



Bioniche Life Sciences Inc. (TSX:BNC)



November 5, 2009

Safe Harbour Statement

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Our Business Model

- Generate cash flow from animal health product line.
- Establish proprietary new food safety vaccine technologies.
- Develop proprietary and large market human cancer therapies.
- Today: Revenues of \$33 million (Animal Health – F'09)
- Future:
 - Bladder cancer Rx in Phase III trial; second trial to start in '10
(both Fast Track; SPA on 2nd)
 - Vaccine to reduce *E. coli* O157 in cattle
(CFIA full license; USDA path to conditional license; first sales)

Corporate Structure

Bioniche Life Sciences Inc.

Animal Health

Bioniche Animal Health

- Largest Canadian-owned animal health company
- Foci:
 - Reducing reliance on antibiotics (immunology);
 - Enhancing reproductive performance;
 - Preventing illness (vaccines)

current sales: \$33M+

Food Safety

Bioniche Food Safety

- Development of animal vaccines to help enhance food & water safety
- *E. coli* O157 cattle vaccine fully licensed in Canada; pending U.S. conditional license
- Other animal vaccines in pipeline (*Salmonella*, *Campylobacter*, *Listeria*)

Human Health

Bioniche Therapeutics

- Drug discovery & development
- Products based on proprietary technologies
- Development: bladder cancer, peritoneal cancers (ovarian, colorectal)

Animal Health Technologies

Strategy: Development of alternatives to antibiotics and improvement of reproductive performance in livestock.

➤ **Immunotherapies** (Mycobacterial cell wall technologies)

- ❖ Increasing global demand for alternatives to antibiotics in agriculture
- ❖ Bioniche was the first to develop and license immunotherapeutics in veterinary medicine
- ❖ Potential future application in companion animal cancer

➤ **Reproductive technologies**

- ❖ Global leader in the field of animal reproduction and assisted reproductive technologies
- ❖ Folltropin®-V is a cornerstone product respected internationally

➤ **Hyaluronan-based technologies**

- ❖ Improving equine performance

➤ **Vaccines**

Revenue Highlights (Animal Health) – F'09

21% Growth in Total Revenues over F'08

Geographic Distribution of Consolidated Revenues by Business Units

(expressed in millions of Canadian dollars)

	2009	2008	Growth
For the twelve-months ended June 30	\$	\$	%
Animal Health - Canada	8.5	6.9	23%
Animal Health - USA	18.3	15.4	19%
Animal Health - Australia	3.9	3.1	26%
Animal Health - Europe	2.6	2.1	24%
Total reported revenues	33.3	27.5	21%

- Strong growth across product lines in every jurisdiction.
- Q4 showed profit of \$0.7M (vs. loss of \$0.2M in F'08)

Food Safety Technologies

Strategy: Develop vaccines for animals against pathogens they may introduce to the human food and water supply, and environment.

