EXECUTIVE INFORMATIONAL OVERVIEW

Bioniche Life Sciences Inc.
231 Dundas Street East
Belleville, Ontario K8N 1E2
Tel: (613) 966-8058 or (800) 265-5464
Fax: (613) 966-4177
www.bioniche.com

Novel Technologies for Cancer, Animal Health, and Food Safety

Snapshot

February 13, 2009

Bioniche Life Sciences Inc. ("Bioniche" or "the Company") is a Canadian biopharmaceutical company that aims to improve the quality of life in both humans and animals through innovative research, technologies, and therapeutics. To develop the proprietary platform technologies that the Company uses to create human and animal therapeutic agents, Bioniche is structured in three global business units: (1) Bioniche Therapeutics (Human Health); (2) Bioniche Animal Health; and (3) Bioniche Food Safety. The Company's most advanced Human Health product candidate is Urocidin™, a treatment for **non-muscle-invasive bladder cancer**† that entered Phase III clinical development in late 2006 after the U.S. Food and Drug Administration (FDA) granted Bioniche **Fast Track** status. A second Phase III trial is likely to begin under the FDA's **Special Protocol Assessment (SPA)** and Fast Track designations after the current Phase III trial is fully enrolled and when financing is available. Bioniche Animal Health markets over 100 products globally, developing products that enhance reproductive performance in animals and reduce the animal health industry's reliance on **antibiotics**. Its line of reproductive products comprises Bioniche Animal Health's largest sales category, with fiscal 2008 revenues of C$17.5 million. A lead Animal Health product is Folltropin®-V, a reproductive hormone that induces **superovulation** in cattle and sheep. Bioniche Food Safety develops veterinary biopharmaceuticals to improve the safety of human food and water supplies. Its most significant initiative is Econiche™, a vaccine administered to cattle that reduces the level of ***Escherichia coli* (*E. coli*) O157:H7** that cattle **shed**, thus minimizing the risk of human illness from contaminated food or water. The vaccine was fully licensed in Canada in October 2008. In addition, in mid-2008, the Company secured C$25 million in government funding for a vaccine production facility scale-up in Belleville, Ontario, Canada, as part of a long-term C$107 million project to create an Animal Health and Food Safety Vaccine Manufacturing Centre.

Recent Financial Data

Ticker (Exchange)	BNC (TSX)*
Recent Price (02/12/2009)	C$0.50
52-week Range	C$0.30 – C$1.12
Shares Outstanding**	~71.1 million
Market Capitalization	~C$35.6 million
Average 3-month Volume	53,853
Insider Owners +5%	<10%
Institutional Owners	~25%
EPS (Qtr. ended 12/31/2008)	(C$0.03)
Employees	200

** Share data in Canadian dollars (C$). At 02/12/2009, C$1.00 = ~US$0.80. ** At December 31, 2008.*

Key Points

Note: Unless otherwise stated, all monetary amounts are in U.S. dollars.

- The Company expects the first Phase III trial for Urocidin™ to be fully enrolled during the first quarter 2009, with safety and efficacy data available one year after full enrollment is achieved.
- The oncology market is forecast to reach $75 billion to $80 billion by 2012. Within this market, in the U.S. and EU, approximately 200,000 new cases of bladder cancer occur each year.
- In October 2008, the **Canadian Food Inspection Agency (CFIA)** granted full licensing approval for Econiche™, the Company's cattle vaccine against *E. coli* O157:H7. Econiche™ is now available for unrestricted use by Canadian cattle producers and veterinarians. In addition, Econiche™ was deemed eligible for a **U.S. Department of Agriculture (USDA)** conditional license in early 2008.
- *E. coli* O157:H7 causes considerable human illness, affecting over 73,000 people and resulting in 2,100 hospitalizations and over 60 deaths in the U.S. each year. Previously, the beef industry had no scientifically validated and licensed on-farm vaccine to reduce problems posed by this pathogen.
- Bioniche has over 300 patents and patent applications for its technologies, as well as a committed employee base with an integrated leadership team that is experienced in a range of key disciplines.
- At December 31, 2008, Bioniche had cash and cash equivalents of over C$5.6 million. The Company expects to supplement its cash position with partnering activities in 2009.

†**BOLD** WORDS ARE REFERENCED IN THE GLOSSARY ON PAGES 63-66.

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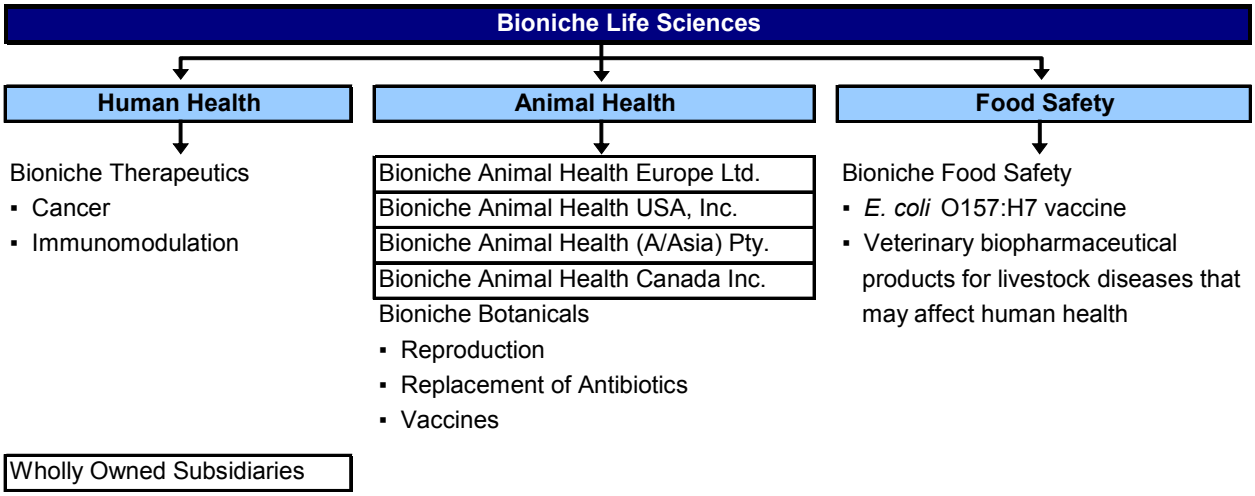
Executive Overview

Note: Unless otherwise stated, all monetary amounts are in U.S. dollars. At 02/12/2009, US$1.00 = ~C$1.24.

Bioniche Life Sciences Inc. ("Bioniche" or "the Company") is a Canadian biopharmaceutical company that seeks to improve the quality of life for both humans and animals worldwide through the discovery, development, manufacturing, and marketing of proprietary products. The Company operates as three global business units: (1) Bioniche Therapeutics (Human Health); (2) Bioniche Animal Health; and (3) Bioniche Food Safety. Within these areas, the Company is focused on developing a pipeline of effective therapies for human bladder, **peritoneal**, and prostate cancers, among others (Human Health); designing technologies that can replace antibiotics in livestock and improve animal reproduction (Animal Health); and establishing food safety vaccines, the first of which is Econiche™, a cattle vaccine that could help reduce the transmission of pathogenic *Escherichia coli* (*E. coli*) O157:H7 into humans (Food Safety). Table 1 summarizes the Company's global organization and focus areas, highlighting the operating focus of each of Bioniche's three business units.

Table 1
Bioniche Life Sciences Inc.
GLOBAL CORPORATE STRUCTURE AND FOCUS AREAS



Sources: Bioniche Life Sciences Inc. and Crystal Research Associates, LLC.

Bioniche Therapeutics (Human Health)

Operating as Bioniche Therapeutics, the Human Health unit is the Company's primary research arm, responsible for developing many of the technologies used in both the Human Health and Animal Health business units. Bioniche Therapeutics has developed the following proprietary platform technologies: (1) **mycobacterial** cell wall-DNA complex (MCC); (2) **oligonucleotides**; and (3) **hyaluronic acid (HA)**. Bioniche's marketed human HA applications have been divested, but the technology continues to be used in select Animal Health products. The Human Health unit also creates proprietary human therapeutic medicinal products. The most advanced product candidate is Urocidin™, an MCC suspension formulation to treat non-muscle-invasive bladder cancer. The Company's MCC technology platform also has the potential to treat other oncology indications, including muscle-invasive bladder, prostate, breast, colon, and ovarian cancer. Bioniche's strategy for the Human Health unit is to develop therapies through clinical proof of concept, and subsequently establish partnerships (where appropriate) to complete clinical studies, acquire regulatory approvals, and market products.

Mycobacterial Cell Wall Technology and MCC

The leading therapeutic platforms for the Human Health unit are mycobacterial cell wall technologies, which are based on the utilization of cell wall fragments from a bacterium called *Mycobacterium phlei* (*M. phlei*). MCC technology is composed of *M. phlei* cell wall fragments that are complexed with the bacteria's

deoxyribonucleic acid (DNA) to form a cell wall-DNA composition. The cell wall complex is fractionated and purified to optimize the presence of DNA. DNA is the active principle component of the molecule that is at least partially responsible for the **immunomodulatory** and direct anticancer activities. The MCC suspension formulation is sterile to ensure that it contains no live microorganisms and that it is free of animal or preservative byproducts, resulting in a decreased risk to patients.

MCC induces **apoptosis** (programmed cell death) in tumor cells and stimulates anticancer **cytokine** production by activating immune **effector cells** (i.e., inducing immune stimulatory and immunomodulatory activity). MCC also has immune **adjuvant** activity, demonstrated by its ability to promote an antibody response against antigens. Bioniche believes that MCC's chemotherapeutic, immunomodulatory, and safety profile characteristics are unique among cancer therapies, and may offer potential in patients who have been immunocompromised by age or prior chemotherapy or whose cancer is refractory (unresponsive) to conventional treatments due to **multidrug resistance (MDR)** and **cell cycle** mutations. Moreover, Bioniche believes that MCC could be used both independent of, and in conjunction with, existing therapies. Combination treatments using MCC are expected to be most effective in treatment-resistant cancers.

In addition to its bladder cancer trials (detailed below and on pages 25-27 under Urocidin™: Mycobacterial Cell Wall Technology for Bladder Cancer), Bioniche intends to proceed with human trials of MCC formulations for other cancer indications as well. Based on preclinical proof-of-principle studies, a specific MCC formulation is also intended to treat tumors that have spread into the abdomen, such as **mesothelioma** and metastatic ovarian and colorectal cancers.

Urocidin™

Urocidin™ is an MCC suspension formulation used to treat bladder cancer. It is infused into the bladder by catheter, where it comes into contact with both cancer and immune system cells. Urocidin™ is initially being developed to treat non-muscle-invasive bladder cancers—those that are still localized to the bladder wall. Non-muscle-invasive bladder cancer is thought to have one of the more stringent treatment **endpoints** in oncology—a "complete response" endpoint, which is defined as a complete lack of tumor, as measured by urine cytology, **cystoscopy** (visual examination) of the bladder, and a bladder biopsy.

In Bioniche's Phase I and II clinical trials of mycobacterial cell wall technologies, patients with non-muscle-invasive **carcinoma *in situ*** who had failed to respond to a conventional therapy—**Bacillus Calmette-Guérin (BCG)**—were treated with the Company's mycobacterial cell wall formulations. In this population, over 45% of patients who received a dose of 8 milligrams (mg) had a complete response in clinical evaluations at weeks 12 and 26. In contrast to BCG, the current **standard of care**, the formulations in these trials were demonstrated to be safe and well tolerated. Unlike MCC, BCG contains live bacteria, which have been found to cause discomfort and inflammation, local and systemic infections, and even fatalities.

Based on its Phase I/II clinical results, Bioniche Therapeutics initiated a two-stage Phase III clinical program for Urocidin™. The first stage, which received the U.S. Food and Drug Administration's (FDA) Fast Track status in May 2006, is intended for patients with non-muscle-invasive bladder cancer that is unresponsive to BCG. This 105-patient trial began in November 2006 and is ongoing at 31 investigational sites across North America. The U.S. Fast Track status provides the potential for expedited FDA review and the ability to file submission documents on a rolling basis, which can serve to accelerate final product approval. In May 2008, over two-thirds of the patients had been enrolled. The Company expects enrollment to be completed in early 2009.

Once full enrollment is achieved in the first Phase III trial, the second Phase III trial is expected to initiate, running concurrently with the first study and commencing when financing is available. The trial seeks to compare Urocidin™ to BCG as a **first-line therapy** in patients with non-muscle-invasive bladder cancer who are at a high risk of cancer recurrence or progression. This trial has both Special Protocol Assessment (SPA) and Fast Track status with the FDA. An SPA is an agreement where, in exchange for a company accepting the agency's input on trial design, the FDA commits to approve the product if the agreed endpoints are reached. While an SPA provides no guarantee of success due to manufacturing and other considerations, it indicates that the FDA agrees with the specific trial design and endpoints.

Bioniche is actively seeking a strategic partner to aid in funding the completion of clinical studies and regulatory filings for Urocidin™, as well as for marketing purposes. Bioniche is currently, and will likely continue to be, the manufacturer of Urocidin™. Bioniche is positioning the pricing of Urocidin™ against chemotherapeutics used to treat bladder cancer. Valstar™ (valrubicin) was an FDA-approved, but now currently unavailable, treatment for **cystectomy**-ineligible patients with BCG-refractory bladder cancer. With a complete response rate of 8% to 16% in BCG-refractory patients, Indevus Pharmaceuticals Inc. (IDEV-NASDAQ), the maker of Valstar™, applied to reintroduce the drug into the U.S. market in April 2007. However, in December 2007, Indevus announced that it had received a non-approvable letter from the FDA due to deficiencies in a third-party manufacturing facility. If this product is reintroduced, Bioniche believes that it may be priced at a substantial premium to BCG in the range of $1,000 per dose for its six-dose regimen. Valstar™ was removed from the market in 2002 due to impurities in its formulation.

Bioniche's Phase III programs aim to improve response rates and tolerability versus existing treatment options. For first-line non-muscle-invasive bladder cancer patients at a high risk of progression, the current treatment is surgical tumor removal (where possible) and BCG **immunotherapy** or chemotherapy. In these patients, Bioniche seeks to generate a response rate that is non-inferior to BCG with enhanced safety and tolerability. For non-muscle-invasive bladder cancer patients who are refractory to BCG treatment, therapy options include surgical removal of the bladder, repeat treatment with BCG, BCG plus **interferon**, or Valstar™ and other unapproved therapies. In these patients, Bioniche targets improved response rates as well as better safety and tolerability. The Company believes that if it can accomplish these targets, its bladder cancer opportunity could be considerable, with a regimen pricing similar to that of Valstar™.

Market Size

The global oncology market was projected to exceed $48 billion in 2008, and is predicted to expand at a compound annual growth rate (CAGR) of 12% to 15% to reach $75 billion to $80 billion by 2012 (Source: IMS Health, Inc. [RX-NYSE] 2008). Moreover, it was estimated that there could be almost 69,000 new cases of bladder cancer in the U.S. during 2008, with over 14,000 disease-related deaths (Source: the American Cancer Society [ACS]). Worldwide, there are approximately 330,000 new cases of bladder cancer each year and 30,000 deaths resulting from the disease. Because bladder cancer generally affects older individuals, these numbers are likely to increase as the global population ages. By 2050, nearly two billion adults over age 60 are expected to be alive, almost triple the 700 million people over 60 who were alive in 2006.

The current therapeutic standard of care for non-muscle-invasive bladder cancer is BCG. This microorganism was initially developed at the turn of the 20th century as a human vaccination against *Mycobacterium tuberculosis*. Approximately 30 years ago, BCG was introduced as a treatment for bladder cancer. While an estimated 30% to 80% of treated patients initially respond to BCG (induction therapy), studies have established that only a small portion of patients (roughly 16%) can fully tolerate the best possible treatment regimens. The inability to complete treatment may limit clinical outcomes and lead to the unnecessary recurrence of tumors. Moreover, approximately 60% to 70% of treated bladder cancer patients experience recurrences, for which BCG becomes less effective with every successive course of therapy. BCG is available in a generic formulation that costs approximately $125 per dose for 21 or more doses. However, bio-containment and disposal requirements, as well as side effects associated with its use that require additional therapy, are believed to significantly increase BCG's point-of-use cost.

Bioniche Animal Health

Established in 1979, Bioniche Animal Health is the Company's longest running operating unit. Bioniche's management believes that, as measured by sales, this unit is one of the largest Canadian-owned animal health biopharmaceutical companies. Global revenues in the Animal Health business have been stable for the last several years: C$27.7 million in fiscal 2008 and roughly C$27.5 million for the same period in 2007. This unit comprises four wholly owned subsidiaries (as listed in Table 1 [page 3]) and a network of global distributors that market the Company's veterinary biopharmaceutical products worldwide. Revenues generated by the Animal Health unit help Bioniche to balance risk, drive innovation, develop products, and support growth at all levels of the Company. This unit supplies niche products to the veterinary market (as listed in Table 11 [pages 30-31]) and has partnerships with many universities that are active in medical and veterinary research.

Bioniche Animal Health's research and development initiatives are focused on two primary outcomes: (1) improving reproductive performance in animals through the use of reproductive hormones and embryo transfer therapies; and (2) reducing the industry's reliance on antibiotics for animal healthcare by using immunotherapeutics and developing effective vaccines. Through its reproduction, embryo media, and embryo transfer equipment and products, the Company seeks to safely maximize the quantity of fertilized embryos that can be transferred with a high probability of producing high-value pregnancies in both commercial and research settings. For example, Bioniche Animal Health's lead product, Folltropin®-V, induces superovulation in cattle and sheep, which causes the ovaries to produce multiple egg follicles. Bioniche believes that Folltropin®-V is the leading follicle-stimulating agent in every major market in the world where it is available for sale.

Bioniche Animal Health also manages the Company's mycobacterial cell wall extract (MCWE) technology, which was the precursor to the Human Health unit's MCC product. MCWE is an immunotherapeutic anti-infective agent designed as an alternative to antibiotics. It is the active ingredient in select immunology products such as SETTLE®, which was the first U.S. Department of Agriculture (USDA)-approved biologic to aid in the treatment of **equine endometritis**, a bacterial infection that affects 25% to 30% of **broodmares** globally. SETTLE® has proven to be a safe, fast-acting, and effective alternative to the antibiotics typically used to treat equine endometritis. In a **challenge study** of 30 endometritis-susceptible mares, SETTLE® cleared infections from 80% of mares with an **intrauterine** administration and 70% of mares with **intravenous** administration after only seven days.

Industry Overview

Antibiotic usage in food-producing animals is causing widespread concern because of the emergence of antibiotic-resistant bacterial strains in the human population. Accordingly, government and regulatory agencies increasingly seek to control the use of antibiotics. Because one of Bioniche's fundamental business objectives is disease prevention via immunomodulation rather than antibiotic or chemical therapeutic agents, the Company expects that trends toward more stringent regulations on products used in animals could present significant opportunities for its Animal Health business.

In 2007, the global animal health market was valued at $17.9 million, which represented approximately 11.4% nominal growth (4.7% real growth) from 2006 (Source: Vetnosis Ltd., a research and consulting firm specializing in global animal health and veterinary medicine). Bioniche believes that the current global market is valued at roughly C$20.5 billion, largely due to the industry's expansion of products for companion animals (e.g., horses, cats, and dogs). As pets continue to become recognized as "family members," the Company anticipates that growth of high-value treatments in this sector is likely to persist.

Of relevance to the reproductive segment of the large animal healthcare market is that over 878,000 bovine embryo transfers were performed during 2005 (the latest year for which data is available from the International Embryo Transfer Society), more than a 10% increase from 2004. Further, roughly 25,000 sheep embryos were transferred in 2005, as well as over 7,000 goat embryos and approximately 14,000 horse embryos. Bioniche expects the growth rate in this market to be modest, with the ability of embryo transfer to rapidly improve herd quality continuing to make embryo transfer a popular practice among leading cattle and swine breeders and producers.

Bioniche Food Safety

The Food Safety business unit was established in July 2001 to develop veterinary biopharmaceutical products that improve the safety of human food and water supplies worldwide. At present, the Food Safety unit's primary initiative is the development and production of Econiche™, a cattle vaccine to decrease the transmission of pathogenic *E. coli* O157:H7 bacteria from cattle to humans. The toxin-containing O157:H7 strain is responsible for the most serious human *E. coli* infections globally and primarily originates from the intestines of healthy cattle. In September 2007, the vaccine was used for the first time by commercial beef producer Top Meadow Farms, a company that raises beef cattle in Ontario and Saskatchewan, Canada. In February 2008, the USDA agreed that it would grant a conditional license for the vaccine, pending the satisfaction of select statutory conditions. The Canadian Food Inspection Agency (CFIA) originally approved Econiche™ for distribution to Canadian veterinarians under a **Permit to Release Veterinary Biologics**. In September 2008, Bioniche received notice from the CFIA indicating that Econiche™ met safety and efficacy requirements, and full licensure was granted in October 2008.

The vaccine is intended to reduce the presence of *E. coli* O157:H7 in cattle. By doing so, it decreases the level of these bacteria in manure, on hides, in ground water, and throughout meat processing plants—all areas that lead to contaminated food and water products. The Company has tested its vaccine in over 30,000 cattle, with results demonstrating a consistent decrease in the number of cattle that shed *E. coli* O157:H7 in their manure or had bacteria colonize their terminal rectal mucosa. For example, in one controlled experiment, Econiche™ demonstrated a 99.47% reduction in shedding from vaccinated cattle. A number of peer-reviewed articles have been published related to the vaccine and its efficacy, including those listed in Table 17 (page 62) in the Appendix. Additionally, Bioniche intends to continue supporting research on the current vaccine as well as next-generation iterations.

Econiche™ was developed in partnership with the University of British Columbia, the Vaccine and Infectious Disease Organization (VIDO) at the University of Saskatchewan, and the Alberta Research Council. This strategic alliance was established in September 2000, with Bioniche holding the global rights to commercialize the vaccine. In April 2004, Bioniche established two academic Research Chairs at VIDO to accelerate the development of vaccines to minimize contamination in food and water. Through the Chairs, Bioniche benefits from research focusing on vaccines against *Campylobacter jejuni* (*C. jejuni*), *Salmonella enteritidis* (*S. enteritidis*), and other animal-to-human transmitted pathogens. *C. jejuni* is a leading cause of bacterial diarrheal illness in the U.S., and *S. enteritidis* is a bacterium found in meat, dairy products, and raw or undercooked eggs.

Foodborne Illnesses

Annually, there are roughly 76 million cases of foodborne diseases in the U.S., with roughly 325,000 hospitalizations and 5,000 deaths (Source: World Health Organization [WHO] 2007). In 2005, roughly 1.8 million people died of diarrheal diseases due to tainted food and drinking water globally. Since *E. coli* O157:H7 was first identified in 1982, outbreaks have been documented in over 30 countries on six continents. Well-known *E. coli* outbreaks include Walkerton, Ontario, Canada (toxic drinking water that sickened nearly 50% of the town), Salinas Valley, California (contaminated spinach), Topps Meat Co., now out of business (21.7 million pounds of contaminated meat), and the Taco Bell Corp. restaurants, a division of Yum! Brands, Inc. (YUM-NYSE) (contaminated food). Moreover, the meat industry will likely see an increase in positive *E. coli* tests beyond 2008, as the USDA's Food Safety Inspection Service implements more stringent laboratory methods to detect the bacteria in beef products. It is clear that the presence of this bacterium in the human food chain has serious consequences if left uncontrolled. Further, the economic cost of such outbreaks is valued in the billions for both Canada and the U.S.

Company Information

Founded in 1979, Bioniche has been operational for almost 30 years. Mr. Graeme McRae (biography on page 10), chairman, president, and chief executive officer (CEO), founded the Company as a small, private animal health products company in Ontario. Supported by local veterinarians, Bioniche sought to develop medicines and vaccines that could reduce the use of antibiotics in the livestock industry. In 1992, Mr. McRae expanded the Company's animal health discoveries to human health applications. In July 1999, it became a publicly traded company that continues to research, develop, manufacture, and market human and animal health products worldwide.

Headquarters and Employees

Bioniche employs 200 people across its three operational divisions. Headquartered in Belleville, Ontario, the Company's 137,000-square foot headquarters include a main office and manufacturing and filling facilities for Folltropin®-V, Colimune®-Oral, and Econiche™, among other products. As part of a long-term C$107 million project to create a state-of-the-art manufacturing facility, the Company has initiated a C$25 million scale-up project for its Belleville facility, which may take up to two years to complete. A 100-acre research and production farm is located nearby. In addition, Bioniche maintains 47,000 square feet in Montréal, Québec, for its Human Health division's operations and related MCC manufacturing; 2,400 square feet in Athens, Georgia, for U.S. sales offices and immunotherapeutic manufacturing; 7,600 square feet in Pullman, Washington, for media manufacture; and 75,000 square feet in Armidale, Australia, for veterinary biologics manufacturing, with 350 acres of land. With a global presence and a portfolio of developing products and technologies, Bioniche believes that it is poised for further growth.

Growth Strategy

At the corporate level, Bioniche operates based on a three-tiered strategy, as outlined below:

(1) Continually improve the therapeutic value of the Company's proprietary technologies for both human and animal use through product development and intellectual property;

(2) Ready these technologies for commercialization either alone or with strategic marketing partners; and

(3) Manufacture as many of the products as possible to increase the Company's profit margins, protect the integrity of its products, and enhance long-term shareholder value.

The Company's business model centers on having the ability to execute in key areas: preclinical research and discovery, technology evaluation and validation, production process development, clinical research, commercial-scale manufacturing, regulatory affairs, and final product commercialization. Bioniche may pursue partnering agreements to add financial resources or for distribution of its product candidates. However, when appropriate, the Company prefers to retain control of its products through late-stage development, including the manufacturing process, to better ensure successful commercialization and to optimize overall returns.

The Company has two strategic priorities: (1) successful completion of the Phase III clinical program of Urocidin™ in the treatment of non-muscle-invasive bladder cancer; and (2) full registration of Econiche™, the *E. coli* O157:H7 cattle vaccine, beyond Canada.

Urocidin™: Mycobacterial Cell Wall Technology for Bladder Cancer

In May 2008, the first of two Phase III clinical trials for Urocidin™ exceeded two-thirds of the 105-patient enrollment level. Once full enrollment is obtained (expected in early 2009), enrollment for the second Phase III trial is likely to begin, assuming that financing is available. Although Bioniche raised approximately C$10 million in 2007 (as part of a C$17.5 million equity financing) to fund the Phase III trials of Urocidin™, it anticipates also requiring strategic collaborations to fully finance the trials. Bioniche continues to consider development and marketing partners in the bladder cancer field, and has been working with an agent to partner this product, with milestone payments and royalties on sales expected to accrue to Bioniche. Both trials have received Fast Track designation from the FDA for expedited review and the ability to file submission documents on a rolling basis to accelerate final product approval.

