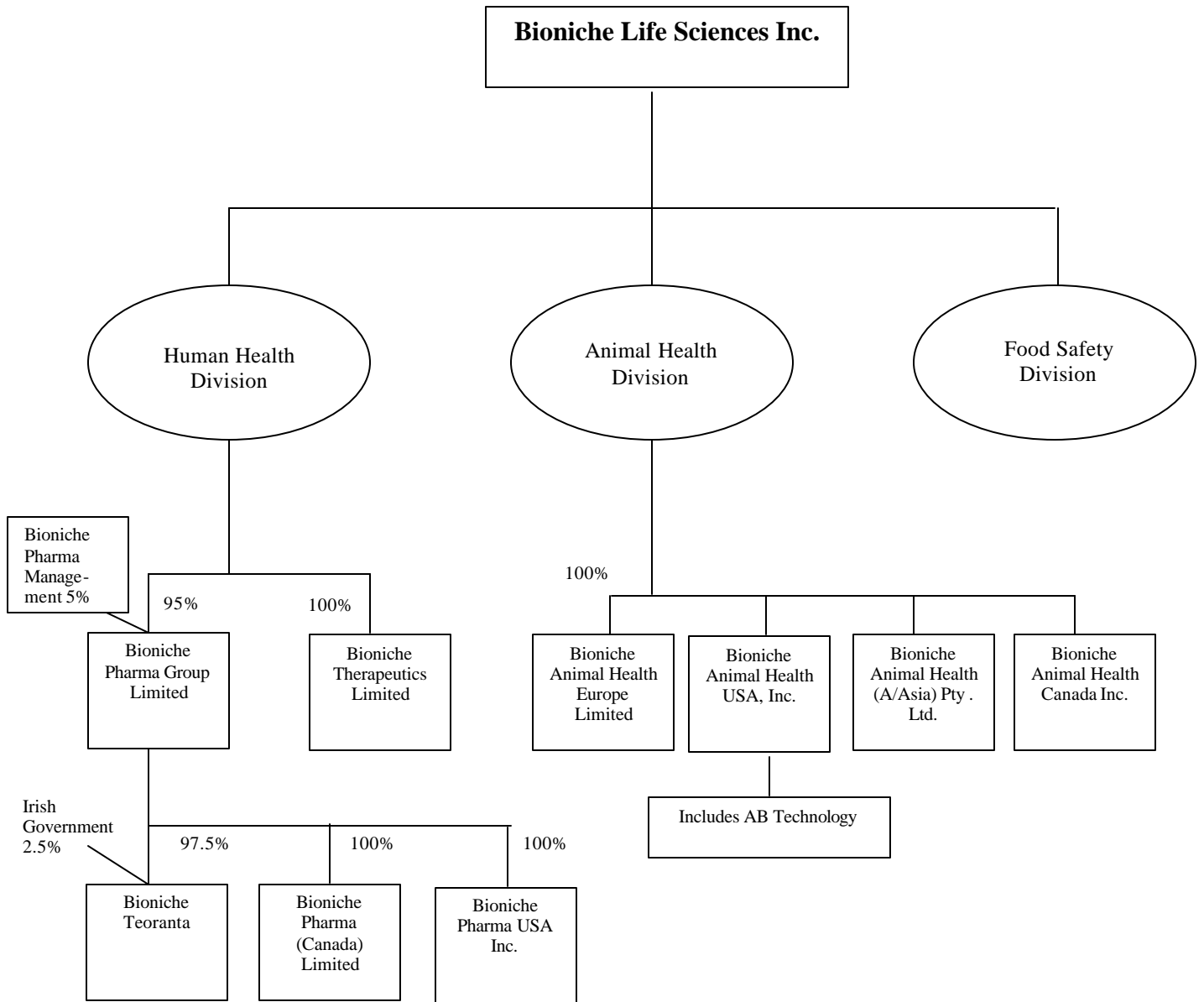
The following is a list of the material direct and indirect subsidiaries of the Company as of July 1, 2004:

Subsidiary	Jurisdiction of Incorporation	Percentage of Voting Securities Owned Directly or Indirectly by the Company	Percentage of Non-Voting Securities Owned Directly or Indirectly by the Company
Bioniche Animal Health USA, Inc.	United States	100%	N/A
Bioniche Animal Health (A/Asia) Pty. Ltd.	Australia	100%	N/A
Bioniche Animal Health Canada Inc.	Ontario	100%	N/A
Bioniche Animal Health Europe Limited	Ireland	100%	N/A
Bioniche Therapeutics Limited	Ontario	100%	N/A
Bioniche Pharma (Canada) Limited	Canada	95% ⁽¹⁾	N/A
Bioniche Pharma USA Inc.	Delaware	95% ⁽¹⁾	N/A
Bioniche Pharma Group Limited	Ireland	95% ⁽¹⁾	100% ⁽¹⁾
Bioniche Teoranta	Ireland	93% ⁽¹⁾	77% ⁽¹⁾

Notes:

- ⁽¹⁾ ICC Equity Partners Limited invested IR£3.5 million in Bioniche Pharma Group Limited in the form of a convertible loan which bears interest at 6% per annum and is convertible into approximately 31% of the voting shares of Bioniche Pharma Group Limited on a fully diluted basis and also holds 100 B ordinary shares of Bioniche Pharma Group Limited.

The following chart depicts the shareholdings of the Company and its principal subsidiaries:



GENERAL DEVELOPMENT OF BIONICHE'S BUSINESS

OVERVIEW

Bioniche Life Sciences Inc. is a leading Canadian biopharmaceutical company that develops, manufactures, and markets proprietary products for human and animal health markets worldwide. The Company is developing a pipeline of anti-cancer therapies based on its proprietary mycobacterial cell wall technologies.

The Company's animal health business was founded in 1979 by Graeme McRae, who believed that the major veterinary pharmaceutical companies were putting insufficient research efforts into alternative treatments to antibiotics as a solution to animal disease. Mr. McRae believed that there had to be more suitable ways of dealing with veterinary diseases that did not have the problems associated with antibiotics, such as residues in the food chain and the development of resistant bacterial species.

In 1992, the human application of the original technologies and an Irish sterile injectables manufacturing plant were licensed into a separate public company called Bioniche Inc. Effective September 1, 1999 all of these businesses were amalgamated under the name of Bioniche Life Sciences Inc.

The Company employs approximately 305 people and has three principal reporting segments: Human Health, Animal Health and Food Safety.

The Human Health division consists of two units:

- Bioniche Therapeutics, the research division of the Company, develops proprietary technologies for use in human medicine. The Company's primary strategy is to develop technologies through to early clinical stage development, then to establish strategic alliances for late stage clinical development, registration and marketing. This division is also responsible for the marketing of the Company's proprietary product *Cystistat*®.
- Bioniche Pharma is responsible for the development, manufacturing and marketing of sterile injectable products and other pharmaceuticals for human health. Its products are currently sold directly to the hospital market in Canada and through pharmaceutical distributors worldwide. It also holds the rights to the Company's proprietary product *Suplasyn*®. In addition, Bioniche Pharma acts as a contract manufacturer for pharmaceutical companies and manufactures products for Bioniche Therapeutics and Bioniche Animal Health.

Bioniche Animal Health, the animal health division of the Company, is responsible for researching, developing, manufacturing and marketing veterinary biopharmaceutical products worldwide. Established in 1979 to develop technologies to replace antibiotics in livestock, management believes that the Company is now the largest Canadian-owned biopharmaceutical animal health company. Bioniche Animal Health has marketing subsidiaries in Canada, the United States, Australia and Europe and operates through distributors worldwide. Research for the animal health division is conducted through Bioniche Therapeutics Limited.

The Food Safety Division was established in July 2001. The division is responsible for researching, developing, manufacturing and marketing veterinary biopharmaceutical products to improve the safety of food and water supplies worldwide. The leading initiative for this division is the development and commercialization of a new cattle vaccine for the prevention of the spread of the deadly *E. coli* 0157:H7 bacteria.

RECENT DEVELOPMENTS

The Company's clinical development program continues to progress well, with preparations for its upcoming Phase III clinical trial using its proprietary Mycobacterial Cell Wall-DNA Complex (MCC), for the treatment of bladder cancer. This will be an international trial involving approximately sixty sites in North America and Europe. The Company is working on the finalization of a single protocol for the trial which will be used in all jurisdictions. The results of the Company's Phase II studies have shown significant positive response rates.

The Company continues to move forward in its program to obtain registration in Canada and the United States of its vaccine to reduce fecal shedding of *E. coli* O157:H7 into the environment. It is this bacterium that causes contamination of food and water which has led to more than 70,000 human infections and sixty deaths annually in the United States as well as the recall of over 20 million of pounds of beef across North America. The Company has previously released positive research results relating to the vaccine, demonstrating that feedlot cattle vaccinated with the vaccine showed a significant reduction of the deadly bacteria in their manure. A vaccine challenge study conducted by the Vaccine and Infectious Disease Organization with the vaccine earlier this year demonstrated a significant reduction in the prevalence of *E. coli* O157 shedding by experimental challenge. Further trials have been completed by Drs. Moxley and Smith from the University of Nebraska – Lincoln to test the efficacy of the vaccine during the backgrounding and feedlot stages of beef production. Safety and efficacy trials are currently underway to satisfy licensing requirements in Canada in the United States. Once these studies are completed, the Company will be in a position to submit the dossier to the regulatory agencies for registration in Canada and the United States. The Company is currently in discussions with the United States Department of Agriculture as to which is the appropriate agency to regulate this vaccine in the United States.

In the past year the Company's animal health division made two strategic acquisitions. On February 11, 2004, the Company acquired the assets of AB Technology Inc., an American veterinary products company in Pullman, Washington, which is considered a leader in the development of embryo transfer media, materials and equipment for the bovine and equine markets. This business fits well with the Company's business strategy and strengthens its focus on animal reproduction. On March 29, 2004, the Company acquired from Pfizer Inc. the intellectual property and other assets of the *Cue-Mate*® business, an innovative livestock reproductive technology. *Cue-Mate*® complements the range of reproductive technologies and services developed and marketed by the Bioniche Animal health division. This acquisition is in line with the Company's business strategy to expand the line of products that complement and enhance its core business. *Cue-Mate*® is a uniquely-designed progesterone delivery device for cows that allows dairy farmers and cattle producers to plan and manage the reproductive timing of their herds. *Cue-Mate*® is currently registered and commercially available in Australia and New Zealand.

To address the Company's capital needs during 2004, the Company was active in raising the following funds.

On September 9, 2003, the Company closed the second tranche of the \$13.5 million loan from a syndicate of Canadian institutions and received the balance of the loan, equal to \$9.45 million. The Company used the proceeds to repay the balance of the \$9.0 million US convertible debenture held by a private investor group and for general corporate purposes. As a result of the early extinguishment of the \$9.0 million US loan and conversion option, a gain of \$1.7 million was realized. This refinancing was aimed at strengthening the Company's balance sheet and complimenting the overall business strategy in North America.

On February 17, 2004, the Company completed a private placement offering of 5,000,000 units at a price of \$2.00 per unit for gross subscription proceeds of \$10 million. Each unit was comprised of one common share and one-half of one common share purchase warrant. The proceeds were used for the MCC bladder cancer program, the development of the *E. coli* O157:H7 vaccine and general corporate purposes.

On May 20, 2004, Bioniche Pharma Group Limited entered into a financing agreement with the Bank of Ireland for the purchase and building of an expanded facility in Galway, Ireland for the manufacture and sale of pharmaceutical injectable products. This loan is comprised of two facilities totalling 8.2 million Euro for land, development costs and purchase of equipment, and two facilities of 2.5 million Euro for currency hedging and interest rate swaps in connection with the loan.

Also in connection with the expansion of the Company's manufacturing facilities in Ireland, on May 20, 2004, Údarás Na Gaeltachta, an Irish development corporation, provided a capital grant of 1.9 million Euro to Bioniche Pharma to be used for upgrades and expansion of the Irish facility and for training. At the same time, Údarás increased its investment in Bioniche Teoranta, a subsidiary of Bioniche Pharma, by purchasing an additional 700,000 Euro in preferred shares. These financing activities are intended to strengthen the Company's manufacturing capabilities and to complement the business strategy in Europe for pharmaceutical injectable products.

On November 3, 2004 the Company completed an equity financing of \$10,000,000 with the Fonds de solidarité des travailleurs du Québec ("FSTQ") and \$2,000,000 with the Fonds d'investissement bioalimentaire, sec ("Fonds Bio"), the proceeds of which are to be used for the Phase III clinical trial with MCC for the treatment of bladder cancer, MCC for animal health applications, and the *E. coli* O157:H7 vaccine development. The investment consists of a private placement offering of 12,000,000 newly created Series 2 preferred shares to FSTQ and Fonds Bio for a total subscription price of \$12,000,000. The Series 2 preferred shares are convertible at the option of the holder into common shares for five years.

To support its intellectual and physical assets, the Company filed a total of eleven new patent applications related to its platform technologies between July 1, 2003 and June 30, 2004. Thirty six patents were granted internationally for the use of hyaluronan technology in the treatment of interstitial cystitis, radiation cystitis and cancer and three patents were granted relating to mycobacterial cell wall technology over this period. From July 1, 2004 to September 30, 2004 period, two further patent applications were filed in the area of MCC technology and thirty-five additional patents were granted internationally, of which thirty-four patents were related to MCC technology, and one related to reproductive technology.

NARRATIVE DESCRIPTION OF THE BUSINESS

BUSINESS STRATEGY

The Company has a three-fold strategy. First, it will take the existing proprietary technologies and continue, through its research and development program, to enhance their proven therapeutic and prophylactic value for human and animal use. Secondly, the Company intends to enhance their intrinsic product value by commercializing these new technologies alone or with strategic partners. Thirdly, it will manufacture as many of its products emerging from the research program as it can to enhance profit margins, protect the integrity of its products and enhance shareholder value.

HUMAN HEALTH DIVISIONS

The Company's human health division consists of two units: Bioniche Therapeutics and Bioniche Pharma. Growth in the Company's total sales of human health products on a worldwide basis was 28.98% for fiscal 2002, 65.50% for fiscal 2003 and 4.89% for fiscal 2004.

Bioniche Therapeutics

Bioniche Therapeutics Limited is engaged in the identification, development, production and commercialization of proprietary technologies for the human health market, which involves both pre-clinical and clinical research.

Business Objectives

Due to the increasing market surveillance of and sensitivity to products of animal origin, a key objective for the Company has been to develop an MCC product that is free of products of animal origin. This has required upgrades to the manufacturing facility in Montreal, Quebec and changes in the manufacturing process for its mycobacterial cell wall compositions. During 2004 the Company completed the required upgrades to the manufacturing facility in Montreal, Quebec. The Company is now able to produce MCC product free of products of animal or plant origin in a GMP environment. All regulatory submissions made by the Company for clinical trials with MCC reflect these changes.

The Company has focussed on developing its *Oligomodulator*TM platform in the areas of immune stimulation, vaccine adjuvant activity and anticancer applications. The Company's objective is to develop one or more oligonucleotide drug candidates for future clinical evaluation.

The Company continues to expand the marketplace for *Cystistat*[®] by advancing its use for multiple types of cystitis focussing on interstitial cystitis, cystitis caused by infections and radiation induced cystitis. The Company is currently engaged in discussions with the United States Food and Drug Administration regarding the potential for approval of *Cystistat*[®] in the United States.