➤ ***E. coli O157 Vaccine***

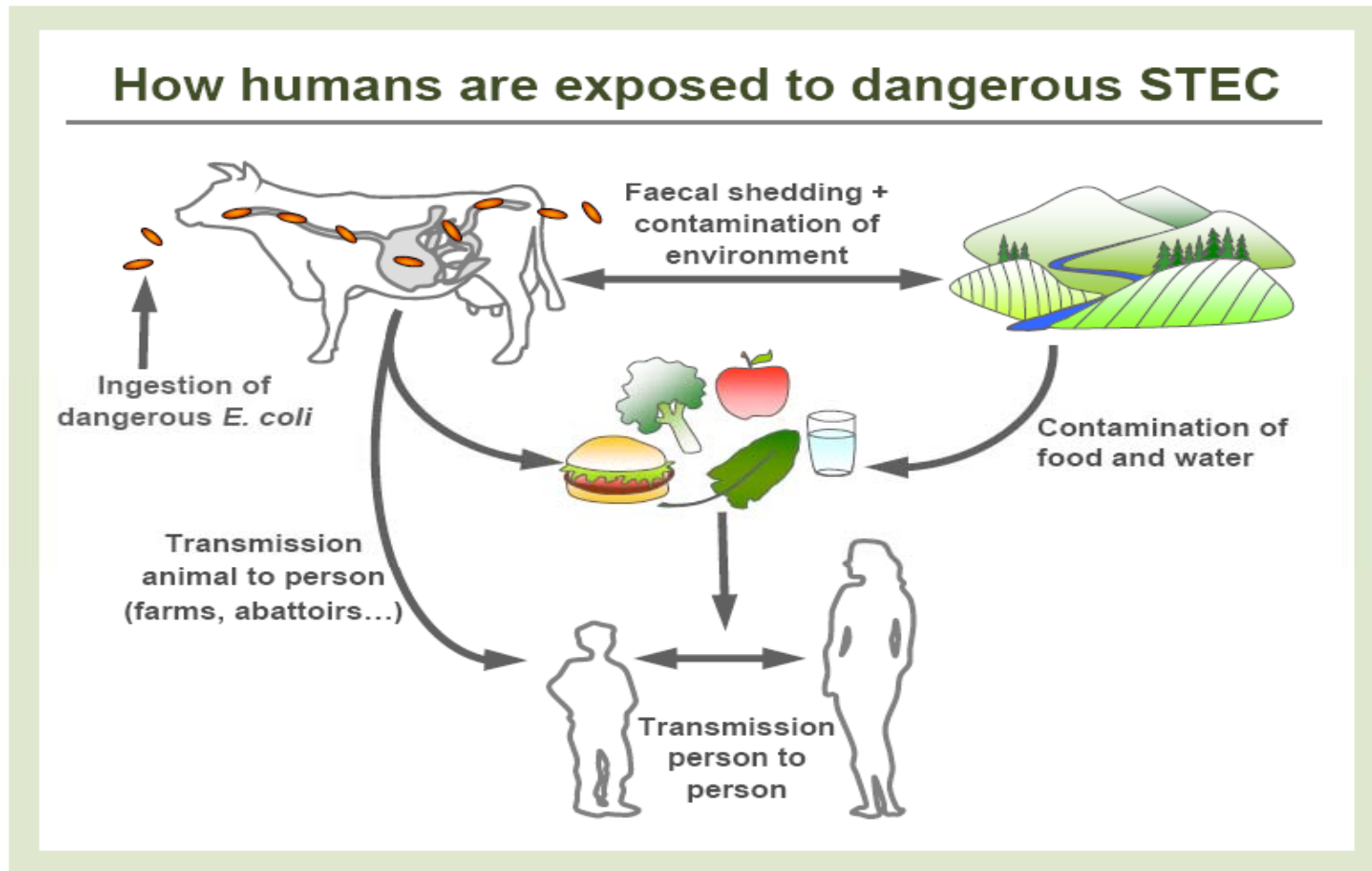
- *Causes 73,000 cases of human infection and 60 deaths per year in the U.S. alone*

➤ ***Salmonella Vaccine***

➤ ***Campylobacter Vaccine***

➤ ***Listeria Vaccine***

From Cattle to Humans



Courtesy of: Dr. John M. Fairbrother

E. coli is not just a "meat" problem

The Bioniche *E. coli* Vaccine



Studies of the vaccine have involved more than 30,000 cattle and have shown the following:

- Up to 99.5% reduction in shedding
- A 97.5% reduction in colonization
- 85% fewer animals shedding
- 63.9% reduced duration of shed in affected animals

