



**ANNUAL INFORMATION FORM**

**Year Ended June 30, 2010**

September 28, 2010,

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## **BIONICHE LIFE SCIENCES INC.**

### **CORPORATE STRUCTURE**

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”.

Bioniche Life Sciences Inc. was formed on September 1, 1999 through an amalgamation of Bioniche Inc., Renaissance Life Sciences Inc. and Vetrepharm Animal Health Inc. pursuant to articles of arrangement issued under the Canada Business Corporations Act.

The Company currently employs approximately 211 people and has three operating units: human health, animal health and food safety.

The human health operations have previously been carried out through Bioniche Therapeutics Limited, a wholly owned subsidiary of the Company. This subsidiary also carried out the research and development activities for the Company. On June 30, 2007, for business planning purposes the Company resolved to transfer the assets and liabilities of Bioniche Therapeutics Limited to the Company and to wind up that subsidiary. The human health operations and research and development activities are now carried out directly by the Company. This area of the Company’s operations continues to be referred to internally as Bioniche Therapeutics. Pursuant to a License, Development and Supply Agreement (“Agreement”) with Endo Pharmaceuticals Inc., the Company established a wholly-owned subsidiary in the U.S., Bioniche Urology Inc., through which Agreement-related transactions may occur. The animal health operations are carried out through four wholly-owned subsidiaries of the Company. These are: Bioniche Animal Health Europe Limited; Bioniche Animal Health USA, Inc.; Bioniche Animal Health (A/Asia) Pty. Ltd.; and Bioniche Animal Health Canada Inc.

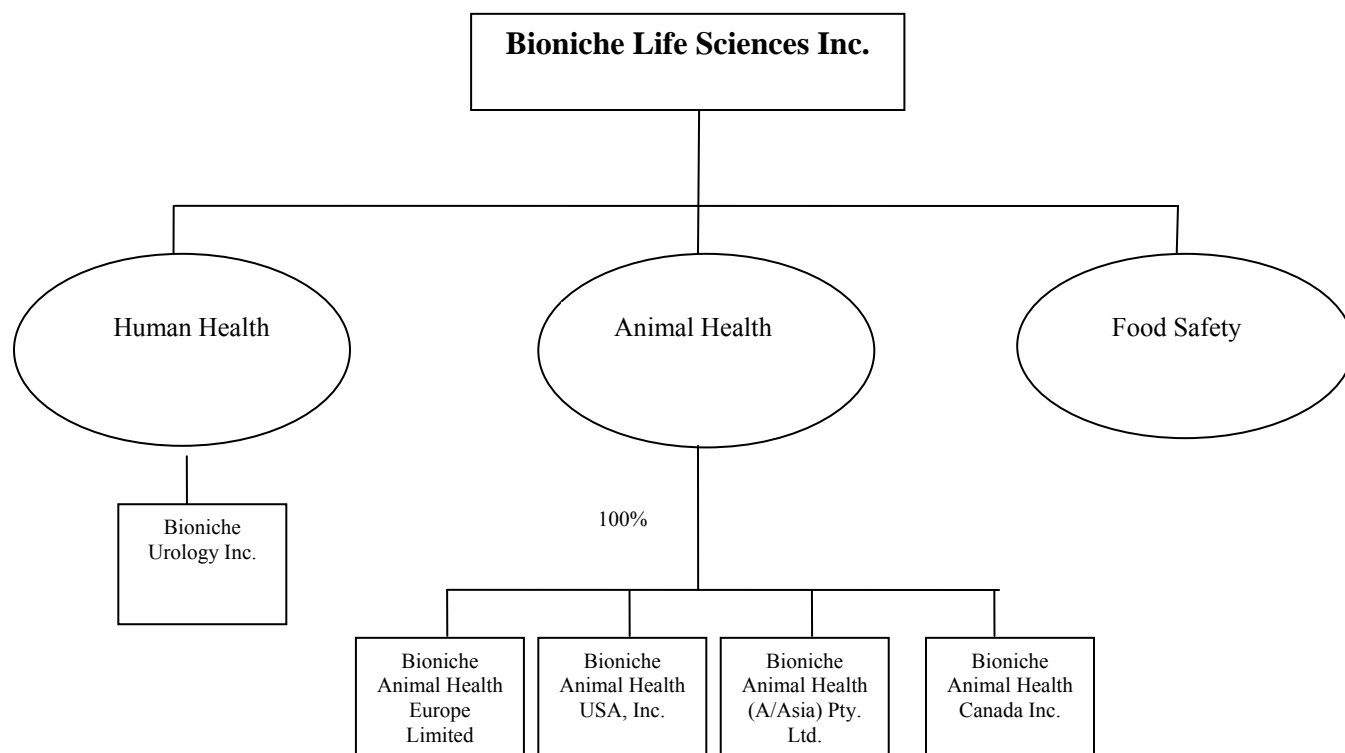
The food safety operations are carried out directly by the Company, through a business unit known as Bioniche Food Safety.

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

The following is a list of the material subsidiaries of the Company as of June 30, 2010:

<b>Subsidiary</b>	<b>Jurisdiction of Incorporation</b>	<b>Percentage of Voting Securities Owned Directly or Indirectly by the Company</b>	<b>Percentage of Non-Voting Securities Owned Directly or Indirectly by the Company</b>
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 Urology Inc.	Delaware	100%	N/A

The following chart depicts the shareholdings of the Company and its material subsidiaries.



## GENERAL DEVELOPMENT OF THE BUSINESS

### OVERVIEW

Bioniche is a Canadian biopharmaceutical company that develops, manufactures, and markets proprietary products for human and animal health markets worldwide.

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 alternatives to antibiotics as treatments for livestock disease. Mr. McRae believed that there had to be more suitable ways of treating animal health diseases without the problems associated with antibiotics, such as residues in the food chain and the promotion of the development of resistant bacterial species. In 1992, the human application of the original technologies, along with 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 human health business unit, referred to as Bioniche Therapeutics, is primarily operated from the Company's production and research facilities in Montréal, Québec, with approximately 63 dedicated employees. It develops proprietary technologies for use in human medicine. The Company's strategy is to develop its therapies through clinical proof of concept and then, where appropriate, to establish alliances to complete clinical studies and obtain regulatory approvals. This business unit's primary focus is the development of the Company's proprietary Mycobacterial Cell Wall-DNA Complex ("MCC") technology for the treatment of cancers, and its clinical development and research activities are focused primarily in support of the commercialization efforts related to this technology.

The animal health business unit, referred to as Bioniche Animal Health, is primarily operated from the Company's head office in Belleville, Ontario, which also contains a product development and production facility. Additional animal health marketing and production facilities are located in Athens, Georgia; Pullman, Washington; and Armidale, Australia. Additionally, a marketing office is located in Ireland. The animal health business unit is responsible for developing, manufacturing and marketing veterinary biopharmaceutical products worldwide. Management believes that Bioniche Animal Health is now the largest Canadian-owned biopharmaceutical animal health company.

The food safety business unit, referred to as Bioniche Food Safety, was established in July, 2001 and operates from the Company's facility in Belleville, Ontario. It 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 cattle vaccine to reduce the spread of the *E. coli* O157 enterohemorrhagic bacterium which can be deadly to humans. Additional food safety products are in earlier stage development.

As of June 30, 2010, approximately 74 employees are employed in the animal health and food safety units, including production facilities for these units. In addition, there are approximately 74 employees supporting all business units and general corporate requirements of the Company.

## THREE-YEAR HISTORY

### Human Health

The Company's clinical development program for human health is focused on MCC technology for the treatment of cancers, and its clinical development and research activities are focused primarily in support of the commercialization efforts related to this technology.

The Company's first product based on MCC technology, trademarked as *Urocidin*<sup>TM</sup>, is a sterile suspension of MCC for the treatment of non-muscle-invasive bladder cancer by trans-urethral infusion into the bladder. The Company's Phase I and Phase II clinical trials using earlier formulations of MCC to treat non-muscle-invasive bladder cancer were completed with positive results.

The Company is now conducting its United States Food and Drug Administration ("FDA") approved Phase III clinical program, involving the following international clinical experts:

- The international principal investigator is Dr. Alvaro Morales, Professor Emeritus of Urology at Queen's University in Kingston, Ontario. Dr. Morales is credited with the introduction of the current standard-of-care therapy for bladder cancer, known as Bacillus Calmette-Guérin ("BCG"), has published over 260 peer-reviewed articles and was the lead investigator for the Company's Phase I and Phase II clinical trials.
- The North American principal investigator is Dr. Harry Herr, a Urologist and Oncologist/Fellow at Memorial Sloan-Kettering Cancer Center in New York City, New York. Sloan-Kettering is generally considered one of the world's premier cancer centers and Dr. Herr is a prominent urologic oncologist, with more than 170 peer-reviewed articles and multiple leadership roles.

The first clinical trial involves *Urocidin*<sup>TM</sup> for the treatment of patients who have failed (are refractory to) BCG, the current standard-of-care bladder cancer therapy. BCG is a vaccine of live, attenuated *Mycobacterium bovis*, a pathogen that causes tuberculosis in cattle and can cause disease in humans. In such patients, BCG is largely ineffective when used as a therapy, with low expected clinical response rates. Additionally, many side effects are associated with BCG therapy. These factors have led Bioniche to believe the need exists for a more effective and better tolerated therapy for bladder cancer patients whose cancer is refractory to BCG.

In response to the Company's Investigational New Drug ("IND") application, the FDA granted "fast track" designation to this first trial in April of 2006. This means that the Company can expect an expedited review by the FDA following completion of the trial. The Company commenced the trial in November 2006. For registration purposes, enrolled patients will be evaluated and the FDA has indicated that the 12-month response rate, as well as safety and tolerability, will be the relevant endpoints of this first Phase III trial. A full complement of 31 North American sites has been qualified to enroll patients and patient recruitment was completed in April 2009. The trial's Data Safety Monitoring Committee held its first meeting in August 2007, at which time it reviewed the data generated to date and recommended that the trial continue unmodified. The Committee has met regularly since then, each time reaching the same conclusion.

The patients at participating sites that are eligible and who choose to participate in this trial represent a very small subset of the BCG refractory patient population in North America. In order to satisfy regulatory authorities, the trial protocol is quite specific and patients must meet numerous criteria to be eligible. A significant proportion of patients who appeared to qualify based upon local pathology assessment (per normal clinical practice) were later found to have cancer of a different grade when

assessed by a central pathologist (per the trial's protocol) and were subsequently disqualified. Ultimately, over 100 evaluable patients had to be enrolled and disqualifications require the Company to recruit replacement patients. Data from all patients involved in the trial, coupled with additional safety information to be collected from a comparative trial, will allow full results to be available for analysis one year after recruitment is completed for the efficacy and safety datasets.

The Company has entered a new phase in its *Urocidin*<sup>TM</sup> clinical development program with the signing of a license, development and supply agreement with Endo Pharmaceuticals Inc. ("Endo") in July, 2009. This strategic partnership provides the Company with financial assistance and guidance in the completion of ongoing and future clinical studies, FDA and international regulatory filings and for the commercialization of *Urocidin*<sup>TM</sup>. The Company is currently, and expects to continue to be, the manufacturer of *Urocidin*<sup>TM</sup>. Endo is based in Chadds Ford, Pennsylvania, and is a publicly-listed company (ENDP – NASDAQ).

Endo is a speciality pharmaceutical company engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used to treat and manage pain, overactive bladder and prostate cancer, among other categories. The history of Endo can be traced back as far as 1920. In modern times, Endo re-commenced operations as a division in 1994, became independent via a 1997 management buy-out from the Dupont Merck Pharmaceutical Company and went public in 2000. Since that time, Endo has increased revenues by ten-fold. Endo markets its branded pharmaceutical products to physicians in pain management, urology, neurology, surgery, oncology, endocrinology and primary care. More information, including past press releases, is available at [www.endo.com](http://www.endo.com).

Under the License, Development and Supply Agreement ("Agreement") with Bioniche, Endo licensed from Bioniche the rights to develop and market *Urocidin*<sup>TM</sup> (now also known as EN3348) for the treatment of non-muscle-invasive bladder cancer. The territories licensed originally consisted of the United States, Mexico and, subject to co-marketing rights, Canada. The Agreement also included a 12-month option to expand the territory to comprise global marketing rights.

Under its Agreement with Endo, Bioniche received an up-front cash payment of US\$20.0 million. The Company also has the potential to receive a further US\$110 million in additional payments linked to the achievement of future clinical, regulatory and commercial milestones. On November 6, 2009 the Company announced that it had met its obligations associated with the first milestone, triggering a payment from Endo of US\$6 million. On February 12, 2010 the Company announced the achievement of two additional milestones and received an additional US\$8 million from Endo.

In addition to the above payments, Bioniche has retained exclusive product manufacturing rights and will receive a net sales-related transfer price for supplying Endo with commercial product. Bioniche believes this agreement will provide it with overall economics that are superior to most biotech-pharma partnership agreements and that Endo represents an optimal development and commercialization partner due to its market and industry expertise.

On February 12, 2010, Endo elected to exercise its option for exclusive rights to develop and market *Urocidin*<sup>TM</sup> globally, thereby becoming responsible for funding 100% of external clinical development costs.

In regards to governance, the Agreement provides for Endo and Bioniche to jointly complete the development and commercialization of *Urocidin*<sup>TM</sup>, pursuant to agreed plans and with oversight by joint committees.

Lastly, the Agreement contemplates that Endo will be granted a right of first negotiation for other clinical indications of MCC technology, where such clinical indications relate to urology or pelvic

disease. Should Endo not elect to enter such negotiations and the parties conclude them to mutual satisfaction within a set period, the Company shall have no further obligations and Endo no further rights.

Bioniche will also continue to examine future indications for *Urocidin*<sup>TM</sup>, other distinct formulations of MCC and it will advance its other human health-oriented technologies. Future indications for *Urocidin*<sup>TM</sup>, as well as other formulations of MCC, will be explored so as not to jeopardize the commercial potential of *Urocidin*<sup>TM</sup> as an intravesical bladder cancer therapy. Other distinct formulations of MCC that may be applicable to urologic or pelvic diseases will be first offered to Endo. Distinct formulations of MCC targeted to diseases outside the urologic and pelvic disease fields will be developed to the point at which partnerships are desirable or required, as will be the case with non-MCC Bioniche human health technologies.

### **Animal Health**

The animal health business has generated relatively stable sales revenues over the past several years. Profits from these sales have been used to further the Company's Phase III clinical program using MCC in the treatment of bladder cancer and for the development of its *E. coli* O157 cattle vaccine program. There are also a number of other technologies within the animal health product portfolio which present growth opportunities for the Company. Once the Company begins to generate revenues from its human health and food safety programs, it will be in a position to redeploy current and new resources into the animal health business to pursue these growth opportunities. The Company continues to explore potential partnership and cross-licensing opportunities with various animal health companies to build upon its current portfolio of products.

In June 2010, the Company announced that it signed an agreement with Bayer Animal Health, a division of Bayer Australia Limited, for the exclusive distribution of the Company's *Cue-Mate*<sup>®</sup> and *Pregnecol*<sup>®</sup> products in Australia. Under the agreement, Bayer Animal Health will become the exclusive distributor of Bioniche's *Cue-Mate*<sup>®</sup> and *Pregnecol*<sup>®</sup> products in Australia. *Cue-Mate*<sup>®</sup> and *Pregnecol*<sup>®</sup> are high quality products with a proven track record in delivering consistent results and enhancing reproductive performance in both beef and dairy cattle. An Australian market of over 15 million cows remains relatively untapped, and market education is critical for *Cue-Mate*<sup>®</sup> and *Pregnecol*<sup>®</sup> to grow. Bayer is expected to help the Company in both expanding the Australian market and in establishing a greater presence within it.

### **Food Safety**

In October 2008, the Company received full licensing approval from the CFIA, making *Econiche*<sup>TM</sup> the world's first fully licensed vaccine designed to reduce the shedding by cattle of *E. coli* O157. A full license allows *Econiche*<sup>TM</sup> to be available for unrestricted use by Canadian cattle producers and their veterinarians.

The Company continues to pursue the registration of the *E. coli* vaccine in the United States. In February 2008, the Company received notice from the United States Department of Agriculture (USDA) that the latest data for its *E. coli* O157 cattle vaccine "meets the 'expectation of efficacy' standard" and is eligible for a conditional license, providing that the Company undertakes a number of steps, including having one step in the manufacturing process completed in a U.S. facility and developing an agreed trial protocol to support full registration. The conditional license, when granted, will provide the Company full access to the U.S. market with the restriction that the Company will not be permitted to use a trademark name for the vaccine. The Company is in the process of completing the required steps in the U.S. at this time and expects a conditional license could be granted by the end of calendar 2010.

The Company has been producing the *E. coli* O157 vaccine in limited quantities in laboratories at its Belleville, Ontario facility in order to supply at least part of the market requirements in the early commercialization years. Production capacity is currently limited and the Company needs to further expand its current manufacturing capabilities to prepare for global market requirements.

To this end, the Company has secured \$25 million in government grants and loans through Industry Canada, Agriculture and Agri-Food (Canada), the Business Development Bank of Canada (“BDC”) and the Ontario Ministry of Economic Development and Trade (“MEDT”). The Company believes that this represents a significant part of the required financing to commence the scale-up of vaccine production at its Belleville facility over the next two years. This will provide capacity of a minimum of 40 million doses of the *E. coli* O157 vaccine.

The construction of the Animal Health and Food Safety Vaccine Manufacturing Centre progressed well in Fiscal 2010, and is on track for completion by March, 2011.

Several studies evaluating the efficacy of the vaccine under field conditions have been conducted by the University of Nebraska-Lincoln. These studies have shown that the vaccine, under field conditions, reduces the number of cattle that shed the bacteria, the amount of bacteria being shed, the presence of the bacteria on the hide, the number of animals colonized by the bacteria and the bacteria’s presence in the environment. These and other results have also been submitted for publication in peer-reviewed veterinary or food safety journals. In 2009, the Company announced the publication of the following four articles:

- “A Two-Dose Regimen of a Vaccine Against *Escherichia coli* O157:H7 Type III Secreted Proteins Reduced Environmental Transmission of the Agent in a Large-Scale Commercial Beef Feedlot Clinical Trial”. *Foodborne Pathogens and Disease*, Volume 5, Number 5, 2008. The researchers concluded that the two-dose vaccine regimen reduces the probability for environmental transmission of *E. coli* O157 within commercial cattle feeding systems.
- “A Two-Dose Regimen of a Vaccine Against Type III Secreted Proteins Reduced *Escherichia coli* O157:H7 Colonization of the Terminal Rectum in Beef Cattle in Commercial Feedlots”. *Foodborne Pathogens and Disease*, Volume 6, Number 00, 2009. The researchers concluded that the two-dose vaccine regimen effectively reduced the probability for *E. coli* O157 colonization of commercially fed cattle at harvest.
- “A Randomized Longitudinal Trial to Test the Effect of Regional Vaccination Within a Cattle Feedyard on *Escherichia coli* O157:H7 Rectal Colonization, Fecal Shedding, and Hide Contamination”. *Foodborne Pathogens and Disease*, Volume 6, Number 7, 2009. The researchers concluded that the two-dose vaccine regimen effectively reduced *E. coli* O157 fecal shedding and hide contamination, and that vaccination of cattle within regions of the feedyard provided greater protection against hide contamination than commingling vaccinates and non-vaccinates.
- “*Escherichia coli* O157:H7 Vaccine Dose-Effect in Feedlot Cattle”. *Foodborne Pathogens and Disease*, Volume 6, Number 7, 2009. The researchers concluded that a three-dose regimen significantly reduced the probability for cattle to shed *E. coli* O157 in feces 65% compared to placebo-treated cattle.