Products

The Company continues to market *Cystistat*[®] one of its two proprietary products in human health. The second product, *Suplasyn*[®] used for the treatment of osteoarthritis is discussed in detail under the heading "Bioniche Pharma."

Cystistat[®] is made from hyaluronan (hyaluronic acid), one of the Company's platform technologies. *Cystistat*[®] is indicated for the temporary replacement of the glycosaminoglycan (GAG) layer in the bladder. There is evidence that the GAG layer of the bladder is deficient in conditions known as cystitis, a group of syndromes of acute or chronic origin. This deficiency contributes to the clinical symptoms in diseases such as interstitial cystitis (IC), cystitis caused by infections, trauma, urolithiasis, urinary retention, neoplasia and radiation induced cystitis. Treatment with *Cystistat*[®] has been shown to alleviate clinical symptoms in patients with several of these conditions, i.e. bacterial cystitis, radiation induced cystitis and IC. *Cystistat*[®] is registered as a medical device in Canada and Europe.

The Company continues to expand the marketplace for *Cystistat*[®] by advancing its use for multiple types of cystitis focussing on interstitial cystitis, cystitis caused by infections and radiation induced cystitis. The Company has initiated and finalized several post-approval European and Canadian studies.

A preliminary study on the use of *Cystistat*® for the prevention of recurrent bacterial cystitis was published in the British Journal of Urology (Constantinides, C, et al, BJU, 93, 1262-1266). This prospective study evaluated forty women with a history of recurrent urinary tract infections (UTI). No patients had a UTI during the five month study and the median time to recurrence after *Cystistat*® treatment was four hundred and ninety-eight days, compared with ninety-six days beforehand. This study shows that *Cystistat*® is a promising therapeutic alternative in patients with recurrent UTI's. Further studies are ongoing in this area to confirm the efficacy of *Cystistat*® for the treatment of recurrent bacterial cystitis.

In April, 2004 the Company initiated an international, randomized, double-blind, placebo-controlled study of *Cystistat*® designed to assess the efficacy and safety of intravesical *Cystistat*® in the treatment of women with interstitial cystitis; the trial is focused on a sub group of IC patients presenting a reduction in maximal bladder capacity of at least 30% in response to the comparative cystometry test (CCT). The CCT test first published in the Journal of Urology by European urologists, Dr. Daha and Dr. Riedl in September 2003 identifies IC patients who have an 80% chance of responding positively to *Cystistat*® treatment. The study is intended to support the reimbursement dossier of *Cystistat*® in the European and Canadian markets. When fully implemented, this study will evaluate one hundred and thirty-seven patients with interstitial cystitis at about twelve sites in Europe and Canada. As of June 30, 2004, nine European and Canadian sites are recruiting patients and the study is on-going.

Research and Development

Mycobacterial Cell Wall-DNA Complex (MCC)

MCC is one of the Company's lead technology platforms. MCC is a cell wall-DNA composition prepared from a pure culture of the bacterium *Mycobacterium phlei*. The cell wall complex has been fractionated and purified to optimize the presence of the active molecule, DNA, which is responsible for the range of immunomodulatory and direct anti-cancer activities.

The Company has focused its preclinical and clinical research on the use of its proprietary MCC technology in the treatment of cancer. These research programs have demonstrated MCC's effectiveness as an immunomodulator and antitumour agent in a range of models. The Company has achieved a research breakthrough by identifying mycobacterial DNA as the active component of *Mycobacterium phlei* cell wall preparations.

Since June 30, 2003, the Company enhanced its patent portfolio with the granting of thirty six new patents for MCC. Five new patent applications were filed for this technology during this period. MCC has a dual mode of action in that it induces apoptosis in cancer cells as well as stimulating anticancer and immunomodulatory cytokine production by immune effector cells.

- *Apoptosis:* The mycobacterial DNA in MCC induces programmed cell death (apoptosis) in cancer cells. The induction of apoptosis occurs in cancer cells including multidrug resistant cancer cells and in cells with mutations in cell cycle regulators. The induction of apoptosis is associated with a dose-dependent inhibition of cancer cell division. This activity has been demonstrated in a wide range of cancer cell lines derived from bladder, breast, leukemia, melanoma, ovarian and prostate tumours. The Company believes that MCC's ability to induce apoptosis in cancer cell lines regardless of the presence of mutations in tumour suppressor genes and multidrug resistance is significant. Accumulated mutations in cancer cells can often lead to significantly greater resistance to treatment, eventually making conventional chemotherapeutic strategies ineffective.

- *Combination with chemotherapeutic agents.* The ability of MCC to interact with chemotherapeutic agents to inhibit the division of human bladder cancer cells has been evaluated. Data to date demonstrates that MCC interacts synergistically with chemotherapeutic agents, thus offering the potential for combination therapy.
- *Immunomodulatory activity:* MCC induces macrophages to produce cytokines including IL-6 and IL-12. IL-12 is known to possess anti-angiogenic activity (prevention of blood vessel formation in tumours) and activates NK (natural killer) and cytotoxic T lymphocytes that are associated with anticancer responses. MCC acts as an immune stimulant following intravesical administration, as evidenced by a stimulation of urinary cytokines.

The Company's pre-clinical studies have demonstrated that MCC suspension does not appear to induce genotypic or phenotypic resistance in human bladder cancer cell lines (derived from low or high grade bladder tumours) following exposure to sub-optimal concentrations of MCC over prolonged periods of time (data presented at the 2003 Annual Meeting of the American Urological Association, Chicago, 2003). MCC suspension has also been shown to significantly inhibit the expression of a number of key intracellular signaling enzymes associated with cell survival and proliferation, results consistent with the ability of MCC to cause cell cycle arrest and induce apoptosis (data presented at the XVIIIth Congress of the European Association of Urology, Madrid, Spain, 2003). MCC has also been shown to interact synergistically with the chemotherapeutic agents Doxorubicin, Epirubicin and Mitomycin c in inhibiting the proliferation of bladder cancer cell lines derived from both high-grade and low-grade bladder cancer (data presented at the American Urological Association Annual Meeting, San Francisco, USA, 2004). In a study presented at the 12th International Congress of Immunology, Montreal, Quebec, 2004, the Company demonstrated that the intravesical administration of MCC in patients with bladder cancer results in elevation of urinary cytokine synthesis, the profile of which is consistent with an activation of monocytes and macrophages in the bladder wall. Further confirmation of MCC's immune stimulant activity was shown by analysis of IgG antibodies against MCC and BCG following its intravesical administration in patients with bladder cancer (data presented at the American Urological Association Annual Meeting, San Francisco, USA, 2004).

The Company has further extended the scope of application of MCC by examining its potential to act as an anticancer agent/immune stimulant in dogs. MCC has been shown to act against canine osteosarcoma cell lines (inhibition of proliferation and induction of apoptosis), as well as interacting synergistically with anti-osteosarcoma chemotherapeutic agents (data presented at the 22nd Annual American College of Veterinary Medicine Meeting, Minneapolis, USA, 2004). The treatment of canine cancer with conventional chemotherapeutics has many of the problems seen in the treatment of human cancer.) for example multidrug resistance, lack of efficacy and toxicity). MCC appears to be well positioned for use in this expanding market place.

The Company's primary research objective is to develop formulations of MCC for the treatment of a range of cancers. These programs are discussed on page 13 under the heading Product Development Candidates

Oligonucleotides

In 2000, the Company announced that its Therapeutics division had discovered a new class of molecules with potential anticancer activity, referred to by the Company under the trademark "Oligomodulator"TM. This new class of molecules with potential clinical anticancer activity and immune modulating properties is composed of short DNA oligonucleotides that appear to possess a range of novel pharmacological activities.

The Company's pre-clinical research indicates that the ability of these molecules to inhibit the division of human cancer cells occurs as a result of blocking the cell cycle and inducing programmed cell death (apoptosis). These oligonucleotides also have the ability to stimulate cytokine synthesis from certain mononuclear cells. Activity has been demonstrated against a range of different human cancer cell types, thus offering potential for their development as novel chemotherapeutic agents with wide ranging applicability for the treatment of cancer.

- On September 19, 2002 the Company presented positive pre-clinical proof of principle data demonstrating in vivo anticancer activity against leukemia and lymphoma of *Oligomodulator*TM BT99-25, one of its lead anti-cancer Oligonucleotide, at the GOAL Leukemia 2002 meeting, held in Miami, Florida.
- On May 30, 2003 the Company presented positive pre-clinical proof of principal data demonstrating immune stimulant and vaccine adjuvant activity of its oligonucleotides BT 99-25 and BT 99-45 at the Modern Vaccines and Adjuvant Delivery Systems Symposium, held in Dublin, Ireland.
- On July 21st 2004, the Company presented positive data demonstrating that its oligonucleotides have the ability to act as costimulators for T-cells, and thus possess a type 2 adjuvant activity at the 12th International Congress of Immunology, Montreal, Quebec. Stimulation of mature Dendritic cells was also demonstrated in the same study. These data provide a mechanistic explanation of the in vivo adjuvant activity previously observed. These results emphasize the potential therapeutic range of application of these molecules (immune stimulant and vaccine adjuvant).

This new technology platform has the ability to quickly synthesize and test new sequences and analogues and the potential to develop oligonucleotide combinations for specific applications (the "toolbox" approach). This approach will enable the Company to tailor the pharmacological activity of the oligonucleotides to the disease (eg. direct anticancer activity or immune stimulation/vaccine adjuvant activity).

In management's view, these recent discoveries represent a significant step forward in the expansion of the Company's technology platform base, which now encompasses both biological and pharmaceutical-based small drug therapeutic entities. It is believed the identification of these molecules will also continue to enhance the Company's intellectual property portfolio. The recent data provides the Company with a solid basis for the clinical development of the *Oligomodulator*TM platform. Since June 30, 2003, the Company filed four additional patent applications for this technology.

The Company is now proceeding to develop the oligonucleotide platform through additional pre-clinical research in the immunomodulatory and anti-cancer areas.

Product Development Candidates

MCC for Bladder Cancer

The Company's Phase I/II study using MCC to treat superficial bladder cancer has been completed. The study involved fifty-five patients who suffered from carcinoma in situ (CIS), one of the most aggressive and difficult to treat forms of superficial bladder cancer, which was refractory to the traditional treatments of *BCG* (Bacillus Calmette-Guérin) or chemotherapy. The positive results were presented at the annual meetings of the American Urology Association in May, 2004 and the Canadian Urology Association in June, 2004. The data presented confirms MCC activity for the treatment of

patients with CIS at the doses of 4 mg and 8 mg per intravesical instillation. The 8 mg dose was shown to be more effective in the terms of efficacy, remains very well tolerated and has been chosen as the active dose to be tested in the Phase III pivotal clinical trial.

The Company is now preparing for the Phase III clinical trial, working in conjunction with international clinical experts, and discussions are ongoing with regulatory agencies. The Company expects to confirm the Phase III requirements by the end of 2004. The proposed pivotal study will recruit patients in North America and Europe in an international randomized comparative Phase III study involving approximately sixty clinical sites in both continents. Dr. Alvaro Morales, Professor of Urology and Oncology at Queen's University in Kingston, Ontario will be the International Principal Investigator. Dr. Harry Herr, Urologist and Oncologist/Fellow at Memorial Sloan-Kettering Cancer Center in New York and at the New York Hospital – Cornell Medical Center will be the North American Principal Investigator, and Dr. Laurent Boccon-Gibod, Urologist and Oncologist at the Bichat-Claude Bernard Hospital in Paris, France will be the European Principal Investigator. The Company has also initiated discussions with different collaborative groups and granting agencies for the support of this pivotal program.

The target population for the Phase III trial will be patients with high risk superficial bladder cancer who are at high risk of progression or recurrence. MCC will be compared directly to BCG (Bacillus Calmette-Guérin). This is a patient population in North America and Europe of approximately 96,000 new patients per year, each requiring forty-two doses over a three-year period. The Company is working on the development of a single protocol for the trial which will be utilized in all jurisdictions, in consultation with the United States Food and Drug Administration, the Canadian Health Protection Branch and the European Medicines Agency ("EMEA"), as well as an international panel of experts.

The Company will also initiate a "Marker Lesion study" with a European collaborative group in the first quarter of 2005 as part of the supportive data needed for the registration of the product in Europe.

MCC for Prostate Cancer

The Phase I study of MCC in prostate cancer was presented at the annual meeting of the Canadian Urology Association. As the Company is now focusing its resources toward the pivotal trial in superficial bladder cancer, this program will be continued once the appropriate funding can be gathered.

MCC for Other Indications

The scientific and clinical data produced by the Company in the past few years has generated a significant interest in the oncology community. The Company is actively discussing with opinion leaders in oncology other potential indications of MCC in the treatment of locally accessible tumours, such as ovarian cancer or metastatic hepatic cancers. These programs will be initiated once additional funding is available.

Sales and Marketing

Cystistat®

The Company has entered into exclusive distribution agreements with various pharmaceutical companies for the distribution of Cystistat® world-wide. In the past year, it has continued to expand its distribution network in Asia, the Middle East and Europe. The following details the countries in which

Cystista® is sold, the pharmaceutical companies with whom distribution agreements have been entered into in such countries and the date such distribution agreements were entered into:

<u>Country</u>	<u>Company</u>	<u>Date</u>
Korea	Ahn-Gook Pharmaceutical Co. Ltd.	July, 2002
China	For-U Biopharma Co. Ltd.	January, 2002
Saudi Arabia	United Corporation for Pharmaceuticals and Medical Services Ltd.	April, 2002
Netherlands	Lapis Lazuli International NV	February, 2002
Switzerland and Liechtenstein	Robapharm AG	April, 2003
Turkey	Gürel Ilac Ticaret A.S.	March 2001
Israel	Medison Pharma Ltd.	February, 2003
Germany	CytoChemia	July, 2000
Italy	Zambon Italia	June, 2000
Austria	Sanova Pharma GesmbH	March, 2000
Greece and Cyprus	Vocate Pharmaceuticals Ltd.	November, 1999
Spain	Laboratorios Rubio, S.A.	October, 1999
Ireland	Technopharm Limited	July, 1999
England, Northern Ireland, Scotland and Wales	Pliva Pharma Limited	December, 1998
Denmark, Norway, Finland, Sweden, Iceland	IPC – Nordic A/S	March, 1997
Malaysia, Brunei and Singapore	Advance Pharma sdn bhd	April, 2003
Taiwan	Harvester Trading Company	September, 2002
Slovak Republic, Bulgaria, Romania, Ukraine, Belarus, Armenia, Azerbaijan, Georgia, Kazakhstan, Cyprus	Medial AG	August, 2003
South Africa, Botswana, Lesotho, Namibia, Swaziland, Mauritius and Kenya	Pharmaco Distribution Ltd.	September 30, 2003
Czech Republic, Hungary and Slovenia	CREAmed Ges.m.b.H	July, 2004
Brazil	Sigma Pharma Limited	July, 2004

Following the termination of the Company's Canadian distributor, the Company has taken on direct marketing and sales responsibilities. The Company is currently in discussions with other distributors for the sale of *Cystistat*® in other parts of the world.