A Canadian (CFIA) full license was granted Oct., 2008

USDA notification of eligibility for conditional license Feb., 2008

E. coli Vaccine Status

- Bioniche has completed most aspects of development:
 - proof of concept ✓
 - field studies ✓
 - adjuvant withdrawal trial ✓
 - pre-license serials ✓
 - field safety trials ✓
- For the USDA conditional license, a plan must be set to move to full licensure, one step of manufacture must be in the U.S. and three serial lots produced.
 - With a full U.S. license, product need not be manufactured there.
- The Canadian regulator (CFIA) issued a full license in October, 2008.
- A \$25 million production scale-up is taking place in Belleville, Ontario:
 - A \$10 million repayable loan was provided by the Ontario government
 - A \$5 million repayable loan was provided by Agriculture Canada
 - A \$5 million repayable loan was provided by Industry Canada (ITO)
 - A \$5 million repayable loan was obtained from BDC



"Best new veterinary product for livestock"

Vaccine Market Potential

There are approximately 199 million cattle in North America and Europe (beef cows, dairy cows, calves):

- **North America**

- 113 million total (approx. 25 million on feedlots)
- Three doses of vaccine per animal at an estimated \$2.00 U.S./dose

- **Europe**

- 86 million total
- Three doses of vaccine per animal at an estimated 5-7 Euros/dose
- Access to the EU will be delayed relative to NA



First commercial vaccine use:
September 21, 2007
Top Meadow Farms
(RR#1 Clarksburg, Ontario, Canada)

Human Health Technologies

Strategy: Develop proprietary and large market human cancer therapies in niche markets.

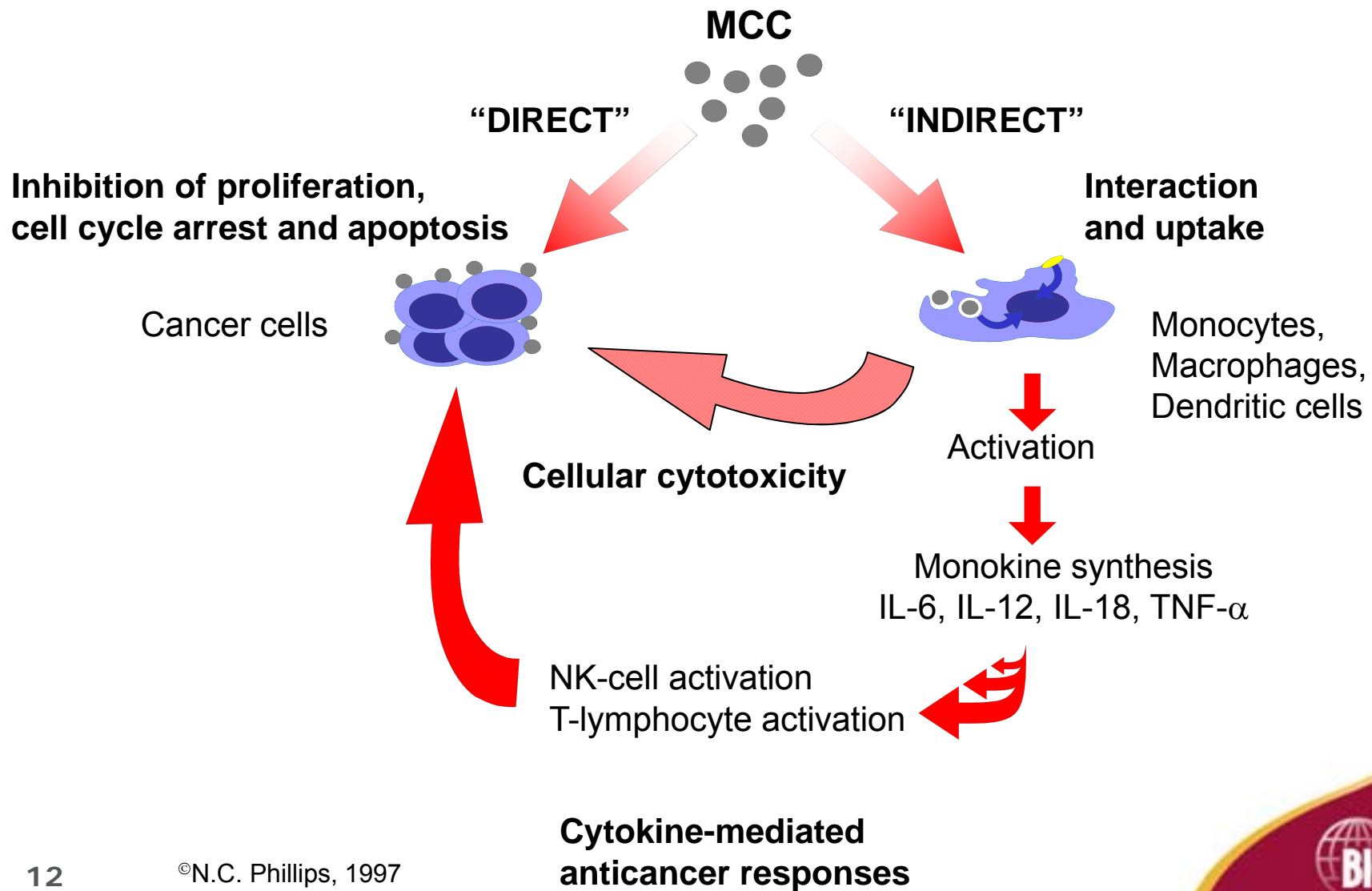
Mycobacterial Cell Wall-DNA Complex (MCC)