The Company received the Animal Pharm Industry Excellence Award at the Animal Pharm Awards in September 2007 for its vaccine against *E. coli* O157 in cattle. *Econiche*<sup>TM</sup> received international recognition as the best new veterinary product for livestock globally.

## Research and Development

Since 1981, Dr. Dragan Rogan, the Company's Chief Veterinary Scientific Officer, has authored and presented over 121 publications. In the last two years, Dr. Rogan has presented at six international meetings and has co-authored more than 20 scientific papers, presentations and posters for various conferences and journals.

In June of 2008, Dr. Rogan was an invited speaker at the 6<sup>th</sup> Congress of Medical Microbiology in Belgrade, Serbia. He gave a presentation entitled, "*E. coli* O157:H7 Type III Secretion Proteins are protective antigens which improve food safety by reducing environmental contamination following vaccination of cattle." Following this, in July of 2008, he presented on the use of immunomodulation with Mycobacterial Cell Wall-DNA Complex ("MCC") as a potential treatment for Endometritis in cattle at the 16<sup>th</sup> International Congress on Animal Reproduction in Budapest, Hungary. That same month, he was also a guest speaker at the XXV World Buiatrics Congress in Budapest, Hungary, presenting on the vaccination of cattle with *E. coli* O157:H7 Type III secretion proteins as a pre-slaughter intervention. In May 2009, Dr. Rogan presented at the 7<sup>th</sup> International symposium on "Shiga Toxin (Verocytotoxin) – Producing *Escherichia coli* Infections" in Buenos Aires, Argentina on the vaccination of cattle with *Escherichia coli* O157:H7 type III secretion proteins. In September 2009, Dr. Rogan was invited to speak at the American Embryo Transfer Association and Canadian Embryo Association Joint Conference in Montréal, Québec, to present on the opportunities for production of recombinant gonadotropins.

Publications and presentations that Dr. Rogan has co-authored over the last two years covered various scientific subjects including *E. coli* vaccination, superovulation and superstimulation in bovines, equine and bovine endometritis, and the synchronization of ovulation in porcines.

On June 23, 2010 the Company announced that it has entered into an exclusive global veterinary license agreement with Trophogen. As a result of this partnership, the Company has gained access to a patented proprietary superagonist hormone technology platform developed by Trophogen (originally licensed from the National Institutes of Health) in veterinary fields. Over the past year, the Company has been evaluating the Trophogen technology in field situations and has gained confidence in its capabilities in reproductive enhancement. This technology will initially be developed into a next generation follicle stimulating hormone. The Company also holds an Option to license additional veterinary reproductive products utilizing Trophogen's superagonist hormone technology.

On August 25, 2010, the Company announced that it has entered into an exclusive global license agreement with the University of Ottawa. The agreement provides commercial access for Bioniche to University of Ottawa's technology for botanical therapeutics (natural health) and pharmaceutical compounds for treating anxiety and related conditions in animal health, human health and aquaculture. University of Ottawa researchers and collaborators at the Universidad Nacional in Costa Rica have been studying these botanicals and compounds extensively for nearly 15 years. The research team combined expertise in botany, biology, medicinal chemistry and neuroscience to develop this unique family of botanicals and compounds from natural sources. They demonstrated the strong anti-anxiety effects through studies in numerous animal models. Preliminary safety and efficacy data have proven promising and show none of the side effects seen with other anti-anxiety medications.

The Company plans to initially explore developing the technology into veterinary products for dogs and horses, where it could help reduce anxiety without the side effects of chemical calming agents. In the future, the Company may also explore the development of human applications for the technology. The licensing agreement includes a commitment to ongoing research at the University of Ottawa.

The Company is involved from time to time in litigation, which arises in the normal course of business. In respect of these claims the Company believes it has valid defenses and/or has made adequate

provision for such claims. The Company believes that no material exposure exists on the eventual settlement of such litigation.

## **Financing and Divestitures**

### *Divestitures*

In July 2009, the Company sold its interest in a regulatory registration in the United States for a veterinary anaesthetic product (*Ketamine*) to Bioniche Teoranta, an unrelated entity, for consideration of \$883,000 (US\$800,000).

### *Laurus*

On December 19, 2007, the Company's three-year revolving credit facility was amended to a maximum available amount of US\$5,500,000. For this renewal and amendment, the Company agreed to pay a fee of US\$1 million. This fee was due and payable upon maturity of the loan in December 2008 or when the loan was paid in full. The fee could be paid in shares or cash at the Company's discretion. If paid in shares, the shares would be priced at the ten-day volume weighted average price on the day of payment. Amounts drawn were based on 90% of eligible accounts receivable and 35% of eligible North American inventory, capped at US\$2,500,000 plus an additional US\$3,000,000, of which approximately US\$3,868,374 was drawn at June 30, 2009.

On March 27, 2008, the Company exercised its right under the agreement with Laurus Master Funds to repay US\$1.75 million of its secured revolving credit facility with Valens U.S. (formerly Laurus Master Funds) in Common Shares. The conversion was in accordance with the formula set out in the original agreement signed in 2005. Shares were priced at the ten-day market average less 15%, which equated to 2,671,900 shares. In addition, the Company issued 200,000 five-year Warrants to purchase Common Shares at an exercise price of \$0.77 per share in exchange for Valens waiving certain volume restrictions relating to the conversion under the agreement. There was no penalty attached to the repayment.

On September 9, 2008, the Company exercised its right under the agreement with Laurus/Valens to convert US\$1.85 million of its revolving facility into equity at the previously negotiated 15% discount to the ten-day volume weighted average price. This resulted in the issuance of 4,565,049 shares and 211,429 five-year Warrants with an exercise price of \$0.49 per share. These issuances were made in exchange for Laurus/Valens waiving certain volume restrictions relating to the conversion under the agreement. There was no penalty attached to the transaction.

The Laurus/Valens loan was set to mature on December 31, 2008. On October 31, 2008, Laurus/Valens agreed to a three-month extension of the maturity date of the revolving credit facility to March 2, 2009. In exchange for the extension, an additional US\$500,000 was to be paid in Common Shares or cash at the discretion of the Company.

On March 2, 2009, the Facility became repayable on demand of the lender, and on April 27, 2009 the maturity date was again amended to June 30, 2009. A fee of US\$400,000 was charged by the lender for this amendment, payable in cash. On June 22, 2009, the maturity date was again amended and the Facility again became repayable on demand.

On July 20, 2009, the Company repaid its Credit Facility in full with Laurus/Valens along with all outstanding associated fees in the amount of US\$1.9 million, totaling US\$5.3 million. All security associated with the debt has been discharged.

### *Unit Offering*

In March 2007, the Company completed a Public Offering of units, raising gross proceeds of \$17.5 million. The units, priced at \$1.20, consisted of one Common Share in the capital of Bioniche and one-half of a Common Share Purchase Warrant. Each whole Warrant entitled the holder to purchase one additional Common Share of the Company at a price of \$1.40 per share for a period of two years from the closing of the Offering. The syndicate of underwriters, led by Haywood Securities and including Desjardins Securities Inc., sold the full base Offering of 13,333,333 units, and elected to exercise part of the overallotment option, resulting in a total Offering of 14,583,333 units and 750,000 Warrants, being the Warrant component of the remaining overallotment units. The underwriters received a commission of 7% plus Compensation Warrants to purchase 7% of the units, Shares or Warrants issued pursuant to the Offering and overallotment, which could be exercised for a period of two years from the closing of the Offering. The Company intended to use approximately \$10 million of the proceeds to continue funding its Phase III trials with MCC in the treatment of bladder cancer, \$500,000 to further the registration of the *E. coli* O157 vaccine and the balance for the continued development of the Company's other products and technologies, as well as for working capital and for general corporate purposes. Effective July 31, 2007, the Company listed and posted for trading the Common Share Purchase Warrants issued in the Offering on the Toronto Stock Exchange. On March 13, 2009 all special Warrants and Compensation Warrants issued under this unit Offering were de-listed. After the Warrants were de-listed, the Company extended the expiry date from March 13, 2009 to May 12, 2009; however the Warrants were not re-listed on the TSX and have since expired unexercised.

### *Government Assistance*

On September 7, 2007, the Company announced an agreement for a government grant from the Rural Economic Development Program ["RED"] in the amount of \$2,000,000 based on eligible expenditures for market development related to its *E. coli* 0157:H7 cattle vaccine. During fiscal 2009, the RED program agreed to accelerate funding from 50% of eligible expenditures to 70%, with the maximum total funding remaining unchanged. As at June 30, 2010, the Company has recognized \$1,862,110 [2009 - \$1,247,260] of this grant related to eligible expenditures incurred since August 16, 2007. As a result of a 10% holdback clause in this agreement, the Company has discounted its holdback receivable of \$186,211 [2009 - \$124,726] to its estimated fair value of \$183,600 [2009 - \$124,726] to its estimated fair value of \$183,599 [2009 - \$116,221] using a discount rate of 5.69% and classified it as a long-term accounts receivable [note 4[b]]. This discount will be amortized over the term that each claim amount is outstanding, using the effective interest method. The eligible amount less the discount has been netted against the related marketing expenses totaling \$612,771 [2009 - \$843,415]. The RED program has agreed to extend the expiry of the agreement to September 30, 2011.

On December 18, 2007, the Company announced that it was eligible to receive up to \$10,000,000 in Ontario government financing in the form of a loan from the Ontario Ministry of Economic Development and Trade's 'Advance Manufacturing Investment Strategy' program ["MEDT"] to fund eligible expenditures made by the Company since April 12, 2007, to scale up a vaccine production facility in Belleville, Ontario. During the incentive period, which runs until August 22, 2013, the loan is interest-free provided the Company meets certain targets by the end of the incentive period. To reflect the benefit of the interest-free period, the loan is discounted to its estimated fair value using a discount rate of 6.5% with the discount shown as a government grant. The discount will be amortized over the interest-free portion of the term of the loan, using the effective interest method. No principal payments are due during the incentive period. Interest at 5.69% begins to accrue on the first day following the incentive period. Beginning August 22, 2014 an annual payment of 20% of the principal balance plus accrued interest to that date becomes due. The loan is collateralized by a second charge on certain property, plant and

equipment at the Company's Belleville, Ontario facility. At June 30, 2009, an advance received under this program to expedite the scale-up of the vaccine production facility was being held as restricted cash.

On December 20, 2007, the Company announced that it was eligible to receive up to \$5,000,000 in federal government financing in the form of a loan from the Department of Agriculture and Agri-Food (Canada) 'Agri-Opportunities' Program ["Agri-Ops"] to fund eligible expenditures made by the Company since September 21, 2007, and to scale-up the aforementioned vaccine production facility. The loan is interest free. To reflect the benefit of the interest-free status of the loan, the loan is discounted to its estimated fair value using a discount rate of 13.50% with the discount shown as a government grant. The discount will be amortized over the term of the loan using the effective interest method. Principal repayment begins July 1, 2013, with payments of \$83,333 per month. At June 30, 2009, an advance received under this program to expedite the scale-up of the vaccine production facility was being held as restricted cash.

As at June 30, 2010, no funds had been advanced under the MEDT or Agri-Ops programs which were restricted in use for future eligible expenses associated with the vaccine manufacturing facility [2009 - \$1,227,374].

As of the date of this report, the Company has recognized \$1,862,110 under the grant from the Rural Economic Development (RED) Program of the Ontario Ministry of Agriculture, Food and Rural Affairs, \$3,893,421 under the Ontario Ministry of Economic Development and Trade (MEDT)'s Advanced Manufacturing Investment Strategy (AMIS) program and \$1,221,393 under the Department of Agriculture and Agri-Food (Canada)'s Agri-Opportunities Program.

It was announced on February 7, 2008 that a further \$5,000,000 had been secured in the form of a commercial loan facility from the Business Development Bank of Canada (BDC) repayable in monthly instalments of \$44,000. As of June 30, 2010, \$1,750,000 has been drawn on this loan. Disbursements in excess of \$1,750,000 will only be made if the Company incurs eligible expenditures on the vaccine manufacturing centre in Belleville, Ontario. This loan facility is collateralized by certain property, plant and equipment at the Company's Belleville, Ontario facility and is subject to certain annual financial and non-financial covenants. The loan bears interest, payable monthly, at the BDC floating base rate [at June 30, 2009 – 4.25%] plus 2%, but the rate may be fixed at the Company's option at the then current BDC base rate. On April 22, 2010, the terms and conditions were amended to postpone monthly payments for twelve months and establish a revised payment schedule to commence May 1, 2011 with one payment of \$20,000, twelve payments of \$25,000, thirteen payments of \$40,000 and fifty-six payments of \$62,000. The interest rate was increased to BDC floating base rate [June 30, 2010 – 4.5%] plus 2.5%.

On July 8, 2010, the Company became eligible to receive up to \$750,000 in the form of an interest-free loan from the Federal Economic Development Agency of Ontario to fund eligible expenses made by the Company between April 1, 2010 and March 31, 2011 to support the development of a pilot-scale fermentation facility. This facility is part of the Company's Animal Health and Food Safety Vaccine Manufacturing Centre. The loan is repayable in equal monthly instalments beginning on July 1, 2011 over a period of five years. Funding related to eligible expenditures amounting to \$40,000 has not been recognized, pending formalization of claims.

#### *Senior Debt*

At June 30, 2010, the Company had total senior debt of \$1,421,238 comprised of a \$1,062,000 loan from the BDC and a \$359,238 mortgage with ANZ bank in Australia. In addition, the Company had capital leases of \$1,360,100.

### *Endo Pharmaceuticals Inc.*

On July 10, 2009, Endo Pharmaceuticals Inc. licensed from the Company the exclusive rights to develop and market *Urocidin*<sup>TM</sup>. Pursuant to the Agreement, Endo paid Bioniche an up-front cash payment of US\$20 million. On November 6, 2009 the Company announced that it had met its obligations associated with the first milestone, triggering a payment from Endo of US\$6 million. On February 12, 2010 the Company announced the achievement two additional milestones and received an additional US\$8 million from Endo. Also on February 12, 2010, Endo elected to exercise its option for exclusive rights to develop and market *Urocidin*<sup>TM</sup> globally. This transaction is described more fully on page 8.

### **Intellectual Property**

The Company continued to expand its intellectual property portfolio over the past three years, with 61 patents issued in various international jurisdictions related to the Company's proprietary technologies during this period. The Company continues to place high importance on the long-term protection of its intellectual property through patents in order to give greater return to stakeholders as the technologies are commercialized.

### **Other**

In 2001, the Company entered into two loan agreements with Technology Partnerships Canada ("TPC"), currently operating as the Industrial Technologies Office ("ITO"), a special operating agency of Industry Canada, for projects related to the MCC technology and the development and commercialization of the *E. coli* O157 cattle vaccine. The Company used consultants to assist in the application for these funds, which was a complicated process due to the complexity of the projects. On September 23, 2005, Industry Canada informed the Company that the structure of compensation for these consultants did not conform to government rules and, accordingly, the Company inadvertently was in default under the program. As a result, the Company entered into a settlement with Industry Canada on the same date, whereby the Company paid to the government an amount equal to the portion of the consultants' fees that were out of program compliance, plus government costs, for a total amount of \$463,974.71 plus interest. This put the Company back in good standing under the program.

In March 2007, the Company agreed to amend its agreement with the ITO regarding the MCC project. The amendments included the extension of the anticipated completion date for the project to September 30, 2011, and the elimination of the obligation to issue a significant number of Share Purchase Warrants to TPC. In exchange, the Company agreed to an acceleration of its (capped) royalty obligations, which it expects to be made between 2010 and 2015, and to make certain cash payments to TPC. Upon the occurrence of a partnership agreement or upon regulatory approval for commercialization, but commencing no earlier than June 2010, the Company will pay TPC \$960,000 per year for five years. This repayment requirement begins in Q1, Fiscal 2011.

On June 24, 2008, the Company amended the pre-existing \$7.6 million Contribution Agreement with the ITO related to its *E. coli* vaccine. The amendment extended the timeline for completion of work on the production scale-up of the Company's vaccine production in Belleville to March 31, 2013.

On June 21, 2010, the ITO and the Company amended the Contribution Agreement related to its *E. coli* vaccine. As a housekeeping measure, this Amendment updated the milestones, activities and expenses associated with vaccine development.

Lastly, the disclosure and governance obligations of public companies continue to increase. The Company has responded to these higher standards by enhancing the number of independent Directors on its Board within the past three years and by developing corporate policies in both governance and administration. It is also upgrading its accounting systems and structure to best enable its growth objectives.

## **NARRATIVE DESCRIPTION OF THE BUSINESS**

### **HUMAN HEALTH PRODUCTS & DEVELOPMENT**

Bioniche Therapeutics, the Company's human health business unit, develops novel and proprietary human cancer therapies. The Company's strategy is to develop its therapies through clinical proof of concept and then, where appropriate, to establish alliances to complete clinical studies and regulatory approvals and for marketing. This involves both pre-clinical and clinical activities. The focus of activity has been on the development of the Company's proprietary MCC technology for the treatment of bladder cancer and other cancers.

#### **Research and Development**

##### *Mycobacterial Cell Wall-DNA Complex (MCC)*

MCC is the Company's lead technology platform. 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 principal component of the molecule, DNA, which is at least partially responsible for its immunomodulatory and direct anticancer activities. To date, the Company has conducted its own pre-clinical and clinical research programs in this area.

The Company has focused its pre-clinical 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 achieved a research breakthrough by identifying mycobacterial DNA as the active principal component of *Mycobacterium phlei* cell wall preparations.

The unique activity profile of MCC is comprised of the following:

- Immune stimulant activity (monocytes, macrophages, dendritic cells) as demonstrated by the ability to induce the synthesis of a range of cytokines and chemokines.
- Immune adjuvant (vaccine) activity as demonstrated by the ability to stimulate an immune response (antibody production) against antigens.
- Direct anticancer activity as demonstrated by the ability to cause cell cycle arrest, inhibit proliferation and induce apoptosis in a wide range of human and animal cancer cells.

