



## Bioniche Life Sciences Inc.



Annual & Special Meeting of Shareholders  
November 9, 2011

# Safe Harbour Statement

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# Agenda

- ❖ The Fiscal Year in Review
- ❖ Our Industry
- ❖ De-Risking the Business
- ❖ Growth Opportunities
- ❖ Financial Picture
- ❖ Impact of IFRS Conversion
- ❖ Investments in Corporate Growth
- ❖ Questions & Answers
- ❖ Reception

# The Fiscal Year in Review

- ❖ Bioniche named of top 50 best small and medium-sized employers in Canada for a second time (based on employee surveys)
- ❖ US\$4 million milestone received from Endo for attainment of contractual efficacy goal in first Phase III clinical trial with *Urocidin*<sup>TM</sup>
- ❖ Completion of concurrent Share Offers in Canada and Australia for gross proceeds of C\$28.9 million (net C\$26 million)
- ❖ Successful IPO in Australia with listing on Australian Securities Exchange effective January 27, 2011
- ❖ First patient enrolled in second Phase III clinical trial of *Urocidin*<sup>TM</sup>
- ❖ Presentation of results from first Phase III clinical trial with *Urocidin*<sup>TM</sup> at European, U.S. and Canadian urology conferences
- ❖ Official opening of Animal Health and Food Safety Vaccine Manufacturing Centre in Belleville, Ontario

## Subsequent to Year-End:

- ❖ Launch/regulatory approval of new animal health products

# Our Industry - Life Sciences

## The Canadian Scene

- ❖ Valeant/Biovail merger in 2010 removed the largest Canadian firm from the domestic industry
- ❖ Revenues of Canadian publicly traded biotech companies (63 in total) fell by 38% in 2010 (without the Valeant acquisition, revenue growth was 1% over 2009)
- ❖ Net loss deteriorated to US\$336 million in 2010 from US\$11 million in 2009
- ❖ R&D expenditures decreased by 23% in 2010 as compared to 2009
- ❖ Market capitalization dropped by 24% in 2010 as compared to 2009

*(Source: Beyond Borders Global Biotechnology Report 2011, Ernst & Young)*

## Regulatory and Development Environment

- ❖ FDA's Center for Drug Evaluation and Research (CDER) approved 15 new molecular entities and 6 new biologics in 2010 (total: 21). This compares to 25 approved in 2009 and 24 in 2008.

*(Source: Nature Reviews Drug Discovery 10, 82-85, February, 2011)*

- ❖ Taking a drug from R&D pipeline to regulatory approval takes an average of 15 years and more than \$1B of investment.

*(Source: Pharmaceutical Research and Manufacturers of America)*

# Our Industry - Animal Health

## Global Industry

- ❖ Valued at \$20.1B in 2010
- ❖ Primarily controlled by seven multinational companies:
  1. Pfizer (US\$3.5B revenues)
  2. Intervet/Schering Plough (US\$2.9B revenues)
  3. Merial (Sanofi Aventis) (US\$2.6B revenues)
  4. Bayer (US\$1.4B revenues)
  5. Elanco (US\$1.4B revenues)
  6. Boehringer Ingelheim (US\$1.2B revenues)
  7. Novartis (US\$1.1B revenues)

*(Source: Vetnosis Executive's Guide, March, 2011)*

# De-Risking the Business: Corporate Level

*Over the last several years, the business has been de-risked through:*

- ❖ Engaging capital markets, governments, and other sources of financing for operations and special projects.
- ❖ Expanding the use of platform technologies which will allow existing production facilities to be more efficiently utilized, while generating new products for sale into global markets.
- ❖ Investing in intellectual property protection through patent maintenance and new patent filing to extend the duration of associated revenues when products become registered.

# De-Risking the Business: Human Health

*Over the last several years, the business has been de-risked through:*

- ❖ The signing of a license, development and supply agreement with Endo Pharmaceuticals Inc. for *Urocidin*<sup>™</sup> for the treatment of non-muscle-invasive bladder cancer.
  - Endo is now leading the Phase III clinical program for *Urocidin*<sup>™</sup> and is covering 100% of external development costs.
  - The Company has retained control over manufacturing, receiving a healthy percentage of the net selling price per dose.
    - In the short-term, the Company will offset the carrying costs of the plant by introducing animal health products based on the platform technology.

# De-Risking the Business: Animal Health

*Over the last several years, the business has been de-risked through:*

- ❖ Generating a healthy revenue stream with good margins and positive earnings before research and development, offering a solid platform on which to build.
- ❖ Expanding market reach for existing products.
- ❖ Acquiring technologies that fit with areas of focus.
- ❖ Engaging partners to allow for a sharing of risk and to enable the Company to have broader reach into targeted markets.