Econiche™: the Cattle Vaccine Against E. coli O157:H7

In late 2006, the Canadian Food Inspection Agency (CFIA) approved Bioniche's *E. coli* O157:H7 vaccine for distribution to Canadian veterinarians under a Permit to Release Veterinary Biologics. The CFIA granted full licensure of Econiche™ in October 2008. In addition, the U.S. Department of Agriculture (USDA) stated that the latest data for the Company's *E. coli* vaccine met the "expectation of efficacy" standard. Thus, the vaccine became eligible for a conditional license in the U.S., which Bioniche is currently working toward (as more fully detailed on page 42). Based on these advances, Bioniche Food Safety continues to progress toward full licensure in the U.S. as well as in other countries. To reach these goals, Bioniche added Dr. Gary Weber to the Food Safety management team, formerly of the USDA and the National Cattlemen's Beef Association. In addition, the Food Safety unit is scaling up production of the Econiche™ vaccine. In mid-2008, Bioniche announced the full receipt of C$25 million of the required financing for the scale-up, which is in progress and likely to be completed in two years. The scale-up was mainly funded through Canadian and Ontario government programs.

Intellectual Property

Bioniche believes in establishing solid, long-term intellectual property protection for its technologies, products, product candidates, and other patentable discoveries. In addition, the Company strives to be innovative, creating new intellectual property and patent families that may extend or expand its current coverage. Whenever possible, Bioniche actively seeks composition, method, or use patents for its technologies and products.

During fiscal 2008 (ended June 30, 2008), the Company was issued 34 patents in various major international jurisdictions for its technologies, comprising two patents issued for the MCC technology; one related to the MCWE technology; 23 pertaining to the oligonucleotide technology; and eight related to Bioniche's reproductive technology. In total, the Company has obtained or filed over 300 patents and patent applications. Table 2 summarizes the Company's worldwide intellectual property position for a selection of its major technology platforms at the end of fiscal 2008. For Bioniche's largest growth drivers—MCC (Urocidin™) and the in-licensed Econiche™ cattle vaccine—the first issued U.S. patents do not expire until late 2018. Both of these patents also have a possible extension period through late 2023.

Table 2
Bioniche Life Sciences Inc.
INTELLECTUAL PROPERTY POSITION

Technology	Number of Patent Applications Pending	Number of Patents Issued or in the EP* Validation Stage	Total Number of Patents and Applications per Technology
MCC	16	113	129
MCWE	4	46	50
Oligonucleotides	60	61	121
Hyaluronan	0	4	4
Botanical	11	1	12
Reproductive	1	23	24
Antiviral	29	2	31
Total	121	250	371

** EP = European Patent*

Note: Econiche™ is protected by a patent stream not included in this table.

Source: Bioniche Life Sciences Inc.

In addition, as production of biologics is complex, Bioniche believes that this inherent protection provides significant barriers to other companies that may seek to create equivalent products. As with many recombinant and naturally derived biologics, the production of generic or "biosimilar" versions is difficult.

Company Leadership

Management

Bioniche's executive management team combines the experience of members who have been with the Company for over 20 years with the fresh perspectives of more recently hired individuals. Table 3 summarizes Bioniche's key management, followed by detailed biographies.

Table 3
Bioniche Life Sciences Inc.
MANAGEMENT

Graeme McRae	Chairman, President, and Chief Executive Officer
Cindy Benning	Vice President, Operations, Corporate Quality, and Regulatory Affairs
François Charette, M.D., MBA	Senior Vice President and Chief Medical Officer
Rick Culbert	President, Bioniche Food Safety
Mohamed Elrafih	Vice President, Manufacturing Operations
Andrew Grant	Divisional President, Bioniche Animal Health Export Sales, Europe and Australia
Cameron Groome	Executive Vice President, Corporate and Strategic Development
Bruce McLeod	Vice President, Human Resources
Patrick Montpetit, CA	Vice President and Chief Financial Officer
Jim Phillips	President, Bioniche Animal Health (global)
Nigel C. Phillips, Ph.D.	Senior Vice President and Chief Scientific Officer
Dragan Rogan, Ph.D., DVM	Vice President, Research and Development, Bioniche Animal Health
Jennifer Shea	Vice President, Communications, Investor and Government Relations
Richard Sutin, LL.B.	Corporate Secretary (interim)
Gary Weber, Ph.D.	President, Bioniche Food Safety (U.S.)

Source: Bioniche Life Sciences Inc.

Graeme McRae, Chairman, President, and Chief Executive Officer (CEO)

Graeme McRae is the founder of both Vetrepharm Animal Health and Bioniche Inc., the predecessor companies to Bioniche Life Sciences Inc. Born in Australia, Mr. McRae has had a lengthy and diversified career in the pharmaceutical industry in both Australia and Canada. In 1971, he joined Pfizer Animal Health (a division of Pfizer Inc. [PFE-NYSE]) in Australia and held various sales and managerial positions. He was transferred to Canada in 1975. In 1979, Mr. McRae founded Vetrepharm Animal Health to focus on research and development in animal health, with a keen desire to develop non-antibiotic solutions for animal health problems. He founded Bioniche Inc. in 1992 to develop Vetrepharm's technologies for human health applications. In May 2008, the Board of Directors named Mr. McRae as chairman, in addition to his roles as president and CEO.

Cindy Benning, Vice President, Operations, Corporate Quality, and Regulatory Affairs

Cindy Benning joined the Company in 1993 as quality control supervisor. She was appointed to the position of vice president, corporate quality and regulatory affairs in December 2001. In July 2005, she took on additional responsibilities related to the Company's operations with a new title of vice president of operations, corporate quality, and regulatory affairs. She has held various positions in quality control and regulatory affairs. Ms. Benning holds a technology diploma in biological sciences from St. Clair College and graduated with a B.S. from the University of Waterloo in 1998. With her extensive experience in **Good Manufacturing Practices (GMP)**, current GMP (cGMP), and 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.

François Charette, M.D., MBA, Senior Vice President and Chief Medical Officer

Dr. François Charette brings over 20 years of combined experience in hospital practice and the pharmaceutical industry. Most recently, he was the general manager and senior vice president of Quintiles Canada, Inc. (a division of Quintiles Transnational Corp.), leading the Canadian affiliate since 2003. Dr. Charette has also served as vice president of scientific affairs at Berlex Canada Inc. (now Bayer HealthCare Pharmaceuticals, Inc.), director of professional and hospital services at the Centre hospitalier Anna-Laberge, director of research at Bristol-Myers Squibb Co. (BMY-NYSE), and associate director of research at Hoechst Canada Inc., after spending 12 years in hospital practice. He earned an M.D. at the University of Montréal and an MBA from Concordia University (Montréal, Québec).

Rick Culbert, President, Bioniche Food Safety

Rick Culbert has an animal health technology diploma from Centralia College of Agricultural Technology and is a graduate of the Advanced Agricultural Leadership Program at the University of Guelph. He joined Bioniche (then Vetrepharm) in 1980 as Ontario regional manager. Mr. Culbert 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 subsequently as president of Bioniche Food Safety in July 2007. Mr. Culbert is also a member of the Canadian Animal Health Institute's Board of Directors.

Mohamed Elrafih, Vice President, Manufacturing Operations

Mohamed Elrafih graduated from the University of Western Ontario with a B.S. in microbiology. He has more than 19 years of experience in the pharmaceutical industry. Mr. Elrafih joined Bioniche in 1984 and became vice president, manufacturing operations in November 2001. He is responsible for all manufacturing and plant operations for Bioniche.

Andrew Grant, Divisional President, Bioniche Animal Health Export Sales, Europe and Australia

Andrew Grant joined Bioniche in 1998 as general manager, Bioniche Animal Health Australia and New Zealand. In 2001, he was promoted to managing director and held that position until his transfer in 2004 to managing director of Animal Health, Europe and the Middle East. In 2007, Mr. Grant was promoted to his current position. He holds a certificate in marketing from the University of Technology in Sydney, Australia. He is also a member of the Australian Institute of Company Directors. Prior to Bioniche, Mr. Grant was a national field and product manager for Boehringer Ingelheim GmbH in Australia.

Cameron Groome, Executive Vice President, Corporate and Strategic Development

Cameron Groome joined the Company in June 2006 and currently serves as the executive vice president, corporate and strategic development. He graduated with a B. Comm., finance and marketing from Concordia University. Mr. Groome previously headed the life sciences investment banking activities for two major Canadian investment dealers: (1) National Bank Financial (2000 to 2004); and (2) Blackmont Capital (2004 to 2006). He has over 17 years of experience, including as a top-ranked equity analyst (1991 to 2000), industry commentator, investment banker, and strategic advisor in the Canadian life sciences industry.

Bruce McLeod, Vice President, Human Resources

Bruce McLeod joined Bioniche in May 2008 as vice president, human resources. Mr. McLeod has seven years of experience in both operations and human resources. Most recently, he served as director of human resources with Farm Credit Canada, Canada's largest provider of business and financial services to farms and agribusinesses. Mr. McLeod previously served as human resources manager with the Saskatchewan Workers' Compensation Board and as an instructor in the business division of the Saskatchewan Institute of Applied Science and Technology. He graduated with a B.A. from Carleton University and a certificate in adult education from Saint Francis Xavier University.

Patrick Montpetit, CA, Vice President and Chief Financial Officer (CFO)

Patrick Montpetit joined the Company in August 2000 as vice president, finance and CFO. Mr. Montpetit is a chartered accountant (CA) with a specialty designation in corporate finance and experience in the biopharmaceutical industry. Currently, he is chairman of the Québec Biotechnology Association (BioQuébec) and a director of the Montréal InVivo industry association. Mr. Montpetit was formerly the director of finance, administration, commercial agreements, and alliances with DSM Biologics Inc., a multinational pharmaceutical company based in Montréal and the Netherlands. Prior to joining Bioniche, he also served as a consultant to a number of biotechnology companies.

Jim Phillips, President, Bioniche Animal Health (global)

Jim Phillips joined Bioniche in 1985 as a sales representative, having previously been a 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. In July 2007, he became president, Bioniche Animal Health (global). Mr. Phillips graduated from the University of Guelph with a diploma in agriculture and has since taken numerous management leadership courses. He also has a longstanding interest in horse racing and sport horses.

Nigel C. Phillips, Ph.D., Senior Vice President and Chief Scientific Officer

Dr. Nigel C. Phillips joined Bioniche in 1996 and has a 24-year research background in biochemistry, immunology, immunopharmacology, and immunomodulatory drug development and formulation. He has directed research programs at the Strangeways Research Laboratory, Cambridge; the Institut Pasteur de Paris; McGill University, Montréal; Université de Montréal; and the Institut Pasteur de Lille. Dr. Phillips received industry training at the pharmaceutical arm of Reckitt & Colman (now Reckitt Benckiser plc [RB-LSE]). He received undergraduate qualifications from the North East London Polytechnic and Institute of Biology in London, England, and undertook postgraduate training at Queen Elizabeth College, University of London. He has a Ph.D. from the University of London.

Dragan Rogan, Ph.D., DVM, Vice President, Research and Development, Bioniche Animal Health

Dr. Dragan Rogan received a Ph.D. in virology and cell-mediated immunity at the University of Belgrade, Yugoslavia, after completing a Master's and a Doctorate in veterinary medicine. He was a university professor of microbiology and immunology in Belgrade before becoming a visiting scientist at the Vaccine and Infectious Disease Organization (VIDO) in Saskatoon, Saskatchewan, in 1986. Dr. Rogan obtained a Ph.D. and came to Canada in 1989, when he joined Bioniche as senior scientist. He went on to become scientific director and then vice president of research and development for Bioniche Animal Health. Dr. Rogan leads a team of researchers with expertise in bacteriology, biochemistry, molecular biology, reproductive physiology, and virology.

Jennifer Shea, Vice President, Communications, Investor and Government Relations

Jennifer Shea joined Bioniche as vice president of communications and investor and government relations in April 2004. For 18 years, Ms. Shea previously worked in progressive corporate communications positions with hospitals in Kingston and Belleville, Ontario. Ms. Shea graduated from Loyalist College with a diploma in broadcast journalism.

Richard Sutin, LL.B., Corporate Secretary (interim)

Richard Sutin is a senior partner and lawyer with Ogilvy Renault LLP in Toronto, Ontario. Mr. Sutin handles capital market transactions as well as mergers and acquisitions for private and publicly traded corporations; provides ongoing corporate and securities law advice to issuers and financial intermediaries; regularly advises Boards of Directors and special Board Committees; and mediates shareholder disputes. Mr. Sutin was called to the Ontario Bar in 1977 after graduating with an LL.B. from Osgoode Hall, York University, and a B.A. (honors) also from York. He is currently a member of Ogilvy Renault's Executive Committee and a co-chair of the firm's Cleantech Team. Mr. Sutin is also a past member of the Advisory Committee to the Ontario Securities Commission.

Gary Weber, Ph.D., President, Bioniche Food Safety (U.S.)

Dr. Gary Weber joined Bioniche in 2008 after working as a self-employed consultant helping select clientele to deal effectively with the forces of change affecting the food and agriculture sector in the U.S. Dr. Weber previously worked with the USDA as national program leader for animal science, and with the National Cattlemen's Beef Association as director of animal health, inspection, and science policy, and as executive director of regulatory affairs. Dr. Weber holds B.Sc. and M.Sc. degrees in animal science from Purdue University and a Ph.D. from Michigan State University.

Board of Directors

Bioniche's Board of Directors oversees the conduct of and supervises the Company's management. Bioniche separates the roles of its management and its corporate governance, reflected in the composition of its Board of Directors. The Board maintains a clear majority of non-management directors. In addition, the Board comprises Audit, Compensation, Corporate Governance and Nominating, Scientific Audit, and Risk Management Committees. Table 4 lists Bioniche's Board members, followed by detailed biographies.

Table 4
Bioniche Life Sciences Inc.
BOARD OF DIRECTORS

Graeme McRae	Chairman, President, and Chief Executive Officer
Stanley Alkemade, DVM	Director
Armen Aprikian, M.D., F.R.C.S.(C)	Observer
Albert Beraldo, CA	Director
Margaret Cunningham, Ph.D., MBA	Director
Pierre-Yves Desbiens, CA, MBA	Director
James Johnson, Ph.D., J.D.	Director
The Honorable Lyle Vanclief	Director

Source: Bioniche Life Sciences Inc.

Graeme McRae, Chairman, President, and Chief Executive Officer

Biography on page 10.

Stanley Alkemade, DVM, Director

Dr. Stanley Alkemade received a veterinary degree from the University of Melbourne, Australia. He returned to Canada in 1971 and ran a mixed veterinary practice in Seaforth, Ontario, for 10 years. He has lectured in the Animal Health Technology Program at the Centralia College of Agricultural Technology. In 1986, he joined Vetrepharm Canada as technical director and was responsible for research and development, product registrations, corporate technical services, and facilities design. He is currently the president of BioMedEx, a project management firm for the pharmaceutical industry.

Armen Aprikian, M.D., F.R.C.S.(C), Observer

Dr. Armen Aprikian is head of the Division of Urology, Department of Surgery at McGill University and is the interim chief of the Department of Oncology at the McGill University Health Centre. He is also a fellow of the Royal College of Physicians and Surgeons of Canada. Dr. Aprikian earned an M.D. through the Faculty of Medicine at the University of Sherbrooke (Québec, Canada) and joined the Urology Training Program there upon graduating. He completed his residency at the McGill University Urology Residency Program (Montréal, Québec) before attending Memorial Sloan-Kettering Cancer Center in New York. Dr. Aprikian subsequently joined the Department of Urology at Montréal General Hospital as an attending surgeon. He served various academic and clinical roles in the Departments of Surgery (Division of Urology) and Oncology before becoming head of the Division of Urology, Department of Surgery at McGill University and interim chief of the McGill University Health Centre's Department of Oncology. To date, Dr. Aprikian's research has primarily focused on prostate and bladder cancers. Dr. Aprikian has received

several awards and honors, including the Everett C. Reid Award for Excellence in Teaching, which he received on three occasions, and the American Society of Clinical Oncology Investigator Award. He was also named the McGill University William Dawson Scholar, and has been an invited lecturer locally, nationally, and internationally in addition to holding numerous visiting professorships.

Albert Beraldo, CA, Director

Albert Beraldo is the president of Alveda Pharmaceuticals Inc., a closely held Canadian company that is a leading supplier of pharmaceuticals to the Canadian healthcare market. Mr. Beraldo formerly served as president and CEO of Bioniche Pharma Group Limited until 2005. He also served as a director of Bioniche Life Sciences Inc. from 1984 to 2005. Mr. Beraldo has a Bachelor's of Commerce from the University of Windsor and has CA designation from the Canadian Institute of Chartered Accountants. He worked in public accounting with Ernst & Whinney (now Ernst & Young) until he joined Vetrepharm Ltd. as financial controller in 1983. Mr. Beraldo has held several positions within the group of companies that amalgamated to form Bioniche, and had a major role in the formation of Bioniche Inc., one of the amalgamating companies.

Margaret Cunningham, Ph.D., MBA, Director

Dr. Margaret Cunningham has a Ph.D. in marketing from Texas A&M University and an MBA from the University of Calgary. Dr. Cunningham is the director of the School of Business, associate dean, and the R. A. Jodrey Chair in the Faculty of Management at Dalhousie University in Halifax, Nova Scotia. She is an award-winning teacher and widely published author. She served as associate professor of marketing at the School of Business at Queen's University in Kingston, Ontario, until late 2008. She had been a professor in the School of Business at Queen's University since 1989.

Pierre-Yves Desbiens, CA, MBA, Director

Pierre-Yves Desbiens is vice president, finance at PureCell 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 PureCell Technologies, Mr. Desbiens held roles as vice president, finance and administration and CFO of Supratek Pharma Inc.; vice president, finance and administration at Chronogen, Inc.; and investment portfolio manager, life sciences at the Québec Solidarity Fund QFL, a venture capital institutional investor in the Canadian life sciences sector. Prior to the Fund, Mr. Desbiens was CFO and general manager of Horizon Sciences & Technologies Inc., a biopharmaceutical company based in Montréal. Before joining the healthcare sector, Mr. Desbiens held different positions in corporate finance with mid-size to multinational corporations, including Domtar Inc., Price Waterhouse (merged with Coopers and Lyband in 1998 to become PricewaterhouseCoopers International Limited), and Oceanix Inc.

James Johnson, Ph.D., J.D., Director

Dr. James Johnson has a Ph.D. in biochemistry as well as a law degree from Emory University, and is a partner of King & Spalding LLP based in Atlanta, Georgia. He has extensive experience in chemical and biotechnology patent prosecution and licensing. Dr. Johnson has served on the Board of Directors of U.S. public life sciences companies and, when required, has also undertaken the role of acting CEO. He performed a postdoctoral fellowship at the Scripps Institute of Oceanography. Dr. Johnson has experience as a faculty member at the Emory University School of Medicine's Departments of Biochemistry and Medicine with an appointment in the Division of Infectious Diseases and as a senior research scientist with the Veterans Administration Hospital Research Laboratories.

The Honorable Lyle Vanclief, Director

The Honorable Lyle Vanclief is a former minister of agriculture and agri-food in the federal government of Canada who is currently employed as an agricultural and agri-food consultant. He served as a member of Parliament in 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 spent 25 years as an agricultural entrepreneur in his home community of Ameliasburg, Ontario. He graduated with a B.S. in agriculture from the University of Guelph in 1966. Mr. Vanclief is an independent director with key responsibilities for governance matters.

Core Story

Bioniche Life Sciences Inc. (“Bioniche” or “the Company”) is a Canadian biopharmaceutical company that is committed to improving the quality of life for both humans and animals worldwide through innovative research, novel technologies, and therapeutics. The Company operates in three global business units: (1) Bioniche Therapeutics (Human Health); (2) Bioniche Animal Health; and (3) Bioniche Food Safety. Each of these units, with their respective products and technologies, is detailed on the accompanying pages.

Bioniche Therapeutics (Human Health)

Note: Unless otherwise stated, all monetary amounts are in U.S. dollars. At 02/12/2009, US$1.00 = ~C$1.24.

The Company's Human Health business, Bioniche Therapeutics, seeks to commercialize human therapeutic medicinal products. This unit continues to develop current technology platforms (e.g., mycobacterial cell wall technology) as well as develop new platforms, including mycobacterial cell wall-DNA complex (MCC) and oligonucleotides. These technologies enable the development of oncology, immunostimulant, and immunomodulation treatments—areas where Bioniche believes that there is a need for safer, more efficacious therapies.

Bioniche Therapeutics' most advanced product candidate is Urocidin™, a potential treatment for non-muscle-invasive bladder cancer based on the Company's MCC technology. Bladder cancer is not considered to be muscle invasive if it is contained within the two innermost layers of the bladder wall—the transitional epithelium (composed of urothelial cells) and the lamina propria (a thin layer of connective tissue). The third layer of the bladder wall is a zone of smooth muscle tissue. Once the cancer spreads into this area, it is called muscle-invasive bladder cancer. Bladder cancer is more fully detailed on pages 18-21, and additional product candidates of Bioniche Therapeutics are listed in Figure 3 (page 24).

Bioniche Therapeutics conducts research through its laboratories at the National Research Council Biotechnology Research Institute (NRC-BRI) in Montréal, Québec. The NRC-BRI is one of the largest Canadian research and development facilities for biotechnology, biochemical engineering, and molecular level biology. This business unit has made a number of significant discoveries since its inception in 1998:

- Characterizing the unique ability of MCC to directly kill cancer cells by inducing apoptosis;
- Identifying oligonucleotide sequences with anticancer and immunomodulatory activities;
- Observing that contaminating material in hyaluronan preparations gives rise to inflammatory cytokine production and consequently developing a cleaner hyaluronan preparation; and
- Recognizing MCC's effectiveness against multidrug-resistant (MDR) cancer cells.

CANCER

Cancer results when the body begins to produce abnormal cells that grow uncontrollably by evading recognition and attack from the immune system. Cancer cells actively promote immune tolerance, and as such, the immune system does not often view cancer cells as foreign or diseased. Accordingly, cancer cells can grow without inhibition into a large tumor mass. Tumors are classified as either benign or malignant. Although benign tumors may cause life-threatening complications, they do not spread to other areas of the body. Conversely, malignant tumors can spread (metastasize) to other local tissues as well as travel throughout the blood to more distant organs. Cancer that has spread is still named after its source location but is referred to as metastatic (e.g., metastatic bladder cancer). Cancer that is detected early, before it has spread to other areas, has the best prognosis. Surgical removal of a tumor is much less effective once tumor cells have invaded additional locations, many of which are undetectable without resorting to time-consuming and costly procedures.

The American Cancer Society (ACS) estimated that there would be over 12.3 million new cancer diagnoses and roughly 7.6 million deaths worldwide during 2007. Approximately 38% of these cases were expected to have occurred in developed nations (Source: *Global Cancer Facts & Figures 2007*). Furthermore, the ACS predicts 27 million new cancer cases and 17.5 million cancer deaths by 2050, primarily due to a rapidly aging population (as detailed on page 20). Altogether, the relative lifetime risk of a male developing cancer is one in two; for women, the risk is one in three. In addition, even after an individual's cancer has been treated and cleared, it may appear again months or years later, called cancer recurrence. Table 5 (page 17) from the ACS estimates the new cases and related deaths in 2008 for a variety of cancers common in the U.S. Cancers that Bioniche Therapeutics seeks to address are highlighted in light blue in Table 5.

Table 5

ESTIMATED NEW CANCER CASES AND DEATHS, U.S., 2008*

	Estimated New Cases			Estimated Deaths		
	Both Sexes	Male	Female	Both Sexes	Male	Female
All sites	**1,437,180**	**745,180**	**692,000**	**565,650**	**294,120**	**271,530**
Oral cavity & pharynx	35,310	25,310	10,000	7,590	5,210	2,380
Tongue	10,140	7,280	2,860	1,880	1,210	670
Mouth	10,820	6,590	4,230	1,840	1,120	720
Pharynx	12,410	10,060	2,350	2,200	1,620	580
Other oral cavity	1,940	1,380	560	1,670	1,260	410
Digestive system	271,290	148,560	122,730	135,130	74,850	60,280
Esophagus	16,470	12,970	3,500	14,280	11,250	3,030
Stomach	21,500	13,190	8,310	10,880	6,450	4,430
Small intestine	6,110	3,200	2,910	1,110	580	530
Colon†	108,070	53,760	54,310	49,960	24,260	25,700
Rectum	40,740	23,490	17,250			
Anus, anal canal, & anorectum	5,070	2,020	3,050	680	250	430
Liver & intrahepatic bile duct	21,370	15,190	6,180	18,410	12,570	5,840
Gallbladder & other biliary	9,520	4,500	5,020	3,340	1,250	2,090
Pancreas	37,680	18,770	18,910	34,290	17,500	16,790
Other digestive organs	4,760	1,470	3,290	2,180	740	1,440
Respiratory system	232,270	127,880	104,390	166,280	94,210	72,070
Larynx	12,250	9,680	2,570	3,670	2,910	760
Lung & bronchus	215,020	114,690	100,330	161,840	90,810	71,030
Other respiratory organs	5,000	3,510	1,490	770	490	280
Bones & joints	2,380	1,270	1,110	1,470	820	650
Soft tissue (including heart)	10,390	5,720	4,670	3,680	1,880	1,800
Skin (excluding basal & squamous)	67,720	38,150	29,570	11,200	7,360	3,840
Melanoma	62,480	34,950	27,530	8,420	5,400	3,020
Other non-epithelial skin	5,240	3,200	2,040	2,780	1,960	820
Breast	184,450	1,990	182,460	40,930	450	40,480
Genital system	274,150	195,660	78,490	57,820	29,330	28,490
Uterine cervix	11,070		11,070	3,870		3,870
Uterine corpus	40,100		40,100	7,470		7,470
Ovary	21,650		21,650	15,520		15,520
Vulva	3,460		3,460	870		870
Vagina & other genital, female	2,210		2,210	760		760
Prostate	186,320	186,320		28,660	28,660	
Testis	8,090	8,090		380	380	
Penis & other genital, male	1,250	1,250		290	290	
Urinary system	125,490	85,870	39,620	27,810	18,430	9,380
Urinary bladder	68,810	51,230	17,580	14,100	9,950	4,150
Kidney & renal pelvis	54,390	33,130	21,260	13,010	8,100	4,910
Ureter & other urinary organs	2,290	1,510	780	700	380	320
Eye & orbit	2,390	1,340	1,050	240	130	110
Brain & other nervous system	21,810	11,780	10,030	13,070	7,420	5,650
Endocrine system	39,510	10,030	29,480	2,430	1,110	1,320
Thyroid	37,340	8,930	28,410	1,590	680	910
Other endocrine	2,170	1,100	1,070	840	430	410
Lymphoma	74,340	39,850	34,490	20,510	10,490	10,020
Hodgkin lymphoma	8,220	4,400	3,820	1,350	700	650
Non-Hodgkin lymphoma	66,120	35,450	30,670	19,160	9,790	9,370
Myeloma	19,920	11,190	8,730	10,690	5,640	5,050
Leukemia	44,270	25,180	19,090	21,710	12,460	9,250
Acute lymphocytic leukemia	5,430	3,220	2,210	1,460	800	660
Chronic lymphocytic leukemia	15,110	8,750	6,360	4,390	2,600	1,790
Acute myeloid leukemia	13,290	7,200	6,090	8,820	5,100	3,720
Chronic myeloid leukemia	4,830	2,800	2,030	450	200	250
Other leukemia‡	5,610	3,210	2,400	6,590	3,760	2,830
Other & unspecified primary sites‡	31,490	15,400	16,090	45,090	24,330	20,760

*Rounded to the nearest 10; est. new cases exclude basal and squamous cell skin cancers and in situ carcinomas except urinary bladder. About 67,770 female carcinoma in situ of the breast and 54,020 melanoma in situ will be newly diagnosed in 2008. †Est. deaths for colon and rectum cancers are combined. ‡More deaths than cases suggests lack of specificity in recording underlying causes of death on death certificates.