The ability to act as an immune stimulant and directly inhibit the proliferation of cancer cells places MCC in a unique category, that of an immunomodulator with chemotherapeutic activity. Such an activity profile is expected to have application in patients who are, or have the potential to be, immunocompromised through age or prior chemotherapy. It would also be applicable in patients where the cancer is known to be resistant to conventional chemotherapy through cell cycle regulator mutations or the selection of multidrug resistance.

The mycobacterial DNA in MCC induces programmed cell death (apoptosis) in cancer cells. 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, colon, 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 the expression of multidrug resistance phenotypes is significant. Accumulated mutations in cancer cells can often lead to significantly greater resistance to treatment, eventually making conventional chemotherapeutic strategies ineffective because of toxicity associated with the dose of chemotherapeutic drug required.

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, either a means of enhancing the activity of MCC or of enabling a dose-sparing regimen for the chemotherapeutic agent.

The ability of MCC to directly affect primary cultures of bladder cancer cells, as opposed to bladder cancer lines, has been examined. MCC causes cell cycle arrest, inhibits cell proliferation, and induces apoptosis in the cells. The ability of MCC to induce these anticancer effects did not appear to be affected by mutational changes in the cancer cells that are commonly associated with resistance to chemotherapy or immunotherapy (data presented at the Canadian Urological Association 61<sup>st</sup> Meeting, Halifax, Nova Scotia, Canada, June 2006).

MCC induces macrophages to produce a range of cytokines including IL-6 and IL-12. IL-12 is known to possess anti-angiogenic activity (prevention of blood vessel formation in tumours) and to activate 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 increased levels of urinary cytokines, or following systemic administration, as evidenced by increased levels of cytokines in circulation. When administered into the bladder of patient with bladder cancer, MCC elicits the induction of cytokines, with a profile that appears to be distinct to that of Bacillus Calmette-Guérin (BCG), the current standard therapy for bladder cancer (data presented at the Canadian Urological Association 61<sup>st</sup> Meeting, Halifax, Nova Scotia, Canada, June 2006).

New data comparing the direct anticancer activity of MCC and of BCG against human bladder cancer cell lines was presented at the American Urological Association Annual Meeting, held in Anaheim, California, U.S.A. in May 2007. This data showed that compared to live BCG, the anticancer activity of MCC towards three human bladder cancer cell lines was uniform, and only required short exposure times. In contrast, the direct anticancer activity of BCG was variable, and required prolonged incubation times not typical of those used in the clinic. This data, in conjunction with the data on the ability of MCC to induce cytokines following intravesical administration, demonstrates that MCC possesses an activity profile that distinguishes it from BCG.

The potential for MCC to act as anticancer agent in other oncology indications has been evaluated in a preclinical study using a model of peritoneal colon carcinomatosis. This model mimics many characteristics of peritoneal carcinomatosis associated with metastatic colorectal, gastric and breast cancer, and is known to respond to immunomodulatory anticancer agents such as Lipopolysaccharide ("LPS"), lipid A and BCG. The results of this study demonstrate that MCC is effective in inducing long-term survival (T/C% > 500) when used to therapeutically treat micrometastases. MCC appears to be effective in the treatment of macrometastases (T/C% > 300) and to be at least equipotent with oxaliplatin, an agent used to treat metastatic cancer (data presented at the Second international Conference on Immunopotentiators in Modern Vaccines, Malaga, Spain 2005). New and updated data was presented at the Cambridge Healthtech Institute's Fifth International World Pharmaceutical Congress in Philadelphia, Pennsylvania, U.S.A. in May 2006. This data, evaluating the survival efficacy of MCC suspension for a period of 12 months in animals with peritoneal colon cancer, confirms and demonstrates a marked

anticancer activity of MCC suspension in this model. Intraperitoneal administration of MCC suspension was well tolerated. At 12 months, only 10% of untreated control rats were still alive, while 70% of rats were still alive after nine intraperitoneal administrations of 0.625 mg MCC suspension. Comparable anticancer activity was seen at higher doses (1.25 and 2.5 mg). Further studies have demonstrated: That MCC has direct anticancer activity against rat colon cancer cells (inhibition of cell division and induction of apoptosis); that MCC is well tolerated following intraperitoneal administration; the immune response in rats following MCC injection into the peritoneal cavity (recruitment of lymphocytes); and the dose-related anticancer activity of MCC in this model. These data were presented at the American Association for Cancer Research Annual Meeting in Los Angeles, California, U.S.A. in April 2007.

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 22<sup>nd</sup> Annual American College of Veterinary Medicine Meeting, Minneapolis, Minnesota, U.S.A., 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, toxicity).

Consolidation of the activity profile of MCC has been achieved by initiating studies to determine the immune adjuvant activity. MCC is a potent immune adjuvant at low doses, and is capable of inducing high levels of antibodies using both model (serum albumin) and therapeutic antigens such as Hepatitis B surface antigen (data presented at the Modern Vaccine/Adjuvant Formulation: Impact on Future Development meeting, Prague, Czech Republic, September 2004).

The following patents were issued for the MCC technology in fiscal 2010:

- Composition and Method for Regulating Cell Proliferation and Cell Death in Japan (03/07/2009), Canada (29/12/2009) and Romania (30/06/2010);
- Composition and Method for the Treatment of Bladder Cancer in Japan (18/12/2009);
- Method for the Treatment of Inflammation in Japan (09/04/2010);
- Chemotherapeutic Composition and Method in Japan (02/10/2009) and Canada (22/06/2010);
- Hyaluronic Acid in the Treatment of Cancer in Canada (22/06/2010).

The Company entered into a licensing agreement with Endo Pharmaceuticals Inc. in July 2009 where Endo Pharmaceuticals acquired the rights to MCC suspension (Urocidin™) as a treatment for bladder cancer.

The Company's primary research objective is to continue to develop formulations of MCC appropriate for the treatment of a range of cancers other than bladder cancer. To this end, the activity of MCC against a range of different cancer types is being evaluated using appropriate proof-of-principle models. The Company's clinical research and development program in this area is described below.

#### *MCC for Bladder Cancer*

The Company's Phase I/II studies using MCC emulsion to treat non-muscle-invasive (superficial) urinary bladder cancer have been completed. The studies involved 130 patients (in two trials) who suffered from carcinoma *in situ* (CIS), an aggressive and difficult to treat form of non-muscle-invasive (superficial) bladder cancer. Most patients had been previously treated with Bacillus Calmette-Guérin

(BCG) or chemotherapy. The results of the second Phase II trial were presented at the annual meetings of the American Urology Association in May 2004 and the Canadian Urology Association in June 2004. The data demonstrated MCC activity for the treatment of patients with CIS at the doses of 4 mg and 8 mg per intravesicular instillation. The 8 mg dose showed possible higher efficacy, remained very well tolerated, and was proposed as the active dose to be tested in the Phase III pivotal clinical trial program.

In February 2009, The Journal of Urology published an article summarizing the Phase II clinical trial results for the Company's proprietary mycobacterial cell wall technology in bladder cancer.

The article, entitled, "Intravesical Mycobacterial Cell Wall-DNA Complex in the Treatment of Carcinoma *In Situ* of the Bladder After Standard Intravesical Therapy has Failed", was co-authored by Drs. Alvaro Morales (Queen's University - Kingston, Ontario, Canada), Kiran Phadke (St.-George Hospital, Kogarah, New South Wales, Australia), and Gary Steinhoff (Vancouver Island Health Authority - Victoria, British Columbia, Canada). The Phase II trial resulted in a complete response rate in the intent-to-treat population of 27.3% at weeks 12 and 26 at a 4 mg dose and a 46.4% response at the same two points in patients receiving an 8 mg dose. Complete response was defined as no evidence of disease as determined by cystoscopy, biopsy and cytology. The product was well tolerated by both dose groups, with 90% of all adverse events being mild to moderate in severity.

The Company is now conducting its Phase III clinical trial program, working in conjunction with international clinical experts and its licensing partner, Endo Pharmaceuticals Inc. The first Phase III clinical trial in non-muscle-invasive bladder cancer that is refractory to BCG therapy involved 105 patients and was fully enrolled in April, 2009. The results of this trial are expected to be publicly available before the end of calendar 2010. This program is described on pages 7, 8, and 9 of this document in the section entitled, "Three Year History - Human Health."

#### *MCC for Other Indications*

The pre-clinical and clinical data produced by the Company in the past few years has generated a significant interest in both the urological oncology and clinical oncology communities. A Phase I clinical study in prostate cancer using MCC and hyaluronan (hyaluronic acid) was presented at the 19<sup>th</sup> Annual Congress of the European Urological Association in March, 2004.

The Company is actively discussing early stage clinical testing in new indications of MCC with opinion leaders in oncology. These programs are in the planning stage.

#### *Oligonucleotides*

In addition to its clinical activities, the Company has created synthetic oligonucleotides ("oligos") based on DNA sequences found in its proprietary MCC technology. These oligos were a new class of compound when discovered and possess both potential anticancer activity and immune modulating properties and appear to possess a range of novel pharmacological activities. The Company believes these novel oligos may be better than existing oligos but, to date, has had limited time and resources to pursue their development or outlicensing.

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*<sup>™</sup> BT99-25, one of its lead anti-cancer oligonucleotides, 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 21, 2004, the Company presented positive data demonstrating that its oligonucleotides have the ability to act as co-stimulators for T-cells, and thus possess a Type 2 adjuvant activity at the 12<sup>th</sup> International Congress of Immunology, Montréal, Québec. 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).
- On April 3, 2007, the United States Patent 7,199,228, “Oligonucleotide compositions and their use to induce apoptosis,” was issued. This patent claims the composition and use of a number of novel oligonucleotide sequences of between 3 and 9 bases in length and containing one or more non-DNA bases where the bases are nebularine, hypoxanthine or uracil. The ability of these oligonucleotides to cause cell cycle arrest and induce apoptosis was disclosed.
- On May 13, 2008, the United States Patent 7,371,734, “Oligonucleotide compositions and their use for the modulation of immune responses”, was issued. Methods of stimulating immune responses in animals or humans using synthetic 6-base oligonucleotides were disclosed. The issued claims cover the use of these oligonucleotides for stimulating mucosal or systemic immune responses.
- On May 23, 2008, the Company presented positive data demonstrating that its oligonucleotide motifs have immune stimulant activity and vaccine adjuvant activity at the Immunopotentiators in Modern Vaccines Conference, Montego Bay, Jamaica. Stimulation of the immune responses to vaccine antigens such as Hepatitis B surface antigen was shown to be independent of cytokine induction in animal models. These results further delineated the differences between the Company’s proprietary oligonucleotides and other oligonucleotides that are being developed as vaccine adjuvants.

The following patents were issued for the Oligonucleotide (ODN) technology in fiscal 2010:

- Therapeutically Useful Synthetic Oligonucleotides issued in Israel (16/09/2009), and the divisional in Europe (20/01/2010, validated in Denmark, France, Germany, Great Britain, Italy, Spain and Switzerland);
- Modulation of FAS and FASL Expression in USA (19/02/2010);
- Oligonucleotide Compositions and Their Use to Induce Differentiation of Cells in South Korea (18/08/2009) and Japan (19/02/2010);
- Therapeutically Useful Triethyleneglycol Cholesteryl Oligonucleotides in Japan (13/11/2009) and USA (22/12/2009);

- Conformation-Activity Relationship of Apoptosis-Inducing Phosphodiester Oligonucleotides in South Korea (12/02/2010) and Japan (05/03/2010);
- Oligonucleotide Compositions and Their Use in Inducing Apoptosis in Japan (30/04/2010).

## Market Analysis

### *MCC*

The Company is currently pursuing the application of its MCC technology for the treatment of non-muscle-invasive bladder cancer.

Due to the lack of successful new bladder cancer products, there has been a lack of detailed third-party analysis of this market. Over the course of its partnering activities, Bioniche has found it necessary to develop in-house analyses of the addressable patient populations for the major markets of North America, the European Union and Developed Asia.

More than 200,000 new cases of bladder cancer are diagnosed each year in the United States and Europe. Approximately 70% of these patients (140,000) are diagnosed with non-muscle-invasive bladder cancer and between 50-60% will have a recurrence in their lifetime.

Through the process of analysis, Bioniche has come to believe that the number of pre-existing patients with unresolved non-muscle-invasive bladder tumors (i.e., prevalence) is a larger figure than the newly diagnosed patients (i.e., incidence). Such prevalence figures are not well-tracked by public health authorities, something that appears to lead to widespread under-estimation of the potential market for bladder cancer therapies.

Additionally, bladder cancer is the fourth most common cancer in men in North America, behind only prostate, colon and lung cancers. When statistics from men and women are combined, bladder cancer still remains within the top ten most common neoplasms. This fact is not widely recognized, even among industry professionals, who tend to overlook bladder cancer in favour of better developed treatment marketplaces.

From a global perspective, the incidence per capita of bladder cancer is significantly higher in Europe than in North America. This is supposed to be due to higher smoking rates and exposure to other environmental carcinogens. However, greater government regulation of healthcare in Europe tends to result in lower prices per dose in that marketplace. More developed markets in Asia (e.g. Japan, South Korea and Taiwan) are again different from North America, with lower per capita incidence of bladder cancer, yet diverse pricing policies.

By compiling the three largest markets – the United States, the European Union and Japan – Bioniche has arrived at defensible estimates of the addressable patient populations for a novel intravesical bladder cancer therapy such as *Urocidin*<sup>TM</sup>. Combining eligible newly-incident patients and unresolved recurrences, Bioniche believes that approximately 350,000 non-muscle-invasive bladder cancer patients could benefit from a better intravesical bladder cancer therapy in those three major markets. The product label claims as permitted by regulatory authorities, the pricing and reimbursement as negotiated with payers and the ultimate efficacy and safety of the product will all drive the extent to which that potential market is captured.

Based on current clinical trial treatment protocols, most patients treated with *Urocidin*<sup>TM</sup> may be expected to receive between six and twenty-one doses over a period of between six weeks and two years. Pricing of existing intravesical non-muscle-invasive bladder cancer therapies varies widely, depending

principally on their intellectual property protections, label claims and general availability. In the United States, per dose pricing of such intravesical therapies has ranged from as little as US\$122 to upwards of US\$3,500. Pricing of *Urocidin*<sup>TM</sup> will be set by Endo Pharmaceuticals Inc., in consultation with Bioniche, once results from registration clinical trials are received and analyzed and following discussions with various stakeholder groups.

In addition to bladder cancer, management believes the Company's MCC technology has potential as an anticancer therapy, both alone and in combination with existing therapies, for the treatment of additional cancers. Pre-clinical models and other analyses suggest that other cancer targets could include prostate, lung, colon, gastric, pancreatic, breast, mesothelioma (a cancer that occurs on the outer lining of the lungs and chest cavity), including managing the spread of such cancers. The Company is evaluating its technology for such applications and is working to develop appropriate pre-clinical, clinical, regulatory and commercial pathways.

The Company believes that, following successful demonstration of clinical efficacy, MCC may have application in cancers where there is an unmet need.

According to the World Health Organization, the global incidence of cancer is increasing because of rapidly aging populations in most countries. By the year 2020, it is estimated that there will be 20 million new cancer patients globally each year<sup>(1)</sup>.

The market size for the following commonly occurring cancers can be estimated in seven major markets, namely France, Germany, Italy, Spain, United Kingdom, Japan, and the United States for 2008<sup>(2)</sup>:

<b><u>Type of Cancer</u></b>	<b><u>Incidence</u></b>	<b><u>Mortality</u></b>
Prostate	463,511	84,784
Breast	458,637	110,840
Lung	484,556	385,979
Colon and Rectum	482,868	188,556
Urinary Bladder	160,090	45,637
Pancreas	110,897	105,773
Gastric (Stomach)	176,299	97,596

The Company believes that, following successful demonstration of clinical efficacy, MCC may have application in cancers where there is an unmet need. The estimated worldwide market size for cancer therapeutics in 2004 was \$36.9 billion<sup>(3)</sup>.

<sup>1</sup>New Cancer Therapeutics, Global Business Insights (2002)

<sup>2</sup>GLOBOCAN 2008 (<http://www.globocan.iarc.fr/factsheets>)

<sup>3</sup>The Cancer Market Outlook to 2010, Global Business Insights (2005)

MCC has shown broad potential applicability for the treatment of various cancers, as evidenced by its published and unpublished activity against a variety of cancer cell lines, *in vitro* and *in vivo*. The overall market for such general oncology indications is large, usually estimated at several tens of billions.

However, the general oncology market is a complex one, with some therapeutic areas better served by existing therapies and highly competitive among multiple treatment options – including surgery, radiation therapy, chemotherapies, biologic and immunotherapies, cryotherapy and hyperthermia.

Before targeting such broader oncology market opportunities, Bioniche has elected to focus its efforts on a more tightly defined specialty area of oncology - uro-oncology. Within uro-oncology, the Company identified non-muscle-invasive bladder cancer as an area with little competition and a great deal of unmet medical need: The current mainstay immunotherapy for non-muscle-invasive bladder cancer dates back over 30 years and, the Company believes, is not optimal in regards to its efficacy, safety and tolerability.

## **Competition**

### *Oncology*

The Company's product candidates for cancer treatment will face competition from both currently used therapies and from new therapies based on the use of novel compounds and technologies. 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 same therapeutic fields. 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 include drugs to treat cancers or other diseases for which a variety of treatments already exist. The Company faces similar competitive concerns from life sciences companies that are working to develop novel treatments based on new classes of drugs or biologics. However, oncology regimens often use a number of therapies in combination, so the market for the Company's products may not necessarily be reduced by 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.

### *Uro-Oncology*

With its focus on uro-oncology, the Company may be less affected by developments in the general oncology market: Historically, very few drugs targeted for the treatment of non-bladder tumors have found their way into the intravesical treatment of non-muscle-invasive bladder cancer.

The Company believes that this state of affairs is driven by the unusual nature of intravesical bladder cancer therapy. Specifically, that drugs or biologics targeted for use in the bladder must be very fast-acting, due to the constant dilutive effect of urine entering the bladder. This requires the conduct of specialized clinical trials in bladder cancer, which thus far has not been of interest to companies focused on general oncology.

Additionally, intravesical bladder cancer therapies are typically administered by urologists, not oncologists, something that has also acted to segment the market from that of general oncology. To effectively market non-muscle-invasive bladder cancer, it is generally believed that a specialized urology-oriented sales force is required. Only some companies have such capability or are willing to commission it.

While the above clinical and commercial circumstances as they relate to general oncology to bladder cancer may change, the Company currently has no evidence to that effect.

Should it begin to develop products for areas outside of non-muscle-invasive bladder cancer, the Company may face significant competition as, in many such areas, a wider variety of treatments already exist. In such areas, the Company faces competitive concerns similar to other biotechnology companies working to develop novel treatments based on new classes of compounds or technologies. However, as many oncology regimens use a number of drugs in combination, the market for the Company's drugs may not necessarily be reduced by the use of other treatments.