- Non-muscle-invasive bladder cancer (*Urocidin*TM)
 - ❖ Refractory
 - ❖ First-line
- Peritoneal cancers
- Metastatic cancers
- Other cancers

Oligonucleotides

- Leukemia

MCC – Mechanism of Action



NMI Bladder Cancer Incidence & Prevalence

U.S., EU 5+, Japan

Total Patient Pool: 350,000

(135,000 new/215,000 recurrent)

Refractory Approval \approx 23% of pts & 12-21+ doses per pt.

Comparative Approval \approx 60% of pts & 12-21+ doses per pt.

Potential Future Usage \approx 15% of pts & 1 dose per pt

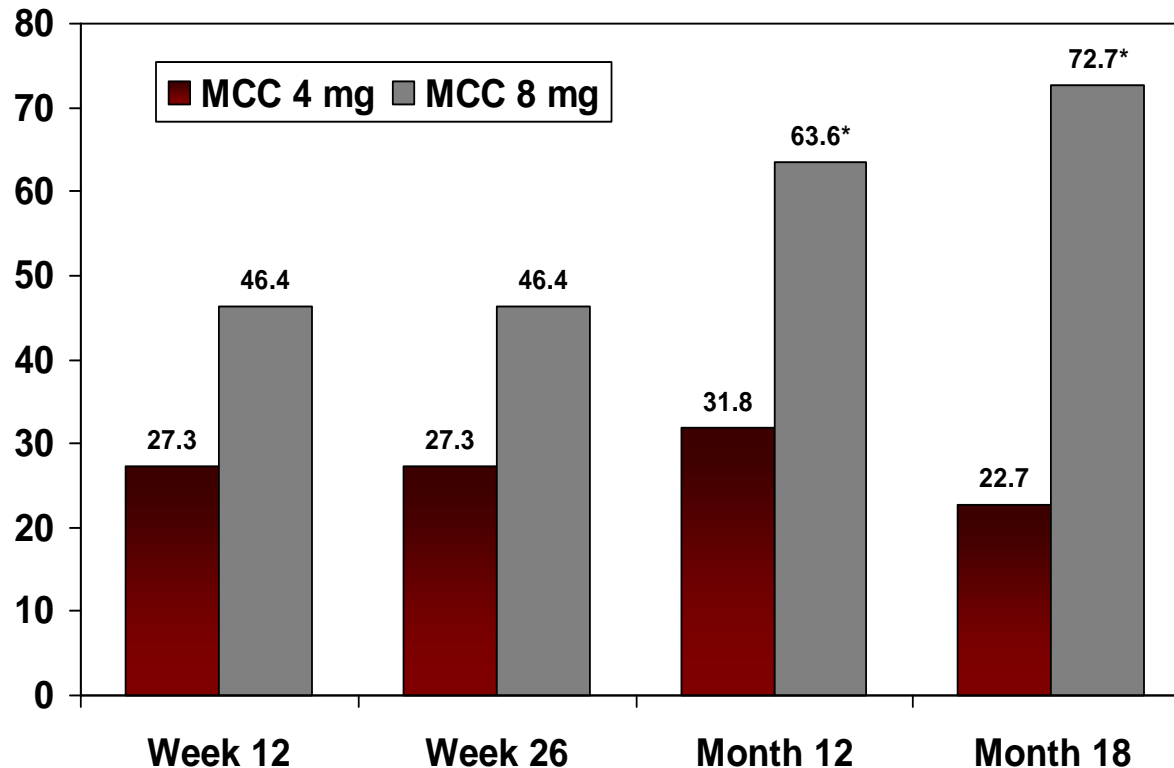
Refractory approval will permit on-label use of Urocidin™ for 1/4 NMI cases.