Source: the American Cancer Society, Inc., Surveillance Research (2008).

Areas targeted by Bioniche Therapeutics

While treatments vary based on the type of cancer involved, most therapies follow a general regimen: surgical removal of the tumor where possible, followed by radiation and/or chemotherapy that may be administered independently or concurrently depending on the level of cancer still present after surgery. In addition to radiation and chemotherapy, patients may be given a variety of adjuvant or second-line treatments, such as immunotherapy. Immunotherapy stimulates the body's natural defenses to recognize and attack cancer cells that had previously gone unnoticed or that are tolerated by the immune system.

However, even a combination of treatments may not be effective in treating all cancer metastases, and most therapies are associated with significant **toxicity** and side effects that often limit treatment. Both radiation and chemotherapy are indiscriminate, as they destroy healthy cells as well as tumor cells and thereby create many severe and potentially life-threatening complications, such as immunosuppression, anemia, vomiting, hair loss, fatigue, decreased blood cell counts, infertility, and damage to the heart, lungs, nerves, kidneys, or reproductive organs. As a result, many companies are focusing on the development of improved cancer treatments that have greater efficacy with less toxicity and that can take a targeted approach to cancer without affecting all bodily cells. This next generation of therapies includes immunotherapies, **anti-angiogenesis** agents, **monoclonal antibodies (MAbs)**, therapeutic and prophylactic cancer vaccines, adjuvant therapies, and gene therapies, among many others.

Bladder Cancer

While Bioniche Therapeutics develops therapies for a range of cancer indications, the unit is currently focused on the advancement of Urocidin™ for bladder cancer. Bladder cancer usually originates in the lining of the bladder, but may quickly spread deeper into the bladder wall and to nearby lymph nodes, where it can then metastasize to adjacent organs, creating a potentially incurable and fatal condition. The interior of the bladder is lined with a layer of urothelial cells, which also line the kidneys, the ureters (the tubes connecting the kidneys to the bladder), and the urethra. The prognosis for bladder cancer is better if it is caught before it begins to invade other tissues. However, once the cancer is no longer confined to the bladder lining, treatment can be extensive and difficult and the patient's life is at greater risk. Even after surgery to remove one or more tumors, roughly 60% to 70% of bladder cancers recur within two years.

It was estimated that there could be almost 69,000 new cases of bladder cancer in the U.S. during 2008, with over 14,000 individuals dying of the disease (Source: the ACS). Worldwide, there are approximately 330,000 new cases and 130,000 deaths per year.

Table 6

BLADDER CANCER SURVIVAL BY STAGE

Stage	Five-Year Relative Survival Rate
0	95%
I	85%
II	55%
III	38%
IV	16%

Source: the American Cancer Society, Inc.

Staging

The first symptom of bladder cancer is usually the presence of blood in the urine (hematuria). Once discovered, the cancer is staged according to its progression and level of metastasis. Stage 0 is the least serious and Stage IV is the most advanced, indicating a high level of spread. Most newly diagnosed cases are classified as either Stage 0 or I. Table 6 lists the percentage of patients at each stage living at least five years after their cancer is diagnosed. When cancer is caught in the later stages, survival rates greatly decrease. Patients who die of a separate disease (e.g., heart disease) are not counted in relative survival rates.

Risk Factors

The greatest risk factor for developing bladder cancer is smoking. However, exposure to other toxic industrial, agricultural, or environmental chemicals may also contribute to the genetic damage that causes bladder cancer. Smoking causes nearly 50% of deaths from bladder cancer among men and 28% in women. It occurs as ingested carcinogens become concentrated in the urinary tract and, with time, increasingly affect the urothelial cells. In addition, bladder cancer can be inherited, although this is believed to be a very rare occurrence.

In general, age, race, and gender all have a significant impact on an individual's likelihood of developing this disease. Men present the disease more often than women, and whites are more likely to develop this cancer than are blacks. In addition, more than 90% of bladder cancer diagnoses are in individuals over the age of 55, with 50% of cases in people over 73 (Source: the Mayo Foundation for Medical Education and Research). Table 7 summarizes risk factors for bladder cancer.

Table 7
RISK FACTORS FOR BLADDER CANCER

- Smoking—the single greatest risk factor due to the carcinogens in tobacco
- Repeated exposure to industrial chemicals, such as those used to manufacture dyes, rubber, leather, textiles, and paint products, as well as arsenic
- Age—the average age at diagnosis is 68 or 69
- Race—whites are twice as likely to develop bladder cancer than blacks or Hispanics
- Sex—men are four times more likely than women to contract bladder cancer
- Undergoing chemotherapy or radiation therapy for a separate cancer indication
- Chronic bladder inflammations/infections, such as can happen with the long-term use of a urinary catheter
- Personal or family history of bladder or related cancers
- Birth defects of the bladder that lead to adenocarcinoma, an unusual bladder cancer

Source: the Mayo Foundation for Medical Education and Research.

Typical Treatments

Currently, surgery is used to treat more than 90% of bladder cancers (Source: the ACS). These vary between minimally invasive **transurethral** tumor resections to a radical cystectomy, which removes the entire bladder, nearby lymph nodes, and the prostate (in men) or the uterus, ovaries, fallopian tubes, and a part of the vagina (in women). Based on cancer type and stage, radiation therapy, immunotherapy, and chemotherapy may also be utilized.

Bacillus Calmette-Guérin (BCG)

Bacillus Calmette-Guérin (BCG) is an immunotherapy that is commonly used in high-risk non-muscle-invasive bladder cancers. BCG is live bacteria that are also used as a human vaccination against tuberculosis in some countries. It was developed from *Mycobacterium bovis*, the causative organism of tuberculosis in cattle, at the start of the 20th century. Specifically, BCG is an attenuated strain of *Mycobacterium bovis*. The use of this organism as an immunotherapeutic was studied in the 1970s, and was first tested for activity against bladder cancer in the 1980s at Queen's University. Bioniche believes that approximately 65% of eligible patients with non-muscle-invasive bladder cancer respond to BCG therapy after the first course of treatment.

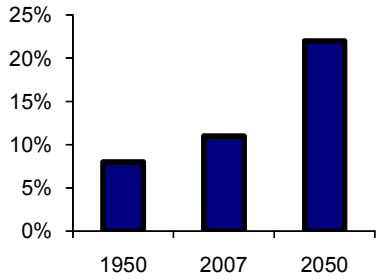
To treat such patients, BCG is administered directly into the bladder via a catheter on a weekly basis for six or more weeks (the induction phase). For patients who can tolerate ongoing treatment with BCG, longer courses of therapy are advised based on the results of several clinical studies. The currently accepted treatment protocol is a total of 21 doses over two years (the maintenance phase). There is some evidence that even longer maintenance—27 doses over three years—is more efficacious (Source: the *Journal of Urology* 2000). However, as published in the *Journal of Urology*, only 16% of patients were able to receive all scheduled doses of the longer regimen. Several doses were withheld to avoid severe toxicities and side effects.

BCG's mechanism of action is not clearly understood. When BCG bacteria are introduced into the bladder, immune cells are drawn to the bladder, where they are believed to attack the cancer. However, this treatment often causes flu-like symptoms accompanied by a burning sensation in the bladder. In addition, live bacteria can colonize the bladder, giving rise to chronic and debilitating **cystitis**, as well as systematically spreading throughout the body, producing **septicemia**, which can be lethal in some cases.

Market Opportunity

Valued at roughly $48 billion in 2008, oncology is one of the largest pharmaceutical markets. With the introduction of improved treatments, it is expected to continue to expand at a compound annual growth rate (CAGR) of 12% to 15% to reach between $75 billion and $80 billion by 2012. Moreover, the growth rate for the oncology market is nearly double the forecasted growth rate for the global pharmaceutical market as a whole (Source: IMS Health 2008). Overall costs of cancer in 2007 were estimated at $219.2 billion, composed of $89 billion for direct medical costs (total of all health expenditures), $18.2 billion for indirect morbidity costs (cost of lost productivity due to illness), and $112 billion for indirect mortality costs (cost of lost productivity due to premature death) (Source: the National Institutes of Health [NIH]). Specifically, bladder cancer is one of the more costly cancers in terms of healthcare expenditures. In the U.S., this indication has among the highest costs per patient from diagnosis to death of all cancers in the Medicare system (Source: the University of Birmingham's Unit of Genetic Epidemiology [UK]).

Figure 1
PROPORTION OF POPULATION 60 YEARS OR OVER: WORLD, 1950-2050



Source: World Population Ageing 2007 (Figure I).

The Effect of Aging Populations on Bladder Cancer

The global aging population is one factor, in particular, that is likely to affect the prevalence of bladder cancers. In developed countries, the number of older persons (those over 60 years) exceeded the number of children (those under 15 years) for the first time in 1998. Globally, this is expected to happen by 2047. By 2050, nearly two billion older persons are expected to be alive, almost triple the 700 million people over 60 who were alive in 2006 (Source: *World Population Ageing 2007* from the United Nation's Department of Economic and Social Affairs, Population Division). Figure 1 illustrates the predicted increase in the world's population aged 60 or older from 2007 to 2050.

Individuals over 80 years old are a rapidly increasing subset within this older population. This segment expands at 3.9% annually, far more than the population as a whole, which is increasing at 1.1% each year (Source: *World Population Ageing 2007*). Accordingly, with an aging population comes the need for improved healthcare services and treatments for the diseases that disproportionately affect older individuals, such as bladder cancer, among others.

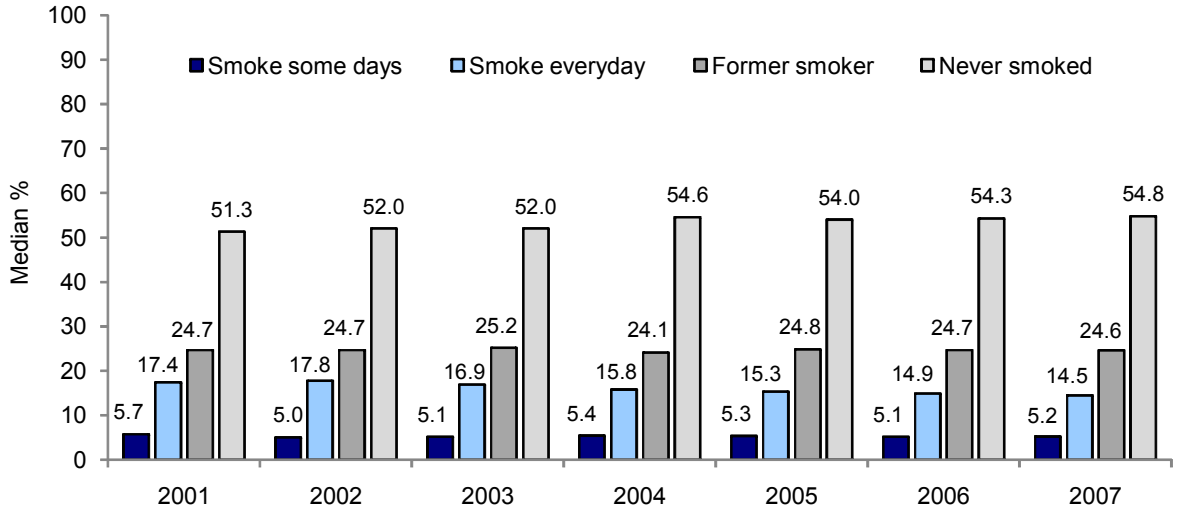
The Effect of Tobacco Use on Bladder Cancer

Tobacco use is the single greatest risk factor for bladder cancer, with smokers being more than twice as likely as nonsmokers to present with the disease (Source: the ACS). An individual's risk increases according to the number of cigarettes used daily and the number of years spent smoking. Therefore, as the population ages, those who continue to smoke or who were former smokers further add to their likelihood of bladder cancer, in addition to other tobacco-related diseases.

Approximately 25% of the U.S. population has a history of smoking, as illustrated in Figure 2 (page 21), while another 20% to 23% are current smokers (those who smoke either "some days" or "everyday"). This widespread tobacco use costs the U.S. approximately $193 billion annually in healthcare costs and lost productivity (Source: the Centers for Disease Control and Prevention's [CDC] *Morbidity and Mortality Weekly Report,* February 8, 2008).

Figure 2

MEDIAN PERCENTAGE OF U.S. POPULATION'S SMOKING STATUS (2001-2007)



** Data for each year includes 51 states (with D.C.), except 2004, for which only 50 locales reported.*

Sources: Crystal Research Associates, LLC and the National Center for Chronic Disease Prevention and Health Promotion's Behavioral Risk Factor Surveillance System.

PLATFORM TECHNOLOGIES

The accompanying pages provide a detailed description of Bioniche Therapeutics' proprietary platform technologies, as well as a summary of Urocidin™, the Company's lead mycobacterial cell wall product candidate in Phase III clinical testing.

Mycobacterial Cell Walls

Since its development in the early 1980s, the mycobacterial cell wall technology platform has been continually tested and refined through preclinical and clinical research at Bioniche. The technology uses a pure **culture** of the bacterium *M. phlei*. The *M. phlei* bacterium is widely located among soil, dust, and plants, as it grows upon decaying vegetable matter. However, this microorganism does not cause disease in humans.

The research and development program at Bioniche Therapeutics has created processes to isolate the cell wall-DNA complex of *M. phlei*. The Company identified DNA as one of the active components of the complex. The DNA is believed to regulate the complex's anticancer and immunomodulatory activities. To support Bioniche's belief of the MCC technology's effectiveness, the Company initiated several research programs testing MCC against various cancer indications. While some of these programs are still at a preclinical stage (as shown in Figure 3 [page 24]), two are in human clinical trials and have demonstrated that Bioniche Therapeutics' approach has both antitumor and immunomodulatory functions.

The most advanced iteration of the mycobacterial cell wall technology is Urocidin™, a bladder-specific formulation of MCC, which is currently in Phase III trials for non-muscle-invasive bladder cancer that has been unresponsive to previous treatments with BCG. Urocidin™ is prepared using *M. phlei* cell wall fragments and does not contain any animal or preservative byproducts. This decreases the risk of disease transmission or allergic reactions in patients who are administered MCC products. Furthermore, MCC is sterile, indicating that there are no live organisms in its preparation. Live bacteria can cause infections and other safety concerns.

MCC's Mechanisms of Action

MCC technology impacts cancer cells through cell cycle arrest and induction of apoptosis (programmed cell death), activation of immune effector cells (such as dendritic cells and monocytes), and stimulation of anticancer **chemokine** and cytokine production by immune effector cells (i.e., immunostimulatory and immunomodulatory activity). The technology also has immune adjuvant activity, as demonstrated by its ability to promote an antibody response against a range of antigens, including that used in the vaccination against hepatitis B. Bioniche believes that its combination of both chemotherapeutic and immunomodulatory characteristics is unique among cancer medications, as these properties provide MCC with potential for use in patients who are immunocompromised, have had prior chemotherapy, or whose cancer is resistant to conventional treatments due to multidrug resistance (MDR) and cell cycle mutations.

- *Cancer Cell Apoptosis.* Apoptosis is a series of programmed molecular steps that the body naturally undertakes in order to eliminate unwanted cells. In cancer cells, this cell death process is often blocked or circumvented. In spite of this, Bioniche has shown that MCC causes cell cycle arrest, inhibits proliferation, and subsequently induces apoptosis in many cancer cell types, including bladder, breast, leukemia, melanoma, colon, ovarian, and prostate cancer. Moreover, data to date has found that MCC can act synergistically with chemotherapeutic agents. Accordingly, there is the potential for combination treatments with chemotherapy and MCC that may enhance the activity of MCC or enable reduced chemotherapeutic dosages.

  Typically, cancer treatments that are unable to eliminate all of the tumor cells become less effective over time. As they are exposed to different chemotherapies, only the drug-resistant cells come to survive—eventually leaving only the MDR cells, against which most therapeutic agents have little effect. In contrast, MCC technology can inhibit the proliferation of, and cause apoptosis of, MDR cells as well as of cells with mutations in their cell cycle regulators. Cell cycle regulators are factors that control the events leading to cell division. Uncontrolled division due to improper cell cycle regulation results in diseases, such as cancer. An accumulation of mutations can produce cancer cells that are even more resistant to treatment, further decreasing the efficacy of conventional chemotherapeutic strategies. The anticancer activity of MCC does not appear to be affected by such mutations. As a result, the Company views MCC's ability to inhibit the proliferation of cancer cells and induce apoptosis even under difficult conditions, such as in MDR or cell cycle regulator-mutated cancer cells, as significant.

- *Immunomodulatory Activity.* In addition to apoptosis, MCC stimulates immunomodulatory activity by inducing monocytic cells, such as **macrophages** (a type of white blood cell), to release chemokines and cytokines, which affect the immune response in several ways. For instance, two of the cytokines that MCC induces are **interleukin 6 (IL-6)**, which is involved in inflammatory reactions, and **IL-12**, which prevents blood vessels from forming and feeding tumors and also stimulates the body's killer immune cells—natural killer (NK) cells and **cytotoxic T-lymphocytes**—to initiate an anticancer response. In particular, Bioniche has discovered that after intravesicular administration (given into the bladder by catheter), MCC increases levels of urinary chemokines and cytokines, as evidence of the technology's immunostimulant functions.

- *Immune Adjuvant Activity.* The Company has also conducted studies to determine MCC's immune adjuvant activity. MCC can work as a potent immune adjuvant at low doses. It induces antibodies against antigens, such as the hepatitis B surface antigen. These characteristics may enable use as a vaccine adjuvant to improve the immunogenicity of the vaccine by stimulating the immune system's production of more antibodies.

Scientific Data Supporting MCC Technology's Anticancer Activity

In April 2007, Bioniche Therapeutics presented data at the American Association for Cancer Research's (AACR) Annual Meeting demonstrating that MCC has significant anticancer activity against micro and macrometastasis in the peritoneal cavity of rats that had peritoneal colon carcinomatosis. This activity was seen following the **intraperitoneal** administration of MCC to animals with disseminated colon cancer. The peritoneal cavity contains the abdominal organs, and an intraperitoneal administration of a medication would entail injecting the substance directly into this area.

Further, the intraperitoneal administration of MCC was well tolerated and associated with significant anticancer activity. By month 12, 70% of rats administered nine doses of 0.625 milligrams (mg) of MCC were still alive. Conversely, only 10% of the untreated control rats were still alive at 12 months. The Company found comparable anticancer activity with higher MCC doses, 1.25 mg and 2.5 mg, as well.

Bioniche also examined MCC's anticancer and immunostimulant functions in canine osteosarcoma (a type of bone cancer) cell lines. Canine cancer typically exhibits similar qualities to human cancers, such as MDR and toxic treatments needing improved efficacy. In the Company's study, MCC technology inhibited proliferation and induced apoptosis of cancer cells, as well as interacted synergistically with anti-osteosarcoma chemotherapeutic agents.

In addition, Bioniche highlighted MCC's direct anticancer activity at the 2007 Annual Congress of the American Urological Association. The data presented showed that MCC could express comparable anticancer activity against low- and high-grade bladder cancer cell lines with a treatment time of only three hours. In contrast, BCG had variable activity against these cancer cell lines and required treatment times of 48 to 144 hours to express optimal anticancer activity.

Oligonucleotides

Oligomodulator™ technology, Bioniche's second proprietary platform, consists of a class of molecules that are composed of short oligonucleotides—small, single-stranded segments of DNA. The Company discovered these molecules in 2000 and has since determined that they have anticancer activity, immunostimulant and immunomodulatory properties, and other pharmacological activities. Preclinical research into the mechanisms of action of these oligonucleotides has shown that they cause cell cycle arrest and are capable of inducing terminal differentiation of apoptosis in cancer cells, thus inhibiting their proliferation. This technology is also bifunctional in that it is associated with chemokine and cytokine synthesis from mononuclear cells and immunomodulatory activity (vaccine adjuvant activity).

In 2002, Bioniche Therapeutics achieved preclinical proof of principle for its Oligomodulator™ platform when the Company tested BT99-25 (a lead oligonucleotide) against leukemia and lymphoma. In this study, BT99-25 demonstrated ***in vivo*** anticancer activity. In 2003, BT99-25 and BT99-45 provided preclinical proof-of-principle results that documented the technology's immunostimulant and vaccine adjuvant activities as well. By 2004, Bioniche Therapeutics' scientists had further clarified the mechanisms of action behind the technology's *in vivo* adjuvant activity. The Oligomodulator™ technology specifically has type 2 adjuvant activity by functioning as a co-stimulator of T-cells and also stimulating mature dendritic cells.

Moreover, Bioniche Therapeutics believes that its oligonucleotide platform has significant potential for development as a range of novel chemotherapeutic agents that could be applicable to a wide array of cancer types. In addition, the Company anticipates that its oligonucleotides could be developed in specific combinations to enable treatment of a select indication—a technique that may allow Bioniche to tailor pharmacological activity to the disease indication. For instance, the Company could create oligonucleotide combinations that are optimized to have anticancer activity or that are maximized for use as an adjuvant to enhance the immune response to vaccines (thus potentially increasing the efficacy of vaccines).

In May 2008, the Company presented data at the Immunopotentiators in Modern Vaccines Conference in Montego Bay, Jamaica. Dr. Nigel C. Phillips (biography on page 12), Bioniche's senior vice president and chief scientific officer, delivered the presentation entitled "Mycobacteria-derived immunopotentiating molecules and their application in vaccine development." The research focused on the development pathway from MCC to the Company's synthetic oligonucleotides, in addition to reviewing their immunostimulatory and immune adjuvant activity. The data demonstrated that Bioniche Therapeutics' proprietary, synthetic oligonucleotides have immunostimulant activity, which indicates potential as a vaccine adjuvant in addition to the previously reported direct anticancer activity. At present, Bioniche Therapeutics is undertaking toxicity studies of its oligonucleotides with the intent of filing an **Investigational New Drug (IND)** application in the future for one or more of its oligonucleotide candidates in order to begin Phase I clinical trials.

Hyaluronic Acid (HA)

Hyaluronic acid (HA) is a natural substance found within the **synovial fluid** in joints. It also occurs in both human and animal connective tissue, as well as in the **aqueous humor** of the human eye. HA is a lubricating and protective substance. The Company's work with HA has been focused on carefully selecting and preparing the material to maintain its purity.

At present, the Company is evaluating its HA technology in combination with the mycobacterial cell wall technology platform as a potential combination treatment for prostate cancer, as detailed below. Previously, Bioniche commercialized two products based on its HA platform technology—Cystistat® to treat symptoms of multiple forms of cystitis (bladder inflammation) and Suplasyn® to treat osteoarthritis. However, in May 2006, the Company sold Cystistat® to Bioniche Teoranta (County Galway, Ireland) for C$10 million. Bioniche Teoranta is a part of Bioniche Pharma Group Ltd., which was previously the Company's sterile injectables division, but was sold to RoundTable Healthcare Partners in May 2005. In addition, in December 2006, Bioniche sold its right to future royalties from Suplasyn®.

Mycobacterial Cell Wall Technology with HA for Prostate Cancer

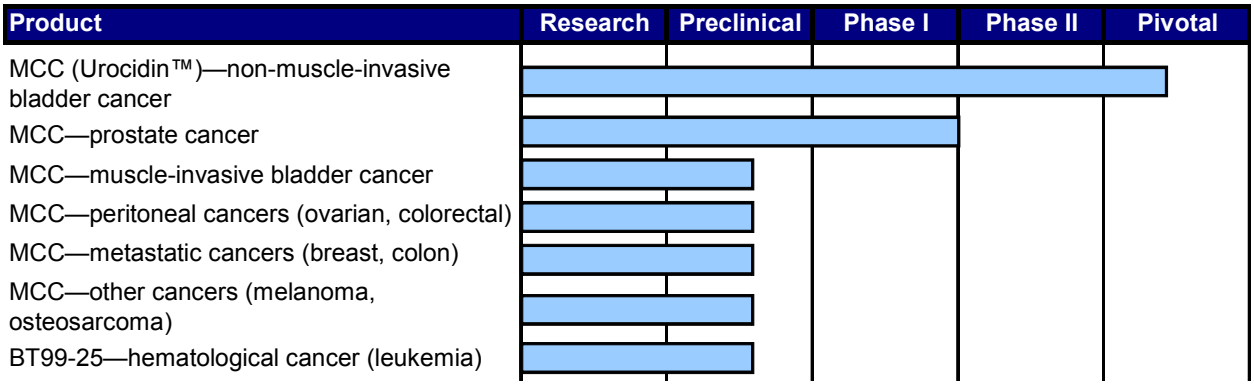
Prostate cancer is one of the most common malignancies affecting men. More than 65% of all prostate cancers occur in men over the age of 65, and it is estimated that by age 80, 90% of men may be diagnosed with the disease (Sources: Alvaro Morales, M.D., a urology and oncology professor at Queen's University [Kingston, Ontario] and the Prostate Cancer Foundation [www.prostatecancerfoundation.org]).

Bioniche completed a Phase I study in patients diagnosed with prostate cancer who were scheduled to receive a prostatectomy to remove all or part of the prostate. MCC combined with HA was injected into the prostate before the men underwent their surgeries. This Phase I study found that the technology can be safely administered to patients with prostate cancer. As this was a Phase I study, no efficacy data was obtained, and the feasibility and applicability of this approach to the treatment of prostate cancer remains to be determined.

PIPELINE CANDIDATES

Using its proprietary technologies, Bioniche develops candidates to treat a variety of human cancers. The Company's most advanced candidate, Urocidin™, is an MCC formulation to treat bladder cancer and is currently undergoing the first trial of a two-part Phase III clinical program. Figure 3 depicts Bioniche Human Health's product pipeline, including each candidate's targeted indication and development stage.