In addition, should it wish to partner such new development projects, the Company may face competition from other companies also seeking to enter into collaborative arrangements with pharmaceutical and biotechnology companies able to assist with completing the development and commercialization processes.

#### *Bladder Cancer*

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

The Company is presently aware of several firms developing, or hoping to develop, novel therapies for different clinical stages of non-muscle-invasive bladder cancer, including chemotherapies, immunotherapy and oligonucleotides. Any such product could become a direct competitor to that of the Company.

#### **Regulatory Environment-Human Health**

Regulation by government authorities in Canada, the United States and the European Union is a significant factor in the 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 manufacturing activities before being allowed to market their products. The safety and efficacy of a new drug must be demonstrated through clinical trials of the drug carried out in accordance with the mandatory procedures and standards established by regulatory agencies. In addition, prior regulatory approval is required before conducting any type of clinical research in humans.

The pharmaceutical industry is required to manufacture products according to Good Manufacturing Practice (“GMP”) guidelines. These are referred to as “cGMP” by the U.S. FDA (current Good Manufacturing Practices) but simply as GMP for the rest of the world. GMP rules may vary slightly between countries, but they 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, GMP states 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. GMP is 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. GMP manufacturing applies not only to product manufactured following product licensing for commercial distribution, but also to product manufactured for use in clinical trials. This means that long before a product is commercialized, there is a need for GMP manufactured product.

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 will not be encountered by the Company in its efforts to secure necessary approvals. These could delay or prevent the Company from manufacturing or marketing its products.

#### *Canada*

In Canada, new drugs are reviewed and approved by the Therapeutic Products Directorate (“TPD”), while new biologics are reviewed and approved by the Biologics and Genetic Therapies Directorate (“BGTD”). New drugs and biologics must pass through a number of testing stages, including pre-clinical testing and clinical trials. Pre-clinical testing involves testing the chemistry, pharmacology and toxicology of 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”) with either the TPD or BGTD to begin clinical trials involving humans.

The CTA must contain specified information, including the results of the pre-clinical 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 or to placebo, 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”) 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 new drug submissions 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 Notice of Compliance with conditions (NOC/c) policy 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.

There are pricing regulations in Canada that govern how and what pricing of new drugs is set at. The PMPRB is the Patented Medicine Prices Review Board. It is a government agency in Canada which regulates drugs that are still under patent and which yet have no generic substitutes. This Board establishes the maximum prices that can be charged in Canada for patented drugs. Endo will be required to obtain their approval on the pricing that it charges for MCC in Canada.

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 any 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.

An additional regulatory requirement in Canada is that all manufacturers and testing laboratories of approved drugs or biologics 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 GMP.

Recently in Canada, the Natural Health Products Directorate was established. This directorate is responsible for the regulation of natural health products and now requires mandatory licensing of these products, which were traditionally regulated as drugs, but were often unregulated due to lack of resources of the regulatory agency. A request for licensing of a natural health product requires a submission which supports the label claims, safety and efficacy of the product. Several products considered "compendial" products have been grandfathered due to existing established safety and efficacy data. In addition to product licensing, manufacturers of natural health products are now subject to establishment licensing requirements. A set of GMP standards specific to natural health products was established. Manufacturers are obligated to comply with these standards and will be audited for compliance to them.

#### *United States*

In the United States, the manufacture and sale of new drugs is controlled by the Food and Drug Administration ("FDA"). New drugs or biologics require FDA approval of a marketing application (i.e., a New Drug Application ("NDA") for drugs or a Biologics Licensing Application ("BLA") for biologics) 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 the CTA that is 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, 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 cGMP regulations for drugs or biologic products, both in a pre-licensing inspection 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. User fees are payable upon submission of a marketing authorization application for a new drug, including sponsor fees, establishment fees and submission fees, and these can total in excess of US\$1 million.

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 new 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. Legislation was recently passed that allows for a twelve-year period of market exclusivity for new biologics. This biologics legislation is applicable to Bioniche and would be supplementary to, but run concurrent with, its issued and pending patents.

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 (although it does not require) the FDA to issue marketing approval after completion of early stage clinical trials. The FDA may, however, require subsequent clinical trials or post-approval efficacy studies.

### *European Union*

Regulatory requirements in the European Union are similar in principle to those of the United States. For novel products, a two-part product approval process by the European Medicines Agency (“EMA”), known as the “centralized process”, is required. Clinical testing and manufacturing facilities, as well as procedure data are presented in a Marketing Authorization Application filed with the Committee for Medicinal Products for Human Use (“CHMP”). The CHMP reviews the application in order to express an opinion about whether the new drug meets the requirements for marketing authorization. If a favourable opinion is received from the CHMP, then the applicant is free to market the product in all European Union countries.

An alternate means of approval in the European Union for products which are not novel is the use of either a decentralized procedure or 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 country’s recommendations.

Clinical trials conducted in EU countries require pre-approval by the regulatory authority for each country where the trial will be conducted. Clinical Trial Applications (“CTAs”) are made to each country, simultaneously with Ethics Committee applications. Once both approvals are received, the trial may be initiated. This could trigger audits of the manufacturer of the clinical trial product or of the investigators by any of the EU country’s regulatory authorities.

### *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 human and financial 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 efficacy 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 PRODUCTS & DEVELOPMENT**

The animal health business of Bioniche Life Sciences Inc. is responsible for developing, manufacturing and marketing its veterinary biopharmaceutical products worldwide. Bioniche Animal Health markets its products directly to veterinarians in Canada, the United States, Australia, in parts of 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 facilities in Athens, Georgia, and in Pullman, Washington in the United States; a marketing office in Melbourne, Australia; manufacturing facilities in Armidale, Australia; and a marketing office in Ireland. Revenues were \$27,876,231 in Fiscal 2010 and \$33,276,208 in Fiscal 2009. In Fiscal 2010, sales of food animal products have been challenged by depressed beef and pork markets in North America and depressed dairy markets globally. The global economy has impacted the market for equine products. The

Company, being subject to the economy of global trade, has also suffered the impact associated with fluctuating exchange and interest rates.

In addition to proprietary technology development, Bioniche Animal Health has successfully leveraged, and continues to pursue, new business alliances that are synergistic with core capabilities in the areas of breeding and reproduction, equine health and performance, and distribution channel management.

## Products

The Company has a product portfolio of more than sixty products, which are categorized in the following product groups: Reproduction and embryo transfer products; immunostimulant products; products based on hyaluronan; polyclonal antibodies; and natural health products.

### *Reproduction and Embryo Transfer Products*

Bioniche's animal health business is primarily focused on reproductive products in the cattle and swine industries. The Company's research into the purification and production of reproductive hormones has resulted in the successful commercialization of the products *Folltropin®-V*, *Lutropin®-V*, *Pregnecol®*, *Cue-Mate®* and *Cue-Mare™* designed for breeding programs primarily in domestic livestock. The Company's reproductive products form the largest sales category within the Bioniche Animal Health product line. Sales revenues from this category were \$17.8 million in Fiscal 2010 and \$22.5 million in Fiscal 2009. Sales of food animal products have been challenged by depressed beef and pork markets in North America and depressed dairy markets globally.

- The Company's main product, *Folltropin®-V* is a leading follicle stimulating hormone used to induce superovulation in cattle to facilitate embryo transfer. Embryo transfer accelerates genetic advancement of herd quality as compared to conventional breeding techniques. *Folltropin®-V* is sold in Canada, the United States, Australia, New Zealand, Mexico, Brazil, Argentina and other Latin American countries, Korea, South Africa, China, the Netherlands, UK, Italy, Spain and Ireland. As resources permit, registration dossiers are being generated for additional markets in the European Union and Asia.
- *Lutropin®-V*, a luteinizing hormone, is used to stimulate ovulation in cattle, pigs, horses and sheep, as well as to stimulate testicular interstitial cells. It is sold in Canada, Brazil and Argentina.
- *Pregnecol®*, an equine serum gonadotropin, is used to stimulate follicle development in functional ovaries, potentially increasing ovulation rates and inducing estrus. *Pregnecol®* has multiple applications that include superovulation and insemination protocols in various domestic species. It is sold in Australia, Canada, New Zealand, Argentina, Israel and other Middle Eastern countries.
- The Company also manufactures pregnant mare serum gonadotropin as a contract manufacturer for a third party in Ireland. The Company is also exploring protocols that may expand the usage of *Pregnecol®* and *Lutropin®-V* in new agricultural markets. This work, if successful, could greatly expand the market for these products.
- In 2004, the Company acquired *Cue-Mate®*, a progesterone delivery device for cows that enables dairy farmers and cattle producers to plan and manage the reproductive timing of

their herds. *Cue-Mate*® is sold in Australia, New Zealand, Chile, China and Argentina. The Company is working towards registrations in North America and Europe.

- In 2009, *Cue-Mare*™, a progesterone delivery device for horses, was registered in New Zealand.
- Successful embryo transfer requires not only hormones, but a variety of media. The Company's media products *ViGro*® and *SynGro*®, as well as other media products, complement the full range of needs for the embryo transfer client. Media used for embryo transfer do not require registration and can therefore be sold internationally, generally without difficulty. The media products are manufactured in the Company's facility in Pullman, Washington.

*Folltropin*®-V and *Lutropin*®-V are manufactured by the Company in its facility in Belleville. The main ingredient is porcine pituitary glands, which are sourced within North America from a company with whom the Company has had a long-term relationship.

The price of this material can be expected to remain stable for the upcoming year. The raw material forms a small percentage of the price of finished product.

*Pregnecol*® is manufactured by Bioniche at its facility in Armidale, Australia, using equine serum sourced from its horse farm in the same location. Because Australia is an isolated continent with strict biocontainment regulations, the Company believes that this serum has a quality advantage in the marketplace.

Some reproductive hormones sold by the Company are manufactured from materials of animal origin. There is a small risk that a disease outbreak in swine, for example, could interrupt supply of raw materials. There is also a risk of other companies entering the market with competing products based on non-animal origin technologies. Any company entering this market with a new hormone will need to go through the lengthy regulatory processes to obtain registration.

#### *Immunostimulant Products: Mycobacterial Cell Wall Extract (MCWE)*

The Company's product development activities have been focused on the emerging technology of immune modulation, which is the stimulation or suppression of the immune system for therapeutic purposes with products known as immunotherapeutics. The purpose of most large animal immunotherapeutics is to stimulate a network of non-specific immune system cells to fight infection using the animal's own immune system, rather than requiring antibiotics or other anti-infectives. The Company has developed and registered animal immunotherapeutics using Mycobacterial Cell Wall Extract (MCWE). 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 program.

Mycobacterial cell walls are the active ingredients in three registered animal health products in North America: *Equimmune*® I.V., *Immunoboost*® and *SETTLE*™.

- *Equimmune*® I.V., sold in the United States and Australia, is a patented immunotherapeutic for the treatment of equine respiratory disease.

- *Immunoboost*®, a mycobacterial cell wall immunotherapeutic sold in the United States, is the first of its kind licensed for the treatment of neonatal calf diarrhea caused by the *E. coli* bacterium. *E. coli* has developed resistance to many antibiotics.
- *SETTLE*™ was approved by the USDA in December 2004 as an aid in the treatment of equine endometritis, a production limiting disease which affects 10% to 20% of broodmares worldwide. The disease results in both low conception rates and loss of pregnancies, both of which are serious concerns for breeders. *SETTLE*™ therapy can also be easily assimilated into reproductive treatment protocols, offering the benefit of enhancing the body's own immune responses. Currently, *SETTLE*™ is registered in the United States and Australia. The Company is pursuing registrations in additional countries and in other species of animals.

The mycobacterial cell wall portfolio of products is manufactured by the Company at its facility in Athens, Georgia and the Company maintains a strong proprietary position for these technologies.

#### *Hyaluronan Products*

Hyaluronan (hyaluronic acid) is a naturally occurring constituent of connective tissue and joint fluid and is a well-established product used globally in animal health treatment. The Company has focused its efforts in two areas.

The first is as a treatment for osteoarthritis, particularly in horses. *Enhance*®, registered in Australia, New Zealand, Canada and Turkey, 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*® intra-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 hyaluronan as a cryopreservative for embryos (called *MAP*®-5) in the embryo transfer industry. *MAP*®-5 is sold around the world, with its primary market being the United States.

These products are manufactured by a former subsidiary, Bioniche Pharma Group Limited, in its facility in Galway, Ireland pursuant to a manufacturing and supply agreement with the Company. Bioniche Pharma Group Limited was recently acquired by Mylan Inc. The Company is currently negotiating the renewal of the manufacturing and supply agreement with Mylan Inc. A number of alternate finished goods suppliers are available in the marketplace. The Company has entered into a supply contract for its requirements of raw hyaluronic acid with a major commercial supplier, and maintains relationships with back-up suppliers. The price of raw material forms a small percentage of the price of finished products.

#### *Polyclonal Antibodies*

The Company's product *Colimune*® is a polyclonal antibody developed as a means of preventing K-99 *E. coli* infections in calves. K-99 *E. coli* causes diarrhea in newborn calves and is a debilitating disease often resulting in death. Mothers vaccinated against K-99 *E. coli* produce antibodies in the first milk (the colostrum) which, ingested the first day of life, can provide calf protection. However, in non-vaccinated cows or when passive transfer of antibody to calves fails, calves remain susceptible to infection. *Colimune*® is used to prevent a K-99 *E. coli* infection and resulting calf losses. This product is manufactured by the Company in its facility in Belleville, Ontario, and is sold in the United States and Canada. Technical challenges have impacted sales of this product in Fiscal 2010. The Company is working to address these challenges to retain future product supply.

### *Natural Health and Nutritional Products*

The Company continues to explore opportunities in the growing natural health product 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*<sup>™</sup>, an echinacea product for the equine industry, and two versions of *Omega-Fend*<sup>™</sup>, an essential fatty acid supplement used to treat skin conditions in dogs. Research is also ongoing to develop a botanical insect repellent. As well, the Company is collaborating with Loyalist College in Belleville and the University of Ottawa in the research and development of a novel manufacturing process involving extraction using supercritical fluid carbon dioxide. This environmentally-friendly process involves extracting active ingredients in plant or animal materials to use in the development of natural products.

On August 25, 2010, the Company announced the signing of an exclusive global license agreement with the University of Ottawa. The agreement provides commercial access for Bioniche to University of Ottawa's technology for botanical therapeutics (natural health) and pharmaceutical compounds for treating anxiety and related conditions in animal health, human health and aquaculture. University of Ottawa researchers and collaborators at the Universidad Nacional in Costa Rica have been studying these botanicals and compounds extensively for nearly 15 years. The research team combined expertise in botany, biology, medicinal chemistry and neuroscience to develop this unique family of botanicals and compounds from natural sources. They demonstrated the strong anti-anxiety effects through studies in numerous animal models. Preliminary safety and efficacy data have proven promising and show none of the side effects seen with other anti-anxiety medications. The Company plans to initially explore developing the technology into animal health products for dogs and horses, where it could help reduce anxiety without the side effects of chemical calming agents. In the future, the Company may also explore the development of human applications for the technology. The licensing agreement includes a commitment to ongoing research at the University of Ottawa.

The Company's natural health products are manufactured by the Company in its facility in Belleville, Ontario. Raw materials for these products are readily available. Although natural health products represent a small portion of the current product line, this is a growing segment with fewer regulatory hurdles than pharmaceuticals or biologicals. The new regulatory requirements associated with natural health products are an advantage for the Company, in that the Company already understands the regulated manufacturing standards.

### **Research and Development**

The Company's animal health business unit performs research activities in-house and in collaboration with diverse research partnerships. Currently, research and development activities are being conducted in the following areas.

#### *Reproduction and Embryo Transfer Products*

The Company has responded to market demands for safer products which do not contain material of animal origin by developing synthetic media which incorporates its patented hyaluronan technology.

The Company, in collaboration with Trophogen Inc., has initiated the development of a high-quality, cost-effective, animal-origin free, recombinant hormone. This recombinant technology will provide cost and production benefits, as well as removing any potential concerns arising from animal-sourced products.

A slow release formulation of *Folltropin*<sup>®</sup>-V is currently being evaluated, further studies are ongoing.

Efforts to synchronize ovulation in sows are being developed. The Company has developed a program utilizing the injection of two hormones at set intervals: *Pregnecol*®, (eCG) is used at weaning, with *Lutropin*®-V, (pLH) injected 80 hours later. Ovulation is synchronized such that only one insemination is required, thereby reducing semen costs. This “barn hour friendly” protocol has many advantages to traditional protocols for estrus induction, making it very attractive for producers. Optimization studies are currently ongoing.

In order to optimize sales of its animal reproduction products, the Company has investigated the use of *Pregnecol*® in combination with *Cue-Mate*®. Preliminary data suggests that this Bioniche-recommended program is very successful and is being adopted by industry, resulting in significantly increased sales of both products. The use of *Pregnecol*® with *Cue-Mate*® provides an alternative to oestradiol benzoate usage for treating anoestrous in cattle. Based on these positive results, future studies are being planned.

#### *Immunostimulants*

The Company is investigating the use of a new formulation of mycobacterial cell wall technology for cancer therapy in companion animals. Studies using canine cancer patients are the most effective means of demonstrating the efficacy of this technology as a therapeutic option. Studies may be done with the mycobacterial cell wall formulation alone or in conjunction with standard therapeutic approaches. The Company believes there are significant markets in North America, Europe and Japan that will be receptive to this therapy. Mycobacterial cell wall therapy is expected to improve the quality of life and extend survival beyond what is achieved with current standards of care.

#### *Vaccines*

The Company is developing a vaccine against *Rhodococcus equi*, a chronic and often fatal cause of bronchopneumonia in foals. The vaccine has been tested and has demonstrated desirable efficacy in controlled challenge studies.

### **Market Analysis**

The global animal health market is currently valued at approximately \$18.5 billion per year (Brakke Consulting 2010 Overview Report). The growth of products for dogs and cats has been the principal contributor, growing at almost twice the rate of products in food-producing animals. The increasing controversy over the widespread use of antibiotics in livestock, combined with the trend of increased spending on the well-being of companion animals, suggests that this pattern will continue for the next several years. 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 pharmaceutical 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 the Company 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*® from Pfizer is an example.

Management believes that the agricultural sector itself is also evolving in the developed world, the result of which will be fewer, but larger, farms. This will exert considerable pressure on commodity pharmaceuticals. However, the Company is unlikely to be affected by this trend as its products are essentially speciality technologies where performance is the customer's priority.

Concern over environmental issues is continually increasing. 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.

Geographically, North America represents approximately 38% of the world market; the European Union represents 34%, and the Asian/Latin American markets account for much of the remaining percentage.

## **Competition**

The global markets for animal health products continue to be rationalized by large pharmaceutical companies, thereby providing opportunities for Bioniche Animal Health to acquire or develop niche products that would not meet the higher revenue generation potential required by the larger competitors.