Market Analysis

MCC

Management believes that the Company's MCC technology has potential as an anti-cancer therapy, both alone and in combination with other therapies. As the development of commercial applications for the MCC technologies is several years away, it is difficult to assess the size of the full potential market. Potential applications for the MCC technology include bladder and prostate cancer, adenocarcinomas and certain types of leukaemia. While focusing on bladder cancer, the Company is evaluating the potential of the technology in other cancers and specifically those cancers that are resistant to immunotherapy and chemotherapy.

The Company believes that following successful demonstration of clinical efficacy, MCC may be used in conjunction with existing therapies, especially in those cancers where such treatment is known to be of marginal effectiveness because of the development of treatment resistance. While full market penetration is not envisaged for any of the following cancers, the market potential for MCC can be estimated by reference to cancer estimates in the United States for 2002:⁽¹⁾

<u>Cancers</u>	<u>Incidences</u>	<u>Deaths</u>
Prostate	189,000	30,200
Breast	205,000	40,000
Lung	169,400	154,900
Colon and rectum	148,300	56,600
Urinary bladder ⁽²⁾	56,500	12,600
Melanoma	53,600	7,400
Leukaemia	30,800	21,700
Pancreas	30,300	21,700
Ovarian	23,300	13,900
Cervical	13,000	4,100

(1) Cancer Facts and Figures - 2002, American Cancer Society.

(2) European incidence is estimated in the medical literature to more than 84,000 new cases per year (Ferlay J, Bray F, Sankila R, Parkin DM. Cancer incidence, mortality and prevalence in the European Union. Lyon: IARC Press. 1999)

Cystistat®

Cystistat® is indicated for treatment of various types of cystitis including interstitial cystitis, radiation cystitis and bacterial cystitis.

The size of the interstitial cystitis market is difficult to assess, as accurate diagnosis is very difficult. It is estimated by management that 180,000 people in the United States have interstitial cystitis. The prevalence of the condition in Europe is believed by management to be approximately the same as in the United States, implying a potential combined European and American market of up to 400,000 sufferers. Management believes that a course of treatment, which consists of between six to twelve doses at a current price of U.S. \$75 per dose, implies a potential American and European market of approximately U.S. \$250 million.

In the United States, approximately 375,000 cases of prostate, uterine, bladder and rectal cancer are diagnosed each year. Of these, management estimates that approximately 90,000 are treated with radiation and approximately 20% develop severe radiation cystitis. The prevalence of this condition in Europe is believed by management to be approximately the same as in the United States. Assuming a treatment of four doses at U.S. \$75 per dose, management believes that the potential European and American market is estimated at U.S. \$10 million.

Competition

Oncology

The Company's cancer treatment product candidates will face competition from both currently used therapies and from new therapies based on the use of novel compounds. The Company expects it may experience competition from established and emerging pharmaceutical and biotechnology companies that have other forms of treatment for the diseases targeted by the Company as well as from other companies operating in the therapeutic fields targeted by the Company. The Company may also experience competition from companies that have acquired or may acquire technology from universities and other research institutions.

The Company may face significant competition as it expands its development programs to develop drugs for diseases for which a variety of treatments already exist. The Company faces similar competitive concerns from biotechnology companies that are working to develop novel treatments based on new classes of compounds. However, as an oncology regimen often uses a number of drugs in combination, the market for the Company's drugs may not necessarily exclude the use of other treatments.

In addition, the Company may face competition from other companies for opportunities to enter into collaborative arrangements with pharmaceutical and biotechnology companies and academic institutions and to obtain licenses to proprietary technology from other parties.

Cystistat®

The interstitial cystitis market represents an unmet medical need. The current market for *Cystistat®* is composed of two therapeutic categories for the treatment of interstitial cystitis: intravesical and oral therapy. *Elmiron*, an oral therapy currently available in the United States, may take over six months for patients to feel some relief. A recent randomized placebo controlled pilot trial on the use of a combination of pentosan polysulfate sodium (*Elmiron*) and hydroxyzine was published in 2003 and showed no statistical difference in the response rate. Other therapies in development, namely resiniferatoxin (RTX), tibial nerve stimulation and *BCG* have also recently failed to reach statistical

significance. *Cystistat*® has been clinically shown to provide relief in the shorter term. *DMSO* (dimethylsulfoxide) is an alternative intravesical therapy but is not widely accepted by interstitial cystitis patients due to some side effects. Management believes that *Cystistat*® has competitive advantages over

these products, including proven efficacy, a favourable safety profile and the obtaining of results in a shorter period of time. As the Company continues to generate additional clinical data to demonstrate clinical efficacy and distributors are established in the European market, management believes it will be able to increase its position in the interstitial cystitis market.

The Company has continued its efforts to expand the therapeutic indications of *Cystistat*® by initiating and finalizing post approval studies at various European and Canadian research institutions to support the marketing efforts.

Bioniche Pharma

The Company's subsidiary, Bioniche Pharma Group Limited, is responsible for the development, manufacturing and marketing of sterile injectable products as well as the Company's proprietary product *Suplasyn*®. Bioniche Pharma manufactures both branded and non-branded products as well as the Company's proprietary products. Its products are primarily sold in the United States, European and Canadian markets. The sales, marketing and business development activities of Bioniche Pharma are largely handled through Bioniche Pharma (Canada) Limited, the Company's subsidiary located in Montreal, Quebec, and by its representative office in Geneva, Switzerland. The Company has negotiated distribution agreements with various pharmaceutical companies worldwide for the marketing and sales of *Suplasyn*®. Bioniche Pharma USA Inc. was incorporated in June, 2002 to handle sales, marketing and business development operations for the United States market.

Bioniche Teoranta, its Irish manufacturing subsidiary, owns and operates a GMP compliant facility located in County Galway, Ireland, consisting of 25,000 square feet of manufacturing facility and a second 20,000 square foot facility comprising packaging, warehousing and office space. The Company recently announced that it is constructing a new cGMP manufacturing facility at its Irish site to accommodate its business requirements. The expansion will provide an additional 25,000 square feet of manufacturing space and is expected to be completed and validated by September, 2005. The expansion has been financed by a loan from the Bank of Ireland of up to 8.2 million Euro, (together with additional facilities of up to 2.5 million Euro to be used for currency hedging and interest rate swaps in connection with this loan). Also in connection with this expansion, Údarás Na Gaeltachta, an Irish development corporation, has provided grant aid totaling 1.9 million Euro and added to its existing equity investment in Bioniche Teoranta by purchasing 700,000 Euro of preferred shares. This expansion will increase the Company's manufacturing capacity and provide upgraded equipment that will improve efficiency.

Bioniche Teoranta has received the necessary approvals from the regulatory authorities in all its major markets including Europe, Canada and the United States to manufacture and sell sterile injectable products manufactured to GMP standards to such markets. Bioniche Teoranta's GMP status is an essential part of Bioniche Pharma's worldwide manufacturing and marketing strategies.

Products

Sterile Injectables and Others

Bioniche Pharma develops, manufactures and distributes sterile injectable pharmaceuticals in vials and pre-filled syringes with a primary focus on the primary care and hospital markets in the United States. The Company's product development focus is on Abbreviated New Drug Applications (ANDA's) for the United States market. During the last few years the Company has obtained a total of eleven

ANDA's. In addition, the Company has additional ANDA's pending and an active portfolio of products in development.

Bioniche Pharma has received ANDA approval in the United States on the following sterile injectable preparations, which it has either commenced marketing or is in the process of launching into the United States market:

PRODUCT	DATE APPROVED
Ketamine HCL 50mg/mL	December 28, 2001
Ketamine HCL 100mg/mL	October 31, 2002
Edetate Disodium 150mg/mL	July 9, 2002
Amiodarone 50mg/mL	October 15, 2002
Promethazine HCL 25mg/mL	November 21, 2002
Dimethyl Sulfoxide Irrigation 50% w/w	November 29, 2002
Milrione Lactate	June 17, 2003
Mesna	December, 2003
Cyanocbalomine	July, 2003
Sotradecol 1%	November, 2004
Sotradecol 3%	November, 2004

The Company also manufactures proprietary hyaluronan based products for the Company's Therapeutics and Animal Health divisions including *Cystistat*®, *Map-5*® and *Enhance*®

Suplasyn®

Suplasyn® is a hyaluronan agent for the management of osteoarthritis. *Suplasyn*® is used as a replacement for synovial fluid, the naturally occurring lubricant in articular joints such as the knee and elbow. Osteoarthritis is associated with synovial fluid degradation, the result being a loss of lubricant effect and considerable pain. Administration of *Suplasyn*® into affected joints replaces and augments the natural supply of synovial fluid. Intra-articular hyaluronic acid therapy is widely accepted in Europe, Asia, and Canada as an effective treatment for osteoarthritis. It is anticipated that this therapy will continue to grow globally.

Registered for use in Canada, in the European Union, and in other jurisdictions, *Suplasyn*® competes in the international viscosupplementation market in various countries around the world. The Company's growth strategy involves the registration of the product in additional markets as well as the development of new indications based on hyaluron technology.

During fiscal 2004 the Company launched *Suplasyn*[®] *md* (mini-dose), a product also used in the management of osteoarthritis. *Suplasyn*[®] *md* (mini-dose) was specifically developed and designed for use in small joints, i.e. hand and foot osteoarthritis.

Product Development Candidates

Bioniche Pharma's product development portfolio focuses on seeking ANDA approval for both niche product opportunities as well as products whose patent is set to expire. In addition the Company aims to develop additional hyaluronon based products to complement its existing *Suplasyn*[®] and *Suplasyn*[®] *md* (mini-dose) products.

Sales and Marketing

General

Bioniche Pharma's sales are derived primarily from three sources:

- (1) *Suplasyn*[®] and its distributor network.
- (2) Sales of branded and non-branded products in the United States.
- (3) Manufacture of products for its affiliated companies.

In the next twelve months the Company forecasts its sales growth to be derived primarily from *Suplasyn*[®], *Suplasyn*[®] *md* (mini-dose) and through the launch of its new ANDA products in the United States. In the longer term the Company plans to continue its aggressive product registration activities in the United States and Europe.

Suplasyn[®]

The Company has entered into exclusive distribution agreements with various pharmaceutical companies for the distribution of *Suplasyn*[®] worldwide. In the past year, the Company expanded its network to include both Central America and Brazil by entering into exclusive distribution agreements with Roche and Sigma Pharmaceuticals respectively. In addition the Company has added new distributors in Eastern Europe, and the Middle and Far East. The following chart details the countries in which *Suplasyn*[®] is sold, the pharmaceutical companies with whom distribution agreements have been entered into in such countries and the date such distribution agreements were entered into:

<u>Country</u>	<u>Company</u>	<u>Date</u>
Iran	Perfuran Co., Ltd.	July, 2001
Saudi Arabia	United Corporation for Pharmaceuticals and Medical Services Ltd.	April, 2002
Kuwait	Q8-Pharmaceutical	March, 2002
France	Chiesi S.A.	November, 2001
Switzerland and Liechtenstein	Robapharm AG **	December, 2002
Egypt	Sunny Medical Group	June, 2001

<u>Country</u>	<u>Company</u>	<u>Date</u>
Malaysia, Brunei and Singapore	Advance Pharma Sdn Bhd **	February, 2001
United Kingdom and Northern Ireland	Pliva Pharma Limited	February, 2001
Taiwan	Harvester Trading Company	October, 2000
Thailand	Pacific Healthcare (Thailand) Co. Ltd. **	July, 2003
Turkey	Gürel İlac Ticaret A.S.	July, 2000
Germany	Merckle GmbH **	January, 2000
Spain	Laboratorios Rubio, S.A. **	October, 1999
Austria	Sanova Pharma GmbH **	March, 1999
Greece	Vocate Pharmaceuticals Ltd. **	November, 1999
Lebanon and Syria	Sadco Sami Dandan & Co. **	January, 2004
Slovak Republic Bulgaria, Romania, Ukraine, Belarus, Armenia, Azerbaijan, Georgia, Kazakhstan, Cyprus	Medial AG & Medial D&P	August, 2003
South Africa, Botswana, Lesotho, Namibia, Swaziland, Mauritius and Kenya	Pharmaco Distribution (Pty) Ltd.	September, 2003
Republic of Ireland	Premier Medical	August, 2004
Guatemala, Belize, El Salvador, Honduras, Nicaragua, Costa Rica, Panama, Bermuda, Bahamas, Cayman Islands, Cuba, Jamaica, Dominican Republic, Haiti, Trinidad & Tobago, Barbados, St. Lucia, St. Vincent, Antigua, Barbuda, Grenada, St. Maarten, Curacao, Aruba, Surinam, Guyana	Productos Roche Interamericana, S.A.	April, 2004
Brazil	Sigma Pharma Limited	July, 2004

** indicates distribution of *Suplasyn™ md*. The Company is currently in discussions with other distributors for the sale of *Suplasyn®* and *Suplasyn® md* (mini-dose) in other parts of the world.

Market Analysis

Sterile Injectables

The market for sterile injectables is primarily institution-based and may be broken down by geographic and product segments.

Geographic Segments:

For practical purposes the injectables market may be regarded as being divided into three geographic segments: North America (the United States and Canada), the European Union and the rest of world (including Central Europe).

Bioniche Pharma's primary market focus is on North America and the European Union. Management believes that North America represents 55% of the global market and, in management's opinion, is also by far the most demanding market from a regulatory point of view. Demand for sterile manufacturing is strong and Bioniche Pharma is well positioned to exploit a significant market opportunity.

In Europe, currently about half the size of the North American market, management estimates that there is a disproportionate lack of high quality injectable manufacturing capacity at a time when regulatory standards are being increased under European Union rules. In management's view, Bioniche Pharma may be in a position to benefit from this situation as a result of its GMP compliant plant in Ireland and its established skills in achieving regulatory clearances.

Product Segments:

The sterile injectables market may be divided into three product segments: branded injectables, speciality or proprietary injectables and non-branded (generic) injectables. Apart from *Suplasyn*®, Bioniche Pharma's target markets are primarily the non-branded and proprietary injectable markets.

Proprietary injectables are products which are still under patent protection and are thus sold exclusively by the patent owner or its licensees. These products generate high margins. In addition, as proprietary products come off patent at different times in different jurisdictions, opportunities may arise in individual markets for Bioniche Pharma.

Non-branded injectables are products which are no longer proprietary, in that they no longer have patent protection, but which are still considered by the pharmaceutical companies that developed them to be their 'property'. This means that their value is expected to decline following patent expiry as competition arises. The non-branded (generic) market presents significant opportunities to Bioniche Pharma because of three factors. Firstly, escalating healthcare costs in all parts of the world have focussed significant attention on the need for the better management of hospital budgets. Inevitably, this has translated into pressure on the regulatory authorities to register generic products as quickly as possible. Secondly, the market is very large. Management believes that the therapeutic injectables market in the United States alone was estimated to be U.S. \$20 billion in 2003. Of this, management believes that approximately 50% of the therapeutic injectable market is currently off-patent and therefore available as generic product. Thirdly, the substantial capital costs and the stringent regulatory compliance demands on manufacturers are major barriers for companies wishing to enter this market. Several years of investment are required to build a facility, have it GMP approved, and to develop a product line. As a result, there are relatively few companies manufacturing generic injectables.