Figure 3
Bioniche Life Sciences Inc.
HUMAN HEALTH PRODUCT PIPELINE



Source: Bioniche Life Sciences Inc.

Urocidin™: Mycobacterial Cell Wall Technology for Bladder Cancer

As detailed on pages 21-23, mycobacterial cell wall technology consists of cell walls prepared from *M. phlei* and used for the treatment of disease. The initial iteration of the technology was termed mycobacterial cell wall extract (MCWE), which was followed by MCC with the discovery of the importance of the nucleic acids complexed to the cell walls. MCC was initially formulated as an emulsion and later as a suspension.

Phase I and I/II clinical programs were conducted with MCWE and MCC emulsions to determine safety and clinical efficacy in patients with non-muscle-invasive bladder cancer. The current Phase III programs are being conducted with the more advanced MCC suspension, Urocidin™, which has been accepted by the U.S. Food and Drug Administration (FDA) as being comparable.

Phase I/II Trial Results

Bioniche's Phase I study treated a small number of patients to test the mechanism of action for the technology. In this study, the formulation was well tolerated, safe, and biologically active. The Company then completed Phase I/II trials and presented the data at the American Urological Association's 99th Annual Meeting in May 2004. The Phase I/II trial was conducted in 55 patients with a superficial (non-invasive) carcinoma *in situ* that had been unresponsive to prior treatments with BCG or chemotherapy. Patients were given either a 4 mg or an 8 mg dose of MCWE or MCC emulsion and were then evaluated at 3, 6, 12, and 18 months.

In the course of the study, three patients stopped treatment. Of the patients who continued with therapy, 43% to 64% had a complete response at 12 months. In bladder cancer, a complete response is defined as the disappearance of all signs of the tumor in response to treatment. Cystoscopic examination, biopsies of the bladder wall, and urine cytology analyses were used to demonstrate that the patients in the study had a complete response. In contrast to BCG, Bioniche's formulations proved to be well tolerated and very few patients discontinued therapy due to side effects. From these results, as well as preclinical analyses, Bioniche determined that 8 mg was the most appropriate dose for its Phase III trials.

Ongoing Phase III Clinical Program for Urocidin™

The clinical program for Urocidin™ includes two separate Phase III trials. After the FDA granted Fast Track status in May 2006, the first of the Company's Phase III trials began in November 2006 in patients with non-muscle-invasive bladder cancer that is unresponsive to BCG. The second pivotal Phase III trial has not yet begun, but is scheduled to begin recruiting—also with Fast Track status—after the first trial has achieved full enrollment and when financing is available. The second trial will likely run concurrently with the first study.

Dr. Alvaro Morales (the international principal investigator) and Dr. Harry Herr (the North American principal investigator) are the lead investigators for the Phase III trials. Dr. Morales, who is on the American Urological Association/American Foundation for Urologic Disease's research committee, previously served as principal investigator for the mycobacterial cell wall technology's Phase I and Phase I/II trials. He is credited with the introduction of BCG as the current standard of care in high-risk bladder cancers. Dr. Herr is from the Memorial Sloan-Kettering Cancer Center (New York) and the New York Hospital-Cornell Medical Center.

The Company upgraded its Pointe-Claire, Québec, manufacturing facility in order to have sufficient product supply for its Phase III trials. In addition, over the past several years, new systems were purchased and installed, with every piece of equipment tested to confirm that it met current Good Manufacturing Practice (cGMP) requirements. Simultaneous to the facility's modifications, Bioniche Therapeutics worked to enhance its MCC technology to reduce manufacturing time, produce higher yields, and incorporate innovative sterilization methods. The Company first produced its new MCC formulations in June 2004 and is now producing sufficient quantities to complete clinical trials. Further, the ownership of an adjacent building allows Bioniche to prepare for commercial production without disrupting clinical supply.

The First Stage of Phase III: A Refractory Fast Track Trial

Patients who participate in the first Phase III trial have either **papillary tumors** or carcinoma *in situ*, which has a high risk of progressing. This study employs an **open-label** clinical trial protocol to establish the safety and efficacy of Urocidin™. Thirty-one North American urology centers are participating in the trial. In May 2008, the Company exceeded two-thirds enrollment of the 105 patients required for the study. Bioniche expects the trial to be fully enrolled in the first quarter 2009, and to be able to report initial results regarding efficacy and safety to the FDA one year after recruitment has ended. Nevertheless, Bioniche Therapeutics intends to follow participants for five years, per current clinical guidelines.

A 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, 105 evaluable patients must be enrolled and disqualifications have required the Company to recruit replacement patients.

Trials that are granted Fast Track status are offered expedited FDA review and the ability to file submission documents on a rolling basis, which can serve to accelerate final product approval. This trial's Fast Track status could facilitate product development and potentially expedite review of a **Biologics License Application (BLA)** or other regulatory submissions for Urocidin™. A BLA submission is targeted upon collection of 6- and 12-month response rates for the patients, supplemented by safety data on additional patients from another trial or trials.

An investigators' meeting was held in April 2007, which provided Bioniche Therapeutics with the opportunity to reiterate both its objectives for this trial and the previously obtained preclinical and clinical data on Urocidin™. The Company also communicated to investigators the expectations of recruitment, reporting, and site monitoring. The primary outcomes of this first Phase III trial are the patients' one-year disease-free survival rates. Secondary outcomes include disease-free survival rates at 3, 6, and 24 months, overall duration of disease-free survival, time to progression to muscle-invasive disease, overall survival, and the rate of overall drug-related side effects leading to treatment delays or discontinuations.

The Company meets with the Data Safety Monitoring Committee (an independent body) every three months to evaluate the progression of the trial. The committee's purpose is to ensure that the patients' safety is addressed properly and that there is an appropriate basis for continuing the trial from an efficacy point of view. In November 2008, Bioniche Therapeutics held its sixth scheduled meeting with the Data Safety Monitoring Committee. Due to the favorable progression of the trial, the committee recommended that the Company continue the trial unchanged until the next triggered or scheduled meeting.

Trial Design

Participants in the first stage of the Phase III trial receive weekly doses of 8 mg of Urocidin™ over a six-week induction period. After three months, patients are evaluated for disease progression. If patients are disease-free, they are then moved into maintenance therapy, where they receive weekly Urocidin™ doses for three-week periods at months 3, 6, 12, 18, and 24. Additional evaluations take place at months 6, 9, 12, 15, 18, 21, and 24. If patients continue to display non-muscle-invasive tumors at month three, the decision of whether to begin the maintenance phase or implement a second six-week induction course is left to the investigator. Individuals who have progressed to muscle-invasive disease by month three will likely be referred to other treatments. This process continues for each remaining evaluation date: disease-free participants continue maintenance treatments and disease-progressing patients discontinue treatment in favor of another medication. In the final 36 months of the study (the follow-up period), evaluations are scheduled at months 30, 36, 42, 48, 54, and 60. All evaluations include a standard cystoscopy, with a mandatory bladder biopsy at month six. Additional biopsies and urine cytology may also be conducted at the evaluations. Table 8 (page 27) summarizes the trial design.

Table 8

Bioniche Life Sciences Inc.

PHASE III TRIAL DESIGN: FIRST STAGE, 8 MG DOSES OF UROCIDIN™ ONCE A WEEK

Period	Scheduled Duration/Interval	Patient Receives the Following:
Induction	First 6 weeks	Weekly 8 mg doses
	At 3 months	Evaluation for disease recurrence or progression*
Maintenance	At 3, 6, 12, 18, and 24 months	Weekly 8 mg doses given for three weeks at each scheduled interval
	At 6 months	Mandatory bladder biopsy
	At 6, 9, 12, 15, 18, 21, and 24 months	Evaluation for disease recurrence or progression
Follow-up	At 30, 36, 42, 48, 54, and 60 months	Evaluation for disease recurrence or progression

** If, at any evaluation, patients are found to have disease progression, they will likely be removed from the study and referred to another treatment course.*

Sources: Crystal Research Associates, LLC and Bioniche Life Sciences Inc.

The Second Stage of Phase III: A Comparative Special Protocol Assessment (SPA) and Fast Track Trial

The second stage of the Phase III program seeks to compare the efficacy and safety of Urocidin™ to BCG as a first-line therapy in non-muscle-invasive bladder cancer patients who are at a high risk of cancer recurrence or progression. Since the Company is evaluating the efficacy of Urocidin™ as a first-line therapy, it is selecting patients who have not had any previous treatment for their cancer. This **double-blind** trial is estimated to include 800 patients from across North America, Australia, and Europe.

In September 2007, Bioniche Therapeutics and the FDA reached a Special Protocol Assessment (SPA) agreement relating to the second stage of the Company's Phase III clinical program. The SPA indicates agreement by the FDA on the study's design, including its endpoints, data analysis, and conduct. The primary endpoints established for second stage of the Phase III trials are disease-free survival after two years and safety, with the desired outcome being the demonstration that Urocidin™ is not inferior to BCG in terms of efficacy, but is superior to BCG in terms of safety. The SPA agreement also assures the Company that, if the endpoints are met, they will likely serve as the basis for approval under a BLA. In March 2008, the FDA advised Bioniche Therapeutics that its Phase III trial also qualified for Fast Track designation. The Company believes that the FDA's approval of its trial endpoints and study design as well as its Fast Track status could lead to a less complicated approval process, provided that the trials are considered successful. The Company anticipates pursuing product approval under a BLA.

Development Funding and Partnerships

The Company intends to manufacture Urocidin™ at its facilities in Pointe-Claire, Québec. It is actively pursuing marketing partnerships to attain further funding for the Phase III trials and manufacturing scale-up in exchange for a portion of product sales.

Industrial Technologies Office (ITO)

Bioniche maintains an agreement with the Industrial Technologies Office (ITO), which was formerly called Technology Partnerships Canada (TPC), under which the office has supplied C$9.6 million to assist with the development of Bioniche's MCC technology. The maturity date for funding was originally set at September 30, 2011, with ITO eligible to receive royalties of 6% of product revenues and an annual cash payment of C$960,000 for five years beginning in June 2010. However, in June 2008, the companies secured an amendment to the original agreement that extended the timeline for completion of work to March 31, 2013. Further, both the royalties and the cash payments are dependent upon Bioniche obtaining regulatory approval for commercialization, and cumulative royalties are capped at C$11.3 million. The cash payments may also be implemented if the Company enters into an agreement with a partner for clinical development or commercialization funding.

Bioniche Animal Health

Note: Unless otherwise stated, all monetary amounts are in U.S. dollars. At 02/12/2009, US$1.00 = ~C$1.24.

As measured by sales, Bioniche Animal Health (www.bionicheanimalhealth.com) is one of the largest Canadian-owned animal health companies today. Over the years, it has provided veterinarians and animal producers with a range of safe vaccines for use in cattle, swine, equine, and companion animals. Bioniche Animal Health also produces a patented immunotherapeutic, reproductive hormones, and nutritional supplements. Altogether, Bioniche Animal Health markets over 100 products to the veterinary market. The Company's major products are listed in Table 11 (pages 30-31).

This unit maintains product development and manufacturing facilities in Belleville, Ontario; marketing and production locations in Athens, Georgia, Pullman, Washington, and Armidale, Australia; and a sales and marketing office in Ireland; as well as in-house laboratories and a 100-acre research farm. Research for this division is conducted through the Company's Bioniche Therapeutics subsidiary (fully detailed on pages 16-27). The company has also established close liaisons with a number of Canadian universities active in medical and veterinary research. To market its products globally, Bioniche Animal Health has subsidiaries in the U.S., Australia, and Europe, as well as a worldwide network of distributors. At the corporate level, nearly all of Bioniche's revenues are currently generated from product sales within its Animal Health business unit, which were C$27.7 million for the 2008 fiscal year.

The Company's Animal Health research and development program is focused on the following two goals: (1) enhancing reproductive performance in animals; and (2) reducing the industry's reliance on antibiotics through vaccines and immunotherapeutics. Table 9 summarizes some of the significant achievements of this business unit.

Table 9
Bioniche Life Sciences Inc.
SIGNIFICANT ACHIEVEMENTS OF BIONICHE ANIMAL HEALTH

- Developed a purified follicle-stimulating hormone (FSH) that initiates superovulation
- Developed a patented immunostimulant for the treatment of equine respiratory disease, neonatal calf diarrhea, and tumors in companion animals
- Developed methods for the production of polyclonal antibodies
- Patented the use of hyaluronic acid (HA) for the cryopreservation of embryos and tissues of animals and humans

Source: Bioniche Animal Health Canada Inc.

ANTIBIOTIC-RESISTANT BACTERIA IN ANIMALS

Chemicals that inactivate or impair the growth of harmful bacteria are called antibiotics. In livestock, antibiotics are used to control a wide variety of bacteria that cause disease. However, excessive or inappropriate use of these medications in food-producing animals is known to create strains of antibiotic-resistant bacteria that can emerge from the human consumption of livestock products. Antibiotic-resistant diseases are more difficult to treat and have higher risks of serious or fatal illness.

One of the most prevalent foodborne bacteria that can be transmitted to humans is *Campylobacter jejuni* (*C. jejuni*). Infected animals can be effectively treated with antibiotics called fluoroquinolones. But in nations where fluoroquinolones are used in food-producing animals, up to 29% of the human population with *Campylobacter* infections show antibiotic resistance, making their illnesses more difficult to treat (Source: the Infectious Diseases Society of America). Alternatively, in Scandinavia, Europe, and Australia, the use of many antibiotics in animals is now prohibited and the infected human population has a far lower level of drug-resistance. Researchers found that of 585 Australian patients with *C. jejuni* isolates, only 2% were resistant to fluoroquinolones (Source: *Clinical Infectious Diseases* 2006).

Animal Health Market

Increasing access to information about food ingredients and sources has raised concern over the long-term effects of antibacterial or chemical residues in food on human health. Consequently, government and regulatory agencies now seek to control the use of products that may cause lasting effects. Thus, one of Bioniche's fundamental business objectives is disease prevention via immunomodulation, not antibiotic or chemical therapeutic agents. As such, Bioniche expects that trends toward more stringent regulations on products used in animals could present opportunities for the Company.

Bioniche estimates that the global animal healthcare market averages roughly C$20.5 billion annually, largely due to growth in products for companion animals (e.g., horses, cats, or dogs). As pets continue to become recognized as family members, the Company anticipates that growth of high-value treatments in this sector is likely to persist. For instance, from 2001 to 2006, the global market for dog care expanded by an average annual growth rate (AAGR) of 4.2% (Source: Datamonitor Ltd.)

Within the total animal health market, the animal biotechnology segment is projected to be worth $12.5 billion by the year 2010, with some of the most significant biotechnology products consisting of vaccines and improvements in animal breeding (Source: Research and Markets [www.researchandmarkets.com]). Further, this industry invests roughly $1 billion annually in research for improvements to animal well-being and to ensure safe food supplies (Source: the International Federation of Animal Health). Table 10 depicts the animal health market as it was valued during 2007, including sales and growth data by region, species, and product group.

Table 10

2007 ANIMAL HEALTH MARKET OVERVIEW BY REGION, SPECIES, AND PRODUCT GROUP (US$)

Animal Health Market by Region			
Region	2007 ($m)	YoY* (%)	Share (%)
North America	6,095	8.8	34.1
Latin America	2,080	11.2	11.6
West Europe	5,670	16.9	31.7
East Europe	815	10.9	4.6
Far East	2,740	7.2	15.3
Rest of World	500	9.8	2.8
Total	17,900	11.4	100.0

Animal Health Market by Species			
Species	2007 ($m)	YoY* (%)	Share (%)
Cattle	4,750	8.7	26.5
Sheep	830	7.8	4.6
Pigs	2,915	12.8	16.3
Poultry	1,935	11.8	10.8
Companion animals/other	7,470	13.0	41.7
Total	17,900	11.4	100.0

Animal Health Market by Product Group			
Product Group	2007 ($m)	YoY* (%)	Share (%)
Medicinal feed additives	2,095	5	11.7
Biologicals	4,175	14.1	23.3
Anti-infectives	2,775	9.3	15.5
Parasiticides	5,200	12.6	29.1
Other pharmaceuticals	3,655	12.5	20.4
Total	17,900	11.4	100.0

** Year over year percentage*

Source: the International Federation for Animal Health (2007) sourcing Vetnosis Ltd., which was formed in January 2008 through the management buy-out of Wood Mackenzie Limited's animal health business.

Embryo Transfer

An embryo transfer is the introduction of a fertilized egg (embryo) into a recipient female animal for gestation and birth. Embryos may be fertilized in a donor female or in the laboratory. This technique increases the reproductive capacity of valuable animals and enables infertile animals to produce offspring without introducing new diseases. The International Embryo Transfer Society estimated that roughly 878,000 bovine embryo transfers were performed during 2005. In addition, the Society estimated that

30,000 swine embryos were transferred, including over 2,200 frozen embryos. During 2005, the number of transfers in cattle continued to reach record highs, partly due to increased activity in Asia and South America as well as technological improvements. The leaders in bovine embryo transfers were North America, Brazil, China, and Korea.

Bioniche: Creating Alternatives to Antibiotics

Bioniche's chairman, president, and chief executive officer (CEO), Mr. Graeme McRae (biography on page 10), founded the Company largely due to his contrasting experiences with antibiotic practices in Australia and North America. Mr. McRae believed that major veterinary pharmaceutical companies were not emphasizing the research and development of alternatives to antibiotics, which were (and still are) widely used to treat livestock disease. As a result, he sought to develop and market more suitable approaches to treating animal diseases that did not present the same problems as antibiotics. One such example is SETTLE® (described on pages 33-34), the first biological product approved by the U.S. Department of Agriculture (USDA) to treat equine endometritis caused by the *Streptococcus zooepidemicus* (*S. zooepidemicus*) bacterium. Other than SETTLE®, the treatment of equine endometritis has used combinations of antibiotics, including some only approved for human use.

MARKETED PRODUCTS

Based on several platform technologies, Bioniche Animal Health's current product portfolio primarily consists of reproductive and embryo transfer therapies, which the Company views as important cash flow generators, and immunology and vaccine products, which serve as growth drivers. Both of these platforms are further described on the accompanying pages. Additional product areas include hyaluronan products (hyaluronic acid [HA] technology is detailed on page 24) and polyclonal antibodies, such as Colimune®-Oral to prevent **K-99** *E. coli* infections in calves (summarized on page 34). Table 11 (below and continued on page 31) summarizes the Company's most significant marketed products based on their targeted areas: Reproductive and Embryo Transfer, Immunostimulants, Hyaluronan, Nutritionals, Vaccines, and Others. Not all products are available in every country. For country-specific product information, please visit the Bioniche Animal Health website at www.bionicheanimalhealth.com.

Table 11
Bioniche Life Sciences Inc.
BIONICHE ANIMAL HEALTH'S MARKETED PRODUCT PORTFOLIO

Reproductive and Embryo Transfer Products	
E.T. Surfactant (All Animals)	ViGro™ Trypsin Wash (All Animals)
ViGro™ Complete Flush Solution (All Animals)	ViGro™ Splitting Plus (All Animals)
ViGro™ Holding Plus (All Animals)	ViGro™ Rinsing Solution (All Animals)
ViGro™ Freeze Plus (All Animals)	ViGro™ TL Hepes (All Animals)
ViGro™ Ethylene Glycol Freeze Plus (All Animals)	SYN**GRO**™ Holding (All Animals)
ViGro™ One Step Thaw Plus (All Animals)	Equine Vitrification Kit (Equine)
Folltropin®-V (Bovine)	Ova-Gest (Ovine)
Cue-Mate® (Bovine)	Pregnecol™ 6000 (Ovine)
Pregnecol™ 6000 (Bovine)	Pregnecol™ 6000 (Porcine)
Lutropin®-V 20 mL (Bovine)	Lutropin®-V 20 mL (Porcine)
Immunostimulants	
Colimune®-Oral (Bovine)	Equimune® I.V. (Equine)
Immunoboost® (Bovine)	Regressin™-V (Equine)
Regressin™-V (Companion Animal)	SETTLE® (Equine)
Hyaluronan	
MAP®-5 (All Animals)	HYALOVET® 20 (Equine)
Enhance® (Equine)	

Sources: Bioniche Animal Health Canada Inc. and Crystal Research Associates, LLC.

Table 11 (cont.)
Bioniche Life Sciences Inc.
BIONICHE ANIMAL HEALTH'S MARKETED PRODUCT PORTFOLIO

Nutritionals	
EPIC Calf Scour (Bovine)	EPIC Daily (Equine)
Omega-Fend™ Canine Omega 3, 6 (Companion Animal)	Nutrequin™ Classic (Equine)
Mammalac Canine (Companion Animal)	Nutrequin™ Liquid (Equine)
CORTA-FLX BIO-ISO-G™ Solution (Companion Animal)	Vetre-Sel-E (Equine)
CORTA-FLX BIO-ISO-G™ Plus (Companion Animal)	EPIC Canadian (Equine)
Omega-Fend™ Canine Omega 3 (Companion Animal)	U-GARD RX (Equine)
Mammalac Feline (Companion Animal)	CORTA-FLX BIO-ISO-G™ Plus (Equine)
Echi-Fend™ (Equine)	Magnitude™ (Equine)
CORTA-FLX BIO-ISO-G™ Solution (Equine)	Nutrequin™ Elite (Equine)
EPIC Foal Neonate (Equine)	
Vaccines	
Caseous D-T (Ovine)	Case Bac (Ovine)
Others	
Pancrease™-V (Companion Animal)	Hippiron® 1000 (Equine)
Pet Loss Sympathy Package (Companion Animal)	Butequine® Paste (Equine)
Vetalar® (Companion Animal)	Hypertonic Saline 7.2% (Other)
Pet Nursing Bottles (Companion Animal)	Derma GeL® (Other)
Pet Loss Coping Booklets (Companion Animal)	MAP®-5 (Other)
Pet Loss Clinic Guide & CD (Companion Animal)	Dimethyl Sulfoxide 99% (Other)
Cronyxin™ (Equine)	

Sources: Bioniche Animal Health Canada Inc. and Crystal Research Associates, LLC.

Reproductive and Embryo Transfer Products

Bioniche Animal Health developed reproduction products to facilitate embryo transfer and breeding programs in both commercial and research settings. Through its products, the Company seeks to safely maximize the quantity of fertilized embryos that can be transferred with a high probability of producing pregnancies. Bioniche Animal Health markets several important reproductive products that use purified hormones to induce superovulation in animals. Superovulation causes the ovaries to produce multiple egg follicles instead of just one. These purified hormone products are designed for use in breeding programs in the cattle and swine industries. Specifically, Bioniche Animal Health's lead product, Folltropin®-V, is used to induce superovulation in cattle and sheep for the embryo transfer industry.

Reproduction and Embryo Transfer: Bioniche Animal Health's Community Focus

Based in Armidale, New South Wales, Bioniche Animal Health (A/Asia) Pty. Ltd., the Company's Australian animal health division, is committed to assisting veterinary science students at the University of Sydney, as they learn the specialized skills required to help save Australia's endangered species. Bioniche Animal Health contributes financially to the University's Assisted Reproductive Technology (ART) course, where students are taught artificial insemination, embryo transfer, and related technologies. These assisted reproduction techniques can then be used to combat the depletion of many endangered or vulnerable species.

Through its contribution to the ART program, Bioniche Animal Health also supports work at the Wombat Research Centre in Central Queensland, Australia. At the Research Centre, staff utilize superovulation and embryo transfer techniques to increase the offspring of over 100 Northern Hairy-nosed Wombats (depicted in Figure 4 [page 32]) living nearby. A wombat is an Australian marsupial, about the size of a badger, that digs extensive burrows and feeds on grasses and roots.

Figure 4

TWO AUSTRALIAN ANIMALS SUPPORTED BY BIONICHE ANIMAL HEALTH

Northern Hairy-nosed Wombat

Stripe-faced Dunnart

Sources: Queensland Conservation Council and www.australianwildlife.org.

The Company also supplies combinations of reproductive hormones to researchers at the University of New England (also in Armidale) to induce mating and ovulation in the non-reproductive females of the Stripe-faced Dunnart species (shown on the right side of Figure 4). The Stripe-faced Dunnart is a carnivorous marsupial that has been classified as a vulnerable species.

Folltropin®-V

Figure 5

Bioniche Life Sciences Inc.

FOLLTROPIN®-V

Source: Bioniche Animal Health Canada Inc.

Depicted in Figure 5, Folltropin®-V is composed of **follicle-stimulating hormone (FSH)**, the pituitary hormone responsible for the stimulation of estrogen production from the follicle cells around the egg. In addition to use in animal reproduction, recombinant human FSH (not from Bioniche) is also prescribed for human females undergoing fertility treatments. The Company's Folltropin®-V is a highly purified, sterile extract obtained from porcine (relating to swine) pituitary glands. It maintains a low ratio of FSH to luteinizing hormone (LH), another pituitary hormone that stimulates ovulation in female mammals. If the FSH:LH ratio is too high, mean ovulation rates tend to decrease. Bioniche Animal Health believes that previous FSH formulations contained too much LH, with significant variances in the FSH:LH ratios. To the Company's knowledge, Folltropin®-V is one of the best-selling FSHs in the animal health marketplace worldwide.

Immunostimulant Technologies and Products

In addition to the Company's current products for immunology and vaccine applications, future development in these areas is expected to be a significant growth driver. Similar to its advent as a technique to treat many diseases affecting human health, immunotherapy is also an emerging technology in animal healthcare. Within this field, the Company is focused on several immunotherapeutic products that stimulate the animal's own immune system to fight off invading bacteria, several of which are based on mycobacterial cell wall extract (MCWE) technology.

Mycobacterial Cell Wall Extract (MCWE)

Bioniche Animal Health's immunotherapeutic platform utilizes MCWE technology, the precursor to mycobacterial cell wall-DNA complex (MCC) technology (widely used for the Company's Human Health initiatives). Also derived from *Mycobacterium phlei* (*M. phlei*), MCWE is an inactivated, deproteinized, injectable cell wall extract that has immunomodulatory and antiviral properties. It is the active ingredient in several of the Company's marketed products, including Equimune® I.V., Immunoboost®, and SETTLE®. The MCWE portfolio of products is manufactured by the Company at its facility in Athens, Georgia. Bioniche Animal Health maintains a solid proprietary position for each of these products. In addition to the

products listed below and on page 34, details of other MCWE products can be found on Bioniche Animal Health's website at www.bionicheanimalheath.com.

MCWE is undergoing preliminary evaluations for its ability to reduce antibiotic reliance and enhance the growth of food-producing animals in addition to its use in already available products. This is particularly important as trends in animal healthcare lead to a decreased use of antibiotics and chemical therapeutics. Future immunotherapeutic initiatives at Bioniche Animal Health will likely continue to focus on biological products that do not contain material of animal origin, thereby reducing the risk of disease transmission.

Equimune® I.V.