The Company is devoted to a strategy of reliance on well-differentiated, technology-based and proprietary products as the backbone of its product line. These niche products are sold to veterinarians by the Company's own sales force in Canada, the United States, Australia and Ireland, and through distributors in other areas of the world. In addition, the Company distributes well-researched products from companies whose products are compatible and offer a marketable competitive advantage.

## **Regulatory Environment**

The development of animal health products requires approval by various government authorities, depending on whether the product is a pharmaceutical, biologic or feed, and depending on the jurisdiction in which approval is required.

### *Canada*

In Canada, the Company develops and markets three main types of animal health products – biologics, feeds 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. Feeds are regulated by the Feeds Section of the CFIA and 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, the 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 the VBS for its review of the product and the facility. The timeframe 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 the Company is approximately \$5,000 for its current line of biologics. At this time, there is no specific requirement for compliance with Good Manufacturing Practices ("GMP") for veterinary biologics, however, the trend in recent years is toward GMP compliance by manufacturers and it is expected that such a regulation will eventually be adopted.

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 Therapeutic Products Directorate ("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 (laboratory animals). Following approval of the IND submission, target animal safety and efficacy studies can be completed. 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").

The cost of review of veterinary drug submissions can range from \$5,000 to \$70,000, depending on whether it is a new or old drug and whether the product is intended for a food producing animal or not. 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 GMP.

Veterinary natural health products currently fall under food and drug regulations in Canada and are regulated as new drugs. Unlike human natural health products, they do not have their own set of regulations. The Veterinary Drugs Directorate is developing a strategy to deal with the unique aspects of veterinary Natural Health Products ("NHPs"), but it is a long process beginning with consultation with stakeholders. At this time, there is no defined timeline for when, or if, specific regulations will be adopted for veterinary NHPs. This concept also applies to Europe and the U.S. There are no specific rules for the regulation and control of veterinary NHPs and, therefore, the expectation is that a request for designation be done before marketing any NHPs that might be considered a new drug in those jurisdictions.

#### *United States*

In the United States, governmental regulation of animal health products is primarily split between two agencies: The United States Department of Agriculture ("USDA") and the Food and Drug Administration ("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 the Company 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 typically done in carefully controlled laboratory/challenge trials. This is normally a much faster process than demonstration of efficacy in clinical trials using client-owned animals. Recent trends with CVB are toward demonstrating efficacy in a field/natural challenge environment.

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. 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 Division – Regulatory Environment”). By contrast, management estimates that it can take up to 11 years and US\$5 million or more to develop a new drug for animals, from commencement of research to market introduction. Approximately three years of this period 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 were 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.

In 2003, the Animal Drug User Fee Act (ADUFA) came into effect allowing the FDA to collect fees from sponsors of new animal drug applications for activities related to applications, establishments and maintenance. This was followed in 2008 by AGDUFA (Animal Generic Drug User Fee Act) which allows for collection of similar fees for sponsors of generic animal drugs. The fees for ADUFA are substantial and can be a deterrent for small companies or for companies developing products with limited markets. The FDA, therefore, is willing to waive certain fees for small companies and for products which will have either a minor use or are used in minor species (MUMS drugs).

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 in which they are manufactured must comply with GMP.

In the European Union, the requirements for animal biologics are similar to those for drugs, in that GMP 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. For these reasons, it can be much more costly and take much longer to obtain approval to market a veterinary biologic in Europe than in North America.

## **FOOD SAFETY BUSINESS UNIT**

As a result of the Company's expertise in animal health, it identified an opportunity to address animal diseases that can pose health risks to humans via food, water and environmental transmission. To pursue this opportunity, the Company's food safety business unit was established in July 2001. Subsequently, a vaccine technology discovered by a researcher at the University of British Columbia became available for development.

The development and commercialization of the *E. coli* O157 cattle vaccine has become the lead project in the Company's food safety business unit. Beyond this, the food safety unit is also researching and developing other animal vaccines that may improve the safety of food and water supplies.

### **Product Development Candidates**

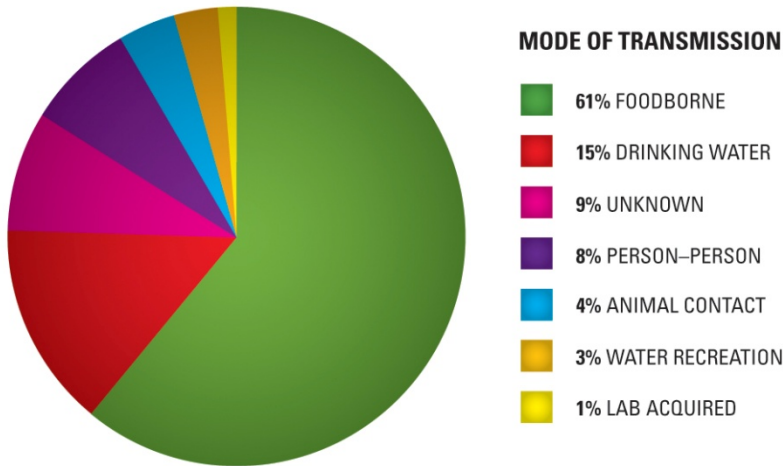
#### *Econiche™: E. coli O157 Cattle Vaccine*

*E. coli* bacteria are micro-organisms normally found in the intestinal tract of all animals. There are hundreds of strains, most of which are non-pathogenic (non-disease causing) to their host; however, certain types cause digestive disturbances and, occasionally, other significant systemic disease in humans. The O157:H7 strain of *E. coli* expresses an extremely potent toxin (shiga-toxin) associated with the bacterium, *Shigella dysenteriae*. Originally known as shiga-toxin producing *E. coli* (STEC), this bacteria are now more widely classified as verocytotoxin-production *E. coli* or VTEC. According to the United States Centers for Disease Control, *E. coli* O157:H7 "can be found on most cattle farms, and it is commonly found in petting zoos and can live in the intestines of healthy cattle, deer, goats and sheep".

*E. coli* O157:H7 has emerged as an important environmental pathogen and is most often associated with consumption of contaminated food or water. Human infection with this bacterium can cause severe bloody diarrhea (hemorrhagic colitis) and, in a percentage of cases, haemolytic-uremic syndrome ("HUS"), a form of kidney failure that can be lethal. These symptoms result from infection with as few as ten *E. coli* O157:H7 bacteria, with those infected potentially having lasting damage to kidney, pancreas, and brain function. Gastrointestinal illness from *E. coli* O157 is also known to increase the risk of subsequently developing Irritable Bowel Syndrome. The low level of bacteria required to cause human illness is of particular concern given that some infected animals are known to shed billions of bacteria per gram of their feces.

While all ruminants may harbour these bacteria, cattle are considered the primary 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 widespread and that the organism is found in, on, and around cattle in most parts of the world. Manure used as fertilizer for crop production and run-off from beef and dairy cattle operations are sources of contamination for the general environment, as well as surface and ground water. The contamination of meat, vegetables, fruits and water as a result of exposure to *E. coli* O157:H7 from livestock feces is a well-recognized and documented threat to human health.

Despite the numerous interventions that have been introduced in beef processing plants during recent years, human illness from contaminated meat continues to occur. This, coupled with outbreaks associated with fruits, raw/edible vegetables, drinking and recreational water, are highlighting the need for pre-harvest (pre-slaughter) interventions.



Two-thirds of all *E. coli* O157:H7 illnesses are linked to food (Centers for Disease Control and Prevention, 2008)

The societal and economic impact of this disease is thought to be considerable:

- The United States Centers for Disease Control estimates that *E. coli* O157:H7 infection affects some 73,000 people per year in the United States, and that 8% of those people develop haemolytic-uremic syndrome (“HUS”). The annual cost in the United States is estimated at more than \$650 million due to medical expenses, lost productivity and death. A study by the George Morris Centre of Guelph, Ontario suggests that more than 26,000 people are made ill by *E. coli* O157:H7 each year in Canada, also at considerable human and economic cost.
- A number of large-scale recalls of hamburger meat have occurred as a result of *E. coli* O157:H7 contamination. Since February 2002, more than 55 million pounds of beef have been recalled in the United States. 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 estimated to be in the billions of dollars in the United States alone.

Approximately 3-5% of HUS patients die, many of them children and senior citizens whose kidneys are more sensitive to damage. Also, a proportion of persons with HUS develop lifelong health problems, such as blindness, paralysis, persistent kidney failure, and the consequences of bowel resection. Many persons with HUS have ongoing abnormalities in kidney function many years later.

In addition to the human costs due to *E. coli* O157:H7 infection, cattle and dairy producers, meat packers, dairy processors, meat and milk distributors, and wholesale and retail food outlets all incur direct and indirect costs associated with this foodborne disease threat, including both litigation and reduced demand for their product. The Canadian Meat Council (“CMC”) estimates that the Canadian beef packing industry has spent \$60 million dollars in capital expenditures over the five years prior to 2006, dedicated to the control, reduction, and intervention of *E. coli* in their facilities.

There are an estimated 110 million cattle in North America alone. Approximately 25 million of these North American cattle are conditioned in feedlots, the first target market for the Company’s *E. coli*

vaccine. Dairy cattle are an additional target market segment, of which there are approximately 14 million animals in North America. Additionally, there are an estimated 86 million cattle in Europe.

To develop and commercialize the vaccine technology, the Company formed a strategic alliance with the University of British Columbia (“UBC”), the Alberta Research Council (“ARC”), and the University of Saskatchewan’s Vaccine & Infectious Disease Organization (“VIDO”), pursuant to which Bioniche retained the worldwide rights to commercialize the vaccine. During the last several years, important contributions in efficacy evaluation have been made by the University of Nebraska-Lincoln. These studies have shown that the vaccine, under field conditions, reduces the number of cattle that shed the bacteria, the amount of bacteria being shed, the presence of the bacteria on the hide, the number of animals colonized by the bacteria and the bacteria’s presence in the environment. These and other results have also been submitted for publication in appropriate peer-reviewed veterinary or food safety journals. Over the past year, the Company announced that four such articles had been published in peer reviewed journals. The articles relate to field trials conducted at the University of Nebraska-Lincoln in 2005 and 2006.

In October 2008, the Company received full licensing approval from the CFIA making *Econiche*<sup>™</sup> the world’s first fully licensed vaccine designed to reduce the shedding by cattle of *Escherichia coli* (*E. coli*) O157. A full license allows *Econiche*<sup>™</sup> to be available for unrestricted use by Canadian cattle producers and their veterinarians.

The Company has commenced limited production of the *E. coli* O157 vaccine at its Belleville, Ontario facility and has commenced internal scale-up of its manufacturing capacity, which is expected to put the Company in a position to supply at least part of the market requirements in the early commercialization years.

The Company has secured \$25 million in government assistance through Industry Canada, the Department of Agriculture and Agri-Food (Canada), the Business Development Bank of Canada (BDC) and the Ontario Ministry of Economic Development and Trade (“MEDT”). The Company believes that this represents a significant part of the required financing to scale-up vaccine production at the Company’s Belleville facility over the next two years. This will provide capacity of a minimum of 40 million doses of the *E. coli* O157 vaccine. The facility will be utilized for the production of additional food safety vaccines as these are developed.

The Company continues to pursue the registration of the *E. coli* vaccine in the United States. In February 2008, the Company received notice from the United States Department of Agriculture (“USDA”) that the latest data for its *E. coli* O157 cattle vaccine “meets the ‘expectation of efficacy’ standard” and is eligible for a conditional license provided that certain conditions are met. The conditional license, when granted, will provide the Company full access to the U.S. market with two restrictions: At least one step in the manufacturing process must be performed in the United States and Bioniche will not be permitted to use a trademark name for the vaccine.

## **Research and Development**

The original research in connection with the *E. coli* O157 vaccine (*Econiche*<sup>™</sup>) was performed by Dr. Brett Finlay at the University of British Columbia (UBC) and Dr. Andrew Potter at the Vaccine and Infectious Disease Organization (VIDO). The Company became involved after the proof-of-concept had been established. Development work was performed on the vaccine in collaboration with the Alberta Research Council. Efficacy studies were performed by the University of Nebraska – Lincoln and VIDO. In October of 2008, the Company was granted full Canadian license for the vaccine by the Canadian Food Inspection Agency (CFIA). The Company is currently preparing for a trial to obtain full U.S. licensure for the *E. coli* O157 vaccine.

The Company continues to explore next-generation *E. coli* vaccines. To this end, the Company is working with collaborators to develop a recombinant-derived vaccine which is expected to be more cost-effective and safer for handling during the manufacturing process.

The Food Safety business unit is also researching and developing other animal vaccines intended to improve the safety of food and water. Over the last 5 years, Bioniche and the Natural Science and Engineering Research Council (NSERC) have jointly sponsored Senior and Associate Industrial Research Chairs at the University of Saskatchewan's Vaccine and Infectious Disease Organization. The Research Chairs were established to undertake research leading to the development of additional food safety vaccines. The Senior Chair, Dr. Andrew Potter, has pursued research and vaccine efforts related to both *E. coli* O157, other shigatoxin-producing *E. coli* serotypes and *Campylobacter jejuni* while the Associate Chair, Dr. Wolfgang Köster, has focused on developing a *Salmonella Enteritidis* vaccine. In North America, *Campylobacter*, *Salmonella*, and *E. coli* are the three leading causes of bacterial gastroenteritis.

### **Sales and Marketing**

In North America, there is a recurring risk of *E. coli* O157:H7 contamination of beef and produce, while at the same time, there is steady growth of branded products designed to compete in a crowded marketplace. The risk to brand equity due to recalls, outbreaks and litigation and the increased regulatory agency and public health sector concern regarding this pathogen all set the stage for establishing a market for the first licensed pre-harvest intervention to reduce the prevalence of this pathogen.

In typical cattle vaccine marketing, the decision-maker as to whether to purchase the product is the owner or producer of the livestock as he/she receives the direct economic benefit of disease avoidance following vaccine use, thus, reduced treatment cost. This is not the case with an *E. coli* O157 vaccine, as this bacterium does not cause illness in cattle. The decision to proceed is made by a combination of influencers, from the slaughterhouse to the retail and fast food outlets.

The Company intends to market the *E. coli* O157 vaccine to the meat production chain, including producers, feedlots, processors, and the wholesale to retail meat trade. As further food safety vaccines are developed, they will be added to this product line.

The Company is positioned to handle distribution through its current animal health marketing and sales forces in the United States and Canada, and expects to seek a strategic alliance with a commercial partner for Europe.

In 2007, the Company received an Animal Pharm Industry Excellence Award for the "best new veterinary product for livestock" for its *E. coli* O157 vaccine. This award recognizes global excellence in pharmaceutical or vaccine development for production animals. In this category, the 12-member panel of judges looked for a product that represents the greatest therapeutic, prophylactic, or production advance in its area.

The Company continues to engage in discussions with key industry stakeholders in both the United States and Canada.

### **Competition**

*E. coli* O157 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 drug or non-drug treatments for use in cattle, interventions to treat water for human consumption, or from process changes in meat

handling. Currently, there is one competing conditionally licensed cattle vaccine in the U.S. for *E. coli* O157. To date, two peer reviewed published papers are available on this product. This competitive vaccine is meant to block iron absorption by the bacteria as opposed to the Company technology, which blocks the bacteria from attaching to the intestinal wall. The appearance of a competitive technology helps to validate the logic of preventing human disease due to *E. coli* O157 by vaccination of cattle.

### **Regulatory Environment**

The development of food 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 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. These products will be regulated as veterinary biologics and, therefore, fall under the jurisdiction of the Canadian Food Inspection Agency's Veterinary Biologics Section. Jurisdiction over the *E. coli* O157 vaccine in the United States is with the United States Department of Agriculture (USDA).

### **INTELLECTUAL PROPERTY**

The Company pursues a policy of actively seeking patent protection for its proprietary technologies. 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 2010 (July 2009-June 2010), the Company was issued thirty-three patents in major international jurisdictions for its various technologies: eight patents issued for the Mycobacterial Cell Wall-DNA Complex (MCC) technology; twenty-one patents issued related to the oligonucleotide technologies; three related to a botanical insect repellent technology; and one related to an antiviral technology.

The Company has nine pending patent applications relating to mycobacterial cell wall technologies collectively, in selected countries worldwide, including Canada, Europe and Japan. Additionally, there are thirty-seven pending patent applications relating to oligonucleotides, twenty-eight relating to anti-virals, and four relating to botanicals. The Company has recently been informed of the allowance of one oligonucleotide application in a major jurisdiction, Europe.

The table below summarizes the total number of worldwide patent applications pending and patents issued at the end of Fiscal 2010 (June 30, 2010).

Technology	Number of Patent Applications Pending	Number of Patents Issued or in EP Validation Stage	Total Number of Patents and Applications per Technology
MCC	6	121	127
MCWE	3	45	48
Oligonucleotides	37	108	145
Hyaluronan	0	2	2
Botanical	4	8	12
Reproductive		24	24
Antiviral	28	3	31
<b>Total No.</b>	<b>78</b>	<b>311</b>	<b>389</b>

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 or held in trade secret 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 it 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 related to 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.

## **CAPITAL STRUCTURE**

The authorized capital of the Company consists of an unlimited number of Common Shares, and an unlimited number of Preferred Shares issuable in series. As of September 28, 2010, there were 73,208,320 issued and outstanding Common Shares. The combined total of shareholdings held by directors and officers at September 28, 2010 is 10,641,811 Common Shares, representing approximately 14.53% of outstanding Common Shares.

The Series 1 Preferred Shares are redeemable by the Company at \$1,000 for each share, together with dividends, if any, which have been declared but not paid. The Series 1 Preferred Shares are non-voting and are entitled to a fixed, non-cumulative preferential dividend at the rate of 12% per annum.

On November 3, 2004, the Company completed an equity financing of \$10 million Cdn. with the Fonds de solidarité des travailleurs du Québec (“FSTQ”) and \$2 million Cdn. with the Fonds d’investissement bioalimentaire (“Fonds bio”). The financing consisted of a private placement offering of 12,000,000 newly created Series 2 Preferred Shares for a subscription price of \$12 million Cdn. The FSTQ subsequently acquired the interest of the Fonds bio.

The Series 2 Preferred Shares are convertible at the option of the holder into Common Shares for five years plus one day at a conversion ratio which is obtained by dividing the fully-accreted value by the applicable conversion price as follows: 25% at \$1.45; 50% at \$2.50; and 25% at \$3.75. The fully-accreted value is calculated as the aggregate subscription price of the preferred shares plus 6% per annum until the earlier of conversion or five years from the date of issuance. After the initial five-year plus one-day term, any Series 2 Preferred Shares outstanding are convertible at the option of the holder, into Common Shares at the fully-accreted value divided by the average market price of the Common Shares less the greater of 5% or the maximum discount permitted by the Toronto Stock Exchange (subject to the issuance of a maximum of 6,521,677 Common Shares in the aggregate on conversion of the remaining Series 2 Preferred Shares). On June 4, 2007, 3,000,000 Preferred Shares were converted into 2,388,323 Common Shares. If the trading price of the Common Shares exceeds \$13.50 for 60 consecutive days, the Company may require the holders to convert the Preferred Shares into Common Shares at the conversion ratio applicable on the date of conversion. The Preferred Shares 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. The FSTQ continues to hold 9,000,000 Series 2 Preferred Shares. Effective November 4, 2009 and based on the current market price for Common Shares, the 9,000,000 Series 2 Preferred Shares outstanding are convertible into 4,133,354 Common Shares.