Suplasyn®

Management estimates the Canadian viscosupplementation market to be somewhere between \$5 million and \$10 million, growing at 10% per year, the United States market to be \$450 million per year, growing at 10% per year, and the European market to be \$150 million, growing at 15% per year. The Company has established an extensive marketing network by entering into distribution agreements with pharmaceutical companies throughout Europe. Since its launch in Germany in mid 2000, *Suplasyn®* has become one of the leading products in that market.

Competition

Sterile Injectables

Bioniche Pharma has invested in excess of \$10 million over the last previous six years in upgrades to its manufacturing facilities and on regulatory and product development activities. Due to the substantial capital costs, rigorous regulatory compliance demands and continuous monitoring of manufacturing standards, sterile injectable products are technically more complex than other pharmaceutical dosage forms such as tablets and capsules. These standards pose a significant entry barrier for many companies attempting to enter the sterile injectable market.

This year, the Company has undertaken a significant additional investment in its Irish operations. As previously noted, in May 2004 Bioniche Pharma received bank and other financing totalling approximately 10.7 million Euro and has commenced a major upgrade to its manufacturing facilities in Ireland to accommodate future growth. The new manufacturing facilities are expected to be completed and validated by September 2005, significantly increasing production capacity of vials and pre-filled syringes.

Suplasyn®

There are a number of competitive hyaluronan based viscosupplementation products in the marketplace for the treatment of osteoarthritis (*Synvisc* manufactured by Genzyme in the United States and *Hyalgan* manufactured by Fidia in Italy). *Suplasyn®* is hyaluronan derived from the fermentation of bacteria and not of rooster comb or other animal origin. As a result, there are no material concerns regarding safety or purity. The Company has established a strong distribution network globally. This, in conjunction with the generation of additional clinical data and a growing market for viscosupplementation therapy in general, has enabled the Company, in management's view, to become a major player in this market.

Human Health Development Human health: a pipeline for growth

PRODUCT	THERAPEUTIC AREA	CATEGORY	RESEARCH	PRECLINICAL	PHASE I	PHASE II	PHASE III	ON MARKET	MARKETS FILED
Suplasyn	Osteoarthritis Viscosupplementation	Medical Device						Canada, Europe, Middle East, Far East, Israel, Iran, China	Eastern Europe South Africa, Central America, Caribbean, Columbia, Taiwan, Indonesia, Mexico
Cystistat	Interstitial Cystitis Radiation cystitis, Cystitis caused by infections, trauma, urolithiasis, urinary retention, and neoplasia.	Medical Device						Canada, Europe, Israel China	Australia, New Zealand Eastern Europe
Sterile Injectables	Approximately 15 products Various therapeutic Sectors							Canada, USA Europe	

PRODUCT	THERAPEUTIC AREA	CATEGORY	RESEARCH	PRECLINICAL	PHASE I	PHASE II	PIVOTAL	ON MARKET
MCC	Bladder Cancer	Drug						
MCC	Prostate Cancer	Drug						
MCC	Other Cancers	Drug						
Sterile Injectables	Approximately 10 product Various therapeutic Sectors	Drug						At various stages of development

PRODUCT	THERAPEUTIC AREA	CATEGORY	RESEARCH	PRECLINICAL	PHASE I	PHASE II	PIVOTAL	ON MARKET
BT 99-25	Leukemia	Drug						
Oligo	Other Cancers	Drug						
Oligo	Immunomodulator	Drug						

Regulatory Environment – Human Health

Regulation by government authorities in Canada, the United States and the European Union is a significant factor in the current research and development activities of the Company. In order to clinically test, manufacture and market drug products for therapeutic use for humans, the Company must satisfy the rigorous mandatory procedures and standards established by the regulatory agencies in the countries in which it currently operates or intends to operate.

The laws of most of these countries require the licensing of manufacturing facilities, carefully controlled research and the extensive testing of products. Biopharmaceutical companies must establish the safety and efficacy of their new products and control over marketing activities before being allowed to market their products. The safety and efficacy of a new drug must be shown through clinical trials of the drug carried out in accordance with the mandatory procedures and standards established by regulatory agencies.

The pharmaceutical industry is required to manufacture products according to Good Manufacturing Practices (“GMPs”). GMP rules may vary slightly between countries, but provide manufacturers with guidance on what the government expects with respect to premises, equipment, sanitation, personnel, manufacturing control, quality control, testing, stability, and sample and documentation retention. In essence, GMPs state that all aspects of the manufacture of a pharmaceutical product must be documented and controlled, from receipt of the materials used to make the product to shipment of the product to the customer. GMPs are enforced through inspection by the Health Products and Food Branch Inspectorate (“HPFBI”) division of the Health Products and Food Branch of Health Canada (the “HPFB”) in Canada, the Food and Drug Administration (the “FDA”) in the United States and by individual country regulatory authorities in the European Union.

Regulatory compliance can take several years and can involve substantial expenditures. For instance, the entire process for human therapeutics from research to market introduction may take as long as twenty years and cost from tens to hundreds of millions of dollars. There can be no assurance that difficulties or excessive costs, which could delay or prevent the Company from manufacturing or marketing its products, will not be encountered by the Company in its efforts to secure necessary approvals.

Canada

In Canada, new drugs are reviewed and approved by the Therapeutic Products Directorate (“TPD”) and new biologics by the Biologics and Genetic Therapies Directorate (“BGTD”). New drugs and biologics must pass through a number of testing stages, including preclinical testing and clinical trials. Preclinical testing involves testing the chemistry, pharmacology and toxicology in a new product *in vitro* and in animals. Successful results (that is, potentially valuable pharmacological activity combined with an acceptable level of toxicity) enable the manufacturer of the new drug to file a Clinical Trial Application (“CTA”) to begin clinical trials involving humans. As well, manufacturers and testing labs are required to have an establishment license issued by HPFBI in order to be able to manufacture or test. This license is issued based on the manufacturer’s compliance with GMPs.

In order to begin clinical trials in Canada, a CTA must be filed with the TPD or BGTD. The CTA must contain specified information, including the results of the preclinical tests completed at the time of the submission and any available information regarding use of the product in humans. In addition, since the method of manufacture may affect the efficacy and safety of a new drug or biologic, information on the manufacturing methods and standards and the stability of the substance and dosage form must be presented to enable TPD or BGTD to conclude that the new drug that may eventually be sold to the public has the same composition as that determined to be effective and safe in the clinical trials. Production methods and quality control procedures for each approved product must be in place to ensure an acceptably pure product, essentially free of contamination, and to ensure uniformity with respect to all quality aspects.

Provided the TPD or BGTD does not reject a CTA, clinical trials can begin. Clinical trials are carried out in three phases or a combination thereof. Phase I involves studies to evaluate toxicity in humans. The new drug is administered to human patients who have met the clinical trial entry criteria in order to determine safety, human tolerance and prevalence of adverse side effects. Phases II and III involve therapeutic studies. In Phase II, efficacy, dosage, side effects and safety are established in a small number of patients who have the disease or disorder that the new drug is intended to treat. In Phase III, there are controlled clinical trials in which the new drug is administered to a statistically significant number of patients who are likely to receive benefit from the new drug. In Phase III, the effectiveness of the new drug is compared to that of standard accepted methods of treatment in order to provide sufficient data for the statistical proof of safety and efficacy for the new drug.

If clinical studies establish that a new drug has value, the manufacturer submits a New Drug Submission (“NDS”) application to the TPD or BGTD for marketing approval. The NDS contains all information known about the new drug, including the results of preclinical testing and clinical trials. Information about a substance contained in a NDS includes its proper name, its chemical name, details on its method of manufacturing and purification and its biological, pharmacological and toxicological properties. The NDS also provides information about the dosage form of the new drug, including a quantitative listing of all ingredients used in its formulation, its method of manufacture, packaging and labelling, the results of stability tests, and its diagnostic or therapeutic claims and side effects, as well as details of the clinical trials to support the safety and efficacy of the new drug. All aspects of the NDS are critically reviewed by the TPD or BGTD. If an NDS is found satisfactory, a Notice of Compliance is issued permitting the new drug to be sold in Canada.

The TPD or BGTD has a policy of priority evaluation of NDSs for all drugs or biologics intended for serious or life-threatening diseases for which no comparable drug product has received regulatory approval in Canada and for which there is reasonable scientific evidence to indicate that the proposed new drug is safe and may provide effective treatment. In addition, a policy called the NOC/c policy (Notice of Compliance with conditions) will allow a Notice of Compliance to be issued for drugs or biologics intended for serious or life-threatening disease for which there is reasonable evidence of safety and efficacy, with the condition that the sponsor will conduct additional studies to support that evidence.

The monitoring of a new drug or biologic does not cease once it is on the market. For example, a manufacturer of a new product must report any new information received concerning serious side effects, as well as the failure of the new product to produce desired effects. As well, if the TPD or BGTD determines it to be in the interest of public health, a Notice of Compliance for a new drug may be suspended and the new drug may be removed from the market.

An exception to the foregoing requirements relating to the manufacture and sale of new drugs is the limited authorization that may be available in respect of the sale of new drugs and biologics for emergency treatment. Under this Special Access Programme, the TPD may authorize the sale of a quantity of a new drug for human use to a specific practitioner for the emergency treatment of a patient under the practitioner's care. Prior to authorization, the practitioner must supply the TPD with information concerning the medical emergency for which the new drug is required, such data as is in the possession of the practitioner with respect to the use, safety and efficacy of the new drug, the names of the institutions at which the new drug is to be used and such other information as may be requested by the TPD. In addition, the practitioner must agree to report to both the drug manufacturer and the TPD the results of the new drug's use in the medical emergency, including information concerning adverse reactions, and must account to the TPD for all quantities of the new drug made available.

The Canadian regulatory approval requirements for new drugs outlined above are similar to those of other major pharmaceutical markets. While the testing carried out in Canada is often acceptable for the purposes of regulatory submissions in other countries, supplementary testing may be requested by individual regulatory authorities during their assessment of any submission. There can be no assurance that the clinical testing conducted under the HPFB authorization or the approval of regulatory authorities of other countries will be accepted by regulatory authorities outside Canada or such other countries.

The Company also markets two products which are considered medical devices in Canada (namely, *Cystistat*® and *Suplasyn*®). Products are classified as medical devices if they are represented for use in restoring, correcting or modifying a body function or the body structure, and are licensed by the TPD. Licensing is a relatively new requirement in Canada and the Company was allowed to license their products under a "grandfather" status without submission of additional supportive data. All manufacturers of medical devices in Canada must be registered under a quality system which closely resembles the ISO 9000 series quality standard.

United States

In the United States, the manufacture and sale of new drugs are controlled by the Food and Drug Administration ("FDA"). New drugs require FDA approval of a marketing application (i.e. a New Drug Application ("NDA") or product license application) prior to commercial sale. To obtain marketing approval, data from adequate and well-controlled clinical investigations, demonstrating to the FDA's satisfaction a new drug's safety and effectiveness for its intended use, are required. Such data are generated in studies conducted pursuant to an Investigational New Drug ("IND") submission, similar to that required in Canada. As in Canada, clinical studies are characterized as Phase I, Phase II and Phase III trials or a combination thereof. In a marketing application, the manufacturer must also demonstrate the identity, potency, quality and purity of the active ingredients of the new drug involved, and the stability of

those ingredients. Further, the manufacturing facilities, equipment, processes and quality controls for the new drug must comply with the FDA's GMP regulations for drugs or biologic products both in a pre-licensing inspection before product licensing and in subsequent periodic inspections after licensing. In the case of a biologic product, an establishment license must be obtained prior to marketing and batch releasing.

A five-year period of market exclusivity for a drug comprising a new chemical entity ("NCE") is available to an applicant that succeeds in obtaining FDA approval of an NCE, provided the active ingredient of the NCE has never before been approved in a NDA. During this exclusivity period, the FDA may not accept for review any abbreviated application filed by another sponsor for a generic version of the NCE. Further, a three-year period of market exclusivity for a new use or indication for a previously approved drug is available to an applicant that submits new clinical studies that are essential to support the new use or indication. During the latter period of exclusivity, the FDA may not approve an abbreviated application filed by another sponsor for a generic version of the product for that use or indication.

A new drug may be approved using an Abbreviated New Drug Application (ANDA) if the drug is a copy of an already marketed drug (listed drug) which is not governed by an exclusivity or patent agreement. ANDAs must include information to prove that the product is equivalent to the listed drug in active ingredients, dosage, form, strength, route of administration, and condition of use. ANDAs do not require the applicant to demonstrate safety or efficacy. The applicant must only demonstrate therapeutic equivalence to the listed drug.

The FDA has "fast track" regulations intended to accelerate the approval process for the development, evaluation and marketing of new drugs used to diagnose or treat life-threatening and severely debilitating illnesses for which no satisfactory alternative therapies exist. "Fast track" designation affords early interaction with the FDA in terms of protocol design, and it permits, (though does not require), the FDA to issue marketing approval after completion of early stage clinical trials (although the FDA may require subsequent clinical trials or even post-approval efficacy studies).

It is the Company's intention to request approval to license medical devices in the United States. Licensing of these devices in the U.S. requires clinical investigations to be carried out prior to pre-market approval by the FDA.

European Union

Regulatory requirements in the European Union are similar in principle to those of the United States. A two-part product approval process by the European Medicines Agency ("EMA") is required in the European Union. Clinical testing and manufacturing facilities and procedures data are presented in a Marketing Authorization Application filed with the Committee for Proprietary Medicinal Products ("CPMP"). The CPMP reviews the application in order to express an opinion that the new drug meets the requirements for marketing authorization. If a favourable opinion is received from the CPMP, approval to market the new drug must then be obtained from the appropriate government agency of each European Union country.

Alternate means of approval in the European Union for products which are not novel include the use of a Mutual Recognition Procedure. In this case, one European Union country is chosen as the reference member country and application is made to that country. If approved, the application then goes to any other European Union countries in which registration is desired simultaneously for review based on the reference member countries recommendations.

General

In general, the process of completing clinical trials and obtaining regulatory approval for a new drug for human use takes a number of years and requires the expenditure of substantial resources. Once a new drug or product license application is submitted, there can be no assurance that a regulatory agency will review and approve the application in a timely manner. Also, regulatory agencies may require post-marketing surveillance programs to monitor a new drug's side effects. Results of post-marketing programs may limit or expand the further marketing of new drugs. A serious safety or effectiveness problem involving an approved new drug may result in a regulatory agency requiring withdrawal of the new drug from the market and possible civil action.

In addition to the regulatory product approval framework, biopharmaceutical companies, including the Company, are subject to regulation under provincial, state and federal law, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and future local, provincial, state, federal and foreign regulation, including possible future regulation of the biotechnology industry.

ANIMAL HEALTH DIVISION

Bioniche Animal Health is responsible for researching, developing, manufacturing and marketing veterinary biopharmaceutical products worldwide. The Company's animal health products are marketed through its subsidiaries in Canada, the United States, Australia and Europe and through selected distributors in the rest of the world. Bioniche Animal Health operates marketing, production and research facilities in Belleville, Ontario; marketing and manufacturing units in Athens, Georgia and in Pullman, Washington in the United States; a manufacturing facility in Armidale, Australia; and a sales and marketing office in Ireland. Growth of the Company's animal health products was 29% for fiscal 2002, 66% for fiscal 2003 and 5 % for fiscal 2004.