Further trials should expand this label to 3/4 of new and recurrent NMI diagnoses.

NMI = non-muscle-invasive

Bladder Cancer Study - Phase II (MCC**)

REFRACTORY PATIENTS



Complete Responses at two doses of MCC. †Patients with confirmed carcinoma in-situ (CIS) at baseline receiving at least 1 instillation (4mg N=21; 8mg Week 12 and 26 N=28, Month 12 and 18 N=11). *Protocol Amendment for MCC 8mg at 12 and 18 month follow-up resulted in a decreased number of patients who re-consented (N=11).

Complete response = no evidence of tumour

*Presented at American Urology Association 2004; selected as conference highlight.
Subsequently published in the Journal of Urology. ** MCC emulsion (earlier formulation of MCC)*

MCC Phase III Bladder Cancer Program

PART ONE (protocol approved by FDA, Health Canada):

Fast tracked by FDA

- 105 evaluable patients
- North America; leading centres across Canada and the U.S.
- Open-label study of efficacy in NMI bladder cancer refractory to BCG.
- Patient recruitment completed in April, 2009
- Results to be available mid-2010

- Trial result targets:
 - Primary endpoint: >20% CR, sustained at one year
 - Safety target: less than 10% unable to tolerate treatment

- Since commencement, nine meetings of the independent DMC have recommended to “continue the trial unmodified”.

MCC Phase III Bladder Cancer Program

PART TWO (protocol approved by FDA):

- Approximately 800 patients
- North America, Australia and Europe
- Randomized, double-blind, multi-centre study comparing MCC to BCG as first-line therapy in non muscle-invasive bladder cancer at high risk of recurrence or progression
- Trial result targets:
 - Safety target is superiority to BCG (*fewer drug-related AEs*)
 - Efficacy target is non-inferiority to BCG
(*primary efficacy endpoint will be duration of disease-free survival of patients after two years*)
- A Special Protocol Assessment (SPA) agreement establishes that the FDA will register the product if target trial results are met.

SPA agreement with FDA
Fast tracked by FDA

Partnership with Endo Pharmaceuticals



HIGHLIGHTS OF AGREEMENT (announced July 10, 2009)

- Endo (NASDAQ: ENDP – market cap: ~\$2.7B) licensed rights for non-muscle-invasive bladder cancer.
- Territories: U.S., Mexico and, subject to co-marketing rights, Canada.
- 12-month option for global marketing rights (to July, 2010).
- Up-front payment of US\$20 million.
- Up to US\$110 million in milestone payments.
- Bioniche retains manufacturing and will receive net-sales-related transfer price.

Bioniche pays all costs through January, 2010.

- Thereafter, costs shared by formula.
- If Endo exercises its global option, it assumes all external development costs.
- Endo right of 1st negotiations for new urologic & pelvic indications of MCC.