## **MARKET FOR SECURITIES**

The Common Shares of the Company are listed and posted for trading on the Toronto Stock Exchange under the symbol “BNC”. The following chart sets out the price range and volume history from July 1, 2009 to June 30, 2010:

Month	Average High	Average Low	Average Close	Total Volume
July 2009	0.62	0.365	0.49	5,899,623
August 2009	0.51	0.43	0.47	1,225,374
September 2009	0.5	0.41	0.475	2,960,534
October 2009	0.5	0.415	0.425	2,039,539
November 2009	0.47	0.37	0.39	2,398,265
December 2009	0.58	0.38	0.56	3,121,144
January 2010	0.82	0.51	0.73	3,318,455
February 2010	1.14	0.66	0.9	5,960,875
March 2010	1.24	0.9	1.03	4,034,321
April 2010	1.22	1.0	1.15	1,302,601
May 2010	1.2	0.93	1.01	2,065,863
June 2010	1.05	0.84	0.89	1,207,832
<b>TOTAL/AVERAGE</b>	<b>0.82</b>	<b>0.60</b>	<b>0.71</b>	<b>35,534,426</b>

Effective July 31, 2007 the Company listed and posted with the Toronto Stock Exchange the Common Share Purchase Warrants issued during the equity financing that was completed in March 2007, under the symbol BNC WT. The following chart sets out the price range and volume history from July 1, 2009 to March 13, 2009. On March 13, 2009 the Warrants were de-listed. After the Warrants were de-listed the Company extended the expiry date from March 13, 2009 to May 12, 2009; however the Warrants were not re-listed and expired unexercised.

Month	Average High	Average Low	Average Close	Total Volume
July 2008	0.34	0.22	0.28	67,500
August 2008	0.25	0.15	0.15	26,000
September 2008	0.20	0.095	0.095	203,000
October 2008	0.17	0.085	0.15	18,879
November 2008	0.11	0.03	0.10	541,200
December 2008	0.10	0.06	0.10	121,500
January 2009	0.10	0.04	0.04	195,366
February 2009	0.05	0.025	0.025	834,050
March 2009	0.02	0.005	0.005	2,073,000
<b>TOTAL/AVERAGE</b>	<b>0.15</b>	<b>0.08</b>	<b>0.11</b>	<b>4,080,495</b>

## **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.

## **HUMAN RESOURCES AND FACILITIES**

As of August 31, 2010, the Company had 211 full-time and part-time employees. The Company's registered and head office is located at 231 Dundas Street East, P.O. Box 1570, Belleville, Ontario, K8N 5J2. It is from this location that 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 foot GMP facility in Montréal at 275 Labrosse Avenue, Pointe-Claire, Québec. In the short-term, this facility will be used primarily for pilot-scale production of some of the Company's technologies. In the longer term, this facility will be the production point for global supply of MCC for bladder and other cancers. The Company has also leased 3,868 square feet of office space at 171 Place Frontenac, Pointe-Claire, Québec H9R 4Z7, which is near the manufacturing facility.

On June 3, 2005, the Company entered into a ten-year lease for the facility located at 271 Labrosse Avenue, adjacent to the existing manufacturing facility. The facility is leased to the Company from Renaissance (London) Investments Inc., a company owned and controlled by Graeme McRae, the Company's Chief Executive Officer. Under the terms of the lease, the Company had the option to purchase the facility by May 31, 2006 by assuming the balance of the loan outstanding. This option to purchase was extended effective May 31, 2006 for an additional two years and further extended to May 28, 2011. The Company has agreed to assume the mortgage and the transfer of ownership is in process. This transaction was recorded as a capital lease obligation as disclosed in Note 10 of the annual Consolidated Financial Statements. The facility consists of 14,000 square feet and will be used for office and laboratory space, with the potential to add additional manufacturing space in the future. This facility will allow the Company to expand the production capacity of its existing MCC manufacturing to meet the projected eventual demand for *Urocidin*<sup>™</sup> for the North American and European clinical trials. The purchase of this facility by a related party was necessitated by the Company's liquidity position at the time of acquisition.

The Company owns a 39-hectare farm property outside Belleville, Ontario which is used to keep horses for *Colimune*<sup>®</sup> production. The Company's pre-clinical and formulation research is conducted at its leased 4,708 square foot research facility located within the Biotechnology Research Institute of the Canadian National Research Council in Montréal, Québec. The lease for these premises expires on November 30, 2010, and an extension to the lease is being negotiated. At the same time, the Company is currently investigating alternatives for the long-term. The Company's clinical trials are carried out by leading clinical investigators at major hospitals and specialty clinics worldwide.

The Company leases a 1,250 square foot laboratory located at 119 Rowe Road, Athens, Georgia in the United States. The term on the lease ended on November 20, 2008 and is now a month to month tenancy. 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 months' 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. This lease is currently set up as a month to month arrangement.

The Company owns a manufacturing facility and a 300-acre farm in Armidale, Australia. The Company leases an additional 1,100 acres of nearby farm land. The manufacturing facility specializes in the manufacture of pregnant mare serum gonadotrophin (PMSG), a reproductive hormone used to enhance fertility in livestock.

On March 29, 2006, Bioniche Animal Health Canada Inc., one of the Company's subsidiaries, purchased two residential/commercial properties. These properties, at 219 and 225 Dundas Street East, Belleville, Ontario abut the property currently owned by the Company in Belleville. As a way of supporting the local community, the Company has leased 225 Dundas Street to Hospice Quinte, under generous terms for ten years. Hospice Quinte, a registered charity, offers respite care services to the dying and their families. The Company is currently evaluating potential different uses for the 219 Dundas Street East property.

On August 26, 2007, the Company's Australian subsidiary, Bioniche Animal Health (A/Asia) Pty. Ltd. leased the offices located at Suite 5, 242 Hawthorn Road, Caulfield, Victoria, Australia as office spaces for the sales and marketing team.

## **RISKS AND UNCERTAINTIES**

The primary risks that may affect the Company are summarized below. If any of the risks or uncertainties occurs, the business, financial condition, prospects, or results of operations for the Company would likely suffer.

### *Early Stage Development*

Several of the Company's products or processes are at an early stage of development. Significant additional investment in research and development and clinical trials of such product and process candidates is required prior to commercialization. A commitment of substantial time and resources is required to conduct research and clinical trials if the Company is to complete the development of any product or process. It is not known whether any of these product or process candidates will meet applicable health regulatory standards and obtain required regulatory approvals, whether such products or processes can be produced in commercial quantities at reasonable costs and be successfully marketed, or if the Company's investment in any such product or process candidate will be recovered through sales or royalties.

### *Cash Flow and Financial Resources*

The Company's cash flow provided by operations for Fiscal 2010 was \$16.6M as compared to cash used in operations of \$3.0M in the same period in Fiscal 2009. This increase is primarily supported by the achievement of the first three milestones under the License, Development and Supply Agreement

with Endo, amounting to \$14.8M [US\$14.0M], and the up-front payment of \$22.3M [US\$20M] under the same agreement.

The Company's investing activities used cash of \$6.6M during Fiscal 2010, primarily on construction costs of \$7.8M for the Vaccine Manufacturing Centre in Belleville, Ontario, offset by government assistance and proceeds from the sale of a product license.

At June 30, 2010, the Company's net working capital totalled \$16.3M, excluding the current portion of non-refundable deferred licensing revenue as compared to negative working capital of (\$0.5M) at June 30, 2009. Shareholders' equity at June 30, 2010 totalled \$8.5M as compared to \$9.1M at June 30, 2009.

Long-term liabilities at June 30, 2010 totalled \$11.9M, excluding non-refundable deferred licensing revenue of \$19.3M, which compares to \$8.2M reported at June 30, 2009. The increase reflects the long-term portion of the required repayment of government assistance to the Industrial Technologies Office (ITO, formerly TPC) of \$3.1M, less repayments of capital leases and long-term debt. The up-front payment related to the licensing agreement with Endo is reflected as non-refundable deferred licensing revenue, the current portion being \$1.5M and the long-term portion being \$19.4M. The total amount received was \$22.3M, which will be recognized in income over 15 years from the date of the Agreement (July 10, 2009), which is the term over which the Company maintains substantive contractual obligations.

The Company has incurred significant losses since its inception, due primarily to its focus on the research and development of its proprietary technologies and has an accumulated deficit of \$96.9M as at June 30, 2010. The Company's committed cash obligations and expected level of expenditures for Fiscal 2011 exceed its committed sources of funds.

At June 30, 2010, the Company had approximately \$11.1M in cash and cash equivalents, balances primarily provided from operations for the year, including the up-front payment of US\$20M and milestone payments of US\$14M from Endo. In the past, the Company has financed its expenditures primarily through public and private placements of common shares, the issuance of debt instruments, and the receipt of government incentives earned on eligible scientific expenditures. The operations of the Company's commercial division (Animal Health) have been financed through this division's own internally generated cash flows, through the use of commercial banking facilities, and through capital leases with equipment vendors. The Company will continue to use these sources of financing as provided by operations or as new credit lines and long-term debt facilities become available. Funding from operations includes anticipated milestone revenues over the next several months, which will be used to finance ongoing internal development commitments related to the Phase III clinical program in bladder cancer and other human health indications. As the milestones and debt facilities are dependent on a number of factors outside of management's control, such as, the outcome of future events and changing market conditions, there is uncertainty concerning the Company's ability to continue as a going concern. Please refer to note 1 of the Company's Annual Consolidated Financial Statements.

The Company was able to advance its key development platforms in both Food Safety and Human Health for the year ended June 30, 2010 with cash provided from the Endo agreement without incurring any additional monthly burn (consolidated cash flow used in operations) during Fiscal 2010, as compared to a monthly burn of approximately \$0.2M during Fiscal 2009.

#### *Foreign Currency Risks*

The Company is exposed to foreign currency risks as a result of the sales of products, purchases of materials, and costs of manufacturing operations in currencies other than the Canadian dollar. The Company operates internationally and a substantial portion of its revenue from product sales is

denominated in US dollars, Euros, New Zealand dollars and Australian dollars. This results in financial risk due to fluctuations in the value of the Canadian dollar relative to these currencies. The Company has a natural hedge for a portion of this risk, in that many of its expenditures are in US dollars, Euros and Australian dollars. Fluctuations in payments made for the Company's products could cause unanticipated fluctuations in the Company's consolidated operating results. At June 30, 2010 and 2009, the Company has not entered into any currency hedging contracts to manage foreign currency risk.

### *Government Regulations*

The manufacture and sale of animal and human therapeutic products are governed by numerous statutes and regulations in the United States, Canada, Ireland, and other countries where the Company intends to market its products. The subject matter of such legislation includes approval of manufacturing facilities, controlled research and testing procedures, review and approval of manufacturing, pre-clinical, and clinical data prior to marketing approval, adherence to GMP during production and storage, and regulation of marketing activities, notably advertising and labeling.

The Company's products and processes will require significant development, pre-clinical and clinical testing, and investment of significant funds prior to their commercialization. There can be no assurance that any such products will actually be developed. The process of completing clinical testing and obtaining required approvals is likely to take several years and require the expenditure of substantial resources.

Furthermore, there can be no assurance that the regulators will not require modification to submissions, which may result in delays or failure to obtain regulatory approval. Any delay or failure to obtain regulatory approvals could adversely affect the ability of the Company to utilize its technology, thereby adversely affecting operations. Further, there can be no assurance that the Company's product candidates will prove to be safe and effective in clinical trials, nor that they will receive the requisite regulatory approval. Foreign markets, other than the United States and Canada, impose similar restrictions.

### *Clinical Trial Results*

Clinical trials are long, expensive and uncertain processes, and Health Canada or the U.S. FDA may ultimately not approve any of the Company's product candidates. The Company may never develop any commercial drugs or other products that generate revenues. The products under research have not yet received regulatory approval. The Company cannot market a pharmaceutical product in any jurisdiction until it has completed thorough pre-clinical testing and clinical trials in addition to that jurisdiction's extensive regulatory approval process. In general, significant research and development and clinical studies are required to demonstrate the safety and effectiveness of products before the Company can submit any regulatory applications. Clinical trials may not be commenced or completed on schedule, and Health Canada or the FDA may not ultimately approve the Company's product candidates for commercial sale. Further, even if the results of the Company's pre-clinical studies or clinical trials are initially positive, it is possible that the Company will obtain different results in the later stages of drug development or that results seen in clinical trials will not continue with longer term treatment. Drugs in late stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. For example, positive results in early Phase I or Phase II clinical trials may not be repeated in larger Phase II or Phase III clinical trials. The results of the Company's Phase III clinical trials with *Urocidin*<sup>™</sup> in bladder cancer may not meet the primary endpoints of the studies, despite promising pre-clinical and early stage clinical data.

In addition, unacceptable toxicities or adverse side effects may occur at any time in the course of pre-clinical studies or human clinical trials or, if any products are successfully developed and approved for marketing, during commercial use of any approved products. The appearance of any such unacceptable toxicities or adverse side effects could interrupt, limit, delay or abort the development of any of the Company's product candidates or, if previously approved, necessitate their withdrawal from the market. Furthermore, disease resistance or other unforeseen factors may limit the effectiveness of the Company's potential products. The clinical trials of any of the Company's drug candidates could be unsuccessful, which would prevent it from advancing, commercializing or partnering the drug. The Company's failure to develop safe, commercially viable drugs would substantially impair its ability to generate revenues and sustain its operations and would materially harm its business and adversely affect its share price.

#### *Intellectual Property Issues*

The Company's success will depend, in part, on its ability to obtain, maintain and enforce patent rights, maintain trade secret protection and operate without infringing the proprietary rights of third parties. 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 or held in trade secret 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. Third parties may claim that the Company infringes upon their intellectual property. Any such claims, with or without merit, could materially harm its business and operating results. 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. While the Company has adopted procedures 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 the rights to its trade secrets.

#### *Competition*

Technological competition from pharmaceutical companies, biopharmaceutical companies and universities is intense, and is expected to increase. Potential competitors of the Company have developed, or may develop, product development capabilities or financial, scientific, marketing and human resources exceeding those of the Company. Competitors may develop products before the Company develops its own products, obtain regulatory approval for such products more rapidly than the Company, or develop products which are more effective than those which the Company intends to develop. Research and development by others may render the Company's technology or products obsolete or non-competitive, or produce treatments or cures superior to any therapy developed, or to be developed, by the Company, or otherwise preferred to any therapy developed by the Company.

### *Dependence on Collaborative Partners, Licensors and Others*

The Company's activities will require it to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others for the research, development, clinical testing, manufacturing, marketing and commercialization of its products. The Company intends to attract corporate partners and enter into additional research collaborations. There can be no assurance, however, that the Company will be able to establish such additional collaborations on favourable terms, if at all, or that its current or future collaborations will be successful.

Should any collaborative partner fail to develop, manufacture, or commercialize successfully any product to which it has rights, or any partner's product to which the Company has rights, the Company's business may be adversely affected. Failure of a collaborative partner to continue to participate in any particular program could delay or halt the development or commercialization of products generated from such program. In addition, there can be no assurance that the collaborative partners will not pursue other technologies or develop alternative products either alone or in collaboration with others, including the Company's competitors, as a means for developing treatments for the diseases targeted by the Company's programs.

Furthermore, the Company will hold licenses for certain technologies. There can be no assurance that these licenses will not be terminated, or that they will be renewed on conditions acceptable to the Company.

### *Potential Product Liability*

Pharmaceutical products involve an inherent risk of product liability claims and associated adverse publicity. Product liability insurance is costly, and availability is limited and may not be on terms which would be acceptable to the Company. An inability to maintain sufficient insurance coverage on reasonable terms or otherwise protect against potential product liability claims could prevent or inhibit the commercialization of the Company's potential products. A product liability claim brought against the Company or withdrawal of a product from the market could have a material adverse effect upon the Company and its financial condition.

### *Key Personnel*

The Company's success is also dependent upon its ability to attract and retain a highly-qualified workforce, and to establish and maintain close relations with research centres. Competition is intense and the Company's success will depend, to a great extent, on its senior executives, scientific staff, and collaborators. The loss of key personnel could compromise the rhythm and success of product development.

### *Suppliers*

The Company is dependent on certain third parties for the supply involved in the manufacturing of certain key products. Although it seeks to secure alternative suppliers, an interruption in the availability

of certain raw material sources could have a material adverse effect on the Company's business and financial condition.

### *Manufacturing Facilities*

The Company relies on having properly validated, fully functioning, and sufficiently sized manufacturing facilities in which to produce its products for market. Should systems fail, or a disaster strike, the ability to produce products would be negatively affected which, in turn, would affect revenue generation. The Company does not currently have backup manufacturing capacity for some of its key products. As a result, it would be forced to turn to external manufacturers should an unexpected event as described above occur.

### *Volatility of Share Prices, Absence of Dividends and Fluctuation of Quarterly Results*

Share prices are subject to change because of numerous different factors related to Company activity, including reports of new information, change in the Company's financial situation, the sale of shares in the market, the Company's failure to obtain results in line with the expectations of analysts, an announcement by the Company or any of its competitors concerning technological innovation, etc. During the past few years, shares of the Company, other biopharmaceutical companies, and the investment market in general have been subjected to extreme fluctuations that were unrelated to the operational results of the companies affected. There is no guarantee that the market price of Company shares will be protected from any such fluctuations in the future. The Company has not paid dividends on its Common Shares to date and does not expect to pay dividends in the foreseeable future. The Company's quarterly operating results have fluctuated in the past and may continue to fluctuate in the future.