Bioniche Animal Health is committed to the discovery and development of innovative biologicals and biopharmaceutical products for the preventative health management of animal diseases. The business strategy has been to consolidate the Company's position in the Canadian market and to build from that into the United States and other parts of the world. This past fiscal year Bioniche Animal Health made two strategic acquisitions. The first was the acquisition of the assets of AB Technology Inc., a world leader in the development of embryo transfer media, materials and equipment for bovine and equine markets. AB Technology now operates as a unit of Bioniche Animal Health USA, Inc. Synergies resulting from the merger will allow the Company to provide embryo transfer practitioners around the world with a range of superior livestock reproductive technologies and services. The second acquisition was the *Cue-Mate*® device which is a uniquely-designed progesterone delivery device for cows that enables dairy farmers and cattle producers to plan and manage the reproductive timing of their herds. The Company acquired the intellectual property and other assets of the *Cue-Mate*® business earlier this year from Pfizer Inc. *Cue-Mate*® is registered in Australia, New Zealand, Chile, and Argentina and currently in the market in Australia, New Zealand, Chile, and Argentina.

Products

Over the past twenty-five years, Bioniche Animal Health has progressively grown by using biotechnology to provide the veterinary market with innovative solutions to meet the changing needs of the animal health industry. Bioniche Animal Health has a product portfolio of over sixty products, based on five platform technologies. The animal health products can be categorized in the following product groups: reproduction and embryo transfer products, products based on hyaluronan, immunostimulant products, polyclonal antibodies, vaccine products and nutraceuticals.

Reproduction and Embryo Transfer Products

The Company's research into the purification and production of reproductive hormones has resulted in the successful commercialization of *Folltropin® V*, *Lutropin® V* and *Pregnenol™* hormone preparations designed for breeding programs in the cattle and swine industries. *Folltropin® V* is used in the embryo transfer industry to induce superovulation in cattle and sheep. *Folltropin® V* is sold in Canada, the United States, Australia, New Zealand, Latin America and Ireland. Registration dossiers are being generated for additional markets in the European Union and Asia. *Lutropin® V* leutinizing hormone is used to induce ovulation in cattle and sheep as well as to treat cystic ovaries in dairy cows. *Pregnenol™* is sold in Australia, Canada, Israel, Palestine and New Zealand. This product is also registered in Ireland as *Stimovar*. *Pregnenol™* is used to increase reproductive efficiency in livestock by increasing ovulation rates and inducing estrus. *AI-Synch™* is the name given to the Company's product offering for the tandem use of *Lutropin® V* and *Pregnenol™* so that swine farmers can synchronize the time of artificial insemination. The Company has an ongoing research program in reproduction and embryo transfer products.

Hyaluronan Products

Hyaluronan is a naturally occurring constituent of connective tissue and joint fluid. The use of hyaluronan in veterinary science is not new but Bioniche Animal Health has focussed its research in two areas. The first is as a treatment for osteoarthritis, particularly in horses; *Enhance®*, registered in Australia and New Zealand, is used as a replacement for synovial fluid, the naturally occurring lubricant in articular joints. Osteoarthritis is associated with synovial fluid degradation, the result being a loss of lubricant effect and considerable pain. Administration of *Enhance®* inter-articularly into affected joints replaces and augments the natural supply of synovial fluid. Intra-articular hyaluronic acid therapy in horses is widely accepted around the world. The Company's second area of focus is a patented use of hyaluron as a cryopreservative called *MAP-5®* for embryos in the embryo transfer industry.

Immunostimulant Products: Mycobacterial Cell Wall Extract (MCWE)

Immunostimulants are a part of an emerging technology in the large animal medicine field called immunotherapy. Mycobacterial Cell Wall Extract (MCWE) has been the focus of Bioniche Animal Health's research and development program. The basis of immunotherapeutics is to stimulate a network of non-specific immune system cells. Using the animal's own immune system, immunostimulants can be used to turn on the immune system and treat disease. Derived from a naturally occurring bacterium *Mycobacterium phlei*, MCWE is an inactivated, deproteinized, delipidated, injectable cell wall extract with immunomodulating properties. This technology is the precursor to MCC, which is the lead technology in the Company's human cancer research program.

The Company has a strong proprietary position for this technology which is the active ingredient in three registered products in North America, *Regressin®*, *Equimune® IV* and *Immunoboost®*. *Equimune® IV* is also registered in Australia. *Regressin®* is licensed as a treatment for specific cancers in companion animals. *Equimune® IV* is a patented immunostimulant for the treatment of equine respiratory disease. *Immunoboost®*, a mycobacterium cell wall fraction immunostimulant, is the first immunostimulant licensed for bovine infectious disease therapy. *Immunoboost®* is also indicated for the treatment of neonatal calf diarrhea. The *E. coli* bacterium has developed resistance to antibiotics, thus rendering many antibiotics ineffective.

Vaccine Products

Polyclonal Antibodies

The Company's product *Colimune*® is a polyclonal antibody product developed as a means of preventing K-99 *E. coli* infections in calves. Under normal situations the mother cow produces antibodies in the first milk (the colostrum) to provide sufficient antibodies to coat the gut wall of the neonatal calf. Where the mother fails to do this, or if the mother was not vaccinated, *Colimune*® is used to prevent an *E. coli* outbreak from affecting the entire herd and accordingly, reduces calf losses.

Vaccines

Sound animal health management programs focus on disease prevention. Vaccines provide immunity against specific diseases that threaten animals. Bioniche Animal Health's research and development program has developed a wide range of animal vaccines for use in cattle, swine, and equine. All of the Company's vaccines use killed bacteria or viruses in contrast to some companies that produce live vaccines using attenuated or weakened live viruses. The Company's focus is on producing vaccines that are effective and have proven safety profiles. Bioniche Animal Health has developed a range of vaccines for both swine and cattle as part of its objective to find alternatives to the use of antibiotics in livestock. Bioniche Animal Health has successfully commercialised a range of vaccines and is currently in the research phase of a new generation of vaccines where the immunomodulation initiated by MCWE will be harnessed with commercially important antigens.

Nutraceuticals

The Company continues to explore opportunities in the growing nutraceutical field. This research area is a natural extension of the Company's extensive animal health research in the field of immunology. Current products include *Echi-Fend*™, an echinacea product for the equine industry and *Omega-Fend*™, an essential fatty acid supplement. Research is ongoing to develop a botanical insect repellent as well as other botanical products for the human, equine and companion animal markets

Research and Development

The Bioniche Animal Health research program has an active product development pipeline in the following areas.

Reproduction and Embryo Transfer Products

The Company is responding to market demands for safer products which do not contain material of animal origin by developing synthetic medias which will incorporate its patented hyaluronan technology.

Immunostimulants

Market demand and regulatory requirements for products with decreased risk of disease transmission have prompted the Company to change its manufacturing processes to produce biological products, including current immunostimulants, which do not contain material of animal origin. This will be an ongoing research and development program in the future.

In September 2004, the Company released the first results of a fully controlled and monitored (GCP) study in Argentina using a formulation of its proprietary Mycobacterial Cell Wall technology to treat bacterial-induced endometritis in mares. The study was performed by Dr. Elida Fumuso, a veterinarian at Universidad Nacional Del Centro De La Provincia De Buenos Aires (UNICEN), Tandil, Argentina, and was presented at the Modern Vaccines/Adjuvants Formulations Conference in Prague, Czech Republic by Dr. Dragan Rogan, Vice-President of Research and Development at Bioniche Animal Health.

Endometritis in mares is an important disease with significant economic impacts to the horse industry. It is estimated that this non-life threatening disease affects 25% to 30% of broodmares worldwide. Generally, endometritis is treated with hormones and intrauterine or systemic antibiotics over a number of days. However, recent studies demonstrated that immunomodulation with a single dose of a Mycobacterial Cell Wall formulation normalized the uterine inflammatory responses and enhanced the prevention and treatment of infectious endometritis and endometriosis. In the reported study, this product was evaluated for its ability to treat an experimentally induced bacterial infection in endometritis susceptible mares.

Vaccines

The Company is currently developing and conducting trials with respect to several vaccines to treat bovine and equine diseases such as a recombinant multivalent vaccine for bovine diarrhea and a vaccine against *Rhodococcus equi*, a chronic bronchopneumonia in foals.

In Development

PRODUCT	THERAPEUTIC AREA	CATEGORY	RESEARCH	PROOF OF CONCEPT TRIALS	REGULATORY TRIALS
Media	Reproduction	----	████████████████████	████████████████████	████████████████████
Endometritis	Reproduction	Biologic	████████████████████	████████████████████	████████████████████
E.Coli/Rota/Corona	Enteritis	Vaccine	████████████████████	████████████████████	████████████████████
R. equi	Respiratory	Vaccine	████████████████████	████████████████████	████████████████████

Sales and Marketing

Bioniche Animal Health's priority market is the veterinarian. Bioniche Animal Health products are speciality items, where the expert opinion of the veterinarian will be the key element in the purchase decision, as opposed to commodity products, where the key decision driver is price.

Reproduction and Embryo Transfer Products

Revenues from this product segment generated \$19.2 million in the fiscal year 2004. The Company made two important acquisitions in 2004: the assets of AB Technology, Inc. and the *Cue-Mate*® device.

The recent acquisition of the assets of AB Technology Inc. has expanded the Company's reproductive product portfolio and allows it to provide further convenience to its customers. The *ViGro*™ media product line is manufactured at the Company's Pullman facility which has FDA approval. Since the acquisition, the Company has expanded the regions where these products can be purchased. As well, additional dossiers are being created to obtain registration in expanded geographic markets for *Folltropin*® V, *Lutropin*® V, *Pregnecol*™ and *Cue-Mate*® products. The Company's innovative protocol of *Lutropin*® V and *Pregnecol*™ (known as *AI Synch*™) used to synchronize estrus and ovulation in swine can increase pregnancy and farrowing rates. This protocol allows ovulation timing to be accurately predicted, removing the guesswork associated with insemination timing.

Hyaluronan

With products such as *Enhance*® and *Hyalovet* for interarticular use and *MAP-5*® for cryopreservation of embryos, Bioniche Animal Health has been a major supplier of hyaluronic acid products to veterinarians for nineteen years. Revenues from this product segment were \$5.9 million.

Immunostimulation

This core focus of the Company generated revenues of \$3.2M in fiscal 2004. The Company will continue to expand this product segment for new indications with a new manufacturing process which ensures that no product of animal origin is used in the growth media or the processing of the finished product.

Vaccines

The Company has developed a range of vaccines for both swine and cattle as part of its objective to find alternatives to the use of antibiotics in livestock. Vaccines provide immunity against specific diseases that threaten animals. Bioniche Animal Health's research and development program has developed a wide range of animal vaccines for use in cattle, swine, and equine including the *Virabos*®, *Dairymune*® and SwineCheck vaccines. *Virabos*® vaccines are respiratory and reproductive disease vaccines for beef cattle, *Dairymune*® are vaccines specifically formulated to meet the needs of the dairy industry and the Bioniche Animal Health line of SwineCheck vaccines target the swine industry. All of the Company's vaccines use killed bacteria or viruses in contrast to some companies that produce live vaccines using attenuated or weakened live viruses. The Company's focus is on producing vaccines that are not only effective but have proven safety profiles.

Canada

The Canadian animal health market continues to be negatively impacted by BSE (Bovine Spongiform Encephalopathy) trade restrictions on sale of live cattle to the United States. Bioniche Animal Health Canada bovine product sales for fiscal 2004 decreased by 18% from 2003. The business unit was able to increase sales in other sectors with the result that total sales were only 10% behind the previous year. In fiscal 2005 the cattle product sector for the Company will incur additional challenges as Pfizer takes over the marketing of the *CIDR* device through its acquisition of Pharmacia. This product was originally registered in Canada by the Company and marketed under a distribution agreement with Pharmacia.

The Company has responded with several activities to increase business. (i) There has been exciting progress with towards timed breeding in swine using the Company's products *Pregneco*™ and *Lutropin*® V. Both of these products are licensed in Canada and are capable of generating significant revenues in the future. (ii) The acquisition of *Cue-mate*®, a competitor to the *CIDR* device, will add future revenue following registration in Canada. (iii) The purchase of AB Technologies (embryo transfer media and equipment) has immediately increased the number of products the Company can offer to embryo transfer veterinarians in addition to *Folltropin*® V. The focus on such core technologies, where the Company manufactures, registers and markets the products, is expected to create a strong foundation for future growth.

United States

The United States animal health market is the largest and most lucrative single market in the world. In 2001, sales in the United States of all products, with the exception of nutritional feed additives, exceeded U.S. \$4.3 billion. Growth for the Company's United States operations was 6% in fiscal 2004. Many well-established distribution companies with varying specializations operate in the market, but demand for these services is falling as the larger multinational manufacturers are moving towards selling their products directly to producers in order to save costs. Bioniche Animal Health, with a track record of negotiating distributor agreements tailored to specific requirements, has the potential to benefit from this trend as distributors seek to replace the business lost from the larger companies. Some distributors are also aggressively developing brand identity with their own labels. Bioniche Animal Health is pursuing relationships with these companies as they have the potential to provide a motivated sales and marketing force with an existing presence in the market. Bioniche Animal Health will continue to use a small but experienced sales force to support its distribution network. This has proved to be an effective approach to specific markets such as those for equine therapeutics and bovine and equine reproduction. To reach broader markets Bioniche Animal Health will expand its sales force or select partners with existing infrastructure.

Bioniche Animal Health's current United States product line includes the following eight major product lines, all of which have significant market potential: (i) *Immunoboost*®, the immune stimulant for the treatment of colibacillosis in neo-natal calves; (ii) *MAP-5*®, the hyaluronan product for use as a cryopreservative for embryo transfer; (iii) *Folltropin*® V, the leading brand of follicle stimulating hormone for use in the highly specialized bovine embryo transfer industry; (iv) full line of embryo transfer media and equipment from AB Technology; (v) *Equimune*®, the immune stimulant for the treatment of respiratory infections in horses; (vi) *Regressin*®, a treatment for cancers in small animals; (vii) *Colimune*®, a polyclonal antibody product for the prevention of K99 *E. coli*; and (viii) the *EPIC* line of equine nutritional supplements.

Europe

To facilitate entry into the European Union, Bioniche Animal Health has maintained a presence in the Republic of Ireland. Bioniche Animal Health (Europe) Ltd., will be the launch pad for the reproductive and immune stimulant technology into the European Union following regulatory approvals. Key management personnel, warehouse facilities, distribution channels and market contacts are in place to support the expansion plans for these market segments. Sales have been growing with the re-introduction of *Folltropin*® V and further expansion and registrations into additional European countries using the mutual recognition pathway.

Bioniche Animal Health is developing sales of *Folltropin*® V and the *Vigro*™ media line in China. Demand for meat and dairy products in China is increasing and the use of embryo transfer to increase the quality and productivity of the beef and dairy herds will increase accordingly. Management believes that in the future China will be an important market for animal health products.

Australia

Bioniche Animal Health A/Asia is a manufacturing facility for *Pregneco*™ and *Ova-gest*® as well as a distribution centre for Bioniche Animal Health products in Australia. The Company has a large stable of products available for sale including *Folltropin*® V, *Pregneco*™, *Ova-gest*® and *ViGro*™ media and other embryo transfer products for the reproduction market as well as *Enhance*®, *Equimune*® and *BC2A*® for the equine market. This past year the Company acquired the intellectual property and other assets of the *Cue-Mate*® business, an innovative livestock reproductive technology. With sales of \$735K, *Cue-Mate*® will complement our range of reproductive technologies and services.