Equimune® I.V. is a patented, single-dose immunotherapeutic that utilizes a proprietary formulation of the Company's MCWE technology to provide a non-antibiotic approach to treat Equine Respiratory Disease Complex (ERDC). ERDC comprises a host of viral and bacterial respiratory organisms that can cause serious acute and chronic respiratory infections. Equimune® I.V. is available in many countries, including Australia and the U.S. During August and September 2007, Bioniche Animal Health increased its supply of Equimune® I.V. to Australia in order to help veterinarians there combat an outbreak of equine influenza. Equine influenza is a viral respiratory infection that causes flu-like symptoms in horses. The outbreak affected more than 3,300 horses on over 400 properties in Australia. The cost of the outbreak was estimated at as much as $1 billion to date (Source: CNN.com).

Immunoboost®

Immunoboost® is a USDA-approved immunostimulant technology used on calves between the ages of one and five days. At birth, calves have a complete but immature immune system, leaving them more susceptible to disease. However, one Immunoboost® injection stimulates a calf's immune system to enhance defense mechanisms against disease. Specifically, the MCWE-based formulation serves as a immunotherapeutic treatment to reduce the mortality and morbidity rates associated with calf **scours** resulting from K-99 *E. coli* infections. In a K-99 *E. coli* challenge study, roughly 90% of calves treated once with Immunoboost® survived versus 42% of controls that received a placebo saline treatment.

In August 2008, Immunoboost® was granted full listing by the Organic Materials Review Institute (OMRI), which indicates that the product meets the national standard for use in organic dairy and beef operations in the U.S. The OMRI is a national nonprofit organization that determines what products are acceptable for certified organic operations under the USDA's National Organic Program. According to Agriculture and Agri-Food Canada (AAFC), the U.S. natural beef market is valued between $500 million and $550 million annually, or roughly 1% of the total U.S. beef sector. The natural beef market has received more exposure in recent years as the utilization of antibiotics and growth hormones in livestock has pushed an increasing percentage of the population to seek more natural alternatives. This backlash against hormone and antibiotic usage in beef production has created an expanding market for natural beef, which is expected to grow at an annual rate of 20% (Source: the AAFC's *Natural Beef Market in the United States* December 2005).

SETTLE®

Depicted in Figure 6, SETTLE® was the first biologic approved by the USDA as an aid to treat equine endometritis. Equine endometritis is a production-limiting disease that the Company believes may affect 10% to 20% of broodmares worldwide. It is detailed further on page 34. SETTLE® was approved for sale in the U.S. during December 2004. In the future, Bioniche Animal Health intends to extend the product's registration to additional countries and for different animal species. Based on research conducted over five breeding seasons, SETTLE® is clinically proven to be a fast-acting, non-antibiotic endometritis therapy for broodmares. It enhances the equine immune system to fight infection. Through the challenge study detailed on page 34, as well as other studies (refer to www.expectbetterresults.com), SETTLE® has proven to be a safe and effective alternative to the antibiotics typically used to treat equine endometritis.

Figure 6
Bioniche Life Sciences Inc.
SETTLE®

Source: Bioniche Animal Health USA, Inc.

Equine Endometritis

While endometritis is not life-threatening, it significantly impacts the equine industry by negatively affecting conception rates among mares and increasing losses during pregnancies. Conventional treatments for equine endometritis include intrauterine or intravenous antibiotics administered for three to four days. If the infection persists beyond this timeframe, it can become chronic and degenerative, requiring many costly and labor-intensive therapies.

Challenge Study

In April 2007, Bioniche's researchers and associates published an article in the *Journal of Equine Veterinary Science* outlining the effectiveness of MCWE (SETTLE®) as a therapy for equine endometritis caused by the *S. zooepidemicus* bacteria. The article details the Company's challenge study of MCWE in 30 endometritis-susceptible mares that were experimentally infected with the bacteria.

After bacterial inoculation, mares were assigned to one of the following three groups: (1) 10 mares, which received SETTLE® intravenously; (2) 10 mares, which received SETTLE® by intrauterine administration; and (3) 10 mares (divided into two subsets of five each), which received a placebo either intravenously or into the uterus. After examinations at 24 hours post-treatment and seven days post-treatment, all animals in the placebo group still had observable endometritis. However, at 24 hours, endometritis was cleared from 60% of mares given intrauterine SETTLE® and 50% of mares dosed intravenously. By seven days after the treatments, 80% (intrauterine) and 70% (intravenous) of mares no longer had endometritis.

Colimune®-Oral—A Polyclonal Antibody

Polyclonal antibodies are produced from a selected strain of K-99 *E. coli* that is enteropathogenic—capable of causing disease in the intestinal tract—and include several specific types of antigens that are related to other toxic strains of *E. coli*. K-99 *E. coli* in newborn calves causes diarrhea and can be life threatening. Mothers of calves that receive the Colimune®-Oral vaccination against K-99 *E. coli* produce the antibodies in their milk, which are then ingested by the calf. This transaction can improve the calf's immune system and help prevent the K-99 *E. coli* infection. Colimune®-Oral is manufactured by the Company at its Belleville, Ontario, facility and sold throughout the U.S. and Canada.

Hyaluronan Products

Hyaluronan or hyaluronic acid (HA) is a natural part of connective tissue and joint fluid that is known to cushion and lubricate such areas. As such, HA is a well-established product used worldwide in animal healthcare practices. Bioniche Animal Health focuses its efforts in two HA-related areas, as summarized below.

- *Enhance®*. This treatment for osteoarthritis (particularly in horses) is registered in Australia, New Zealand, and Turkey. Osteoarthritis is associated with the degradation of synovial fluid—a naturally occurring lubricant—in joints, causing a loss of lubricant effect and pain to the animal. Bioniche Animal Health's Enhance® is used to replace the joint-related (articular) synovial fluid.

- *MAP®-5.* Bioniche Animal Health has patented the use of HA as a **cryopreservative**—a medium to aid the preservation of cells—for embryo transfers. While the Company markets MAP®-5 globally, its primary market is the U.S.

Former subsidiary Bioniche Pharma Group Limited manufactures the HA products in its Galway, Ireland, facility pursuant to a manufacturing and supply agreement with Bioniche Animal Health. In general, the cost of the raw material is a small percentage of the price of the finished product. Additionally, the Company has entered into what it considers to be a favorable long-term supply contract for its raw HA requirements with a major commercial supplier, and maintains relationships with backup suppliers as well.

Natural Health and Nutritional Products

The Company continually explores opportunities in the expanding natural health sector as an extension of its animal health immunology research. Bioniche Animal Health's nutritional products include an Echinacea product for horses (*Echi-Fend*™) as well as two versions of an essential fatty acid supplement to treat skin conditions in canines (*Omega-Fend*™). Bioniche also seeks to develop a botanical (plant-based) insect repellent.

Bioniche Animal Health has partnered with Loyalist College (Belleville) and the University of Ottawa to research and develop an environmentally friendly extraction process to remove active ingredients in plant materials for use in the development of natural products. The Company believes that the natural health sector provides a significant opportunity as it is a growing segment with fewer regulatory hurdles than pharmaceuticals or biologicals. Further, as Bioniche Animal Health currently complies with regulated manufacturing standards at its Belleville facility, any new regulatory requirements that surface for natural health products are an advantage to the Company because its manufacturing facilities already meet these standards. The natural health line of products is manufactured by the Company at its Belleville facility.

Vaccine Products

Bioniche Animal Health's vaccine development programs focus on preventing animal diseases via products that are both effective and safe. The Company uses killed bacteria and viruses in its vaccines, rather than live or attenuated (weakened) components. This business unit has provided customers with a wide range of animal vaccines, including the following: (1) *Virabos*, which works against respiratory and reproductive diseases in beef cattle; (2) *Dairymune*, for the dairy industry's needs; and (3) *SwineCheck*, which targets the swine industry.

At present, Bioniche Animal Health is conducting early stage trials for several vaccines to treat bovine and equine diseases, such as a recombinant multivalent vaccine for bovine diarrhea and a vaccine against *Rhodococcus equi* (*R. equi*), which causes a bacterial pneumonia in **foals**. Currently, the Company is performing a proof-of-principle study for the *R. equi* vaccine. If successful, Bioniche Animal Health expects to produce three pre-license serials for registration in North America. Future vaccine development is likely to be centered on proprietary vaccines to address both food safety and animal diseases. To this extent, Bioniche maintains internal development teams and external collaborations.

Partnerships and Collaborations

Bioniche Animal Health has partnered with a number of universities that are active in medical and veterinary research. In Canada, Bioniche works with the University of British Columbia, the University of Saskatchewan, Guelph University, Queen's University, and Loyalist College, among others. In the U.S., the Company also collaborates with multiple universities, including the University of Nebraska-Lincoln, Colorado State University, and Purdue University. Outside of North America, Bioniche has relationships with the Universities of Sydney and New England in Australia and local universities and commercial partners in South America. Partnerships with university researchers in North America and throughout the world generate important scientific data in support of the Company's marketed animal health products.

To bolster its commercial animal health portfolio, the Company made two strategic acquisitions.

- First, it acquired the assets of AB Technology Inc. in January 2004. AB Technology, which now operates as a unit of Bioniche Animal Health USA, Inc., leads the development of embryo transfer media, materials, and equipment for the bovine and equine reproductive markets.

- Second, it gained rights to Cue-Mate® from Pfizer Inc. in April 2004. Cue-Mate®, a second-generation progesterone delivery device for cows, is marketed in Australia, New Zealand, Chile, and Argentina. Cue-Mate® enables dairy farmers and cattle producers to manage the reproductive timing of herds.

In addition to these, Bioniche is currently evaluating other potential collaborations, partnerships, technology licenses and product acquisitions, for which information is not yet publicly available.

Bioniche Food Safety

Note: Unless otherwise stated, all monetary amounts are in U.S. dollars. At 02/12/2009, US$1.00 = ~C$1.24.

Established in July 2001, Bioniche's Food Safety business unit (termed Bioniche Food Safety) is the Company's newest business unit, arising out of Bioniche's expertise in animal health. This unit creates veterinary biopharmaceutical products to address livestock diseases that pose risks to human health via contaminated food, water, and other environmental factors. Specifically, Bioniche Food Safety focuses on the research, development, manufacture, and marketing of livestock vaccines.

This business unit's lead initiative is Econiche™, a vaccine for *Escherichia coli* (*E. coli*) O157:H7 that is administered to cattle. Presently, there are no other *E. coli* vaccines available (Source: the Centers for Disease Control and Prevention [CDC]). While there have been several approaches aimed at reducing *E. coli* levels in pre-slaughter cattle (e.g., changes to animal husbandry practices and feed rations as well as feeding animals probiotics, antibiotics, and bacteriophages), Bioniche Food Safety believes that vaccination is likely to be the most effective method at breeder, fair, **feedlot**, and dairy levels. By reducing *E. coli* O157:H7 in cattle, Bioniche seeks to decrease the amount of *E. coli* bacteria in cattle environments, as well as in food and water sources.

Bioniche Food Safety continues to evaluate different formulations of its *E. coli* O157:H7 cattle vaccine that may have superior efficacy or improved production efficiencies. These types of product modifications could extend the Company's intellectual property protection as well as enhance its economic outlook. Beyond Econiche™, Bioniche Food Safety also continues to research and develop additional vaccines for animals that may improve the safety of food and water supplies.

FOODBORNE ILLNESSES

Foodborne illnesses are essentially infectious or toxic diseases that people contract by consuming contaminated food products. These diseases constitute a widespread, growing health problem around the world. In 2005, approximately 1.8 million people died of diarrheal diseases due to tainted food and drinking water globally (Source: the World Health Organization [WHO]). In the U.S., there are an estimated 76 million cases of foodborne diseases annually, which include 325,000 hospitalizations and approximately 5,000 deaths. Generally, up to 30% of the population of industrialized countries is believed to be afflicted with a food-related illness each year (Source: WHO). While statistics in developing countries are not as well documented, the prevalence of diseases due to inadequate food safety is believed to be high.

Foodborne diseases not only affect health, but they also have an economic impact. In Canada, the annual costs of all foodborne illnesses and deaths are estimated to exceed C$1 billion. In the U.S., the USDA's Economic Research Service (ERS) estimated that costs related to **Shiga toxin**-producing *E. coli* O157 in 2007 were roughly $459.7 million, based on the CDC's estimate of 73,480 cases of this strain of *E. coli*. In late 2006, a two-week *E. coli* warning was issued by the FDA for fresh spinach. Because approximately three-quarters of all U.S.-grown spinach is harvested in California, the *E. coli* warning was thought to create losses of roughly $74 million for California's agribusinesses, costing each spinach farmer roughly $3,500 (Source: MSNBC 2006). Many countries must also contend with the effect that foodborne diseases may have on exports.

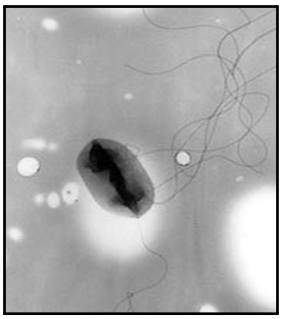
Escherichia coli (E. coli)

E. coli, specifically the O157:H7 strain that secretes a potent toxin, is a newer bacterium, having emerged over the past few decades. *E. coli* typically resides in both human and animal intestines, but can also survive in a range of other environments. There are hundreds of strains of *E. coli*, most of which are harmless. However, five classes of these bacteria are capable of causing inflammation of the stomach and bowels, potentially leading to serious disease. Bioniche Food Safety is focused on inhibiting the spread of the *E. coli* O157:H7 strain, which causes severe illness, disease outbreaks, and death when it is transferred to humans. In relation to public health, this strain is responsible for the most human *E. coli* infections (Source: WHO).

E. coli O157:H7

First recognized in North America in 1982, *E. coli* O157:H7 is known to cause bloody diarrhea, cramps, anemia, and kidney failure. In the U.S., there are roughly 73,000 cases of *E. coli* O157:H7 resulting in 2,100 hospitalizations and 60 deaths each year (Source: CDC). In Canada, the *E. coli* O157:H7 strain is linked to roughly 1,400 reported laboratory-confirmed infections annually (Source: Health Canada). In a 2007 report, a Canadian nonprofit agricultural think-tank (the George Morris Centre) suggested that the lower Canadian figure is due to less laboratory confirmation in its public health system, and that the real incidence in Canada may be as high as 26,000. While *E. coli* O157:H7 is primarily associated with the consumption of raw or undercooked beef, the bacteria may also come from consuming raw milk, contaminated water, or other infected food products. Figure 7 shows a photomicrograph of the *E. coli* O157 strain.

Figure 7
E. COLI O157 STRAIN



Source: the Centers for Disease Control and Prevention (CDC).

In 2007, roughly half of the cases were associated with the consumption of contaminated fresh produce (fruits and vegetables), as opposed to just meat. Exposure to tainted food accounts for 63% to 85% of all cases of **enterohemorrhagic *E. coli*** (Source: WHO). While less common, the bacteria can also be transmitted from human to human if proper hygiene is not maintained.

The toxins produced by *E. coli* O157:H7 first damage the lining of the intestine, and can manifest as several different illnesses, largely dependent on the age of the person contracting the disease. In particular, the O157:H7 strain causes approximately 20,000 cases of hemorrhagic colitis in the U.S. yearly (Source: www.medicinenet.com). Hemorrhagic colitis, also commonly called "hamburger disease," is an inflammation of the colon that results in bloody diarrhea and severe abdominal cramps. It lasts for around a week. Approximately 2% to 7% of all people infected with *E. coli* O157:H7 develop hemolytic-uremic syndrome (HUS), a potentially fatal illness characterized by anemia, acute kidney failure, seizures, and comas. HUS is the most common cause of acute kidney failure in infants and children and is caused predominantly by *E. coli* O157:H7. After intensive care treatment, HUS has a 3% to 5% death rate.

Elderly individuals often develop thrombotic thrombocytopenic purpura (TTP) as a result of *E. coli* O157:H7; however, this indication may also affect younger populations. In TTP, patients' red blood cells and platelets are destroyed, leading to anemia, impaired kidney functions, and damage to the nervous system. In addition, platelets clump together to form blood clots in the body's blood vessels, leading to bleeding under the skin and purpura (purple-colored spots).

Treatments for *E. coli* O157:H7-derived diseases are often complex and require intensive hospital care as simple antibiotics and antidiarrheal medicines have not proven useful (Source: CDC). Most treatment regimens center upon replacing fluids and electrolytes to prevent dehydration. HUS treatments in particular entail blood transfusions and dialysis, but these patients may still develop life-long complications, such as blindness, paralysis, persistent kidney problems, and possible bowel removal.

The Main Source of *E. coli* O157:H7: Infection of Healthy Cattle

The primary origin of *E. coli* O157:H7 is in the intestines of healthy cattle, although the bacteria can also be found living within chicken, deer, sheep, and pigs. While carrying *E. coli*, some types of animals do not become ill. As a result, healthy cattle do not display symptoms of an infection, making diagnosis of the bacteria very difficult. In addition, cattle shed the bacteria into their fecal matter in a sporadic fashion, making occasional fecal testing for the presence of *E. coli* O157:H7 an unreliable measure of the prevalence of infection in herds. In general, there is a higher prevalence of *E. coli* O157:H7 during the summer and early fall months when hotter and dusty or muddy conditions prevail.

Bioniche has identified that roughly 60% of cattle have over 20% prevalence of *E. coli* O157:H7 in the summer months, while only 10% of cattle have this level of prevalence in winter. Based on studies conducted by Bioniche, the Company has established proof of concept that its cattle vaccine can

approximate winter shedding levels in summer months. Further, Bioniche Food Safety believes that vaccination of an entire feedlot can decrease the environmental load and subsequent re-infection rate with each successive cycle.

Transfer from Cattle to Humans

- Farms, Fairs, and Petting Zoos. *E. coli* is transferred to humans in several ways, one of which is through contact with the feces of an infected animal. This method is especially prominent at farms, fairs, and petting zoos, where animals and people (particularly young children) come in close contact. In these situations, *E. coli* O157:H7 can be transferred from the hand to the mouth after touching an infected surface or animal. The bacteria can be found on the ground, railings, feed bins, animal fur, saliva, and feces. In addition, *E. coli* O157:H7 can be transferred by consuming food or water contaminated by feces (e.g., due to unsanitary conditions) or even—as researchers have recently concluded—ingesting or inhaling contaminated dust particles (Source: OutBreak, Inc., a nonprofit consulting company designed to assist companies with food safety challenges). A recent journal publication indicated that over 90% of animal fairs and exhibits tested positive for *E. coli* O157:H7 (Source: *Emerging Infectious Diseases* [a journal of the CDC] May 2006).

- Contaminated Meat Products. Cattle farms are a significant source of *E. coli* O157:H7 infection. The National Academy of Sciences, Institute of Medicine (NASIM) estimates that nearly 30% of animals going to slaughter are infected with *E. coli* O157:H7. During slaughtering, the cattle's hide, intestines and feces may come into contact with the carcass, spreading the bacteria to the meat. With such a high prevalence rate, any breakdowns in sanitization, testing, or cooking procedures (the meat must be heated to 160° Fahrenheit to kill the *E. coli* bacteria) may allow tainted beef to reach consumers. In the U.S., more *E. coli* O157:H7 infections are contracted from undercooked ground beef than from any other food (Source: CDC). Ground beef that tests positive for *E. coli* O157:H7 prior to shipment can be pre-cooked (at a significant lost profit to the processor) and then used in prepared meals. Raw meat that is found to be positive after shipment must be recalled and destroyed, as was nearly 25 million pounds as recently as the fall of 2007.

- Run-off From Cattle Farms. Each day, a single animal can produce some 66 pounds (30 kilograms [kg]) of manure. Farmers use this manure for many different functions, including natural fertilization for fields, compost that is sold to local garden stores, replacements for sawdust, and even as a power source by converting the methane into energy. Yet, each gram of manure is capable of containing 10 million fecal **coliform** organisms, which may include *E. coli* O157:H7 (Source: OutBreak, Inc.). When bacteria-ridden manure is washed into irrigation systems, either due to inadequate farming practices or heavy storms that cause flooding, *E. coli* O157:H7 can contaminate fruits and vegetables. Apples picked up from the ground, seeds, alfalfa sprouts, lettuce, spinach, parsley, and other fresh produce have all been shown to be contaminated in this manner in recent years, leading to multiple *E. coli* outbreaks. Moreover, **potable** aquifers and waterways can also be infected by run-off from cattle farms and quickly affect large populations, as was the case in Walkerton, Ontario, Canada, during May 2000 (detailed on page 39).

- Dairy Farm Contamination. Dairy farms can also spread *E. coli* O157:H7. Raw milk has been implicated as the source of several *E. coli* outbreaks, likely due to fecal matter present on cow udders and unsafe production facilities. Accordingly, yogurt, cheese, and other dairy products are also at risk. In addition, older dairy animals are frequently processed into ground beef, making them an important potential source of contamination. There are approximately 15 million dairy cattle in North America. In the U.S. alone, there are 65,000 dairy farms, 99% of which are family owned and operated (Source: America's Dairy Farmers®).

Economic Impact on Cattle Farmers

There are an estimated 123 million cattle in North America and 62 million cattle in Europe. After the advent of *E. coli* O157:H7, beef producers and agriculture regulatory agencies, such as the USDA, made significant investments to protect meat products from bacteria. Annually, individual beef producers spend $2 million to $3 million on improved equipment, training, and testing to help reduce levels of *E. coli* O157:H7, as well as techniques to ensure overall meat safety.

In spite of these proactive measures, contaminated meat continues to lead to heavy losses for meat packers (slaughter houses). From 2000 to 2007, nearly 50 million pounds of beef were recalled in North America, resulting in significant costs to the food industry in terms of lost sales, recalls, and litigation. In addition, meat is continuing to test positive prior to leaving packing facilities, and as such, it must be pre-cooked and sold at much lower prices (Source: the *Chicago Tribune* 2007). A February 2003 article in *Meat & Poultry* magazine estimated the cost of *E. coli* to the U.S. food industry at $2.7 billion. Losses in the Canadian food industry due to concerns over *E. coli* O157:H7 are approximated at more than C$33 million annually (Source: the George Morris Centre). The meat industry may experience even higher *E. coli*-related costs in the future, as the USDA's Food Safety Inspection Service begins to implement more stringent laboratory methods to detect the bacteria in beef products.

E. coli O157:H7 Outbreaks

Since it was first identified in 1982, *E. coli* O157:H7 has been documented in more than 30 countries on six continents. To date, the largest *E. coli* O157:H7 outbreak occurred in Japan in 1996, affecting between 6,300 and 9,450 school children (Source: the WHO). This outbreak was linked to contaminated fresh radishes in school lunches.

Canada

In late 2008, an *E. coli* O157:H7 outbreak in North Bay, Ontario, caused roughly 250 individuals to be tested for the infection, with 50 cases confirmed by the North Bay Parry Sound District Health Unit. The outbreak was sourced to undercooked beef from Harvey's, a Canadian fast food restaurant.

Over the six years prior to 2006/2007, there was an average of five recalls per year due to *E. coli* O157:H7 in Canada (Source: the George Morris Centre). One of North America's worst *E. coli* outbreaks took place in Walkerton, Ontario, in 2000. Heavy storms during May 2000 washed large amounts of cattle manure into the town's water wells. In less than a week, the *E. coli*-laden manure polluted the city's water systems, sickening at least 2,500 people from Walkerton, a small town of 5,000 people at the time (Source: Canwest News Service 2008). Seven deaths were attributed to the outbreak, which took more than $7 million and six months to decontaminate (Source: CNN).

A health study by a collaborative team of researchers from the University of Western Ontario (London, Ontario), the University of Toronto (Toronto, Ontario), McMaster University (Hamilton, Ontario), and the University of British Columbia (Vancouver, British Columbia) tracked the health challenges facing 4,561 residents of Walkerton and surrounding areas between March 2002 and August 2008. Patients were monitored for side effects including renal disease, diabetes, hypertension, irritable bowel syndrome (IBS), and reactive arthritis. A more detailed screening was conducted with pregnant women to assess the relationship between illness from water consumption and hypertension in pregnancy. The results of the study suggest that survivors of severe *E. coli* O157:H7 infection and *Campylobacter* gastroenteritis demonstrate poorer long-term health regardless of whether they experienced overt HUS.

Within two years of the outbreak, Walkerton residents who had experienced bacterial gastroenteritis during the outbreak were three times more likely to develop IBS. Further, within four years of the outbreak, residents who had experienced symptoms of severe gastroenteritis were 33% more likely to develop hypertension and a 38% more likely to develop reactive arthritis than those who did not become ill at the time of the outbreak, and similar results were shown for the likeliness of reduced kidney function. Researchers plan to continue monitoring health in the community through hospital and health records until 2030 to assess the long-term health implications. In addition to the Walkerton outbreak, Table 12 (page 40) lists all of the *E. coli* infections from Ontario, Canada, that occurred between 1996 and 2005.

Table 12
E. COLI CASES BY YEAR IN ONTARIO, CANADA: 1996 TO 2005

Year	Sporadic Cases (%)	Outbreak-associated Cases (%)	Total
1996	427 (91%)	40 (9%)	467
1997	427 (100%)	0 (0%)	427
1998	346 (86%)	56 (14%)	402
1999	355 (95%)	18 (5%)	373
2000	442 (25%)	1,270 (75%)	1,712
2001	317 (89%)	40 (11%)	357
2002	331 (84%)	61 (16%)	392
2003	282 (62%)	172 (38%)	454
2004	285 (91%)	27 (9%)	312
2005	250 (91%)	25 (9%)	275
Total	3,462 (67%)	1,709 (33%)	5,171

Source: Canada Communicable Disease Report. "Descriptive epidemiology of verotoxin-producing E. coli reported in Ontario, 1996-2005." April 1, 2007, Vol. 33, No. 7, Table 2.

United States

In October 2008, over 40 cases of *E. coli* O157:H7 were confirmed in relation to commercial bagged lettuce. The bacteria infected 30 individuals from Michigan, with the remainder of cases spanning Illinois, Ohio, New York, and Oregon. In the past 12 years, the FDA has reported 22 *E. coli* O157:H7 outbreaks linked to the consumption of leafy greens, causing illness in over 700 people.