## **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 July 30, 2010 is set out below.

<b>Name and Municipality of Residence</b>	<b>Position with the Company</b>	<b>Principal Occupation</b>	<b>Director of Company since</b>
Armen Aprikian (4) Montréal, Québec	Observer to Board	Head, Division of Urology, Department of Surgery, McGill University, and Interim Chief of Department of Oncology, McGill University Health Centre	N/A
Stanley Alkemade, DVM Arva, Ontario (4),(5),(6)	Director	President of BioMedEx, a pharmaceutical industry consulting firm.	September 1999
Cindy Benning (5) mgt. rep. Frankford, Ontario	Vice-President, Operations, Quality and Regulatory Affairs	Vice-President of the Company since December 2001; previously held positions within the Company.	N/A

<b>Name and Municipality of Residence</b>	<b>Position with the Company</b>	<b>Principal Occupation</b>	<b>Director of Company since</b>
Debi Butler Corbyville, Ontario	Corporate Controller	Previously Interim Controller	N/A
Albert Beraldo Toronto, Ontario (1),(2),(6)	President, Alveda Pharmaceuticals Inc.	Previously a director and employee of the Company.	November 6, 2008
Monique Champagne Ile Bizard, Québec (4)	Vice-President, Clinical Research	Previously Director, Clinical Research since March, 2006; before joining the Company, held research and development management positions at Xanthus Life Sciences, Supratek Pharma Inc., PriceWaterhouseCoopers, Quintiles Canada, Wyeth-Ayerst Research and Scat Canada Inc.	N/A
François Charette, M.D., MBA Outremont, Québec	Senior Vice-President and Chief Medical Officer	Senior Vice-President of the Company since July 11, 2005; previously served as General Manager and Senior VP of Quintiles Canada Inc. and prior to that served as VP of Scientific Affairs at Berlex Canada	N/A
Rick Culbert Belleville, Ontario	President, Bioniche Food Safety	Previously President Bioniche Animal Health Canada Inc.	N/A
Margaret Cunningham, Ph.D. Halifax, Nova Scotia (1), (3) (6)	Director	Director, School of Business Administration, Dalhousie University since January 1, 2009  Dean Faculty of Management since April 2010	October 24, 2003
Pierre-Yves Desbiens, CA, MBA (1), (2), (6) Montréal, Québec	Director	Vice President, Finance PurGenesis Technologies Inc.	May 5, 2005
Mohamed Elrafih Belleville, Ontario	Vice-President, Manufacturing Operations	Vice-President of the Company since November 2001; previously held positions within the Company.	N/A

Brian Ford, CA, Ameliasburg, Ontario	Chief Financial Officer	Joined the Company in September 2009; previously the proprietor of PetersFord Consulting	N/A
Andrew Grant Belleville, Ontario	Divisional President, Bioniche Animal Health Export Sales, Europe and Australia	Previously Managing Director of Bioniche Animal Health (A/Asia) Pty. Ltd. and Bioniche Animal Health Europe Limited	N/A
Cameron Groome Mississauga, Ontario	Executive Vice-President, Corporate and Strategic Development	Executive Vice-President, Corporate and Strategic Development since June 2006. Previously worked as an equity analyst, industry commentator, investment banker and corporate advisor.	N/A
James Johnson Ph.D. (4),(6) Highlands, North Carolina	Director	Founder & Partner, Johnson & Associates  Previously Partner, King & Spalding LLP, law firm. Prior to that, Partner, Kilpatrick Stockton, law firm.	December 1997
Bruce McLeod Belleville, Ontario	Vice-President, Human Resources	Previously worked as Director of Human Resources with Farm Credit Canada and prior to that HR Manager with the Saskatchewan Workers' Compensation Board.	N/A
Graeme McRae (2), (4), (5), (6) Belleville, Ontario	Chairman of the Board, President and Chief Executive Officer, Director	Chairman of the Board, President and Chief Executive Officer of the Company.	June 1979
Jim Phillips Orangeville, Ontario	President, Bioniche Animal Health (global)	Previously President Bioniche Animal Health USA, Inc.	N/A

Nigel C. Phillips Pointe Claire, Québec	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 Montréal.	N/A
Nick Photiades (1) Brossard, Québec	Director	Management and strategic planning consultant	September 17, 2009
Dragan Rogan Belleville, Ontario	Chief Veterinary Scientific Officer	Previously Vice President, Research and Development, Animal Health from 1989 to 2010.	N/A
Jennifer Shea Belleville, Ontario	Vice-President, Communications, Investor & Government Relations and Assistant Secretary	Previously Corporate Communications Manager promoted to Director, Corporate Communications, Investor & Government Relations since April 2004	N/A
Rick Sutin (5) Toronto, Ontario	Interim Corporate Secretary	Senior Partner Oglivy Renault LLP	N/A
Lyle Vanclief (3), (6) Ameliasburg, Ontario	Director	Agricultural and Agri- Food Consultant; former Cabinet Minister (Agriculture and Agri- Food) and Member of Parliament, Government of Canada; former agricultural entrepreneur.	September 20, 2005

Gary Weber Severn, Maryland	President, Bioniche Food Safety, USA	Previously worked for United States Department of Agriculture (USDA) as National Program Leader for Animal Science and the National Cattlemen's Beef Association as Director of Animal Health, Inspection and Science Policy and Executive Director of Regulatory Affairs	N/A
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- (1) Member of the Audit Committee
- (2) Member of the Compensation Committee
- (3) Member of the Corporate Governance & Nominating Committee
- (4) Member of the Scientific Audit Committee
- (5) Member of the Risk Management Committee
- (6) 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.

**Dr. Armen Aprikian** (observer to the Board). Dr. Aprikian is the Head, Division of Urology, Department of Surgery, McGill University, and Interim Chief of Department of Oncology, McGill University Health Centre.

**Cindy Benning** 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. In July of 2005 she took on additional responsibilities related to the Company's operations, with a new title of Vice-President of Operations, Quality & Regulatory Affairs. She has held various positions in Quality Control and/or Regulatory Affairs. Ms. Benning 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, she is an important resource for the company's clinical development program and facility expansion plans.

**Albert Beraldo** is the President of Alveda Pharmaceuticals Inc., a privately owned Canadian company that is a leading supplier of pharmaceuticals to the Canadian health care market. Albert formerly served as President and CEO of Bioniche Pharma Group Limited until 2005. He also previously served as a director of the Corporation from 1984 to 2005. Mr. Beraldo has a Bachelor of Commerce degree from the University of Windsor and has a Chartered Accountant designation from the Canadian Institute of Chartered Accountants. He worked in public accounting with Ernst and Whinney until he joined Vetrepharm as Financial Controller in 1983.

**Debi Butler** is a Certified General Accountant with an Honours Bachelor of Commerce degree from Laurentian University. Debi joined Bioniche in 2000 and has held progressive roles in the Company's finance department before being appointed as Corporate Controller in 2009. Debi has over thirty years of accounting experience gained in the fields of banking, public accounting and both private and publicly traded companies.

**Monique Champagne** joined the Company in March, 2006 as Director, Clinical Research with 19 years of experience in international research. She held research and development management positions at Xanthus Life Sciences, Supratek Pharma Inc., PriceWaterhouseCoopers, Quintiles Canada, Wyeth-Ayerst Research and Scat Canada Inc. Monique received her Master's degree in Pharmaceutical Science and her Bachelor's degree in Pharmacy, both from the University of Montréal. Monique was recently promoted to the position of Vice-President, Clinical Research.

**Dr. François Charette** was previously the General Manager and Senior Vice-President of Quintiles Canada Inc., leading its Canadian affiliate since 2003. Prior to this, he served as Vice-President of Scientific Affairs at Berlex Canada Inc., Director of Professional and Hospital Services at the Centre hospitalier Anna-Laberge, Director of Research at Bristol-Myers Squibb Inc., and Associate Director of Research at Hoehst Canada Inc. after spending 12 years in hospital practice. He earned his Medical Degree at the University of Montréal and his Master of Business Administration degree from Concordia University.

**Rick Culbert** has a diploma from Animal Health Technology from Centralia College of Agricultural Technology; and is a graduate of the Advanced Agricultural Leadership Program, University of Guelph. Rick joined Bioniche (then Vetrepharm Inc.) in 1980 as the Ontario Regional Manager. He has held progressively senior roles in the Animal Health division of the Company before being appointed as President of Bioniche Animal Health Canada, Inc. in 2002 and was promoted to President, Bioniche Food Safety in July 2007. Rick is a member of the Canadian Animal Health Institute's Board of Directors.

**Margaret Cunningham** has a Ph.D. in marketing from Texas A&M University and an MBA from the University of Calgary. Dr. Cunningham is currently the Director, School of Business Administration, Dean Research, Faculty of Management, and R.A. Jodrey Chair of Dalhousie University. Previously she was a Professor of marketing and the Director of the Centre for Corporate Social Responsibility at the School of Business, Queen's University.

**Pierre-Yves Desbiens** is Vice-President, Finance at PurGenesis Technologies Inc. He holds a Bachelor's degree in Accounting from the University of Québec and an MBA from the Hautes Études Commerciales of the University of Montréal. Before joining PurGenesis, Mr. Desbiens was Vice President, Finance and Administration at Supratek Pharma Inc., Vice-President, Finance and Administration at Chronogen Inc., Investment Portfolio Manager, Life Sciences, at the Fonds de solidarité des travailleurs du Québec, a venture capital institutional investor in the Canadian life sciences sector, and Chief Financial Officer and General Manager of Horizon Sciences & Technologies Inc., a biopharmaceutical company based in Montréal. Before joining the health care sector, Mr. Desbiens held different positions in corporate finance with mid-size to a multinational corporation, including Domtar Inc., Price Waterhouse, and Oceanix Inc.

**Mohamed Elrafih** joined the Company in 1984 and became Vice-President, Manufacturing Operations in November 2001, responsible for all manufacturing and plant operations for the Company. Mohamed graduated from the University of Western Ontario with a Bachelor's Degree in Science (Microbiology). He has held positions of increasing responsibility in the manufacturing operations of the Company.

**Brian Ford** joined the Company in September 2009 as the new Chief Financial Officer. Brian is a chartered accountant and financial professional with over 26 years of experience serving private

corporations and publicly traded entities. Most recently, he was the Proprietor of PetersFord Consulting, a firm focused on finance and business risk services. Previously, he held several positions with increasing responsibilities with Ernst & Young, his last position being Principal of Business Risk Services in the firm's Toronto office. He has earned a Graduate Diploma in Accounting from the University of McGill, a B.A. (Economics, History, English) from the University of Guelph, and is a Member of the Ontario Institute of Chartered Accountants.

**Andrew Grant** joined Bioniche in 1998 as General Manager, Bioniche Animal Health Australia and New Zealand. In 2001, he was promoted to Managing Director, Bioniche Animal Health Australia/New Zealand and held that position until his transfer to Managing Director Animal Health, Europe and the Middle East in 2004. In 2007, Andrew was promoted to Divisional President, Bioniche Animal Health Export Sales, Europe and Australia. With this appointment, Andrew and his family relocated to the Bioniche Corporate Offices in Belleville, Ontario, Canada. Andrew graduated from Saint Stanislaus College, Bathurst, NSW, Australia and holds a certificate in Marketing from the University of Technology in Sydney Australia. Andrew is also a member of the Australian Institute of Company Directors. Prior to his employment with Bioniche, Andrew was a National Field and Product Manager for Boehringer Ingelheim in Australia.

**Cameron Groome** joined the Company in June 2006 and currently serves as the Executive Vice President Corporate and Strategic Development. Cameron graduated with a Bachelor of Commerce, Finance and Marketing, from Concordia University (Montréal, Québec). Cameron previously headed the life sciences investment banking activities for a major Canadian investment dealer. He has more than fifteen years of experience as an equity analyst, industry commentator, investment banker, and corporate advisor and industry commentator in the Canadian life sciences industry.

**Dr. James Johnson** has a doctorate in biochemistry in addition to his law degree and is a partner at his new firm, Johnson & Associates. Previously he was a partner of King & Spalding LLP based in Atlanta, Georgia. Prior to that he was a partner at the law firm of Kilpatrick Stockton. He has extensive experience in chemical and biotechnology patent prosecution and licensing.

**Bruce McLeod** joined the Company in May 2008. Mr. McLeod has had seven years experience in both operations and human resources with Farm Credit Canada, most recently as Director of Human Resources. Previously Bruce served as the Human Resources Manager with the Saskatchewan Workers' Compensation Board and Instructor in the Business Division of the Saskatchewan Institute of Applied Science and Technology. Bruce graduated with a B.A. from Carleton University and holds a Certificate in Adult Education from Saint Francis Xavier University.

**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. Mr. McRae serves as Chairman, President & CEO of the Company.

**Jim Phillips** joined Bioniche (then Vetrepharm Inc.) in 1985 as Territory Sales Representative, having worked previously as a Research and Testing Technician in the Racetrack Division of Agriculture Canada. He has held progressively senior roles in the Animal Health division of the Company before being appointed as President of Bioniche Animal Health USA, Inc. in 1997 and was promoted to President, Bioniche Animal Health (global) in July 2007. Jim graduated from the University of Guelph with a

Diploma in Agriculture and has taken numerous management leadership courses during his career. He has a longstanding interest in horse racing and sport horses.

**Dr. Nigel C. Phillips** joined the Company in 1996. Dr. Phillips has an extensive research background in biochemistry, immunology, immunopharmacology and immunomodulatory drug formulation. Dr. Phillips has directed research programmes at the Strangeways Research Laboratory, Cambridge, the Institut Pasteur de Paris, McGill University, Montréal, the University of Montréal 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.

**Nick Photiades** is currently a management and strategic planning consultant. In November 2008 he retired after a career with the Business Development Bank of Canada where he was Senior Director, Life Sciences, Venture Capital Division. During his last fifteen years at BDC he invested in many high technology companies and assisted them in negotiating licensing, partnership agreements and in raising funds in Canada, USA and Asia; several of his invested companies were successfully divested. Nick holds a Bachelor of Science degree in Physics from Concordia University and a graduate Diploma in Management from McGill University. He has served as a director in several public and private high technology companies mainly in the biotechnology area; he also served on the board of directors of the Chamber of Commerce of Metropolitan Montréal and presently serves in St. Mary's Hospital Foundation Board.

**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 the animal health operations of the Company and was recently appointed the Chief Veterinary Scientific Officer. He leads a team of researchers, with expertise in bacteriology; biochemistry; molecular biology; reproductive physiology; and virology.

**Jennifer Shea** joined the Company in April 2004 as the Corporate Communications Manager, promoted to Director, Corporate Communications, Investor and Government Relations and recently promoted to Vice-President, Communications, Investor and Government Relations. Jennifer also holds the position of Assistant Corporate Secretary. She previously worked in progressive Corporate Communications positions with hospitals in Kingston and Belleville, Ontario for eighteen years. Jennifer is a graduate of the Broadcast Journalism program at Loyalist College.

**Rick Sutin** is the Company's Corporate Secretary. Rick is a senior partner at the law firm, Ogilvy Renault. He holds a B.A. (Hons.) from York University, an LL.B. from Osgood Hall, York University and was called to the Ontario Bar in 1977. Rick has expertise in capital market transactions, mergers, acquisitions for private and publically traded corporations, securities law and sat on a number of boards.

**Lyle Vanclief** is an agricultural and agri-food consultant. He served as a Member of Parliament for the Government of Canada from 1988 to 2004. Throughout his political career, Mr. Vanclief held several parliamentary appointments, his most recent as Minister of Agriculture and Agri-Food. Prior to serving in public office, Mr. Vanclief previously spent 25 years as an agricultural entrepreneur in his home community of Ameliasburg, Ontario (Prince Edward County). Mr. Vanclief has completed the Director Education Program and has been certified at the Rotman School of Management. He graduated with a Bachelor of Science degree in Agriculture from the University of Guelph in 1966. Mr. Vanclief will be

inducted into the Canadian Agricultural Hall of Fame at the Royal Agricultural Winter Fair on November, 2010 in Toronto.

**Dr. Gary Weber** joined the Company in April 2008 after working as a self-employed consultant assisting select clientele to deal effectively with the forces of change affecting the food and agriculture sector in the United States. Previously Gary worked for the United States Department of Agriculture (USDA) as National Program Leader for Animal Science; and the National Cattlemen's Beef Association as Director of Animal Health, Inspection and Science Policy and Executive Director of Regulatory Affairs. Gary holds both a B.Sc. and M.Sc. degree in Animal Science from Purdue University and a Ph.D. from Michigan State University.

### **Committees of the Board**

There are five committees of the Board: the Audit Committee, the Compensation Committee, the Corporate Governance and Nominating Committee, the Scientific Audit Committee, and the Risk Management Committee. The current members of the Audit Committee are Pierre-Yves Desbiens, Margaret Cunningham, Albert Beraldo and Nick Photiades, 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 Company prior to the presentation of such statements to the Board. The Audit Committee also oversees management reporting and internal controls. As Pierre-Yves is not standing for re-election, the Board will elect another Board member to fill the vacant position on this Committee.

The Compensation Committee is currently comprised of Albert Beraldo, Pierre-Yves Desbiens and Graeme McRae (for all matters except his own compensation). Albert Beraldo and Pierre-Yves Desbiens are unrelated Directors. This Committee reviews compensation decisions for executive and senior management staff, and is responsible for assessing Directors' compensation. As Pierre-Yves is not standing for re-election, the Board will elect another Board member to fill the vacant position on this Committee.

The Corporate Governance and Nominating Committee addresses the constitution and independence of the Board and the functions of the Board and its committees. This Committee currently consists of Lyle Vanclief, Peggy Cunningham and Graeme McRae. Lyle Vanclief and Peggy Cunningham are unrelated Directors.

The Company's Corporate Disclosure Committee, consisting of the Chairman, President and Chief Executive Officer, Chief Financial Officer and Vice President, Communications, Investor and Government Relations reports to this Committee.

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. Dr. Armen Aprikian also participates as an observer.

The Risk Management Committee addresses areas of risk exposure and consists of Stanley Alkemade, Rick Sutin, Graeme McRae and Cindy Benning.

### **CONFLICTS OF INTEREST**

While no conflicts of interest have arisen, the following circumstances could give rise to potential conflicts of interest.

One of the Company's Directors is a related Director as his firms receive fees for services he provides to the Company. Stanley Alkemade provides consulting services to the Company. Nick

Photiades has also provided consulting services to the Company relating to seeking financing for the expansion of the MCC manufacturing facilities.

One Director of the Company is indebted to the Company. Graeme McRae is Chairman of the Board, President & Chief Executive Officer of the Company and a Director. Details of this indebtedness are disclosed in the Company's Information Circular of its Annual Meeting of shareholders last held on November 5, 2009.

## **INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

On June 3, 2005, the Company entered into a ten-year lease of a building located at 271 Labrosse Avenue from Renaissance (London) Investments Inc. ("Renaissance"). Renaissance acquired the building on that date and the purchase price was financed entirely by a mortgage loan. Renaissance is owned and controlled by Graeme McRae, the Chairman of the Board, President and Chief Executive Officer and a director of the Company. The Company has the option to purchase the building by May 31, 2006 by assuming the balance of the mortgage loan outstanding by Renaissance. Minimum lease payments are \$16,667 per month and the Company made (received) other payments related to the leased property of (\$56,350) in 2010, \$2,223 in 2009, \$20,503 in 2008, and \$88,570 in 2007. This option has been extended to May 28, 2011. The Company has agreed to assume the mortgage and the transfer of ownership of this property is in process.

## **AUDIT COMMITTEE INFORMATION**

### Audit Committee Charter

The charter of the Audit Committee of the Corporation's Board of Directors is attached to this Annual Information Form as Schedule A.