Export Markets

Bioniche Animal Health exports approximately \$2 million of products throughout South America, the Middle East and Asia every year. The demand for high quality reproductive products in Asia increased dramatically in the last half of fiscal 2004, contributing U.S. \$0.5 million to export sales. The Company has commenced doing business in China with a Chinese distributor, and anticipates creating a joint venture in the next year. A corporation has been formed, of which the Company owns 55% of the shares, but which is not at present an operating company.

PRODUCT	THERAPEUTIC AREA	CATEGORY	MARKETS APPROVED IN
Folltropin-V	Embryo Transfer	Drug	Canada, New Zealand, Australia, Brazil, Argentina, Ireland
Lutropin-V	Reproduction	Drug	Canada
MAP - 5	Embryo Transfer	Cryopreservative	Worldwide
Coliume-Oral	Enteritis	Biologic	Canada, USA
Pregnecol	Reproduction	Drug	Canada, Australia, Ireland New Zealand, Isreal
MCWE:			
Equimmune IV	Anti-viral - Equine	Biologic	USA, Austrailia, New Zealand, Ireland
Regression	Cancer	Biologic	Canada, USA
Immunoboost	Anti-bacterial	Biologic	USA

* (Not a complete list. Only major products have been listed here. Animal product portfolio comprises over 45 veterinary products, for cattle, swine horses and companion animals)

Market Analysis

The global animal health market is currently valued at approximately \$20.5 billion per year. Management believes that the growth of products for dogs and cats has been the principal cause of growth in the animal health market, growing at almost twice the rate of products for the livestock food-producing sector, which has been static. Management believes that health expenditures on pets will continue to increase, as consumers become interested in high value treatments, such as cancer treatments, and as the pet becomes considered a family member more and more.

In the livestock sector, management believes the indiscriminate use and abuse of antibiotics, combined with resistance concerns in human medicine, will create opportunities for alternative therapies

Major animal health product manufacturers continue to seek acquisitions and licensing opportunities in an attempt to overcome increasing competition and to build shareholder value. Additionally, as large health companies' research and development is focused on the human health markets, the veterinary divisions of these companies are entering into joint ventures with small research or biotechnology companies to secure access to new products.

Management believes that Bioniche Animal Health is in a position to benefit in a number of ways from this rationalization. Significant market niches (livestock reproduction) will likely be of decreasing interest to multinational companies and the number of technologies being pursued by large companies should also decline as they focus only on those with high volume potential. Mergers have also made available a large pool of competent, experienced manpower. As multinationals concentrate on their strengths, opportunities arise for smaller firms to acquire non-strategic products. The Company's acquisition of *Cue-Mate*® acquisition from Pfizer is an example.

Management believes that the agricultural sector itself is also rationalizing in the developed world, the result of which will be fewer but larger farms. This will exert considerable pressure on commodity pharmaceuticals; however, Bioniche Animal Health is unlikely to be affected by this trend as its products are essentially specialty items where performance is the customer's priority.

Concern over environmental issues has increased. Consumers and activist groups now have greater access to information than ever before and are increasingly vocal about the possibility of antibacterial or chemical residues in foods and their possible long-term effects on human health. This in turn, has caused governments to implement more stringent regulatory requirements relating to the introduction of new products, even when such products may have been previously demonstrated to be free of adverse effects and readily available in neighbouring countries, without apparent cause for concern. These developments and trends present opportunities in the global market for the Company, as one of its fundamental business objectives is the prevention of disease through immunomodulation rather than through antibiotic or chemical therapeutic agents.

Mycobacterial Cell Wall Extracts (MCWE/MCC) from *M. phlei* are currently undergoing preliminary evaluation for their ability to reduce antibiotic reliance and promote enhanced growth in food producing animals.

Geographically, the global market is comprised of North America, which represents approximately 30% of the world market, the European Union, which represents 22% and is the most tightly regulated despite being not yet unified, and the Asian/Latin American markets.

Competition

In Canada, the competitive environment continues to change through industry consolidation, especially with the Pfizer purchase of Pharmacia. While certain market segments, namely the embryo transfer sector continues to grow, the BSE issue has significantly decreased the value of health products used in the bovine sector. It was anticipated that the border with the United States for live cattle would have been opened by this time, but this has not occurred. This continues to affect the Company's sales in the bovine sector adversely.

The global markets for Animal Health products are being rationalized by the large companies, thereby providing opportunities for Bioniche Animal Health to acquire or develop products that would not meet the higher revenue generation potential required by the larger competitors. Examples are the acquisition of *Cue-mate*® from Pfizer and the acquisition of AB Technologies.

Bioniche Animal Health is committed to a strategy of reliance on well-differentiated, technology-based products as the backbone of its product line, which is promoted to veterinarians by its own sales force in Canada, the United States, Australia and Ireland and through distributors in other areas of the world. In addition to its own product offerings to veterinarians, the Company distributes products from companies that have well researched products and a marketable competitive advantage.

Regulatory Environment

The development of animal health products by Bioniche Animal Health requires approval by various government authorities.

Canada

In Canada, Bioniche Animal Health develops and markets two main types of animal health products, biologics and drugs. Biologics are regulated by the Veterinary Biologics Section (“VBS”) of the Canadian Food Inspection Agency (“CFIA”) pursuant to the *Health of Animals Act* and the regulations thereunder. Drugs are regulated by both the Veterinary Drugs Directorate (“VDD”) (a division of the Health Products and Food Branch of Health Canada (“HPFB”)) and the Health Products and Food Branch Inspectorate (another division of the HPFB) pursuant to the *Food and Drugs Act* and the regulations thereunder.

In order to grant a license to market a veterinary biologic in Canada, VBS must be provided with a complete submission which includes intensive characterization of the starting materials, evidence of control over the manufacturing process, evidence of safety and efficacy of the product in the target animal, results of quality control tests of the final product and stability of the final product. The facilities used for manufacturing and testing must also be licensed and a fee is charged by VBS for its review of the product and the facility. The time frame for an approved submission could range from six to twenty-four months. Review of biologics applications and annual licensing fees are under cost recovery programs and the cost of annual maintenance to Bioniche Animal Health is approximately \$5,000 for its current line of biologics. Currently there is no specific requirement for compliance with GMPs for veterinary biologics, however, the trend in recent years is toward GMP compliance by manufacturers and it is expected that such compliance will be in effect within the next two to three years.

The product development and approval process for new animal drugs in Canada is similar to the requirements for human drugs with the exception that the submission review is performed by the VDD rather than the TPD since the VDD reviewers have specific experience in animal drugs. An Investigational New Drug (“IND”) submission is required before clinical trials can begin. The IND submission must establish the chemical characterization of the product, its manufacturing process and the safety in non-target animal species (lab animals). Following approval of the IND submission, target animal safety and efficacy can be done. An additional requirement for veterinary drugs is the assessment of human safety if the drug is to be given to food producing animals. Following successful review of a New Drug Submission, a Notice of Compliance will be issued as well as a Drug Identification Number (“DIN”).

In addition to the product approval process for new drugs, annual maintenance fees are required to maintain the facility license and the DINs. Government audits are carried out on all drug manufacturers to ensure compliance with GMPs.

United States

In the United States, governmental regulation of animal health products is primarily split between two agencies, the United States Department of Agriculture (the “USDA”) and the Food and Drug Administration (the “FDA”). Vaccines for animals are considered veterinary biologics and are regulated by the Center for Veterinary Biologics (“CVB”) of the USDA under the auspices of the *Virus-Serum-Toxin Act*. Alternatively, animal drugs, which generally include all synthetic compounds, are approved and monitored by the Center for Veterinary Medicine (“CVM”) of the FDA under the auspices of the *Federal Food, Drug and Cosmetic Act*.

Most of the regulated products presently sold or under development by Bioniche Animal Health are or will be regulated by the USDA. The purpose of the *Virus-Serum-Toxin Act* is to ensure that veterinary biologics sold in the United States are safe and efficacious. Pre-market testing is performed by the manufacturer and the CVB prior to approval of the product for sale, as well as on each new lot. Although the procedures for licensing products by the USDA are formalized, the acceptable standards of performance for any product are agreed upon between the manufacturer and the CVB. For novel products that are unlike others already licensed, the agreement on expected performance standards is typically reached through a dialogue between the CVB and the manufacturer. The formal demonstration of acceptable efficacy of the product is done in carefully controlled laboratory trials. This is normally a much faster process than demonstration of efficacy in clinical trials using client-owned animals.

GMP requirements for animal drugs are the same as those for human drugs and therefore strict quality assurance and quality control procedures must be adhered to during the processing of animal drugs. However, the drug development process for human therapeutics is much more involved than that for animal drugs. The entire process for human therapeutics from research to market introduction may take as long as 20 years and cost tens to hundreds of millions of dollars. (See “Human Health Divisions – Regulatory Environment”). By contrast, management estimates that it can take up to 11 years and US\$5 million to develop a new drug for animals, from commencement of research to market introduction. Of this time, approximately three years is spent in the clinical trial and review process. This time requirement for animal drugs is significantly shorter than the analogous time requirement for human drugs in part because clinical trials may be conducted immediately in the animal for which the drug is intended. Also, for animal drugs, unlike human drugs, advantages over existing therapies do not have to be demonstrated. In addition, with the enactment of the *Animal Drug Availability Act* (“ADA”) in October 1996, substantial reductions in the time and cost to license some new animal drugs by the FDA are anticipated although two to three years is usual. The ADA was designed to streamline the animal drug approval process in order to provide more registered drugs for animal use. The ADA mandates a binding pre-submission conference at which the CVM and the applicant agree on the types of data the FDA will require. The ADA also removes the requirement that field investigations be done in every instance and allows the CVM to accept different types of proof of a drug’s safety and efficacy.

Regulations governing the export of drugs and biologics have also been relaxed by the passage of the *Export Reform Enhancement Act of 1996*. Under this Act, drugs and biologics produced in the United States do not have to be licensed for sale in the United States before export if they are approved for sale in the importing country.

European Union

European Union requirements for approval of animal drugs are similar to Canadian and U.S. requirements. Clinical trials must be carried out to establish safety and efficacy in the target animal and safety in humans if the target animal is food producing. The product and its starting materials must be adequately characterized and tested and the facilities where they are manufactured must comply with GMPs.

In the European Union, the requirements for animal biologics are similar to those for drugs in that GMPs must be adhered to throughout the manufacturing process and safety and efficacy must be established. Adequate characterization of starting materials is essential, as there are safety concerns with products of biological origin.

FOOD SAFETY DIVISION

The Food Safety division of the Company was established in July 2001. The division is responsible for researching, developing, manufacturing and marketing veterinary biopharmaceutical products to improve the safety of food and water supplies worldwide. The leading initiative for this division is the development and commercialization of a new cattle vaccine for the prevention of the spread of the deadly *E. coli* O157:H7 bacteria. This vaccine is designed to reduce the load of the pathogenic bacterium *E. coli* O157:H7 in cattle manure, thereby reducing contamination into the environment, ground water and in cattle processing plants. In addition, the Company is currently researching other products in the food and water safety field.

Product Development Candidates

E. coli O157:H7 Vaccine

Escherichia coli bacteria are normal organisms found in the intestinal track of all animals. Most *E. coli* are non-pathogenic to their host, however certain types cause digestive disturbances and occasionally other significant systemic disease. *E. coli* O157:H7 bacteria cause significant disease in humans and are most often associated with consumption of contaminated food or water. Ruminant livestock (e.g. cattle) are considered the major reservoir of *E. coli* O157:H7 worldwide. Numerous studies have demonstrated that the incidence of *E. coli* O157:H7 in beef and dairy cattle is wide spread and that the organism is found in, on and around cattle in all parts of the world. Use of manure as fertilizer for crop production and run off from beef and dairy cattle operations is a source of contamination for the general environment as well as surface and ground water. *E. coli* O157:H7 contamination of food and water as a result of fecal shedding by livestock is a well recognized and documented threat to human health.

The economic impact of this disease is thought to be considerable. A number of large scale recalls of hamburger meat have occurred as a result of *E. coli* contamination. Since January 2000, over 20 million pounds of beef has been recalled in North America. The Centre for Disease Control estimates that *E. coli* O157:H7 infection affects some 70,000 people per year in the United States, and that 5,000 of those people develop Haemolytic Uremic Syndrome (HUS), a disease characterized by kidney failure. Five percent (250) of HUS patients die, many of them children and senior citizens whose kidneys are more sensitive to damage. The annual cost in the United States is estimated at more than \$650 million due to medical expenses, lost productivity and death. In addition to the direct human costs due to *E. coli* O157:H7 infection, cattle and dairy producers, meat packers and dairy processors, meat and milk distributors and wholesale and retail food outlets all incur direct and indirect (demand for their product) costs associated with this foodborne disease threat. The cost of *E. coli* O157:H7 to the food industry as a result of recalls, destroyed food, control measures and lost demand due to loss of consumer confidence is estimate in the billions (\$2.7 Billion – Meat & Poultry, February 2003) of dollars in the United States alone.

The Company's *E. coli* O157:H7 vaccine is being developed by a strategic alliance formed in September 2000 and composed of the University of British Columbia (UBC), the Alberta Research Council, the University of Saskatchewan's Vaccine & Infectious Disease Organization (VIDO), and the Company, which holds the rights to worldwide commercialization of the vaccine.

Industrial Research Chairs

The Company, in partnership with the Vaccine & Infectious Disease Organization (VIDO) at the University of Saskatchewan, recently announced two appointments to the *Natural Science and Engineering Research Canada (NSERC)/Bioniche Industrial Research Chairs* in vaccines to reduce food and water contamination. The two individuals who will fill the Chairs are Dr. Andy Potter (Senior Chair) and Dr. Wolfgang Köster (Associate Chair). The Research Chairs were established to undertake research leading to the development of additional food safety vaccines to fight infectious diseases of animals, including *Salmonella enteritidis*, *Campylobacter jejuni*, and *Cryptosporidium parvum*. These three animal-to-human-transmitted pathogens cause illnesses that can be serious and, in some cases, fatal. Certain strains of *E. coli* can cause kidney failure in young children and infants; *Salmonella* can lead to reactive arthritis and serious infections; and *Campylobacter* may be the most common precipitating factor for Guillain-Barre syndrome, according to the Partnership for Food Safety Education.

PRODUCT	THERAPEUTIC AREA	CATEGORY	RESEARCH	PROOF OF CONCEPT TRIALS	REGULATORY TRIALS
E. coli O157:H7	Food Safety	Vaccine	██████████	██████████	██████████
Food Safety Chair Products					
Salmonella enteritidis	Food Safety	Vaccine	████	████	████
Campylobacter jejuni	Food Safety	Vaccine	████	████	████
Cryptosporidium parvum	Food Safety	Vaccine	████	████	████

Sales and Marketing

In typical animal health marketing, the decision maker is the owner or producer of the livestock. In food safety marketing, the decision is a combination of influencers from the slaughter house to the fast food outlet, as well as to producers.

The Company intends to market the *E. coli* vaccine to the meat production chain, including producers, feedlots, processors, and the whole sale to retail meat trade. As further food safety vaccines are developed, they will be added to this product line.