# De-Risking the Business: Food Safety

*Over the last several years, the business has been de-risked through:*

- ❖ Securing government financing for \$25 million to construct and equip the state-of-the-art Animal Health and Food Safety Vaccine Manufacturing Centre in Belleville, Ontario.
  - *Econiche*<sup>TM</sup> cattle vaccine against *E. coli* O157 to be the first commercial vaccine produced here.
  - Other Food Safety and Animal Health vaccines will also be manufactured here.

# Vaccine Manufacturing Centre



- \$28 million expansion completed April, 2011 (\$25 million in repayable government/quasi-government assistance)
- Largest livestock vaccine manufacturing facility in Canada
- Capacity to supply Canadian animal vaccine requirements *(in excess of \$125 million (over 95%) imported – primarily from U.S. – each year)*
- Being validated to meet international regulatory standards (Good Manufacturing Practice – GMP)
- Scale-up for commercial production to begin in early 2012



# Growth Opportunities - Human Health



## ❖ Commercialization of Bladder Cancer

- To complete Phase III trials and secure regulatory approvals
- To generate revenues from commercial supply of *Urocidin*<sup>TM</sup>

## ❖ Advancement of New MCC Indications

- To pursue development of new MCC-based products
- Partnering of non-intravesical MCC products

Bioniche believes that it can continue to demonstrate concrete value creation within its Human Health business.

# Growth Opportunities - Animal Health



## ❖ Internal Product Pipeline

- *Rhodococcus equi* vaccine against respiratory disease of foals
- MCC canine cancer/bovine immunotherapy applications
  - a new formulation of mycobacterial cell walls
- Low Molecular Weight Hyaluronic Acid (HA) for equine joints  
(*Canadian approval announced October 27, 2011*)
- Market expansion for existing products (*e.g., Folltropin®-V, Cue-Mate™*)

## ❖ In-Licensing Opportunities - we are actively assessing:

- Technologies that fit with core capabilities in animal reproduction
- Technologies that fit with core capabilities in the equine field
- Technologies that complement our companion animal product line  
(*e.g., Sin Susto - canine calming product*)

# Growth Opportunities – Food Safety



- ❖ U.S. registration of *E. coli* O157 vaccine (conditional license)
  - *In regulatory process*
- ❖ First Marquee orders from the United States
  - *Upon conditional licensure*
- ❖ International registrations of the *E. coli* O157 vaccine
  - *Applications underway*
- ❖ Development of future food safety vaccines
  - *Salmonella*

# Financial Picture – Fiscal '11 Year-End

For the period ended <i>in millions \$</i>	June 2011	June 2010
<b>Assets</b>		
<u>Current</u>		
Cash	15.4	11.1
Short Term Investment	1.5	-
Receivables & Inventory	15.1	15.3
Other Current Assets	1.3	1.0
	<u>33.3</u>	<u>27.4</u>
<u>Long-Term</u>		
Tangible	27.8	16.6
Intangible and Others	8.5	8.1
Total Assets	<u>69.6</u>	<u>52.1</u>
<b>Liabilities and Shareholders' Equity</b>		
<u>Current</u>		
Payables	8.5	9.7
Current Portion of L-T Debt & Others	1.7	1.2
Current Portion of non-refundable deferred revenue	1.5	1.5
	<u>11.7</u>	<u>12.4</u>
<u>Long-Term</u>		
Senior Debt & Loans	2.7	2.5
Employee Future Benefits	2.0	-
Gov't Assistance Loans	13.4	7.0
Deferred Gov't Incentives	-	2.4
Non-refundable deferred revenue	17.9	19.3
	<u>47.7</u>	<u>43.6</u>
<u>Shareholders' Equity</u>		
Share Capital	134.1	105.4
Deficit	(112.2)	(96.9)
	<u>69.6</u>	<u>52.1</u>

- ❖ \$16.9M in cash and cash equivalents.
- ❖ Strong working capital.
- ❖ Revenues of \$36.0 million.
- ❖ Basic and fully-diluted loss per share of (\$0.17) for F11.

# Impact of IFRS Conversion

Key areas of difference for Bioniche:

- Non-refundable deferred revenue
- Property, plant and equipment
- Provisions and government assistance
- Presentation of depreciation

# Investments in Corporate Growth

Meeting capital requirements, including completion of the VMC and the pilot-scale fermentation facility, and renovations to the existing MCC/ <i>Urocidin</i> <sup>TM</sup> plant in Montreal.	\$ 8.3M
Advancing work on new applications for MCC.	\$ 1.0M
Advancing second generation <i>Econiche</i> <sup>TM</sup> vaccine and <i>Salmonella</i> vaccine.	\$ 0.7M
Advancing development of new animal health products from internal pipeline.	\$ 3.7M
Acquiring new products/technologies/licenses in animal health.	\$ 2.0M
<b>Total growth-related investments (not including associated corporate overheads)</b>	<b>\$15.7M</b>

# *Questions & Answers*



*Thank-you for attending.*

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