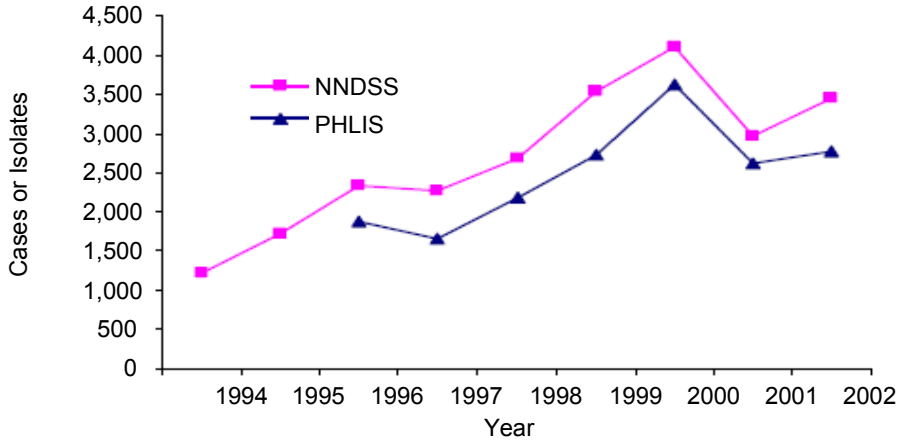
In October 2007, Topps Meat Company, formerly one of the U.S.'s largest manufacturers of frozen hamburgers and other meat products, went out of business following an *E. coli* O157:H7 outbreak. The company's meat is thought to have first sickened people in July 2007, but was not officially recalled until the end of September 2007, after the bacteria had affected eight states. Altogether, Topps recalled over 21.7 million pounds of ground beef products, which was likely caused by inadequate process controls in the company's production line (Source: the *New York Times,* October 6, 2007).

On September 18, 2007, Dole Food Company, Inc. announced a voluntary product recall of its "Hearts Delight" bagged salad mix due to contamination with *E. coli* O157:H7. As a result, the manufacturer had to withdraw 528 bags of salad from its Canadian retailers and 4,530 bags from nine U.S. states. Previously, in September 2006, the FDA found that Dole's Baby Spinach was contaminated with *E. coli* O157:H7, resulting in 205 confirmed illnesses and three deaths across 26 states. While the exact source of this infection is unknown, investigators believe that a potential cause could have been the proximity of irrigation wells and surface waterways exposed to feces from cattle and wildlife to the fields where the produce was grown (Source: the FDA March 2007). In addition, more than 70 people became ill in December 2006 from eating *E. coli* O157:H7-infected lettuce at Taco Bell restaurants in five eastern states. Related to this outbreak, 33 people in Minnesota, 47 people in Iowa, and one person in Wisconsin also contracted *E. coli* O157:H7 from lettuce at Taco John's International, Inc.'s restaurants.

In 2004 and 2005, there were three *E. coli* O157:H7 outbreaks from agricultural fairs, festivals, and petting zoos located in North Carolina, Florida, and Arizona. Collectively, 173 visitors to these events contracted *E. coli* O157:H7, with 22 cases of HUS (Source: *Morbidity and Mortality Weekly Report* December 2005). At the North Carolina State Fair in 2004, illnesses were traced to children who had stepped or fallen in manure, used a pacifier or cup, or sucked their thumb while in the petting zoo. Both the Florida and Arizona cases were related to direct contact with infected animals or indirect contact with contaminated surfaces, such as railings. The average age of patients in these outbreaks was four to five years old. Based on data from two U.S. reporting agencies, Figure 8 (page 41) highlights the history of *E. coli* O157:H7 cases in the U.S. from 1994 until 2002.

Figure 8

HUMAN *E. COLI* O157* ISOLATES IN THE U.S., 1994 TO 2002**



** Only isolates with H7 antigen or which produce Shiga toxin are considered pathogens and reported.*

*** Based on data from the Public Health Laboratory Information System (PHLIS) and the National Notifiable Disease Surveillance System (NNDSS).*

Source: U.S. Department of Health and Human Services.

ECONICHE™: THE CATTLE VACCINE AGAINST *E. COLI* O157:H7

Bioniche Food Safety's lead project is Econiche™, its *E. coli* O157:H7 cattle vaccine that was developed in partnership with the University of British Columbia, the Alberta Research Council, and the Vaccine and Infectious Disease Organization (VIDO). This strategic alliance has been in place since September 2000, with Bioniche continuing to hold worldwide rights for the product's commercialization. The vaccine is intended to reduce the prevalence of *E. coli* O157:H7 in cattle and their manure, which in turn reduces the amount of contamination going into cattle processing plants, the environment, or groundwater. The vaccine also reduces the number of cattle that can host the *E. coli* bacteria.

Groundwork for the *E. coli* O157:H7 vaccine was initiated at the University of British Columbia in 1995 when Dr. Brett Finlay discovered that *E. coli* O157:H7 bacteria secrete specific proteins that the bacteria inject directly into an intestinal cell wall. In doing so, *E. coli* O157:H7 creates its own attachment site in the intestine that is developed from a variety of proteins. Bacteria adhere to these proteins and then colonize in the intestine, where they are able to release toxins directly into the bloodstream. Dr. Finlay initially envisioned a vaccine to protect children and then determined that a more sensible approach would be a cattle vaccine to reduce bacterial prevalence at the source. Based on this sequence of events, Dr. Finlay decided to try to immunize against the attachment of the bacteria, thereby reducing colonization. To assist with this endeavor, he partnered with VIDO. Subsequently, Dr. Dragan Rogan (biography on page 12), vice president, research and development at Bioniche Animal Health, recognized the potential of an *E. coli* vaccine and Bioniche became the commercial partner in the vaccine's development. Following, in 2001, the Industrial Technologies Office (ITO) granted Bioniche C$7.6 million in the form of a repayable loan to develop the vaccine. In September 2007, the Company was also awarded a C$2 million grant from the Ontario Ministry of Agriculture, Food, and Rural Affairs' Rural Economic Development program for market development related to the *E. coli* O157:H7 vaccine.

Vaccine Production

To manufacture its vaccine, Bioniche grows the *E. coli* O157:H7 bacteria and then purifies some of the secreted proteins that are required for the bacteria's attachment and colonization. Once vaccinated, the cattle's immune system produces antibodies that interfere with the attachment proteins. If unable to connect by way of these proteins, the *E. coli* O157:H7 cannot colonize, or reproduce in that animal, thereby reducing the environmental and food-chain contaminating burden by reducing bacterial prevalence in manure shed by the animal.

Limited production of the *E. coli* O157 vaccine has commenced at Bioniche's Belleville, Ontario, facility. In June 2008, the full C$25 million of required financing was obtained for the scale-up of the Company's internal manufacturing facility. Government assistance was obtained through Industry Canada, Agriculture and Agri-Food Canada (AAFC), the Business Development Bank of Canada (BDC), and the Ontario Ministry of Economic Development and Trade (MEDT). Bioniche is undertaking the expansion of its production capacity at a weighted average cost of capital that it believes to be favorable. The two-year scale-up is expected to provide a minimum capacity of 40 million doses of the *E. coli* O157:H7 vaccine per year. The Company's targeted wholesale price is C$2.00 per dose. Commissioning of the plant is targeted for 24 months from the start of construction, with revenues from this production capacity anticipated in 2010. Moreover, the C$25 million investment is part of a long-term, C$107 million project to create a state-of-the-art Animal Health and Food Safety Vaccine Manufacturing Centre.

Full Licensing Approval in Canada

In October 2008, Econiche™ received full licensing approval from the Canadian Food Inspection Agency (CFIA) after completing quality control tests on three pre-commercial batches of the vaccine to verify consistency of manufacturing processes. Full licensing by the CFIA permits the unrestricted use of Econiche™ by Canadian cattle producers and their veterinarians. The timing of the license was beneficial to Bioniche as it followed an *E. coli* O157 outbreak in North Bay, Ontario, with roughly 50 laboratory-confirmed illnesses and an additional 200 cases under investigation in November 2008 (referenced on page 39). The Canadian supply of Econiche™ is expected to be manufactured at the Belleville facility, with limited production likely during the expansion period.

Conditional License (U.S.)

The USDA initially reviewed data on this vaccine in August 2005, and requested that a further field use efficacy trial be completed. The Company conducted the trial, according to the USDA-approved protocol, at the University of Nebraska-Lincoln in 2006 (detailed on page 44) and submitted data to the USDA in spring 2007. In October 2007, the Company received a letter from the USDA indicating that, based on the agency's preliminary statistical treatment of the results from the 2006 study, the data did not support licensure. Bioniche then submitted additional statistical analyses and supporting rationale to the USDA and, on February 5, 2008, announced the receipt of a USDA notice stating that the latest data for the *E. coli* vaccine met the expectation of efficacy standard, making the vaccine eligible for a conditional license. To receive its conditional license, Bioniche must conduct a significant manufacturing step in the U.S. and develop a plan to meet the USDA's expected requirements for full licensure. The Company is working to complete these requirements in 2009. As part of the conditional license and in order to provide the vaccine to U.S. cattle producers, the Company is required to produce three validated production lots to be filled in the U.S. in accordance with the **Virus-Serum-Toxin Act of 1913**, as amended in 1985. Bioniche is not permitted to use a trademark name for the vaccine in the U.S. under the USDA conditional license; however, the Company is free to market the vaccine and there are no restrictions on sales volumes.

To aid in meeting expectations for a conditional license, Bioniche has added Dr. Gary Weber to the Company's management team (biography provided on page 13). Dr. Weber previously worked with both the USDA and the National Cattlemen's Beef Association. Bioniche believes that Dr. Weber's knowledge of the regulatory environment and cattle industry is an important asset as the Company works to meet expectations for the conditional U.S. license. Moreover, the Company intends to apply for product registration in Europe and other countries that have large cattle populations as well.

Vaccine Use

Bioniche Food Safety does not intend for its vaccine to serve as a replacement for any currently employed methods to reduce bacterial contamination in meat, produce, water, or other foodstuffs. Rather, the vaccine is designed to be a licensed and scientifically validated technique to reduce *E. coli* that can be used at the farm level, before the animal is processed. Bioniche Food Safety's *E. coli* O157:H7 cattle vaccine was used for the first time by a commercial beef producer, the Ontario-based Top Meadow Farms, in September 2007. Top Meadow Farms integrated use of the *E. coli* O157:H7 vaccine into its Top in Field™ cattle rearing standards, under the auspices of CFIA regulations governing the sale of the vaccine in Canada. The Top in Field™ designation marks Top Meadow Farms' commitment to high

standards of animal husbandry, care, and welfare. The beef producer abides by its Top in Field™ standards and mandates that its suppliers and affiliate farms do so as well. Top Meadow Farms maintains over 1,500 acres of land in Ontario, on which the company grazes its Limousin cattle. It does not use antibiotic-based products or animal byproducts in its cattle feed.

In addition, Bioniche identified two other early adopters of its vaccine: (1) a veterinarian with a cattle farm near Walkerton, Ontario, Dr. David Biesenthal; and (2) the Canadian Agriculture Museum in Ottawa, Ontario. As described on page 39, Walkerton had earlier experienced the damage of an *E. coli* outbreak. The Canadian Agriculture Museum is a demonstration farm with a 45-head dairy herd. After interacting with the museum's animals, four children had previously become infected with *E. coli* O157:H7.

Initial Target Markets

Prior to full licensure in Canada, Bioniche Food Safety's marketing team evaluated potential customers, including beef producers, feedlot operators, slaughterhouse operators, and cattle producer organizations, and provided these entities with data from the vaccine's previous field and challenge studies. North American feedlots, which are estimated at roughly 25 million cattle, are the first target market for Econiche™, as Canadian cattle producers and their veterinarians are permitted unrestricted use by the CFIA. The Company anticipates that the potential retail selling price of its vaccine could be less than C$10.00 per head of cattle, which equals less than C$0.02 per pound of beef. A subsequent market for the vaccine will likely be the 14 million dairy cattle located throughout North America. Bioniche Food Safety is also evaluating the potential to vaccinate cattle held in show barns or petting zoo settings. Econiche™ was recently recognized by the Canadian Association of Fairs and Exhibitions (C.A.F.E.) as a way to significantly reduce the risk of *E. coli* O157 transmission. Further, C.A.F.E. supports a proof-of-vaccination policy throughout Canada to ensure that the fair and exhibitions sector takes reasonable steps to protect the public.

In an effort to educate potential consumers and create awareness about the benefits of Econiche™, the Company hosted a two-day conference in June 2008 entitled "*E. coli* O157 Vaccine: Added Value or Added Cost" in Toronto, Canada. The audience included veterinarians and representatives from the food industry, including beef, dairy, and other commodity producers. As a guest speaker at the conference, Mr. Kevin Grier, a senior market analyst with the George Morris Centre, presented data that was completed for Bioniche on the cattle vaccine in the form of an economic cost-benefit analysis. Factoring in costs pertaining to medical expenses, recalls, and litigation, as well as the impact on market demand, the analysis demonstrated that there is a potential C$2.00 saved for every C$1.00 spent on vaccination of a Canadian cattle herd.

Efficacy Data

Bioniche Food Safety has tested its vaccine in more than 30,000 cattle over the past five years—a level of testing that the Company believes is unusually high for an animal vaccine. Results demonstrated a consistent decrease in the number of cattle that shed *E. coli* O157:H7 in their manure or were colonized by it at their rectal junction. For example, a controlled experiment at VIDO demonstrated a reduction in shedding of 99.47% in vaccinated cattle. Additional controlled challenge studies found that three doses of the vaccine administered three weeks apart caused a 36.5% reduction in the number of days that *E. coli* O157:H7 was shed in cattle feces, as well as a significant decrease in the quantity of bacteria shed. Vaccine efficacy in these challenge tests proved to be more than 99%.

In addition to reducing the level of bacteria shed in the feces, Bioniche Food Safety's cattle vaccine has been shown to decrease the prevalence of *E. coli* O157:H7 on animal hides. In 2005, the Company conducted a feedlot study of 168 vaccinated cattle and found that hides of immunized animals were 58% less likely to be contaminated than the hides of placebo cattle.

University of Nebraska-Lincoln

The most recent efficacy data was obtained through testing at the University of Nebraska-Lincoln and published in *Foodborne Pathogens and Diseases* (Vol. 5, No. 5) in late 2008. Under field conditions, studies at this University showed that the Company's vaccine contributes to a significant reduction in shedding and colonization of *E. coli* O157:H7 in cattle. Data simulations and modeling studies of 5,000 penned animals predicted that summer shedding of *E. coli* O157:H7 in feedlots could be reduced to the same levels that are seen during winter. The lower level of *E. coli* O157:H7 that is encountered during winter is more readily controlled than that experienced in summer. Other trials have confirmed that active shedding is the primary source of *E. coli* O157:H7 spread in a feedlot.

In commercial feedlots, University of Nebraska-Lincoln researchers evaluated the efficacy of using two instead of three vaccinations per cow in over 20,000 cattle from 19 commercial feedlots. In comparison to non-vaccinated cattle, inoculated cattle were 75% less likely to have *E. coli* O157:H7 colonization. In addition, ropes hung over the feed bunks of vaccinated animals (to test for possible environmental contamination passed through cattle saliva) were less likely to test positive for *E. coli* O157:H7 than those over the bunks of unvaccinated animals. A separate study of cattle that were vaccinated three times showed they were 98.3% less likely to have colonizing bacteria in their intestine than non-vaccinated animals. Furthermore, 144 inoculated cattle in field feedlot settings were also shown to have a reduced likelihood of colonizing *E. coli* O157:H7 in the terminal rectum versus a placebo group of animals. Feedlot settings present a particularly tough efficacy hurdle as, in the field, cattle are exposed to high and variable *E. coli* levels. This makes the measurement of product efficacy challenging when vaccinated and non-vaccinated animals are mingled in such a scenario.

Safety

In addition to its efficacy data, Bioniche Food Safety has provided safety data on the risk of self-injection (of the vaccine administrator) to the CFIA and Health Canada. In December 2006, Health Canada found that there was no risk of toxicity associated upon accidental self-injection.

Research Indications/Chairs

Bioniche Food Safety is further developing other product candidates to improve the safety of food and water consumed by humans, including assessing its *E. coli* O157:H7 cattle vaccine for efficacy against other *E. coli* strains. Further research indications are being explored in partnership with VIDO at the University of Saskatchewan and the University of British Columbia. Following the *E. coli* O157:H7 vaccine, Bioniche Food Safety is most advanced in its work toward the development of vaccines against *Campylobacter jejuni* (*C. jejuni*), which is one of the leading causes of bacterial diarrheal illness in the U.S. that is often isolated from healthy cattle, chickens, birds, and flies, and *Salmonella enteritidis* (*S. enteritidis*), a bacterium found inside raw or undercooked eggs.

To accelerate the development of additional vaccines to reduce food and water contamination, Bioniche established two Natural Science and Engineering Research Canada (NSERC)/Bioniche Industrial Research Chairs in April 2004. The Chairs are held by Dr. Andy Potter (senior chair), an associate director of research at VIDO, and Dr. Wolfgang Köster (associate chair), a senior scientist of the Drinking Water Microbiology group at the Swiss Federal Institute for Environmental Science and Technology (Dübendorf, Switzerland). These Research Chairs are funded with an investment from Bioniche of C$400,000 each year for a period of five years from the date the Chairs were implemented as well as matching funds awarded by the NSERC for the same five-year period. Through this partnership with VIDO, Bioniche benefits from research into *C. jejuni* and *S. enteritidis*, among other animal-to-human transmitted pathogens.

Competition

Bioniche is a multifaceted company with competition across several industries. This section is divided to reflect competition for each of the Company's business units. These are not exhaustive listings but are representative of the type of competition that the Company may face as it seeks to market its products or, as in the case with some already available products, gain increased market share. Additional competition may be derived from companies that also seek to establish collaborations with some of the same third parties (other companies, organizations, or academic institutions) with which Bioniche seeks to partner or license proprietary technology.

Human Health

Due to the prevalence of potential cancer therapeutics, only companies that have developed or are developing products for bladder cancer (Bioniche Therapeutics' most significant oncology initiative) are included below. In the U.S. alone, there are over 100 oncology drugs currently in clinical development (Source: the Pharmaceutical Research and Manufacturers of America [PhRMA] 2009). Oncology regimens typically incorporate several treatments, and Bioniche believes that its MCC technology can be synergistic with many other therapies. As a result, even products listed below may not necessarily exclude use of the Company's cancer approach.

- *Indevus Pharmaceuticals Inc.* Indevus' Valstar™ is approved by the FDA for use as a therapy in BCG-refractory carcinoma *in situ* of the bladder in patients who are ineligible for a cystectomy (bladder removal). Its target population consists of patients who would likely have high morbidity or mortality risks as a result of an immediate cystectomy. Given the FDA's recognition of a response rate between 8% and 16%, this product is not used as an alternative to cystectomy, but rather as a last resort for ineligible patients. Previously available, Valstar™ was removed from the market in 2002 due to impurities in its formulation. In December 2007, Indevus received a non-approvable letter from the FDA for Valstar™ related to a New Drug Application (NDA) supplement submitted to the FDA in May 2007. Indevus intended to continue working toward the reintroduction of Valstar™. In January 2009, Endo Pharmaceuticals Holdings, Inc. announced its intent to buy Indevus for $370 million.

- *Physion s.r.l.* Physion is an Italian company that electrifies and warms the bladder, intending to improve the potency of the chemotherapeutic mitomycin C. This process is called electromotive drug administration (EMDA). EMDA uses an electrical current to impart an accelerated, directional movement (toward the tissues) of ionized drugs in an intravesicular solution. The goal of EMDA is to deliver a greater quantity of drug deeper into tissue than passive diffusion. It is also intended to control the rate of drug administration by varying the intensity of the electric current. Currently, results remain inconclusive.

- *Spectrum Pharmaceuticals, Inc. (SPPI-NASDAQ).* Spectrum's EOquin® is in Phase III development for the treatment of early stage non-invasive bladder cancer following full surgical removal of tumors. In its Phase II trials, 67% of patients had a complete response to treatment after receiving EOquin® into the bladder. To date, EOquin® has shown to be well tolerated, with local toxicity consisting of bladder inflammation, increased urinary frequency, painful urination, and the presence of blood in the urine. Phase III studies began in April 2007 and are expected to be fully enrolled by the end of 2009. In January 2008, the European Medicines Agency (EMEA) reported that Spectrum's current placebo-controlled studies could be sufficient for a regulatory decision regarding European registration. In October 2008, Spectrum entered into an exclusive collaboration agreement with Allergan, Inc. for EOquin®. Per the terms of the agreement, Spectrum received $41.5 million from Allergan at closing, and may obtain additional payments of up to $304 million depending on the achievement of certain development, regulatory, and commercialization milestones.

- *Viventia Biotechnologies Inc.* This private Canadian company employs a monoclonal antibody (MAb) discovery platform to develop a portfolio of product candidates, including Vicinium™, which is now in a Phase II clinical study for the treatment of non-invasive BCG-refractory carcinoma *in situ* of the bladder. Vicinium™ is a cytotoxic-conjugated MAb targeting a molecule called EpCAM that resides on the surface of cancer cells. It is being developed as a potential local therapy for the treatment of bladder cancer by intravesicular instillation.

- *Bedford Laboratories™.* Bedford is one of the largest suppliers of injectable pharmaceuticals to the hospital market. Bedford is a division of Ben Venue Laboratories, Inc., a contract manufacturer that is a subsidiary of Boehringer Ingelheim GmbH. One of Bedford's products, thiotepa, is indicated for the treatment of superficial (non-invasive) papillary carcinoma of the bladder by local administration. Thiotepa can also be used to treat breast and ovarian cancers as well as Hodgkin's and non-Hodgkin's lymphomas. Thiotepa is a toxic, small-molecule alkylating agent of the nitrogen mustard type and between 10% and 100% of its dose is absorbed systemically. Hair loss and low white blood counts (leading to infections and anemia) usually occur in more than 30% of patients. In addition, there is a slight risk that patients may develop leukemia in later years. Bioniche does not believe that this drug is widely used in bladder cancer due to efficacy and toxicity concerns.

- *The National Cancer Institute (NCI).* Part of the National Institutes of Health (NIH), the NCI was created as an element of the approved National Cancer Act of 1937 to conduct and foster cancer research. The NCI is currently accepting participants into more than 20 active clinical trials for treatments of early stage bladder cancers. Among these trials, which can be accessed from the NCI's Clinical Trials directory (www.cancer.gov/clinicaltrials), the institution is currently investigating gemcitabine—a chemotherapy drug used to treat a variety of cancers—which can potentially be injected directly into the bladder to treat bladder cancer. Included is a Phase II study of gemcitabine in patients with recurrent bladder cancer that has not responded to previous BCG treatments, in addition to a randomized double-blind Phase III study of gemcitabine after surgery in treating patients with newly diagnosed or recurrent bladder cancer.

  Gemcitabine is also currently marketed by Eli Lilly & Co. (LLY-NYSE) as Gemzar® for combination with other chemotherapies or medications to treat metastatic non-small cell lung cancer (in patients for whom surgery is not possible), metastatic breast cancer, recurrent ovarian cancer (at least six months following platinum-based therapy), and locally advanced or metastatic pancreatic cancer. In Phase I/II clinical trials at Eli Lilly, gemcitabine used to treat bladder carcinoma in situ refractory to BCG elicited a complete response in four out of nine patients (44.4%) after six instillations of the therapy. Disease-free survival following the study ranged from seven months to over 33 months. Bioniche believes that the patent protection for Gemzar® is expected to expire in November 2010.

- *Medical Enterprises Group*. This private Dutch company is focused on the development of minimally invasive therapeutic technologies. Medical Enterprises is presently developing a treatment for superficial bladder cancer using its proprietary Synergo® technology, which entails simultaneously heating the local urinary bladder wall (hyperthermia) and flushing the bladder with mitomycin through a urinary catheter. Mitomycin is an antitumor antibiotic used to slow or stop the growth and spread of cancer cells in the body. Medical Enterprises is presently conducting a Phase III clinical trial to compare the efficacy of its Synergo® treatment versus BCG in patients with superficial bladder cancer. Synergo® technology has been approved by the European regulatory authorities (**CE Mark**), and Medical Enterprises is currently seeking FDA approval.

Animal Health

As large pharmaceutical companies focus on human healthcare, veterinary units of these companies may become eligible for joint ventures or non-strategic technology and product acquisitions by smaller research companies, similar to Bioniche's acquisition of Cue-Mate® from Pfizer. The companies listed on page 47 presently provide products to the animal healthcare marketplace.

- *Pfizer Animal Health.* As a division of Pfizer Inc., Pfizer Animal Health develops vaccines and prescription medications, offers technical support and service, and conducts significant research into new veterinary medicine techniques. This unit offers a full range of products for livestock, horses, and companion animals, such as Rimadyl® (carprofen) for canine arthritis and Equimax™ to eliminate major equine parasites, including tapeworms, in a single dose. In addition, Pfizer Animal Health has more than 30 technical service veterinarians who work with owners, producers, and veterinarians to help identify and solve health challenges as well as improve animal health and well-being.

- *Merial Ltd.* Merial is a joint venture between Merck & Co., Inc. (MRK-NYSE) and sanofi-aventis (SNY-NYSE) that estimates its market share at 14%. Operating in more than 150 countries, Merial maintains 16 manufacturing sites, eight research and development centers, and 5,000 employees worldwide. Merial's products include Frontline®, Heartgard®, and Ivomec®, among many others. In response to the equine influenza outbreak, Australia imported roughly 650,000 doses of vaccine from Merial in late 2007/early 2008 (Source: CNN.com).

- *Fort Dodge Animal Health.* Wyeth's (WYE-NYSE) Fort Dodge Animal Health division offers a range of biological and pharmaceutical products for the companion animal, equine, livestock, swine, and poultry industries, including West Nile-Innovator®, Duramune® Adult canine vaccine, CYDECTIN® Pour-on (to control parasites in cattle), the Pyramid® vaccine line (for bovine viruses), Quest® Gel (for equine parasites), and EtoGesic® Tablets (to manage canine osteoarthritis). Fort Dodge Animal Health was founded in 1912 and has been a part of Wyeth since 1945. With nearly 3,300 global employees, the unit distributes products in over 100 countries.

- *Boehringer Ingelheim Vetmedica, Inc*. Headquartered in St. Joseph, Missouri, Boehringer Ingelheim Vetmedica is a subsidiary of Boehringer Ingelheim Corporation that develops and markets products and technologies for horses, cattle, swine, and companion animals. Boehringer Ingelheim Vetmedica recently added a biological manufacturing facility, a research and development complex, and centralized warehousing facilities to its St. Joseph site.

- *Novartis Animal Health Inc.* A division of Novartis AG (NVS-NYSE), Novartis Animal Health is dedicated to maintaining and improving the health and welfare of pets and farm animals. The company is developing treatments for common pet ailments, such as internal and external parasites, arthritic pain control, and renal, heart, and allergic diseases, as well as insecticides for farm fly and pest control. For the livestock and farmed fish industries, Novartis Animal Health offers vaccines and therapeutic products to treat parasitic and bacterial infections. This unit is present in almost 40 countries, employing approximately 2,700 individuals worldwide.

Food Safety

Many of the companies listed in the Animal Health competition section above, among others, also conduct ongoing research into animal vaccines that may be able to prevent against epidemics of foodborne illnesses. In addition, organizations around the world, such as VIDO, the National Institute of Allergy and Infectious Diseases (NIAID), the United Nations' International Vaccine Institute (IVI), and the Food and Agriculture Organization of the United Nations (FAO), also focus on vaccines to prevent against foodborne illnesses.