The Company continues to move forward in its program to register the *E. coli* O157:H7 vaccine in Canada and the United States. The Company has previously released positive research results relating to the vaccine, demonstrating that feedlot cattle vaccinated with the vaccine showed a significant reduction of the deadly bacteria in their manure. A vaccine challenge study conducted by VIDO with the vaccine earlier this year demonstrated a significant reduction in the prevalence of *E. coli* O157 shedding by experimental challenge. Further trials have been completed by Drs. Moxley and Smith from the University of Nebraska – Lincoln to test the efficacy of the vaccine during the backgrounding and feedlot stages of beef production. Safety and efficacy trials are currently underway to satisfy licensing requirements in Canada in the United States. Once these studies are completed, the Company will be in a position to submit the regulatory dossier to the regulatory agencies for registration in Canada and the United States.

As the vaccine product will follow the typical animal health pathway to producers, the Company will be placed to handle distribution through its current marketing and sales forces in the United States and Canada. In addition, once regulatory approval is imminent, the Company will appoint a team of experts, consisting of food safety specialists, veterinarians, epidemiologists coordinated by a business manager to “sell” the benefits to the decision makers. This team will also be involved with field demonstrations to prove the benefit of the vaccine to potential users. It is the intention of the Company to introduce and manage the supply of the *E. coli* O157:H7 vaccine in North America and to consider partners in other parts of the world.

Competition

E. coli O157:H7 infection and its treatment are attracting significant attention, and competitive vaccines or other solutions for this problem may be developed and commercialized by other companies in the veterinary health market. The competition could come from other drug treatments for the animals, non-drug treatments for the animals, changes in treating water for human consumption, or from process changes in meat handling. There are other vaccines under development but the stage of development is not known. Currently there is no licensed therapy for *E. coli* O157:H7, but other pre-harvest solutions may include:

- antibiotics, which in today's regulatory environment are less acceptable;
- feed additives such as probiotics are being tested, but so far show variable effectiveness;
- vaccination with the Company's *E. coli* O157:H7 antigens which has demonstrated significant reduction of shedding into the environment.

Regulatory Environment

The development of food and water safety products by the Company requires approval by various government authorities, depending on the claims the Company wishes to make about these products. The typical products which the Company is developing, including the *E. coli* O157:H7 vaccine, will be used to reduce infection of a food producing animal with a bacteria which is pathogenic to humans but may not be harmful to the host animal. In this case, the products will be regulated as Veterinary Biologics and therefore under the jurisdiction of the Canadian Food Inspection Agency's Veterinary Biologics Section. The jurisdiction of food safety claims in the United States is currently under discussion with the United States Department of Agriculture.

Water safety claims will be governed by the Environmental Protection Agency in the United States and the Ministry of Environment in Canada.

INTELLECTUAL PROPERTY

The Company actively pursues a policy of seeking patent protection for its proprietary technology. The Company believes that patent and trade secret protection is important in its business, and that its success will depend, in part, on its ability to obtain and enforce strong patents, to maintain trade secret protection and to operate without infringing the proprietary rights of others. For the fiscal year 2003 to 2004, the Company had thirty-six patents issued relating to hyaluronan technology, two patents issued relating to MCC technology and one related to MCWE technology. The Company has fifty-seven patent applications pending relating to MCC (thirty-five), MCWE (thirteen), and hyaluronan (ten) technologies in selected countries worldwide, including Canada, the United States, Australia, Europe and Japan. Additionally, there are sixty-two relating to oligonucleotides, six botanical and six reproductive patent applications that are pending. There can be no assurance that pending patent applications will be allowed, that the Company will develop additional proprietary products that are patentable, that issued patents will provide the Company with any competitive advantage or will not be challenged by any third parties, or that patents of others will not have an adverse effect on the ability of the Company to do business. Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of the Company's products, or design around the products patented by the Company. In addition, the Company may be required to obtain licenses under patents or other proprietary rights of third parties. No assurance can be given that any licenses required under such patents or proprietary rights will be available on terms acceptable to the Company. If the Company does not obtain such licenses it could encounter delays in introducing one or more of its products to the market, while it attempts to design around such patents, or could find that the development, manufacturing or sale of products requiring such licenses could be foreclosed. In addition, the Company could incur substantial

costs in defending itself in suits brought against it on such patents or in suits in which it attempts to enforce its own patents against other parties.

Until such time, if ever, that patent applications are filed, the ability of the Company to maintain the confidentiality of its technology may be crucial to its ultimate possible commercial success. It is the Company's policy to require its employees, consultants and parties to research agreements to execute confidentiality agreements with the Company. While the Company has adopted procedures designed to protect the confidentiality of its technology, no assurance can be given that such arrangements will be effective, that third parties will not gain access to the Company's trade secrets or disclose the technology, or that the Company can meaningfully protect its rights to its trade secrets.

HUMAN RESOURCES AND FACILITIES

On June 30, 2004 the Company had approximately 305 full-time and part-time employees, forty-one of whom hold advanced degrees in science and business, including sixteen employees with Ph.D or M.D. degrees. Thirty-two individuals directly support research and development activities. Fifty-one individuals are engaged in business development, finance, legal and administrative activities.

The Company's registered and head office is located at 231 Dundas Street East, Box 1570, Belleville, Ontario, K8N 5J2, where administrative, sales and financial matters are handled. This Company-owned facility consists of a 137,000 square foot biotechnology pilot and manufacturing plant purchased from Bristol-Myers Squibb Canada Inc. in July, 1999. The Company has renovated one-third of this facility. The facility currently comprises: (i) corporate offices; (ii) a pharmaceutical production unit which is regulated by Health Canada's Health Products and Food Branch Inspectorate; (iii) two biological production units which are regulated by the Canadian Food Inspection Agency's Veterinary Biologics Section; (iv) quality control and research laboratories; (v) an animal health research and development unit; (vi) animal housing facilities, and (vii) a natural health products production unit which is regulated by Health Canada's Natural Health Products Directorate, and (viii) warehouse and distribution areas.

The Company owns a 27,000 square feet FDA approved GMP facility in Montreal at 275 Labrosse Avenue, Pointe-Claire, Quebec H9R 1A3. This facility will be used primarily for pilot-scale production of some of the Company's technologies. The Company has also leased 3,868 square feet of office space at 171 Place Frontenac, Pointe-Claire, Quebec H9R 4Z7 which is near the manufacturing facility.

The Company owns a 39-hectare farm property outside Belleville, Ontario which is used to keep horses for *Colimune*® production and other animals for research and development purposes. In November, 2002, the Company sold its 72 hectare farm in Putnam, Ontario.

Bioniche Therapeutic's preclinical and formulation research is conducted at its leased 2000 square foot research facility located within the Biotechnology Research Institute of the Canadian National Research Council in Montreal, Quebec. The lease for these premises expires on November 30, 2004 and will be renewed. At the same time, the Company is currently investigating alternatives for the long term. Bioniche Therapeutic's clinical trials are carried out by leading clinical investigators at major hospitals worldwide.

Bioniche Pharma's production plant, located in County Galway, Ireland, is a 25,000 square foot ISO 9001 compliant facility, leased in September 1988 for a term of 999 years (pending certain terms and conditions as set out in the lease agreement) by the Company's subsidiary, Bioniche Teoranta. The Irish plant employs 107 people and is dedicated to the manufacture of small volume parenterals in glass vials and syringes. Both personnel and the facility are qualified to manufacture sterile injectables in

accordance with GMP acceptable to the United States, Canadian and European regulatory standards. The plant manufactures injectable drug products on a contract basis and also manufactures the Company's two proprietary products, *Cystistat*® and *Suplasyn*® as well as products for Bioniche Animal Health such as *MAP-5*® and *Enhance*® products. The Company also has a 20,000 square foot facility comprising packaging, warehouse and office space. The Company is currently expanding its manufacturing facilities by approximately 25,000 square feet. Construction on the new facility has begun, and is expected to be completed by September of 2005.

The Company leases a 1,250 square foot laboratory located at 119 Rowe Road, Athens, Georgia in the United States for a term ending November 20, 2004. The renewal of this lease is currently being negotiated. This facility produces and distributes animal immunostimulant products to the United States, Canada, Ireland, Australia, South Africa and several South American, Central American and Middle Eastern countries. The Company also leases a 1,200 square foot office in Bogart, Georgia terminable on 12 month's notice.

In February, 2004 the Company acquired the assets of AB Technology Inc. of Pullman, Washington. This included the leased premises of 7,605 square feet of office and manufacturing space and 583 square feet of warehouse space.

In August, 2001 the Company acquired an animal health business including a manufacturing facility and a 300-acre farm in Armidale, Australia. The Company leases an additional 1100 acres of farm land. The manufacturing facility specializes in the manufacture of pregnant mare serum gonadotrophin ("PMSG"), a reproductive hormone used to enhance fertility in livestock.

SELECTED FINANCIAL INFORMATION FOR THE COMPANY

The following tables set forth selected financial information relating to the Company.

	Year ended June 30	Year ended June 30	Year ended June 30
	2004	2003	2002
	\$	\$	\$
Statement of Operations			
Sales	53,756	50,702	40,089
Interest and miscellaneous income	651	857	449
Total Revenue	54,407	51,559	40,538
Expenses:			
Research and development	13,609	14,687	11,820
General and Administrative	17,407	15,652	13,458
Amortization (including Goodwill)	2,220	2,490	1,733
Interest	4,257	3,898	3,044
Net loss	(7,813)	(6,449)	(4,818)
Net loss per share	(.24)	(.23)	(.17)
Cash dividends declared per common share	nil	nil	nil
	As at June 30	As at June 30	As at June 30
(in thousands of dollars, except for per share data)	2004	2003	2002
	\$	\$	\$
Balance sheet data:			
Cash and cash equivalents	8,245	9,848	11,146
Accounts receivable	16,582	13,130	8,455
Capital assets	23,548	15,534	14,878
Intellectual property	19,288	18,400	18,071
Total assets	79,313	66,211	60,134
Current liabilities	17,407	12,728	10,135
Long term liabilities	29,274	21,978	16,506
Total liabilities	51,199	37,653	28,278
Capital stock	57,667	47,901	44,722
Deficit	(37,123)	(30,937)	(24,488)
Total shareholders' equity	25,034	24,689	28,176

⁽¹⁾ Certain comparative figures have been reclassified to conform with the financial presentation adopted in the current year.

CONSOLIDATED FINANCIAL STATEMENTS

Reference is made to the sections entitled "Management Report", "Consolidated Balance Sheet", "Consolidated Statements of Loss", "Consolidated Statements of Deficit", "Consolidated Statements of Cash Flow" and "Notes to Consolidated Financial Statements" of the Company's 2004 Annual Report, which is incorporated herein by reference.

DIVIDEND POLICY AND RECORD

The Company's current intention is to reinvest its earnings to finance the growth of its business. The Company does not intend to pay dividends on its common shares in the foreseeable future. The board of directors of the Company will review this policy from time to time having regard to the Company's financial condition, financial requirements and other factors considered relevant.

PRINCIPAL SHAREHOLDERS

As at October 1, 2004, the directors and officers of the Company and its subsidiaries as a group owned, directly or indirectly, or exercised control or direction over, 8,669,757 Common Shares of the Company representing 24% of the issued and outstanding Common Shares and 85,802 A ordinary shares of Bioniche Pharma Group Limited, a subsidiary of the Company, representing 5% of the issued and outstanding A ordinary shares of such subsidiary.

On November 3, 2004 the Company completed an equity financing with the Fonds de solidarité des travailleurs du Québec ("FSTQ") and the Fonds d'investissement bioalimentaire, sec ("Fonds Bio"). The investment consisted of a private placement offering of 12,000,000 newly created Series 2 preferred shares to FSTQ and Fonds Bio for a total subscription price of \$12,000,000. The Series 2 preferred shares are convertible at the option of the holder into common shares in accordance with a specified conversion formula. The preferred shares shall have voting rights on the basis of the number of common shares that the holder would have if the preferred shares were converted into common shares on the date of the applicable shareholders' meeting.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Reference is made to the section entitled "Management's Discussion and Analysis" of the Company's 2004 Annual Report, which section is incorporated herein by reference.

MARKET FOR SECURITIES

The common shares of the Company are listed and posted for trading on The Toronto Stock Exchange under the symbol "BNC".

DIRECTORS AND OFFICERS

The name, municipality of residence, position with the Company and principal occupation of each of the directors and officers of the Company as of November 17, 2004 is set out below.

Name and Municipality of Residence	Position with the Company	Principal Occupation	Director of Company since
Stanley Alkemade, DVM Arva, Ontario (5),(6),(8)	Director	President of BioMedEx, a pharmaceutical industry consulting firm.	September, 1999
Albert G. Beraldo, CA Beaconsfield, Quebec (8)	President and Chief Executive Officer of Bioniche Pharma and Director	President and Chief Executive Officer of Bioniche Pharma.	April, 1984
David Butts (4),(6),(8) Sofia , Bulgaria	Director	Principal, Hayhurst, Robinson, law firm.	December, 1997
Margaret Cunningham, Ph.D. Kingston, Ontario (1), (8)	Director	Associate Professor, School of Business, Queens University. Ms. Cunningham has been a professor at the School of Business, Queens University since 1989.	October 24, 2003
Hy Isenbaum, FCA Toronto, Ontario (1),(2),(3),(8)	Chairman and Director	Consultant, Soberman, Isenbaum & Columby, accounting firm.	February, 1992
James Johnson Ph.D. (4),(5),(8) Highlands, North Carolina	Director	Partner, Kilpatrick, Stockton LLP, law firm.	December, 1997
Jacques Lapointe (1),(2),(3),(8) Milton, Ontario	Director	Chairman and Interim CEO of ConjuChem Inc.	May 7, 2002
Graeme McRae (2),(5),(7),(8) Belleville, Ontario	President and Chief Executive Officer, Director	President and Chief Executive Officer of the Company.	June, 1979
Nicholas Photiades (2),(3), (8) Montreal, Quebec	Director	Director, Business Development Bank of Canada	September 12, 2003
Leslie Dunlop (4),(6),(7) Belleville, Ontario	Vice-President, Corporate Counsel	Vice-President, Corporate Counsel since November, 2001. Lawyer; previously served as Corporate Counsel, The Quaker Oats Company of Canada Limited	N/A

Name and Municipality of Residence	Position with the Company	Principal Occupation	Director of Company since
Patrick Montpetit, CA (7) Lorraine, Quebec	Vice-President, Finance and Chief Financial Officer	Vice-President, Finance and Chief Financial Officer of the Company since August, 2000; previously served as Director of Finance, Administration, Commercial Agreements and Alliances with DSM Biologics Inc.	N/A
Dr. Nigel Phillips Pointe Claire, Quebec	Senior Vice-President and Chief Scientific Officer	Senior Vice-President and Chief Scientific Officer of the Company since January, 1999; previously served as Associate Professor, Faculty of Pharmacy, University of Montreal.	N/A
Dr. Marc Rivière Saint-Lambert, Quebec	Senior Vice-President, Medical Affairs and Chief Medical Officer	Senior Vice-President, Medical Affairs and Chief Medical officer since February, 2002; previously served as managing Director, Xenon Genetics Research.	N/A
Dr. Dragan Rogan Belleville, Ontario	Vice President, Research and Development , Animal Health	Vice President, Research and Development, Animal Health since 1989.	N/A
François Schubert Montreal, Quebec	Chief Operating Officer	Chief Operating Officer with the Company since October 18, 2004; previously served as Vice- President of Corporate Business Development at Pharmascience.	N/A

Name and Municipality of Residence	Position with the Company	Principal Occupation	Director of Company since
Martin Warmelink Belleville, Ontario	President, Bioniche Food Safety and Vice-Chairman Bioniche Animal Health	President, Bioniche Food Safety Division as of July 2001 and President of Bioniche Animal Health division as of July, 2002; previously held senior marketing management positions with several major Canadian agricultural and pharmaceutical companies, Schering Plough, Ayerst (Ft. Dodge), Langford Labs and Cyanamid.	N/A
Mohamed Elrafih Belleville, Ontario	Vice-President, Manufacturing Operations	Vice-President of the Company since November, 2001; previously held positions within the Company.	N/A
Cindy Hickey Frankfurt, Ontario	Vice-President, Regulatory Affairs and Quality Assurance	Vice-President of the Company since December, 2001; previously held positions within the Company.	N/A
Gail Garland Grafton, Ontario	Vice-President, Business Development	Vice-President of the Company since October, 2003; previously held a Senior Sales and Management position with Johnson and Johnson & Alcon Laboratories Inc.	N/A

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

(3) Member of the Nominating Committee

(4) Member of the Corporate Governance Committee

(5) Member of the Scientific Audit Committee

(6) Member of the Risk Management Committee

(7) Member of the Corporate Disclosure Committee

(8) Each director has been elected to hold office until the date of the company's next annual meeting of shareholders

The following are brief biographies of the directors and officers of the Company:

Dr. Stanley Alkemade received his veterinary degree from the University of Melbourne, Australia. He came to Canada in 1971 and ran a mixed veterinary practice in Seaforth, Ontario for the next ten years. He has lectured in the Animal Health Technology program at the Centralia College of Agricultural Technology. In 1986, he joined Vetrepharm Canada Inc. as Technical Director and was responsible for

research and development, product registrations, corporate technical services and facilities design. He is now the President of BioMedEx, a project management firm for the pharmaceutical industry.