Alliance Objectives

Bioniche had specific objectives for a development & commercialization alliance. These included the following matters:

- Obtaining financial resources to complete its registration trial program.
- Securing sales, reimbursement & distribution expertise.
- Supplementing its existing capabilities (across all areas).
- Keeping manufacturing as a core skill set.
- Retaining its voice in development & commercialization decisions.
- Maximizing its proportion of project economics.
- Making certain *Urocidin*TM gets to bladder cancer patients & their urologists.

Challenges

Partnering a new product in the field of bladder cancer presented Bioniche with some unique, and sometimes unexpected challenges:

- Our opportunity stems from a real absence of new treatments.
- No new treatments resulted in a lack of market research.
- No market research meant unanswered questions.
- Unanswered questions increased perceived risk.
- Increased perceived risk made many potential partners reluctant.

Bioniche's challenges were in filling-in all these information gaps and then in finding partners willing to engage within Bioniche's objectives.

This process was neither easy nor straightforward.

Alliance Process

There are many obstacles on the road to a product alliance:

- Generation of adequate results in all development specialties
- Organization and presentation of data to potential partners
- Selection of qualified counterparties and advisors
- Counterparty evaluation of data and deal team engagement
- Framing of alliance parameters and agreement to proceed
- Negotiation of alliance terms and authorization to contract
- Contracting process and approvals to proceed
- Board approvals to execute final contracts



All taking place amid Pharma industry reorganizations, layoffs, mergers and multiple changes in strategic direction.

Alliance Terms

Financial

- Bioniche funded to registration application (2012) in the event Endo takes WW rights or
- Bioniche funded at least one year past the expiry of Endo's RoW option

Responsibilities

- Planning and implementation – joint (as agreed between our teams)
- Governance and approvals – joint (via JDC & JCC)
- Regulatory – Endo (with input from Bioniche)
- Marketing – Endo (with Canadian co-promotion option for Bioniche)
- Manufacturing – Bioniche (with step-in rights for Endo)

Other Matters

- RoW option – Endo has a 12-month option to take-up WW rights (July, 2010)
- Right of first offer – Endo offered MCC applications in urology/pelvic fields

Alliance Implications

Management believes Bioniche's alliance with Endo Pharmaceuticals is a transformative event for both the Company and *Urocidin*TM. The alliance has accomplished all of Bioniche's key partnering objectives:

- Validated *Urocidin's* potential with a qualified partner.
- Obtained finances for completion of registration trial program.
- Secured sales, reimbursement and distribution expertise.
- Supplemented its existing capabilities across all areas.
- Kept manufacturing as a core skill set.
- Retained its voice in development and commercialization decisions.
- Maximized its proportion of project economics.
- Increased the certainty *Urocidin* will get to patients and their urologists.

With these objectives achieved, Bioniche is now poised to realize the full value of its investment in the human health applications of MCC technology.

Value Creating Events

anticipated timing – subject to change

Timing (calendar year)	Event
Q4, 2007-Q1, 2008	Securing of non-dilutive financing to commence Phase I manufacturing scale-up for <i>E. coli</i> cattle vaccine ✓
2008	Path to conditional license of <i>E. coli</i> cattle vaccine in U.S. (via USDA), path to full license in Canada (via CFIA) ✓ ✓
Q4, 2008	Full registration of <i>E. coli</i> cattle vaccine in Canada ✓
Q1, 2009	<i>Urocidin</i> TM Phase III trial refractory recruitment completed ✓
Q3, 2009	Closing of partnership agreement for <i>Urocidin</i> TM ✓
2009/2010	Conditional license for <i>E. coli</i> cattle vaccine in the U.S.
2009/2010	Achievement of pre-commercialization milestone payments for <i>Urocidin</i> TM
2010	First U.S. sales of <i>E. coli</i> cattle vaccine
2010	Results of refractory Phase III NMI bladder cancer trial
2011	Belleville, ON vaccine manufacturing centre operational



*Please join us for a Reception
in the Great Room*



*Celebrating 30 years of
innovation in 2009*