E. coli Focus

Approaches to controlling illness and contamination related to *E. coli* continue to be explored. Some alternative techniques that are being pursued include potential treatments for the human manifestation of the disease, new post-harvest interventions, and pre-harvest (on-farm) control measures. However, Bioniche believes that its vaccine appears to be the only scientifically validated, pre-harvest intervention that is approaching full licensure in North America.

Milestones

Operating Highlights

- In October 2008, Econiche™ received full licensing approval from the Canadian Food Inspection Agency (CFIA). The Company had previously announced on September 24, 2008, that the data package for the vaccine provided definitive evidence that the vaccine met the CFIA's efficacy and safety requirements for full licensing.
- In March 2008, Bioniche was awarded Fast Track status by the FDA for its upcoming comparative study for Urocidin™, the second stage of a two-part Phase III clinical program. In November 2008, the Data Safety Monitoring Committee (an independent body) held its sixth meeting regarding this clinical trial and recommended that Bioniche "continue the trial unmodified."
- In February 2008, the USDA agreed that Bioniche's E. coli O157:H7 vaccine met the expectation of efficacy standard and could be eligible for a conditional license in the U.S. if the Company developed a plan that would collect sufficient data to move the product to full licensure in the U.S.

Financial Highlights

- In September 2008, Bioniche converted a portion of its revolving credit facility with the Valens U.S. family of funds (formerly Laurus Master Funds), issuing 4.6 million shares and freeing up $1.85 million in additional borrowing capacity. In addition, the Company is expected to issue 211,429 five-year Warrants to purchase Common Shares with an exercise price of C$0.49 per Common Share in exchange for Laurus/Valens waiving several volume restrictions on the conversion of borrowings into Common Shares set out in previous agreements.
- In June 2008, the Company amended a pre-existing C$7.6 million contribution agreement with the Industrial Technologies Office (ITO) of Industry Canada. With C$25 million in funding through a loan and various government assistance programs in place, Bioniche had the required financing to commence the Belleville facility scale-up over the next two years.
- In March 2008, Bioniche converted a portion of its revolving credit facility with Laurus/Valens, issuing 2.7 million shares. In addition, the Company agreed to issue 200,000 five-year Warrants to purchase Common Shares with an exercise price of C$0.77 per Common Share, in exchange for Laurus/Valens waiving select volume restrictions relating to the conversion under the agreement.
- In February 2008, the Company entered into a 10-year term loan with the Business Development Bank of Canada (BDC) for C$5 million. At June 30, 2008, C$1.75 million had been drawn.
- In December 2007, the Company amended its revolving credit facility with Valens. Under the amended facility, the Company has a maximum borrowing limit of $5.5 million of which $3.0 million is unrestricted, versus the previous maximum of $4.0 million. With reduced restrictions, this amendment represented an immediate increase to available funds of $3.0 million as there are no restrictions based on asset base calculation for the added funds.
- In December 2007, the Company received C$10 million in financing from the Ministry of Economic Development and Trade's (MEDT) Advanced Manufacturing Investment Strategy (AMIS) program and C$5.0 million in federal government financing from the Agriculture and Agri-Food Canada's (AAFC) Agri-Opportunities program to support the Belleville production facility scale-up.

Miscellaneous Highlights

- In January 2009, the Company was named one of the Top 50 Best Small and Medium-Sized Employers in Canada. Bioniche was ranked 13th by its employees. The rankings are primarily determined using the results from employee opinion surveys, where 18 key engagement drivers are detailed and analyzed. The evaluation process also includes an assessment of organizational practices and perspectives from the leadership team. More than 250 companies across Canada registered to participate in the study.

- In October 2008, results of a large-scale commercial beef feedlot study with Bioniche's E. coli O157 vaccine were published in *Foodborne Pathogens and Disease*, a peer-reviewed scientific journal.
- In July 2008, Dr. Dragan Rogan, vice president, research and development at Bioniche Animal Health, presented data regarding the Company's E. coli O157 cattle vaccine at the XXV World Buiatrics Congress in Budapest, Hungary.
- In April 2008, the Company appointed Dr. Gary Weber as president of Bioniche Food Safety (U.S.).
- In December 2007, the Company was honored as one of Canada's Top 10 Life Sciences Companies for 2008. Bioniche was selected by a group of venture capital investors based on the Company's attractiveness as an exceptional investment in Canada.
- In November 2007, two articles were published in the Journal of Food Protection, both in regard to the efficacy of Bioniche's cattle vaccine. The articles related to field challenge studies conducted at the University of Nebraska-Lincoln involving nearly 900 animals in 2002 and 2003.

Fiscal 2009 Objectives

Through the successful execution of the Company's business strategy, Bioniche aims to accomplish the objectives listed in Table 13 during fiscal 2009, which began in July 2008. The Company has already fulfilled some of the objectives in Table 13, such as receiving full Canadian licensure for Econiche™.

Table 13
Bioniche Life Sciences Inc.
FISCAL 2009 OBJECTIVES

Objective	Status
Generate cash flow by increasing revenue and productivity, as measured by the consolidated EBITDA in the Animal Health business unit.	▪ The Company is meeting this objective. The Animal Health EBITDA (earnings before interest, taxes, depreciation, amortization, and foreign exchange) has shown an increase of 58% for the three months ended September 30, 2008, versus the same period in fiscal 2008. ▪ Sales in Animal Health have increased by C$2.2 million, or 37%, during the first quarter of fiscal 2009 versus the same period in 2008.
Progress to full Canadian license for the *E. coli* O157 cattle vaccine, while selling available vaccine (limited quantities) to Canadian veterinarians under the "Permit to Release Veterinary Biologics" and continuing to pursue registration in the U.S. via the USDA.	▪ Subsequent to the quarter ended September 30, 2008, the Company announced that Econiche™, believed to be the world's first vaccine designed to reduce the shedding by cattle of *E. coli* O157, received full licensing approval from the CFIA. The Company is now able to promote the sale of Econiche™ in Canada. ▪ Bioniche is in the process of meeting requirements for a U.S. conditional license, which it expects the USDA may grant later in 2009.
Begin to scale up vaccine production at the Company's Belleville, Ontario, facility. This two-year project is expected to have an annual capacity of at least 40 million doses of the *E. coli* O157 vaccine. The scale-up is expected to cost approximately C$25 million, as it is the first phase of a long-term C$107 million project to create an Animal Health and Food Safety Vaccine Manufacturing Centre.	▪ The Company has secured government assistance in the form of two interest-free loans based on eligible expenditures from the Ontario Ministry of Economic Development and Trade (AMIS program) and AAFC's Agri-Opportunities program, in addition to a loan facility with the BDC for the Phase I scale-up. A further C$5 million was provided to the scale-up through an amendment to a pre-existing contribution agreement with the ITO of Industry Canada. A total of C$25 million in funding and assistance was announced (collectively) in December 2007, February 2008, and June 2008. The Company is finalizing the engineering of the facility, with tenders planned to be issued subsequently. Scale-up is expected to be completed by mid-2010.
Successfully conclude a marketing partnership transaction for the Company's bladder cancer technology.	▪ Bioniche is in ongoing discussions with potential marketing partners and hopes to conclude a partnership agreement in 2009.

Source: Bioniche Life Sciences Inc.

Key Points to Consider

Note: Unless otherwise stated, all monetary amounts are in U.S. dollars. At 02/12/2009, US$1.00 = ~C$1.24.

- Bioniche is a Canadian biopharmaceutical company committed to improving the quality of life for humans and animals worldwide through innovative research, novel technologies, and therapeutics. Bioniche operates in three business units: (1) Bioniche Therapeutics (Human Health); (2) Bioniche Animal Health; and (3) Bioniche Food Safety.

- The Human Health unit functions as Bioniche's research arm, developing proprietary technologies, such as the unit's primary initiative, Urocidin™, which is a novel treatment for non-muscle-invasive bladder cancer. A Fast Tracked Phase III trial for Urocidin™ is ongoing in non-muscle-invasive bladder cancer patients who are unresponsive to the standard therapy. A second Phase III trial for potential as a new first-line therapy is likely to proceed once full enrollment is achieved for the first Phase III trial and when funding is available. Full enrollment is expected in early 2009.

    - The average age for bladder cancer diagnosis is 68 to 69. As such, the aging global population is contributing to higher bladder cancer rates for which patients' treatment options are either associated with severe side effects or require life-altering surgeries. The American Cancer Society (ACS) expected roughly 69,000 new cases of bladder cancer in the U.S. during 2008. Worldwide, there are approximately 330,000 new cases and 130,000 deaths per year.

- Operating since 1979, the Animal Health unit is one of the largest Canadian-owned animal health biopharmaceutical companies, as measured by sales. Altogether, this unit has over 100 globally marketed products that help reduce the industry's reliance on antibiotics.

    - The global animal health market is using fewer antibiotics as excessive use of these substances creates antibiotic-resistant bacterial strains that may be transmitted to humans. As a result, governments are placing more stringent regulations on antibiotics, which may benefit Bioniche's non-antibiotic immunomodulation products.

- The Food Safety unit creates veterinary biopharmaceutical products to address livestock diseases that pose risks to human health via contaminated food and water supplies. Its lead product is a cattle vaccine (Econiche™) to reduce the transmission of *Escherichia coli* (*E. coli*) O157:H7 by cattle feces.

    - In February 2008, the U.S. Department of Agriculture (USDA) deemed Econiche™ eligible for a conditional license in the U.S. Further, in October 2008, the Canadian Food Inspection Agency (CFIA) granted full licensing approval for the cattle vaccine after the Company completed quality control tests on three pre-commercial batches to verify consistency of the manufacturing process.

    - The *E. coli* O157:H7 strain accounts for more *E. coli* outbreaks than any other strain, affecting over 73,000 people, with 2,100 hospitalizations and 60 deaths in the U.S. each year. In 2003, the cost of *E. coli* to the U.S. food industry was estimated at $2.7 billion (Source: *Meat & Poultry*). Canadian losses total more than C$33 million annually (Source: the George Morris Centre).

- By May 2008, the Company had secured the required C$25 million in financing to scale up *E. coli* O157:H7 vaccine production over the next two years to a minimum capacity of 40 million doses. The scale-up is part of a long-term C$107 million product to create a state-of-the-art Animal Health and Food Safety Vaccine Manufacturing Centre in Belleville, Ontario.

- The Company has over 300 issued and pending patents for its products and platform technologies. For its largest growth drivers—Urocidin™ and Econiche™—the first issued U.S. patents do not expire until late 2018, with possible restoration periods through late 2023.

- Bioniche has committed employees and an integrated leadership team with expertise in numerous key disciplines. Bioniche's executive management combines the experience of members who have been with the Company for 20 or more years with the perspective of more recently hired individuals.

- At December 31, 2008, Bioniche had cash and cash equivalents of over C$5.6 million versus cash and cash equivalents of nearly C$4.4 million at June 30, 2008.

Historical Financial Results

Tables 14, 15, and 16 summarize Bioniche's key historical financial statements—its unaudited Interim Consolidated Statements of Loss, Deficit, and Comprehensive Loss, Balance Sheets, and Statements of Cash Flows. The Company's fiscal year end is June 30.

Note: Financial statements are in Canadian dollars (C$). At December 31, 2008, C$1.00 = ~US$0.81.

Table 14
Bioniche Life Sciences Inc.
INTERIM CONSOLIDATED STATEMENTS OF LOSS, DEFICIT, AND COMPREHENSIVE LOSS
(Unaudited - see going concern uncertainty note on page 54)
For the three and six months ended December 31

	Current Quarter 2008 C$	Last Year Quarter 2007 C$	Current Year to Date 2008 C$	Last Year to Date 2007 C$
REVENUE				
Sales	**8,609,695**	6,514,261	**16,711,936**	12,419,045
Cost of sales (excluding amortization)	**3,409,786**	2,687,177	**7,127,237**	5,166,481
	5,199,909	3,827,084	**9,584,699**	7,252,564
EXPENSES				
Administration	**1,579,051**	1,973,720	**3,097,378**	3,603,134
Marketing and selling	**1,866,462**	1,729,968	**3,627,402**	3,370,091
Quality assurance	**—**	200,354	**—**	370,784
Interest on long-term debt	**86,530**	35,980	**169,234**	73,930
Other interest, net	**76,294**	(21,526)	**111,513**	(84,346)
Accreted interest on discounted receivables and interest-free loans	**(4,118)**	—	**(13,906)**	—
Amortization of property, plant, and equipment	**338,092**	282,375	**676,446**	564,162
Amortization of intangible assets	**194,231**	214,130	**408,360**	428,259
Amortization of financial expenses	**601,124**	117,641	**960,253**	152,807
Foreign exchange loss (gain)	**(29,993)**	118,541	**(22,909)**	316,514
	4,707,673	4,651,183	**9,013,771**	8,795,335
Income (loss) before research and development expenses and other items	**492,236**	(824,099)	**570,928**	(1,542,771)
Research and development expenses, gross	**3,185,117**	3,663,747	**7,030,277**	7,230,414
Less: government incentives	**(490,112)**	(374,735)	**(1,006,248)**	(718,583)
Change in unrealized loss (gain) on foreign currency embedded derivatives	**—**	44,453	**59,693**	(138,203)
Loss before income taxes	**(2,202,769)**	(4,157,564)	**(5,512,794)**	(7,916,399)
Provision for income taxes	**162,412**	59,601	**177,078**	113,524
Net loss and comprehensive loss for the period	**(2,365,181)**	(4,217,165)	**(5,689,872)**	(8,029,923)
Transition adjustment due to change in accounting policy	**—**	—	(39,350)	134,674
Deficit, beginning of period	**(88,115,690)**	(72,308,699)	**(84,751,649)**	(68,630,615)
Deficit, end of period	**(90,480,871)**	(76,525,864)	**(90,480,871)**	(76,525,864)
Basic and diluted net loss per share	**(0.03)**	(0.07)	**(0.08)**	(0.13)
Weighted-average number of Common Shares outstanding	**71,018,609**	62,073,503	**69,106,748**	61,977,023

Source: Bioniche Life Sciences Inc.

Table 15
Bioniche Life Sciences Inc.
INTERIM CONSOLIDATED BALANCE SHEETS
(Unaudited - see going concern uncertainty note on page 54)

	As at December 31, 2008 C$	As at June 30, 2008 C$
ASSETS		
Current		
Cash and cash equivalents	**5,635,249**	4,399,065
Accounts receivable	**5,781,538**	6,443,299
Inventories	**5,991,912**	4,738,765
Prepaid expenses and deposits	**727,526**	640,326
Foreign currency embedded derivatives	**—**	59,693
	18,136,225	16,281,148
Long-term		
Property, plant, and equipment	**9,640,527**	9,718,157
Intangible assets	**7,280,338**	7,688,698
Goodwill	**456,155**	456,155
Long-term accounts receivable	**875,712**	478,852
	36,388,957	34,623,010
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current		
Revolving credit facility	**5,038,495**	2,593,059
Accounts payable and accrued liabilities	**10,077,958**	8,341,398
Income taxes payable	**219,890**	104,592
Current portion of long-term debt and obligations under capital leases	**882,654**	706,505
	16,218,997	11,745,554
Long-term		
Long-term debt	**1,343,835**	1,673,853
Obligations under capital leases	**1,107,889**	1,176,237
Government assistance loans	**785,665**	—
Deferred government incentives	**3,626,251**	3,606,926
	23,082,637	18,202,570
Shareholders' equity		
Share capital	**95,369,909**	92,941,966
Special Warrants	**2,174,008**	2,174,008
Other paid-in capital	**6,243,274**	6,056,115
Deficit	**(90,480,871)**	(84,751,649)
	13,306,320	16,420,440
	36,388,957	34,623,010

Source: Bioniche Life Sciences Inc.

Table 16

Bioniche Life Sciences Inc.

INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited - see going concern uncertainty note on page 54)

For the three and six months ended December 31

	Current Quarter 2008 C$	Last Year Quarter 2007 C$	Current Year to Date 2008 C$	Last Year to Date 2007 C$
OPERATING ACTIVITIES				
Net loss for the period	**(2,365,181)**	(4,217,165)	**(5,689,872)**	(8,029,923)
Add (deduct) non-cash items:				
Amortization	**1,133,447**	614,146	**2,045,059**	1,145,228
Unrealized foreign exchange loss (gain)	**460,031**	21,667	**366,273**	(53,451)
Change in unrealized loss (gain) on foreign currency embedded derivatives	**—**	44,453	**59,693**	(138,203)
Accreted interest on discounted receivables	**(4,118)**	—	**(13,906)**	—
Stock-based compensation	**63,051**	347,665	**125,144**	432,411
Warrants issued to consultants	**—**	—	**700**	—
Employee share ownership plan	**162,775**	163,553	**340,198**	311,322
	(549,995)	(3,025,681)	**(2,766,711)**	(6,332,616)
Net change in non-cash working capital balances	**764,235**	(1,475,702)	**196,002**	(830,764)
Cash provided by (used in) operating activities	**214,240**	(4,501,383)	**(2,570,709)**	(7,163,380)
INVESTING ACTIVITIES				
Proceeds from maturity of short-term investments	**—**	—	**—**	9,500,000
Government incentives received on account of property, plant, and equipment	**53,074**	2,807	**53,074**	4,641
Purchases of property, plant, and equipment	**(384,666)**	(73,688)	**(522,578)**	(272,397)
Cash provided by (used in) investing activities	**(331,592)**	(70,881)	**(469,504)**	9,232,244
FINANCING ACTIVITIES				
Proceeds from deferred government incentives	**102,401**	18,701	**102,401**	49,965
Proceeds from government assistance	**143,339**	—	**776,431**	—
Payment of financing fees – debt	**(11,036)**	—	**(11,036)**	—
Proceeds from revolving credit facility	**8,591,273**	8,505,017	**16,976,011**	13,451,976
Repayment of revolving credit facility	**(7,146,912)**	(5,281,835)	**(13,266,396)**	(10,380,520)
Repayment of capital lease obligations	**(71,345)**	(29,164)	**(130,025)**	(64,323)
Repayment of senior and other long-term debt	**(137,844)**	(4,861)	**(170,989)**	(9,612)
Cash provided by financing activities	**1,469,876**	3,207,858	**4,276,397**	3,047,486
Net increase (decrease) in cash and cash equivalents during the period	**1,352,524**	(1,364,406)	**1,236,184**	5,116,350
Cash and cash equivalents, beginning of period	**4,282,725**	8,004,353	**4,399,065**	1,523,597
Cash and cash equivalents, end of period	**5,635,249**	6,639,947	**5,635,249**	6,639,947

Source: Bioniche Life Sciences Inc.

Risks

Some information in this report relates to future events or future business and financial performance. Such statements can be only predictions and the actual events or results may differ from those described due to, among other things, the risks detailed in Bioniche's Annual Information Filing (AIF), press releases, and other forms filed from time to time. The content of this report with respect to Bioniche has been compiled primarily from information available to the public and released by the Company through news releases and System for Electronic Document Analysis and Retrieval (SEDAR) filings. Bioniche is solely responsible for the accuracy of that information. Information about other companies has been prepared from publicly available documents and has not been independently verified by Bioniche. For more complete information about Bioniche, refer to the Company's website at www.bioniche.com.

One should carefully consider the risks and information about Bioniche's business described below as well as the other information and risks included in the Company's SEDAR filings and other public documents. One should not interpret the order in which these considerations are presented as an indication of their relative importance. The risks and uncertainties described below are not the only ones the Company faces. Additional risks and uncertainties not presently known or those it currently considers to be immaterial may also have an adverse effect on its business. If any of the matters described in the accompanying risk factors were to occur, Bioniche's business, financial condition, results of operations, cash flows, or prospects could be materially adversely affected.

Going Concern Uncertainty Note

As of December 31, 2008, the Company had incurred significant losses and had an accumulated deficit of C$90,480,871. The Company's committed cash obligations and expected level of expenses for the year exceeds the cash and cash equivalents on hand. To date, Bioniche has financed its cash requirements primarily through issuances of shares and debt, investment tax credits, sale of products, royalties, government grants, and a revolving credit facility. The Company's revolving credit facility expires on March 2, 2009. The Company is actively working on replacing the revolving credit facility with other banking partners and at the same time is negotiating a partnership deal for Urocidin™. While Bioniche expects to conclude successfully on these two matters in the near term, its ability to continue as a going concern is dependent upon successfully concluding one or both of these matters in the near term or obtaining an extension of the revolving credit facility until such negotiations are successfully concluded. The Company's ability to continue as a going concern is also dependent upon its ability to continue to sell its products at positive margins, to bring new products to market, to obtain regulatory approvals, to enter into research collaborations, to obtain additional financing, and to achieve future profitable operations. The successful resolution of these matters is dependent upon factors outside of Bioniche's control, and therefore, there is significant uncertainty about the Company's ability to continue as a going concern.

The interim consolidated financial statements presented on pages 51-53 do not give effect to any adjustments to the amounts and classifications of assets and liabilities that might be necessary should Bioniche not be successful in its efforts to obtain additional financing, or to receive significant funds on entering into research collaborations. Such adjustments could be material.

The interim consolidated financial statements do not contain all disclosures required by generally accepted accounting principles (GAAP) for annual financial statements and, accordingly, these financial statements should be read in conjunction with the most recently prepared annual consolidated financial statements for the year ended June 30, 2008. The unaudited interim consolidated financial statements follow the same accounting policies and methods of their application as outlined in the most recent annual consolidated financial statements, except as described in Note 2 of the Company's interim financial statements filed with SEDAR on February 6, 2009.

The preparation of the interim consolidated financial statements requires management to make estimates and assumptions that affect the reported amount of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the interim consolidated financial statements, and the reported amounts of revenues and expenses during the reporting periods. Reported amounts and note disclosures

are determined using management's best estimates based on assumptions that reflect the most probable set of economic conditions and planned courses of action. Actual results, however, may differ from estimates used in the interim consolidated financial statements and such differences may be material.

Impact of Capital Market Conditions

Current capital and credit market conditions may have a significant negative impact on the Company's ability to obtain financing. Economic uncertainty may negatively impact Bioniche's customers, suppliers, and lenders in ways that are difficult to foresee and at unpredictable times. The bankruptcy of a significant customer would result in the write-off of outstanding accounts receivable and the loss of future business with this customer. The bankruptcy of a key supplier could result in a disruption to Bioniche's business resulting in lost revenues. Credit market uncertainty could make the Company's existing lenders hesitant to advance further funds or call existing loans.

Cash Flow and Financial Resources

The current burn rate of approximately C$0.8 million per month on average is expected to remain and grow during the remainder of fiscal 2009. In the near term, Bioniche will likely require cash to fund operations. The Company believes that it will be able to obtain long-term capital to support its corporate objectives. Bioniche is currently pursuing many opportunities to raise financial resources. However, it is impossible to guarantee the availability of additional financial resources or that these will be available under acceptable terms and conditions. If the Company is unsuccessful in obtaining adequate funds or in obtaining funds on reasonable terms, it may need to undertake the following:

- Terminate or delay clinical trials of its product candidates;
- Delay the scale-up of manufacturing capabilities;
- Curtail significant product development programs;
- Sell or assign rights to its technologies, existing products, or product candidates; and/or
- Undertake a corporate reorganization, which could include reducing certain early stage preclinical research activities, deferring development programs, or implementing other cost reduction initiatives.

Bioniche may be unable to obtain partnerships for one or more of its product candidates, which could curtail future development and negatively impact its share price.

The Company's product candidates require significant funding to reach regulatory approval upon positive clinical results. Such funding, in particular for Urocidin™ in bladder cancer, may be very difficult or impossible to raise in the public markets without significant dilution. If such partnerships are not attainable, the development of these product candidates may be significantly delayed or stopped altogether. The announcement of such delay or discontinuation of development may have a negative impact on Bioniche's share price. In addition, the Company's strategy for the research, development, and commercialization of its products requires entering into various arrangements with corporate collaborators, licensers, licensees, and others, and the Company's commercial success is dependent upon these outside parties performing their respective contractual responsibilities. The amount and timing of resources that such third parties will devote to these activities may not be within the Company's control. Bioniche cannot assure investors that such parties will perform their obligations as expected. The Company also cannot guarantee that its collaborators will devote adequate resources to its programs. In addition, Bioniche could become involved in disputes with its collaborators, which could result in a delay or termination of the related development programs or result in litigation. The Company intends to seek collaborative arrangements to develop and commercialize some of its products. Bioniche may not be able to negotiate collaborative arrangements on favorable terms or at all in the future, and there is no guarantee that current or future collaborative arrangements will be successful.

Clinical trials are long, costly, and involve uncertain processes, and Health Canada or the U.S. Food and Drug Administration (FDA) may ultimately not approve any of the Company's product candidates. Bioniche may never develop any further 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 preclinical 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 Bioniche can submit any regulatory applications. Clinical trials are long, costly, and involve uncertain processes. 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 Bioniche's preclinical 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 Bioniche's upcoming Phase III clinical trial with Urocidin™ in bladder cancer may not meet the primary endpoint of the study despite promising preclinical and early stage clinical data.

In addition, unacceptable toxicities or adverse side effects may occur at any time in the course of 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 Bioniche'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.

Early Stage Development

Several of Bioniche's products and 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 resources and time is required to conduct research and clinical trials if Bioniche is to complete the development of any product or process. It is not known whether any of these product or process candidates can 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 Bioniche's investment in any such product or process candidate will be recovered through sales or royalties.

Manufacturing Facilities

Bioniche relies on having properly validated, fully functioning, and sufficiently sized manufacturing facilities 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 likely 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 occur.

Government Regulations

The manufacture and sale of animal and human therapeutic products are governed by numerous statutes and regulations in the U.S., Canada, Ireland, and other countries where Bioniche 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, preclinical, and clinical data prior to marketing approval; adherence to Good Manufacturing Practices (GMP) during production and

storage; and regulation of marketing activities, notably advertising and labeling. The Company's products and processes will likely require considerable development, preclinical and clinical testing, and investment of significant funds prior to 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 U.S. and Canada, impose similar restrictions.

Key Personnel

Bioniche's success is largely dependent upon its ability to attract and retain a highly qualified workforce, and to establish and maintain close relations with research centers. Competition is intense and the Company's success depends, 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.

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.

Volatility of Share Prices

Share prices are subject to change because of numerous factors related to Company activity, including reports of new information, changes in Bioniche's financial situation, the sale of shares in the market, the Company's failure to obtain results in line with the expectations of analysts, or announcements by Bioniche or any of its competitors concerning technological innovation, among other factors. During the past few years, shares of Bioniche, 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 the Company's shares will be protected from any such fluctuations in the future.

Intellectual Property Infringement Claims

Third parties may claim that the Company infringes upon their intellectual property. Any such claims, with or without merit, could materially harm Bioniche's business and its operating results.