### Composition of the Audit Committee

The members of the Audit Committee are currently Pierre Yves Desbiens (chair), Margaret Cunningham, Albert Beraldo and Nick Photiades. Each of them is "independent" and "financially literate" for the purposes of Multilateral Instrument 52-110 – Audit Committees (MI 52-110). As Pierre-Yves is not standing for re-election, the Board will elect another Board member to fill the vacant position on this Committee.

### Relevant Education and Experience

Pierre-Yves Desbiens is Vice-President, Finance at PurGenesis Technologies Inc. He holds a Bachelor's degree in Accounting from the University of Québec and an MBA from the Hautes Études Commerciales of the University of Montréal. Before joining PurGenesis, Mr. Desbiens was Vice President, Finance and Administration at Supratek Pharma Inc., Vice-President, Finance and Administration at Chronogen Inc., Investment Portfolio Manager, Life Sciences, at the Fonds de solidarité des travailleurs du Québec, a venture capital institutional investor in the Canadian life sciences sector, and Chief Financial Officer and General Manager of Horizon Sciences & Technologies Inc., a biopharmaceutical company based in Montréal. Before joining the health care sector, Mr. Desbiens held different positions in corporate finance with mid-size to a multinational corporation, including Domtar Inc., Price Waterhouse, and Oceanix Inc.

Margaret Cunningham has a Ph.D. in marketing from Texas A&M University and an MBA from the University of Calgary. She has been Associate Professor of Marketing at the School of Business, Queen's University since 1989.

Albert Beraldo is the President of Alveda Pharmaceuticals Inc., a privately owned Canadian company that is a leading supplier of pharmaceuticals to the Canadian health care market. Albert formerly served as President and CEO of Bioniche Pharma Group Limited until 2005. He also previously served as a director of the Corporation from 1984 to 2005. Mr. Beraldo has a Bachelor of Commerce degree from the University of Windsor and has a Chartered Accountant designation from the Canadian Institute of Chartered Accountants. He worked in public accounting with Ernst and Whinney until he joined Vetrepharm as Financial Controller in 1983.

Nick Photiades is currently a management and strategic planning consultant. In November 2008 he retired after a long career with the Business Development Bank of Canada where he was Senior Director, Life Sciences, Venture Capital Division. During his last fifteen years at BDC he invested in many high technology companies and assisted them in negotiating licensing, partnership agreements and in raising funds in Canada, USA and Asia; several of his invested companies were successfully divested. Nick holds a Bachelor of Science degree in Physics from Concordia University and a graduate Diploma in Management from McGill University. He has served as a director in several public and private high technology companies mainly in the biotechnology area; he also served on the board of directors of the Chamber of Commerce of Metropolitan Montréal and presently serves in St. Mary's Hospital Foundation Board.

#### Pre-Approval Policies and Procedures

In accordance with its charter, the Audit Committee pre-approves all audit and non-audit services not prohibited by law to be provided to the Corporation by its external auditors. If the Audit Committee delegates to one or more of its members the authority to pre-approve any such permitted audit and non-audit services, any such pre-approval is then presented to the Audit Committee at its next scheduled meeting following the pre-approval.

The Audit Committee also reviews the fees paid by the Corporation to the external auditor and other professionals in respect of audit.

#### External Auditor Service Fees

##### *Audit Fees*

The aggregate fees billed by the Company's auditors, Ernst & Young, for audit services for the fiscal years ended June 30, 2010 and June 30, 2009 were \$258,800 and \$270,525 respectively.

##### *Audit Related Fees*

The aggregate fees billed by the Company's auditors, Ernst & Young, for assurance and related services related to the performance of the audit not included in the amount shown above for the fiscal years ended June 30, 2010 and June 30, 2009 were \$Nil and \$9,375 respectively. These services were comprised of accounting consultation.

### *Tax Fees*

The aggregate fees billed by the Company's auditors, Ernst & Young, for tax compliance, tax advice and tax planning services for the fiscal years ended June 30, 2010 and June 30, 2009 were \$117,933 and \$226,535 respectively. These services were comprised of the preparation of tax returns and tax planning services.

### *All Other Fees*

The aggregate fees billed by the Company's auditors, Ernst & Young, which were translation services for the fiscal years ended June 30, 2010 and June 30, 2009 were \$51,200 and \$50,350 respectively.

### **TRANSFER AGENT**

The Company's transfer agent and registrar is CIBC Mellon and the Company's register is held in Toronto, Ontario, Canada.

### **MATERIAL CONTRACTS**

At June 30, 2010, the Company had capital commitments with respect to plant and machinery under construction in relation to the vaccine manufacturing facility in the amount of \$15.0M [2009 – nil]. A portion of these commitments will be financed through government incentives and assistance and through loans with the Business Development Corporation for a combined amount of approximately \$10.0M.

On June 21, 2010, the Company signed an Amendment Agreement with the Industrial Technologies Office (formerly Technologies Partnership Canada) amending the Contribution Agreement related to its *E. coli* vaccine. As a housekeeping measure, this Amendment updated the milestones, activities and expenses associated with the vaccine development.

On April 19, 2010, the Company announced that it has received a repayable investment of \$750,000 from the Federal Economic Development Agency of Ontario (Fed Dev Ontario). The investment will support the development of a Pilot-Scale Fermentation Facility as an adjunct to the Company's Animal Health and Food Safety Vaccine Manufacturing Centre. This investment is repayable to Fed Dev Ontario in equal monthly payments of \$12,500.00 commencing on July 1, 2011. The Company will fund the additional \$750,000 required to complete the construction of the Pilot-Scale Fermentation Facility.

On July 23, 2009, the Company sold its interest in a regulatory registration in the United States for a veterinary anaesthetic product - *Ketamine* - to Bioniche Teoranta.

On July 10, 2009, the Company licenced the exclusive rights to develop and market *Urocidin*<sup>TM</sup> in the United States and Mexico to Endo Pharmaceuticals Inc. Endo had a one-year option from the date of signing to exercise an option for the global rights and has since exercised that option. This transaction is more fully described on page 8 of this report.

On June 24, 2008, the Company signed an Amendment Agreement with the Industrial Technologies Office (formerly Technologies Partnership Canada) amending the original Contribution Agreement related to the *E. coli* O157 vaccine development. The Amendment extends the timeline for

completion of work on the production scale-up of the Company's vaccine production in Belleville to March 31, 2013.

On February 8, 2008, the Company entered into a ten-year term loan agreement with the Business Development Bank of Canada (BDC) for \$5 million. This loan is collateralized by certain property, plant and equipment at the Company's Belleville, Ontario facility and is subject to certain financial and non-financial covenants. It is repayable monthly at the BDC floating base rate plus 2%, with the final payment on February 1, 2018. At June 30, 2010, \$1.750 million had been drawn with future draws based on certain qualified expenditures. On April 22, 2010, the terms and conditions were amended to postpone monthly payments for twelve months and establish a revised payment schedule to commence May 1, 2011 with one payment of \$20,000, twelve payments of \$25,000, thirteen payments of \$40,000 and fifty-six payments of \$62,000. The interest rate was increased to BDC floating base rate [June 30, 2010 – 4.5%] plus 2.5%.

On December 20, 2007, the Company announced that it had received \$5 million in federal government financing in support of its vaccine production facility scale-up. The \$5 million loan, disbursements under which are based on a percentage of eligible expenditures is being provided through the new Agri-Opportunities Program of the Department of Agriculture and Agri-Food (Canada) (AAFC). The loan provides reimbursement for 20% of eligible costs to March 31, 2011, after which the contributions are to be repaid by the Company over five years beginning July 1, 2013. Certain other pre-conditions are ascribed to the loan, outlined in the repayable contribution agreement dated December 19, 2007 and posted at [www.sedar.com](http://www.sedar.com).

On December 18, 2007, the Company announced that it had received \$10 million in Ontario government financing in support of its vaccine production facility scale-up in Belleville, Ontario, Canada. The \$10 million loan, disbursements under which are based on a percentage of eligible expenditures, is being provided through the Ministry of Economic Development and Trade (MEDT)'s Advanced Manufacturing Investment Strategy (AMIS). Under the terms of the loan agreement, AMIS will reimburse 50% of eligible costs incurred for a five-year period to September 30, 2013. The loan is then repayable over five years at an annual interest rate of 5.69%.

On September 7, 2007, the Company announced that it had received a \$2 million grant from the Rural Economic Development (RED) Program of the Ontario Ministry of Agriculture, Food and Rural Affairs. The grant, which is based on a percentage of eligible expenditures, will be applied to support the market development expenditures incurred related to the Company's *E. coli* O157 cattle vaccine. The grant commenced on August 17, 2007 and expires at August 31, 2010. The Ministry reimburses grant funds to the Company in the proportion of 50% of eligible costs.

## **ADDITIONAL INFORMATION**

A copy of the Company's additional information including financial statements and Management's Discussion and Analysis for the fiscal years ended June 30, 2009 and June 30, 2010 may be obtained upon request from the Secretary of the Company and on SEDAR at [www.sedar.com](http://www.sedar.com).

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 to be held on November 9, 2010. Additional financial information is included in the Company's Fiscal 2010 Annual Report which will be available October 19, 2010.

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, 2010, 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 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 Legal Department, P.O. Box 1570, Belleville, Ontario, K8N 5J2, or by fax to (613) 966-4049.

## **SCHEDULE "A"**

### **AUDIT COMMITTEE CHARTER**

#### **Name**

There shall be a committee of the Board of Directors (the "Board") of Bioniche Life Sciences Inc. (the "Corporation") known as the Audit Committee.

#### **General Purpose**

The Audit Committee has been established to assist the Board in fulfilling its oversight responsibilities with respect to the following areas: The Corporation's external audit function; internal control and management information systems; the Corporation's accounting and financial reporting requirements; the Corporation's compliance with law and regulatory requirements; the Corporation's risks and risk management policies; and such other functions as are delegated to it by the Board. Specifically, with respect to the Corporation's external audit function, the Audit Committee assists the Board in fulfilling its oversight responsibilities relating to: The quality and integrity of the Corporation's financial statements; the independent auditors' qualifications; and the performance of the Corporation's independent auditors.

The Audit Committee is intended to facilitate and provide a means of open communication between management, the external auditors and the Board.

#### **Composition and Qualifications**

The Audit Committee shall consist of as many members as the Board shall determine, but in any event, not fewer than three members who are appointed by the Board. The composition of the Audit Committee shall meet all applicable independence, financial literacy and other legal and regulatory requirements. More specifically, all members of the Audit Committee shall be "unrelated" and "financially literate" and at least one member shall have "accounting or related financial experience", as such terms are defined by the TSX Corporate Governance Guidelines<sup>1</sup> or such other applicable law, rule or guideline.

The Board shall designate the Chairman of the Audit Committee and, in so doing, shall consider the recommendation of the Corporate Governance and Nominating Committees. The Chairman shall have responsibility for overseeing that the Committee fulfills its mandate and duties effectively.

Each member of the Audit Committee shall continue to be a member until a successor is appointed, unless the member resigns, is removed or ceases to be a director. The Board, following consideration of the recommendation of the Corporate Governance and Nominating Committees, may fill a vacancy which occurs in the Audit Committee at any time.

#### **Meetings**

The Chairman of the Audit Committee, in consultation with the Audit Committee members, shall determine the schedule and frequency of the Audit Committee meetings, provided that the Audit Committee will meet at least four times in each fiscal year and at least once in every fiscal quarter. The Audit Committee shall have the authority to convene additional meetings as circumstances require. A

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<sup>1</sup> Section 475(13) of the TSX Guidelines defines "financial literacy" as the ability to read and understand a balance sheet, an income statement, a cash flow statement and the notes attached thereto and "accounting or related financial experience" as the ability to analyse and interpret a full set of financial statements including the notes attached thereto, in accordance with generally accepted accounting principles.

schedule for each of the meetings will be disseminated to Audit Committee members prior to the start of each fiscal year. A detailed agenda for each meeting will be disseminated to Audit Committee members as far in advance of each meeting as is practicable.

The Audit Committee shall meet separately, periodically, with management, counsel and the external auditors. The Audit Committee shall meet separately with the external auditors at every meeting of the Audit Committee at which external auditors are present.

### **Responsibilities**

The Audit Committee is mandated to carry out the following responsibilities:

#### **External Auditors**

Subject to applicable law, the Audit Committee shall be responsible for the appointment, compensation, oversight and termination of the external auditor. The external auditor shall report directly to the Audit Committee and shall be accountable to the Board and Audit Committee as representatives of the shareholders.

The Audit Committee shall pre-approve all non-audit mandates for services the external auditor shall undertake.

The Audit Committee shall satisfy itself, on behalf of the Board, that the external auditor is independent of management. In assessing such independence, the Audit Committee shall discuss with the external auditors, and may require a letter from the external auditor outlining, any relationships between the external auditors and the Corporation or its affiliates.

The Audit Committee shall review the audit plan of the external auditors, the integration of the external audit with the internal control program, and the results of the audit, which shall include reviewing the external auditor's letter to management and management's response thereto and other material written communications between management and the external auditors.

The Audit Committee shall satisfy itself, annually or more frequently as the Audit Committee considers appropriate, as to the external auditors' internal quality control procedures and any material issues raised by the most recent internal quality control review, or peer review, of the external auditor, or by any public enquiry, review, or investigation by governmental, professional or other regulatory authorities.

The Audit Committee shall periodically review and discuss with management and the external auditors the quality and acceptability of the Corporation's accounting policies and practices, the materiality levels which the external auditors propose to employ, any significant changes in the accounting policies and any proposed changes in accounting or financial reporting that may have a significant impact on the Corporation.

The Audit Committee shall discuss with management and the external auditors all alternative treatments of financial information within generally accepted accounting principles that have been discussed with management by the external auditors, the ramifications of these alternative treatments and the treatment preferred by the external auditors.

#### **Financial Information**

The Audit Committee shall discuss with management and the external auditors whether the audited annual financial statements present fairly (in accordance with Canadian generally accepted accounting principles) in all material respects the financial condition, results of operations and cash flows of the

Corporation as of and for the periods presented and, where appropriate, recommend for approval to the Board, the annual audited financial statements of the Corporation.

The Audit Committee shall discuss with management and the external auditors whether the unaudited quarterly financial statements present fairly (in accordance with generally accepted accounting principles) in all material respects the financial condition, results of operations and cash flows of the Corporation as of and for the periods presented and, where appropriate, recommend for approval to the Board, the unaudited quarterly financial statements of the Corporation.

The Audit Committee shall review the Annual Report to Shareholders and other financial information (including the annual and quarterly Management's Discussion and Analysis of Financial Condition and Results of Operations, the Annual Information Form and any prospectus or offering circular) prepared by the Corporation with management and, where appropriate, recommend for approval to the Board and recommend for filing with regulatory bodies.

The Audit Committee shall review any news releases and reports to be issued by the Corporation containing earnings guidance or financial information for research, analysts and rating agencies. The Audit Committee shall also review the Corporation's policies relating to financial disclosure and the release of earnings guidance and the Corporation's compliance with financial disclosure rules and regulations.

The Audit Committee shall discuss with management and the external auditors important trends and developments in financial reporting practices and requirements and their effect on the Corporation's financial statements.

### **Internal Control**

The Audit Committee shall oversee the adequacy and effectiveness of the Corporation's internal control systems, through discussions with the Corporation's external auditors and management and shall report to the Board on an annual basis.

The Audit Committee shall review annually the Corporation's Code of Business Conduct and its effectiveness and enforcement.

### **Risk Management**

The Audit Committee shall review with management the principal risks facing the Corporation, and the policies, processes and procedures for management's monitoring and managing of such risks or exposures. If necessary, the Audit Committee will mandate, monitor and evaluate the steps management has taken to monitor and manage such exposures, including insuring against such risks, where appropriate.

### **Compliance with Legal and Regulatory Requirements**

The Audit Committee shall review, with management and any internal or external counsel as the Committee considers appropriate, any legal matters (including the status of pending litigation) that may have a material impact on the Corporation and any material reports or inquiries from regulatory or governmental agencies.

The Audit Committee shall review with counsel the adequacy and effectiveness of the Corporation's procedures to ensure compliance with the legal and regulatory responsibilities.

## **Other**

The Audit Committee shall also perform such other activities related to this Charter as requested by the Board.

The Audit Committee shall review and assess the adequacy of this Charter annually and shall submit any proposed changes to the Board for approval.

The Audit Committee may delegate its authority and duties to subcommittees or individual members of the Committee as it deems appropriate.

## **Reporting**

The Audit Committee shall report its deliberations and discussions regularly to the Board and shall submit to the Board the minutes of its meetings.

## **Resources**

The Audit Committee shall have the authority, in its sole discretion, to retain independent legal, accounting and other consultants to advise the Audit Committee at the expense of the Corporation. The Audit Committee shall be provided with the necessary funding to compensate the external auditors and any other advisors they engage.

The Audit Committee may request any officer or employee of the Corporation or the Corporation's external counsel or external auditors to attend a meeting of the Audit Committee or to meet with any member of, or consultants to, the Audit Committee. The Audit Committee shall have full access to all of the Corporation's books, records, facilities and personnel.

## **Complaints Procedure**

Any director, officer or employee who has any concern or complaints regarding accounting, internal control or auditing matters, any potential violations of law or regulatory provisions, unethical or illegal conduct may, in accordance with the Code of Ethical Conduct and Business Practices, make an anonymous submission through the Bioniche portal pursuant to the Company's policy on Reporting of Unlawful Activity. The concern/complaint will be anonymously directed to the Lead Director of the Corporate Governance and Nominating Committee as well as an appointed representative of the Company's Legal Department. Such submissions are not traceable to the sender by either the Company or its IT department.

For shareholders and those without access to the Bioniche portal, submissions may be made in writing, marked confidential, and deposited in the Legal Department's internal mail slot or mailed to the Company, marked confidential, to the attention of the Lead Director of the Corporate Governance and Nominating Committee. The unopened envelope will be forwarded to the Lead Director for review. The Lead Director of the Corporate Governance and Nominating Committee and Legal Department representative will conduct an investigation with the assistance of the Audit Committee and internal departments within the Company, as deemed appropriate. The complaint will be investigated according to established procedures for review. Where action is deemed warranted, action will be taken to resolve the situation which has been the source of the complaint.

### **Limitation on the Oversight Role of the Audit Committee**

Nothing in this Charter is intended, or may be construed, to impose on any member of the Committee a standard of care or diligence that is in any way more onerous or extensive than the standard to which all members of the Board are subject.

Each member of the Committee shall be entitled, to the fullest extent permitted by law, to rely on the integrity of those persons and organizations within and outside the Corporation from whom he or she receives financial and other information, and the accuracy of the information provided to the Corporation by such persons or organizations.

While the Audit Committee has the responsibilities and powers set forth in this Charter, it is not the duty of the Audit Committee to plan or conduct audits or to determine that the Corporation's financial statements and disclosures are complete and accurate and in accordance with generally accepted accounting principles in Canada and applicable rules and regulations. These are the responsibility of management and the external auditors.