Albert Beraldo currently serves as President and Chief Executive Officer of Bioniche Pharma. He has a Bachelor of Commerce degree from the University of Windsor and has a Chartered Accountant designation. He worked in public accounting with the accounting firm of Ernst & Whinney until he joined Vetrepharm Inc. as Financial Controller in 1983. Mr. Beraldo has held several positions within the group of companies which amalgamated to form the Company and played an integral role in the formation of Bioniche Inc., one of the amalgamating companies.

David Butts has Canadian degrees in pharmacy and law, and is a partner in the law firm Hayhurst Robinson based in Budapest with operations in Eastern Europe. Mr. Butts specializes in corporate and commercial law in the biotechnology and pharmaceutical industries. He has also acted as corporate counsel for Burroughs Wellcome in Canada.

Margaret Cunningham has a Ph.D. in marketing from Texas A&M University and an MBA from the University of Calgary. She is Associate Professor of marketing at the School of Business, Queens University. Ms. Cunningham has been a professor at the School of Business, Queens University since 1989.

Hy Isenbaum is a Fellow Chartered Accountant and the founder of the firm Soberman, Isenbaum and Colomby. As the managing partner, a position he held until 1993, he built his firm to be the 15th largest accounting practice in Canada. He is a past Chairman of the Board of the Mount Sinai Hospital in Toronto. He was appointed by the Ontario Ministry of Health as Ombudsman to the Medical Review Committee of the College of Physicians and Surgeons. He currently serves on the Board of Directors of the Samuel Lumenfeld Research Institute in Toronto and was critical to the establishment of the Institute. Mr. Isenbaum is also a Governor of the Weizman Institute of Science in Israel and sits on the board of a number of private and public companies.

Dr. James Johnson has a doctorate in biochemistry in addition to his law degree and is a partner of Kilpatrick, Stockton LLP based in Atlanta, Georgia. He has extensive experience in chemical and biotechnology patent prosecution and licensing. He leads Kilpatrick, Stockton LLP's biomedical and chemical practice group.

Jacques Lapointe received a Bachelor of Commerce degree as well as a MBA (Finance) from Concordia University in Montreal. He also completed an EPBA at Columbia University, New York. Mr. Lapointe served as President, Chief Operating Officer and Director of Biochem Pharma Inc. Prior to that, he worked for twelve years with Glaxo Wellcome plc with responsibilities as President and CEO of Glaxo Canada, Managing Director for the U.K., Regional Director for a number of other countries, and Worldwide Director of Business and Commercial Development. Prior to Glaxo Wellcome, Mr. Lapointe held roles through a 17 year tenure with Johnson & Johnson and McNeil Pharmaceuticals Canada Inc. Mr. Lapointe is currently the Chairman and interim CEO of ConjuChem Inc.

Graeme McRae is the founder of both Vetrepharm Inc. and Bioniche Inc., two of the predecessor companies to the Company. Born in Australia, McRae has had a lengthy and diversified career in the pharmaceutical industry in both Australia and Canada. In 1971, Mr. McRae joined Pfizer Animal Health in Australia and held various sales and managerial positions with that company. Mr. McRae was transferred to Canada in 1975. In 1979, Mr. McRae founded Vetrepharm to focus on research and development in animal health, with an emphasis on developing non-antibiotic solutions for animal health problems. Bioniche Inc. was founded in 1992 by Mr. McRae to develop Vetrepharm's technologies for human health applications.

Nicholas Photiades has been a Director, Life Sciences, Venture Capital Division of Business Development Bank of Canada for over six years. He acts as a director of various corporations.

Leslie Dunlop joined the Company in November 2001. Prior to joining the Company, she established the position of in-house counsel at The Quaker Oats Company of Canada Limited, which she held for eight years. Before going in-house, she worked for five years in a large law firm in Toronto.

Mohamed Elrafi joined the Company in 1984 and became Vice President, Manufacturing Operations in November 2001, responsible for all manufacturing and plant operations for BLSI. Mohamed graduated from the University of Western Ontario with a Bachelor Degree in Science (Microbiology). He has 19 years of experience in the pharmaceutical industry, holding positions of increasing responsibility in the manufacturing operations of the Company.

Gail Garland joined the Company in June 2003 and currently serves as Vice President Business Development for the Company. She has a Bachelor of Science from Carleton University in Ottawa and an MBA from Rotman School of Management, University of Toronto. Ms. Garland has several years of progressive experience working for major pharmaceutical companies including Alcon, McNeil Pharmaceutical, Allen & Hanburys (Glaxo) and Johnson & Johnson where she was VP eBusiness and Corporate Services. She has held senior roles in sales and marketing as well as administration and general management.

Cindy Hickey joined the Company in 1993 as Quality Control Supervisor. She was appointed to the position of Vice President, Corporate Quality & Regulatory Affairs in December 2001. She has 19 years of experience in the pharmaceutical industry, holding various positions in Quality Control and/or Regulatory Affairs. Hickey holds a Technology Diploma in Biological Sciences from St. Clair College and also graduated with a Bachelor of Science Degree from the University of Waterloo in 1998. With her extensive experience in GMP, cGMP & Quality Assurance as well as in Regulatory Affairs for both human and veterinary health products in international regulatory markets, Ms. Hickey is an important resource for the company's clinical development program and facility expansion plans.

Patrick Montpetit joined the Company in August, 2000 as Vice-President, Finance and Chief Financial Officer. Mr. Montpetit is a Chartered Accountant with considerable experience in the biopharmaceutical industry. Mr. Montpetit was formerly the Director of Finance, Administration, Commercial Agreements and Alliances with DSM Biologics Inc., a multinational pharmaceutical company based in Montreal and the Netherlands. Prior to joining the Company, he served as a consultant to a number of biotech companies.

Dr. Nigel Phillips joined the Company in 1996. Dr. Phillips has an extensive research background in biochemistry, immunology, immunopharmacology and immunomodulatory drug formulation which stretches over the past 24 years. Dr. Phillips has directed research programmes at the Strangeways Research Laboratory, Cambridge, the Institut Pasteur de Paris, McGill University, Montreal, the University of Montreal and the Institut Pasteur de Lille, in addition to receiving extensive pharmaceutical training and management experience within the pharmaceutical division of Reckitt & Colman. Dr. Phillips received his undergraduate degree at North East London Polytechnic in London, England and his Ph.D. from Queen Elizabeth College, University of London.

Dr. Marc Rivière joined the Company in February, 2002 and is the Senior Vice-President and Chief Medical Officer. Dr. Rivière received his Tropical Medicine Certification from the Université Bordeaux II, France and Medicine Doctorate from Université Paul Sabatier, Toulouse, France in 1984. He is a Board certified physician in France, bilingual, and has over fifty publications and scientific communications to his credit. Prior to joining the Company in February, 2002, Dr. Rivière served as managing Director, Xenon Genetics Research Inc. and played an integral role in the Montreal-based

company's business development projects. Previous experience includes: Corporate Vice President of Planetmedica S.A., Brussels; President of Planetmedica Inc., Canada; Vice President of Clinical Affairs, Aeterna Laboratories Inc., Canada; Executive Vice President and Regional Director, Canada, of Quintiles Inc., Canada; Vice President and Managing Director of Benefit Canada Inc.; and Vice President, Health Care Management, Benefit International, Paris, France. Dr. Rivière practiced medicine until 1993 while teaching and acting as consultant for various international organizations.

Dr. Dragan Rogan joined the Company in 1989. He received his Ph.D. in Virology and Cell-Mediated Immunity at the University of Belgrade, Yugoslavia after completing his Masters and Doctorate in Veterinary Medicine. Dr. Rogan was a University Professor of Microbiology and Immunology in Belgrade before becoming a Visiting Scientist at the Vaccine and Infectious Diseases Organization in Saskatoon, Saskatchewan in 1986. He obtained his Ph.D. and emigrated to Canada in 1989, when he joined the Company as Senior Scientist, went on to become Scientific Director, then Vice-President of Research & Development for Bioniche Animal Health. He leads a team of researchers, with expertise in bacteriology; biochemistry; molecular biology; reproductive physiology; and virology.

François Schubert joined the Company in October, 2004 and has been actively involved in both the public and private sectors of the national and international biopharmaceutical industry for more than 25 years. Amongst his previous employment, Mr. Schubert was President and CEO of PROCREA BioSciences from 2001 to 2003, Worldwide Vice-President of Global Health Outcomes for Glaxo-Wellcome plc in the U.K. from 1996 to 2001, and Director of Pharmacy at the Royal Victoria Hospital in Montreal from 1978 to 1989 as well as Assistant Director of Professional and Hospital Services from 1986 to 1989. Mr. Schubert is a graduate of Montréal and McGill Universities in Pharmacy, Health Administration, and Public Health. He further trained in Business Administration (Fuqua School of Business) at Duke University (USA), INSEAD (France) and London Business School (UK) and acquired three Fellowships (FASCP, FASHP, FCSHP). He was also Past-President of the Canadian Pharmacist Association and Vice-President of the Fédération Internationale Pharmaceutique (F.I.P.).

Martin Warmelink is the President of the Company's Animal Health and Food Safety divisions. Mr. Warmelink joined the Company in June, 2001 and has over 20 years Canadian and International experience in animal health. He is a multi-lingual (English, Dutch, French, German) agricultural sales and marketing professional with comprehensive experience in creating new markets, optimizing merged sales forces and designing/implementing all aspects of the marketing and sales process. He has held senior marketing management positions with several of the major players in the Canadian agricultural and veterinary pharmaceutical industry including Schering Plough, Ayerst (Ft. Dodge), Langford Labs and Cyanamid.

Committees of the Board

There are seven committees of the Board: the Audit Committee, the Compensation Committee, the Nominating Committee, the Corporate Governance Committee, the Scientific Audit Committee, the Risk Management Committee and the Corporate Disclosure Committee.

The members of the Audit Committee as of June 30, 2004 were Hy Isenbaum, Jacques Lapointe and Margaret Cunningham, all of whom are unrelated directors. The role of the Audit Committee is to review the interim financial statements with the Chief Financial Officer and the year-end financial statements with the Chief Financial Officer and the auditors of the Corporation prior to the presentation of such statements to the Board. The Audit Committee also oversees management reporting and internal controls.

The Compensation Committee as of June 30, 2004 was comprised of Hy Isenbaum, Jacques Lapointe and Nicholas Photiades, all of whom are unrelated Directors, as well as Graeme McRae, a related Director, for all matters except his own compensation. The Compensation Committee reviews

compensation decisions for executive and senior management staff and is responsible for assessing the adequacy of directors' compensation.

The Nominating Committee as of June 30, 2004 was comprised of Hy Isenbaum, Jacques Lapointe and Nicholas Photiades, all of whom are unrelated Directors. The Nominating Committee is responsible for the nomination of new Directors.

The Corporate Governance Committee addresses the constitution and independence of the Board and the functions of the Board and its committees. This committee presently consists of David Butts and James Johnson, both of whom are outside directors, together with the Corporation's corporate secretary and in house legal counsel, Leslie Dunlop, as an *ex officio* member.

The Scientific Audit Committee oversees the strategic direction and integrity of the scientific development program. The committee presently consists of Stanley Alkemade, James Johnson and Graeme McRae.

The Risk Management Committee address areas of risk exposure, consists of David Butts and Stanley Alkemade as well as Leslie Dunlop as an *ex officio* member.

The Corporate Disclosure Committee consists of Graeme McRae, Patrick Montpetit and Leslie Dunlop. This Committee ensures that timely, accurate and balanced disclosure of material information about the Corporation will be consistent with legal and regulatory requirements.

ADDITIONAL INFORMATION

A copy of the Company's financial statements for the year ended June 30, 2004 may be obtained upon request from the Secretary of the Company.

Additional information, including directors' and officers' remuneration and indebtedness, principal holders of the Company's securities, options to purchase securities and interests of insiders in material transactions, where applicable, is contained in the Company's information circular for its annual meeting of shareholders held on November 8, 2004.

When the Company's securities are in the course of a distribution pursuant to a prospectus or when a preliminary prospectus has been filed in respect of a distribution of the Company's securities, upon request to the Secretary, the Company will provide to any person:

1. One copy of this annual information form together with one copy of any document, or the pertinent pages of any document, incorporated by reference in this annual information form;
2. One copy of the Company's audited consolidated financial statements contained in the Annual Report for the year ended June 30, 2004, together with the report of the auditors thereon, and one copy of the most recent of the Company's interim consolidated financial statements that have been filed subsequent to such audited financial statements;
3. One copy of the Company's information circular in respect of its most recent annual meeting of shareholders that involved the election of directors or one copy of any annual filing prepared instead of that information circular, as appropriate; and
4. One copy of any other documents that are incorporated by reference into the preliminary prospectus or short form prospectus and are not required to be provided under 1, 2 or 3 above.

At any other time, one copy of each of the documents referred to in 1, 2 and 3 above may be obtained upon request to the Secretary of the Company, provided that the Company may require payment of a reasonable charge if the request is made by a person who is not a shareholder of the Company.

Any request for any documents referred to above should be made to the Secretary, Attention: Legal Department, P.O. Box 1570, Belleville, Ontario K8N 5J2 or by fax to (613) 966-4177.