Suppliers

The Company is dependent on certain third parties for the supply involved in the manufacturing of certain key products. Although Bioniche 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.

Other Risks and Uncertainties

If any of the following risks occur, the Company's business, results of operations, or financial condition could be materially adversely affected.

- Bioniche expects to continue to experience losses. In addition, it is also difficult to estimate timing and future costs of its research and development programs.

- The Company is indirectly subject to price regulation in certain countries and this could affect its gross margin.

- Bioniche may not achieve its projected development goals in the timeframes it announces and expects.
- Rapid technological change could make the Company's products obsolete.
- Bioniche faces uncertainties related to regulatory approval, which could result in delays in product commercialization in certain territories.
- Even if the Company obtains marketing approval, its products will likely be subject to ongoing regulatory review.
- Bioniche's products, if approved, may fail to achieve market acceptance.
- Development of drugs can be costly and may require years of research and development activities.
- If the Company cannot raise additional capital on acceptable terms, it may delay or be unable to pursue further development of its product portfolio, obtain regulatory approvals, or commercialize its product candidates.
- If Bioniche is unable to protect its intellectual property rights, its competitors may develop and market products with similar features that may reduce demand for its products and the effective commercialization of its products may be inhibited.
- The Company may become involved in lawsuits to protect or enforce its patents, which could be costly and time consuming.
- If third-party manufacturers of Bioniche's products fail to devote sufficient time and resources to its concerns, or if their performance is substandard, the Company's clinical trials and product introductions may be delayed and its costs may rise.
- Bioniche may not be able to manufacture its products in commercial quantities, which would prevent it from marketing its products.
- The Company may not be able to successfully achieve its goals.
- Bioniche may incur losses associated with foreign currency fluctuations.
- The Company is subject to the risk of product liability claims, for which it may not have or may not be able to obtain adequate insurance coverage.
- Some of the Bioniche's products may use hazardous materials, and as a result the Company could be exposed to potential liability claims and to costs associated with complying with laws regulating hazardous waste.
- Future sales of Common Shares by the Company or its existing lenders or shareholders may cause Bioniche's stock price to fall.
- The Company has never paid dividends on its Common Shares, and it does not anticipate paying any cash dividends in the foreseeable future.
- Bioniche has international operations that expose the Company to additional business risks.

Recent Events

Note: Unless otherwise stated, all monetary amounts are in U.S. dollars. At 02/12/2009, US$1.00 = ~C$1.24.

02/06/2009—Bioniche Life Sciences Inc. announced financial results for the second quarter of its 2009 fiscal year, ended December 31, 2008. These results are presented on pages 51-53.

02/03/2009—Announced that its president of Bioniche Food Safety, Mr. Rick Culbert (biography on page 11), participated in a Canadian Beef Value Chain Roundtable in Gatineau, Québec. The two-day Roundtable involved representatives from regulatory authorities, ranchers, feedlot operators, processors, retail and food service representatives, feed suppliers, and others. They met to develop a strategy focused on improving the competitiveness of the Canadian beef industry through market access and development, the regulatory environment, research and innovation, and information transfer.

01/14/2009—Named one of the Top 50 Best Small and Medium-Sized Employers in Canada. Bioniche was ranked 13th by its employees. The rankings are primarily determined using the results from employee opinion surveys, where 18 key engagement drivers are detailed and analyzed. The evaluation process also includes an assessment of organizational practices and perspectives from the leadership team. More than 250 companies across Canada registered to participate in the study.

11/24/2008—Presented data about its proprietary mycobacterial cell wall-DNA complex (MCC), trademarked Urocidin™, to an international audience of urologists at the 2008 Société Internationale d'Urologie (SIU) Congress in Santiago, Chile, on November 22, 2008.

11/17/2008—Announced that its first Phase III clinical trial of Urocidin™ for the treatment of bladder cancer was authorized to continue unmodified. The Data Safety Monitoring Committee held its sixth scheduled meeting regarding this clinical trial in early November 2008. The role of this independent body is to confirm that the safety of enrolled patients is being appropriately addressed and that, from an efficacy point of view, there is an appropriate basis for continuing the trial.

11/07/2008—Announced financial results for the first quarter of its 2009 fiscal year ended September 30, 2008. Consolidated revenues for the first quarter totaled C$8.1 million, an increase of 37% from the C$5.9 million recorded in the same period in fiscal 2008.

10/27/2008—Announced that Econiche™, the Company's *Escherichia coli* (*E. coli*) O157:H7 vaccine for cattle, received full licensing approval from the Canadian Food Inspection Agency (CFIA).

10/17/2008—Announced that the results of a large-scale commercial beef feedlot study with Econiche™ were published in *Foodborne Pathogens and Disease* (Vol. 5, No. 5, 2008), a peer-reviewed scientific journal.

09/24/2008—Received notice from the CFIA indicating that the data package for the Company's cattle vaccine provided definitive evidence that the vaccine meets the efficacy and safety requirements for full licensure.

09/19/2008—Announced financial results for the fiscal year ended June 30, 2008. Due to increased sales of Bioniche Animal Health's products in the U.S. and Europe, consolidated revenues for fiscal 2008 increased 0.7% to C$27.7 million versus C$27.5 million in fiscal 2007. The overall gross profit margin was 57% for fiscal 2008 versus 55.6% in fiscal 2007. Gross research and development expenses increased C$1.0 million in fiscal 2008, reaching C$15.9 million, versus C$14.9 million in fiscal 2007. The increase in costs was attributed to the ongoing Phase III clinical program for the Company's Urocidin™ bladder cancer therapy and the Econiche™ vaccine development program. The basic and fully diluted net loss per share for fiscal 2008 was (C$0.26) versus a net loss per share of (C$0.32) in fiscal 2007.

09/09/2008—Announced the conversion of a portion of the Company's revolving credit facility with the Valens U.S. family of funds (formerly Laurus Master Funds) into Common Shares. Bioniche converted $1.85 million of the revolving facility into equity at the previously negotiated 15% discount to the 10-day volume weighted average price on September 5, 2008. This results in the issuance of 4,565,049 shares. The conversion is in accordance with the formula set out in the original agreement signed in 2005. In addition, the Company is expected to issue 211,429 five-year Warrants at market price ($0.49 per share) in exchange for Valens U.S. waiving several volume restrictions relating to the conversion under the agreement, without penalty.

08/25/2008—Announced that Bioniche Animal Health was granted full listing by the Organic Materials Review Institute (OMRI) for its Immunoboost® immunostimulant technology for calves. The OMRI is a U.S. nonprofit organization that determines which input products are acceptable for use in organic production and processing. Only OMRI-listed products may be used on operations that are certified organic under the U.S. Department of Agriculture's (USDA) National Organic Program. The addition of Immunoboost® to the official OMRI list indicates that this biological product met the national standard for use in organic dairy and beef operations in the U.S.

08/18/2008—Announced that the Company's first Phase III clinical trial with a formulation of Urocidin™ for the treatment of bladder cancer was progressing well. The Data Safety Monitoring Committee held its fifth scheduled meeting on August 14, 2008, regarding this clinical trial. After its meeting, the Committee recommended that Bioniche continue the trial unmodified until the next scheduled or triggered meeting.

07/10/2008—Presented data regarding its *E. coli* O157:H7 cattle vaccine at the XXV World Buiatrics Congress in Budapest, Hungary. The presentation, entitled "Vaccination of cattle with *E. coli* O157:H7 type III secretion proteins as a pre-slaughter intervention method to reduce *E. coli* O157:H7 prevalence," was made by Dr. Dragan Rogan (biography on page 12), vice president, research and development at Bioniche Animal Health, and was co-authored by Dr. David Smith, Dr. Rod Moxley, Dr. Andy Potter, and Ms. Julie Yome. The World Buiatrics Congress is the largest event of its kind in the cattle industry and is attended by scientists from universities and research institutes; practitioners working with dairy and beef cattle and other ruminants; consultants; and post-doctorate, Ph.D., and graduate students of veterinary medicine and animal science from around the world.

06/27/2008—Hosted a two-day conference in Toronto entitled "*E. coli* O157 Vaccine: Added Value or Added Cost." The audience included veterinarians and representatives from the food industry, including beef, dairy, and other agricultural commodity producers.

06/25/2008—Announced that Bioniche secured an amendment to a pre-existing C$7.6 million contribution agreement with the Industrial Technologies Office (ITO) of Industry Canada that is expected to support the scale-up of its vaccine production facility in Belleville, Ontario. The amended agreement extended the timeline for the completion of work on the production scale-up to March 31, 2013. This funding is likely to be combined with the C$10 million in Ontario government financing through the Ministry of Economic Development and Trade's (MEDT) Advanced Manufacturing Investment Strategy (AMIS) program, C$5 million in federal government financing through the Agri-Opportunities program of the Agriculture and Agri-Food Canada (AAFC), both announced in December 2007, and a loan of C$5 million from the Business Development Bank of Canada (BDC) announced in February 2008. With C$25 million in available funding, the Company has the required financing to complete the scale-up of vaccine production at its Belleville facility over the next two years, which is expected to provide a minimum capacity of 40 million doses of Econiche™. The funding is part of a long-term C$107 million project to create a state-of-the-art Animal Health and Food Safety Vaccine Manufacturing Centre.

06/17/2008—Presented data regarding the Econiche™ cattle vaccine at the sixth Congress of Medical Microbiology - Mikromed 2008 in Belgrade, Serbia. The presentation was made by Dr. Rogan.

05/23/2008—Reported two presentations made by Bioniche researchers at international conferences. The Company presented at the annual meeting of the American Urological Association (AUA) held in Orlando, Florida. The presentation, entitled "Quantification of chromosomal aberrations by multiprobe fluorescence *in situ* hybridization profile (FISH) of 9 human bladder cancer cell lines commonly used in urological research," was made by Ms. Sonia Ménard, a research associate on the Bioniche preclinical research and development team. In addition, the Company was invited to present at the Immunopotentiators in Modern Vaccines Conference in Montego Bay, Jamaica. The presentation, entitled "Mycobacteria-derived immunopotentiating molecules and their application in vaccine development," was made by Dr. Nigel C. Phillips (biography on page 12), Bioniche's senior vice president and chief scientific officer.

05/12/2008—Provided an update on the clinical and non-clinical development of MCC. Over two-thirds of the 105 patients required for the Company's first Phase III clinical trial with MCC (Urocidin™) had been enrolled. In addition, on May 8, 2008, the Data Safety Monitoring Committee held its fourth scheduled meeting regarding this clinical trial. The committee recommended that Bioniche continue the trial unmodified until the next scheduled or triggered meeting.

05/09/2008—Announced financial results for the third quarter ended March 31, 2008. For the three- and nine-month periods ended March 31, 2008, consolidated revenues totaled C$7.2 million and C$19.6 million, respectively, versus C$6.4 million and C$20.1 million for the corresponding periods in fiscal 2007. The increase in sales in the current quarter reflects increased sales of Animal Health products in the U.S. and export markets. In addition, for the three- and nine-month periods ended March 31, 2008, basic and fully diluted loss per share totaled (C$0.07) and (C$0.20), respectively, versus a loss of (C$0.10) and (C$0.25) for the corresponding periods in fiscal 2007. Bioniche also announced that its Board of Directors unanimously agreed to appoint Mr. Graeme McRae (biography on page 10) as chairman (in addition to his role as president and chief executive officer [CEO]) at the quarterly meeting held on May 8, 2008. The appointment of a new chairman became necessary with the passing of the Company's former Board chair, Mr. Hy Isenbaum, in April 2008 (see 04/18/2008 for greater information).

04/21/2008—Announced that the Company has appointed Dr. Gary Weber (biography on page 13) as president, Bioniche Food Safety (U.S.).

04/18/2008—Announced that Bioniche's long-time Board chair, Mr. Hy Isenbaum, has passed away. Mr. Isenbaum was chair of the Board since 1999 when the Company was formed. Mr. Isenbaum was a fellow chartered accountant and the founder of the firm Soberman, Isenbaum, and Colomby. As the managing partner, a position he held until 1993, he built his firm to be the 15th largest accounting practice in Canada. He was a chairman of the Board and chairman emeritus of the Mount Sinai Hospital in Toronto. He was appointed by the Ontario Ministry of Health as ombudsman to the Medical Review Committee of the College of Physicians and Surgeons. He served on the Board of Directors of the Samuel Lumenfeld Research Institute in Toronto and was instrumental in the establishment of the institute. Mr. Isenbaum was also a governor of the Weizman Institute of Science in Israel and sat on the Boards of a number of private and public companies.

03/27/2008—Announced that the Company exercised its right under an agreement made in 2005 to repay $1.75 million of its secured revolving credit facility with Valens in Common Shares. This conversion was expected to result in new available funds of $1.75 million. Accordingly, the Company's capacity to borrow under the revolving credit facility after the conversion is anticipated to be approximately $3.2 million, determined by a formula that measures existing levels of inventory and accounts receivable.

Appendix

For more information about Bioniche's technologies, trials, studies, or general developments, please consult the Company's website at www.bioniche.com or any of the recent publications listed in Table 17.

Table 17

Bioniche Life Sciences Inc.

RECENT PRESENTATIONS AND PUBLICATIONS BY BIONICHE'S SCIENTISTS AND RESEARCH PARTNERS

D.R. Smith, R.A. Moxley, R.E. Peterson, T.J. Klopfenstein, G.E. Erickson, S.L. Clowser. A two-dose regimen of a vaccine against *Escherichia coli (E. 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* 5(5): 589-598.
D.R. Rogan, D.R. Smith, R.A. Moxley, A.A. Potter, and J.L. Yome. Vaccination of cattle with *E. coli* O157:H7 type III secretion proteins as a pre-slaughter intervention method to reduce *E. coli* O157:H7 prevalence. XXV World Buiatrics Congress, Budapest, Hungary, July 10, 2008.
D.R. Rogan. *E. coli* O157:H7 type III secretion proteins are protective antigens which improve food safety by reducing environmental contamination following vaccination of cattle. Sixth Congress of Medical Microbiology, Mikromed 2008, Belgrade, Serbia, June 14, 2008.
N.C. Phillips. Mycobacteria-derived immunopotentiating molecules and their application in vaccine development. Immunopotentiators in Modern Vaccine Conference, Montego Bay, Jamaica, May 20, 2008.
S. Ménard, C. Casas, A. Prada, Y-S. Fan, M.C. Filion, and N.C. Phillips. Quantification of chromosomal aberrations by multiprobe fluorescence *in situ* hybridization profile (FISH) of 9 human bladder cancer cell lines commonly used in urological research. American Urological Association, Orlando, Florida, U.S., May 23, 2008.
D. Rogan. Vaccination of cattle with *E. coli* O157:H7 type III secretion proteins reduces shedding, colonization, and hide contamination. Buiatrie 2007, Société Française de Buiatrie, Paris, France, November 16, 2007.
R.E. Peterson, T.J. Klopfenstein, R.A. Moxley, G.E. Erickson, S. Hinkley, D. Rogan, and D.R. Smith. Efficacy of dose regimen and observation of herd immunity from a vaccine against *E. coli* O157:H7 for feedlot cattle. *Journal of Food Protection* 2007, 70:2561-2567.
R.E. Peterson, T.J. Klopfenstein, R.A. Moxley, G.E. Erickson, S. Hinkley, G. Bretschneider, E.M. Berberov, D. Rogan, and D.R. Smith. 2007. Effect of a vaccine product containing type III secreted proteins on the probability of *E. coli* O157:H7 fecal shedding and mucosal colonization in feedlot cattle. *Journal of Food Protection* 70:2568-2577.
N.C. Phillips, S. Ménard, D. Surprenant, D. Ke, M. Filion. The anticancer activity of mycobacterial cell wall-DNA complex (MCC) against human bladder cancer cell lines is different to BCG. 2007 Annual Meeting of the American Urological Association, Anaheim, California, U.S., May 2007.
D. Rogan, A. Potter, D. Smith, C. Strauss. Vaccination reduces shedding and colonization of *E. coli* O157:H7 in cattle. Fourth International Conference on Vaccines for Enteric Diseases, Lisbon, Portugal, April 2007.
M.C. Filion, B. Filion, N.C. Phillips, C. Mignard, O. Raguin, F. Bichat (presenting authors: Nigel C. Phillips and Francis Bichat). Anticancer activity of MCC in a model of rat colon cancer peritoneal carcinomatosis. American Association for Cancer Research (AACR) Annual Meeting 2007, Los Angeles, California, U.S., April 2007.
D. Rogan, E. Fumosa, E. Rodriguez, J. Wade, S.F. Sanchez Bruni. Use of mycobacteria cell wall extract (MCWE) in susceptible mares to clear experimental induced endometritis with *streptococcus zooepidemicus*. *Journal of Equine Veterinary Science* March 2007, 27(3): 112-117.
D. Rogan. Enterohaemorrhagic *E. coli* O157:H7 vaccine reduces shedding and colonization of bacteria in vaccinated animals. Animal Pharm and Informa Life Sciences' Veterinary Vaccines Conference, Hamburg, Germany, December 2006.
D. Smith, R. Moxley, T. Klopfenstein, G. Erickson. Effect of regional vaccination within the feedyard on *E. coli* O157:H7 rectal colonization, fecal shedding, and hide contamination. International Symposium on Shiga Toxin (Verocytotoxin)-Producing *E. coli* Infections, Melbourne, Australia, October 2006.
S. Ménard, D. Surprenant, A. Morales, M.C. Filion, and N.C. Phillips. Effect of formulation on the direct anticancer activity of MCC against human bladder cancer cell lines. 61st Annual Meeting of the Canadian Urological Association, Halifax, Nova Scotia, Canada, June 2006.

Source: Bioniche Life Sciences Inc.

Glossary

Adjuvant—A substance that enhances the effectiveness of a primary therapy.

Anti-Angiogenesis—Preventing the formation and growth of new blood vessels.

Antibiotics—Chemicals that inactivate or damage bacteria.

Apoptosis—Programmed cell death; this physiological process is necessary for the elimination of superfluous, diseased, or damaged cells and the formation of new cells.

Aqueous Humor—The clear fluid that is in the anterior and posterior chambers of the eye.

Bacillus Calmette-Guérin (BCG)—An attenuated live mycobacteria that stimulates the immune system in order to treat bladder cancer. It is also used to vaccinate against tuberculosis.

Biologics License Application (BLA)—A request to the FDA to authorize the marketing of a biological product in interstate commerce.

Broodmares—Female horses used for breeding.

Canadian Food Inspection Agency (CFIA)—The Canadian government agency dedicated to safeguarding food, animals, and plants that enhance the health and well-being of Canada's people, environment, and economy.

Carcinoma *In Situ*—Cancer only of the cells in which it began. It has not yet spread to nearby tissues.

CE Mark—Conformité Européenne. A mandatory European marking for certain product groups to indicate conformity with the essential health and safety requirements set out in European Directives. To permit the use of a CE Mark on a product, proof that the item meets the relevant requirements must be documented.

Cell Cycle—The sequence of events by which a cell duplicates its chromosomes and divides into two.

Challenge Study—Studies that entail the administration of a substance in order to assess the reaction, whether documenting the occurrence of normal physiological responses or to evoke an immunologic response in a previously sensitized subject.

Chemokine—A soluble protein produced and released by a wide variety of cell types during the initial phase of the body's response to injury, allergens, antigens, or invading microorganisms.

Coliform—Of or relating to the bacilli that commonly inhabit the intestines of humans and other vertebrates, especially the colon bacillus.

Cryopreservative—A medium to aid the preservation of cells or tissue by freezing at very low temperatures.

Culture—To grow *in vitro* (which is in an artificial environment).

Cystectomy—Removal of the bladder (usually complete).

Cystitis—Inflammation of the urinary bladder and ureters.

Cystoscopy—An examination of the urethra and urinary bladder with a cystoscope, which is a tubular instrument used to examine the interior of the urinary bladder and ureter.

Cytokine—A substance that is produced by cells of the immune system and can affect the immune response. Cytokines can also be produced in the laboratory by recombinant DNA technology and given to affect immune responses.

Cytotoxic T-Lymphocytes—A type of white blood cell developed in the bone marrow that directly attacks foreign antigens and acts as an immune system regulator. Also called cytotoxic T-cells.

Double-Blind—A clinical trial design in which neither the participating individuals nor the study staff know which participants are receiving the experimental drug and which are receiving a placebo (or another therapy).

Effector Cells—Cells that perform a specific function in response to a stimulus; usually used to describe cells in the immune system that are responsible for cell-mediated toxicity.

Endpoints—Overall outcomes that the protocol is designed to evaluate.

Enterohemorrhagic *E. coli*—Strains of *E. coli* usually of the serotype O157:H7 that produce a toxin and are apparently responsible for a hemorrhagic form of colitis without fever, which can be very severe, spread primarily by contaminated beef. May also cause microangiopathic hemolytic anemia, renal failure, and the hemolytic-uremic syndrome (HUS).

Equine Endometritis—An inflammation of the endometrium.

***Escherichia coli* (*E. coli*) O157:H7—**A virulent foodborne pathogen found primarily in cattle that causes severe, sometimes life-threatening illness. Its symptoms include hemorrhagic colitis, hemolytic uremic syndrome (HUS), and thrombotic thrombocytopenic purpura (TTP).

Fast Track—An FDA status reserved for products that demonstrate the potential to treat a serious or life-threatening condition that has unmet medical needs. Fast Track designation, which was mandated by the FDA Modernization Act of 1997, can potentially facilitate development and expedite the review of BLAs.

Feedlot—A building or pen where livestock are fattened for market.

First-Line Therapy—The first type of treatment given for a condition or disease.

Foals—Horses that are less than one year old.

Follicle-Stimulating Hormone (FSH)—A hormone produced by the pituitary gland that stimulates development of the follicles in the ovaries, promoting the release of ova.

Good Manufacturing Practices (GMP)—The quality system regulation overseen by the FDA, which includes requirements related to the methods, facilities, and controls used for designing, manufacturing, packaging, labeling, storing, installing, and servicing products intended for human use.

Hyaluronic Acid—A polysaccharide found in large amounts in connective tissue, in the synovial fluid of the joints and the aqueous humors of the eye; a cementing and protective substance.

IL-12—One of a group of related proteins made by white blood cells and other cells in the body. IL-12 is made mainly by B-lymphocytes and macrophages. It causes other immune cells to make cytokines and increases the growth of T-lymphocytes. It may also block the growth of new blood vessels. IL-12 made in the laboratory is used as a biological response modifier to boost the immune system in cancer therapy.

Immunomodulatory—Changing the body's immune system with agents that activate or suppress its function.

Immunotherapy—Treatment with drugs that act by stimulating or enhancing an immune response against a specific disease.

***In Vivo*—**In a living organism.

Interferon—An antiviral protein produced by cells that have been invaded by a virus.

Interleukin 6 (IL-6)—A type of biological response modifier (a substance that can improve the body's natural response to infection and disease).

Intraperitoneal—Administered or withdrawn from within the abdominal cavity.

Intrauterine—Within the uterus.

Intravenous—An injection administered directly into the vein.

Investigational New Drug (IND)—The application by which a manufacturer requests that the FDA allow human testing of its drug product.

K-99—A protein surface antigen associated with enterotoxigenic strains of *E. coli*.

Macrophages—White blood cells that engulf and kill microorganisms, remove dead cells, and stimulate the action of other immune system cells.

Mesothelioma—A malignant tumor on the covering of the lung or the lining of the pleural and abdominal cavities that is often associated with exposure to asbestos.

Monoclonal Antibodies (MAbs)—Synthetic antibodies. Chemicals or radiation tagged to the MAb may be delivered directly to tumor cells. Alternatively, the MAb itself may be capable of tumor cell destruction.

Multidrug Resistance (MDR)—An adaptation or genetic modification of tumor cells to anticancer drugs that make the drugs less effective.

Mycobacterial—Of the genus *Mycobacterium*. Any of many rod-shaped, aerobic bacteria that cause diseases such as tuberculosis and leprosy.

Non-Muscle-Invasive Bladder Cancer—Bladder cancer that is contained within the two innermost layers of the bladder wall: the transitional epithelium (composed of urothelial cells) and the lamina propria (a thin layer of connective tissue). The third layer of the bladder wall is a zone of smooth muscle tissue. Once the cancer spreads into this area, it is called muscle-invasive bladder cancer.

Oligonucleotides—Small, single-stranded segments of nucleic acid that are typically 20 to 30 nucleotide bases in size and are synthesized *in vitro*.

Open-Label—A trial designation indicating that participants and investigators know what medication is being tested and what dose is being used.

Papillary Tumors—Small nipple- or cauliflower-shaped tumors that are attached to the urothelial layer (inner lining) of an organ.

Peritoneal—Pertaining to the lining of the abdominal cavity.

Permit to Release Veterinary Biologics—The CFIA's Veterinary Biologics unit reviews and approves applications for 'restricted use' of veterinary biologics in special situations where an appropriate licensed veterinary biologic is unavailable. Via a Veterinary Biologics Product License, Import Permit, or Permit to Release Veterinary Biologics, various restrictions and conditions are applied, depending on the nature of the product, country of origin, target species, intended use, and associated risks.

Potable—Safe to drink.

Scours—Diarrhea in livestock.

Septicemia—Disease caused by the spread of bacteria and their toxins in the bloodstream. Also called blood poisoning.

Shed (Shedding)—A term used to describe the release of organisms (bacteria, protozoa, viruses) into the environment from an infected animal. The organisms may be in the stool, urine, respiratory secretions, or vaginal discharges. The shedding animal may or may not exhibit symptoms of disease.

Shiga Toxin—A poison released by certain types of bacteria including *E. coli* O157:H7.

Special Protocol Assessment (SPA)—An official FDA evaluation of Phase III clinical study protocols. It provides trial sponsors with a written agreement that the proposed design and analysis of the studies would be adequate to support a license application submission if the study is performed according to the SPA and the results are successful.

Standard of Care—Treatment regimen based on state-of-the-art participant care.

Superovulation—Stimulation of the ovaries, usually done with hormones, that causes them to produce multiple eggs instead of one.

Synovial Fluid—Fluid that lubricates and facilitates movements of the joint.

Toxicity—An adverse effect produced by a drug that is detrimental to the participant's health. The level of toxicity associated with a drug varies depending on the condition that the drug is treating.

Transurethral—Performed through or by way of the urethra.

U.S. Department of Agriculture (USDA)—The federal department that administers programs that provide services to farmers, including research and soil conservation efforts to stabilize the farming economy. It was created in 1862.

Virus-Serum-Toxin Act of 1913—First enacted in 1913 and revised in 1985, the Virus-Serum-Toxin Act was intended to ensure the safe and effective supply of animal vaccines and other biological products. The act and its regulations are administered by the USDA's Animal and Plant Health Inspection Service.

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Crystal Research
associates

Jeffrey J. Kraws and Karen B. Goldfarb
Phone: (609) 306-2274
Fax: (609) 395-9339
Email: eio@crystalra.com
Web: www.crystalra.com

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