

**“Molecular Medicine:  
The Path to Personalized Medicine”**

**Speech by Steve West, President, MDS Nordion to the  
Canadian Nuclear Association’s Winter Seminar**

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**ABSTRACT:** Canada’s nuclear infrastructure has helped to position this country as a global leader in supplying medical isotopes, products that have long been used to prevent, diagnose and treat disease. Canada now has the opportunity to be a catalyst in the global race to develop personalized medicines. By better understanding how disease works at the cellular level, *molecular medicine* can lead to tailored and more effective treatments for individuals. The pursuit of innovation goes beyond finding new applications for radioisotopes. It’s about embracing a new innovation model involving business, universities and research institutes here and abroad. Canada has the potential to be a global centre of excellence in applying molecular medicine for medical innovation.

## **“Molecular Medicine: The Path to Personalized Medicine”**

### **I. INTRODUCTION**

{slide: cover slide}

- Good morning. Thank you Murray for the introduction.
- To many of you in the room today our medical isotope story should be familiar. MDS Nordion is well known as the leading global supplier of medical isotopes.
- What may not be as familiar to you is how the world of medical innovation is unfolding and why this is so important to us.
- More specifically, the global pursuit of “personalized medicine” – presents unique opportunities for MDS Nordion.

### **II. SITUATION TODAY**

- I’m proud to say that the MDS Nordion success story is based substantially on our links with the Canadian nuclear industry, an infrastructure which is largely unique to Canada.

{slide: Chalk River}

- Many medical isotopes are reliably produced at the NRU research reactor at Chalk River. In fact, one isotope produced there – molybdenum-99 – is used ultimately in 80% of all nuclear medicine imaging procedures, such as diagnosing the condition of the heart and determining whether a heart attack has occurred or not.

{slide: OPG, etc}

- We’ve partnered with OPG, Bruce Power and Hydro-Québec to produce cobalt-60 in their power reactors. This important isotope is used by our customers, like Johnson & Johnson, to sterilize a vast array of single-use medical supplies, such as syringes and bandages, and a broad array of consumer products worldwide, including contact lens solution and cosmetics. (I use neither of these I might add.)

{slide: TRIUMF}

- On the west coast, our operation at the TRIUMF facility located on the University of British Columbia campus produces a variety of cyclotron-based isotopes also used to diagnose disease.

- This is a world class example of a successful public private alliance. We are able to call upon the resident technical and scientific expertise at TRIUMF. This has assisted us to produce and develop medical isotopes for export and create new radiopharmaceutical capabilities.
- In Laval, we own and operate the Canadian Irradiation Centre. Our research irradiator studies the optimum dose of radiation for new products in order to ensure sterility and meet quality requirements.
- It is also an international training facility. We train the trainers. Nuclear regulators and operators from around the world come to Laval to learn how to regulate or safely use commercial irradiators, the large machines used by J&J, for instance, to sterilize products.

{slide: MDS Nordion}

- Taking all this infrastructure together, combined with MDS Nordion's facilities in Ottawa, we have made a substantial healthcare impact worldwide in the prevention, diagnosis and treatment of disease.
- The numbers speak for themselves: \$338M in revenues and adjusted EBITDA, or profit, exceeding \$100M. This return is allowing us to reinvest back into the business to help spur future growth.

{slide: preventing disease/sterilization}

- Here are some more statistics and perspectives: Approximately 45% of all the world's disposable medical supplies are sterilized using cobalt-60 and some 80% of the global market requirements for this isotope are fulfilled by MDS Nordion.

{slide: body scan}

- Worldwide, thanks to MDS Nordion production, some 43,000 diagnoses occur every day for nearly 100 diseases, conditions and infections.

{slide: teletherapy}

- Also, about 45,000 cancer treatments take place every day throughout the world. The image shown here is our latest generation machine, known as the Equinox.

{slide: pipeline}

- And, as an interesting aside, going well beyond healthcare, radioisotopes are used for industrial testing. Radiography cameras image the interior of pipelines and examine the structural integrity of aircraft welds, among other applications. Think

of this the next time you board an airplane: radiation technology could have identified a hairline fracture during its manufacture and helped to prevent a catastrophe.

{slide: Canada map with locations}

- On many fronts, the production, processing and supply of isotopes is a true Canadian success story: over 50% of the world's medical isotopes come from MDS Nordion and these isotopes have become highly integrated into the health care systems of many countries around the world, including in the United States, Europe and Japan.

### **III. THE CHALLENGES**

{slide: MDS Nordion}

- It has taken us several decades for us to build this business: a portfolio of radiation-based technologies used worldwide to prevent, diagnose and treat disease.
- But is there any guarantee that our value proposition created yesterday is sufficient for tomorrow? Can we rest on our laurels? How can we differentiate ourselves going forward?
- Let me give you a quick point of reference: a number of years ago, we were bigger than a competitor of ours, UK-based Amersham.
- Amersham was privatized in the 1980's for some US\$70 million. In 2003, this company was sold to GE for US\$9.5 billion. Amersham obviously did something right and if you examine their history, innovation was clearly a critical success factor in their growth.
- This is not the time to explain the different paths taken by us and Amersham. But I raise this to make a point: others are out to innovate, grow and add value. If we don't, others will.
- So, what brave new world do we face? I'm going to start by outlining the challenges facing the delivery of medical care, itself.

{slide: medical challenges: diagnosis}

- Today, disease is basically diagnosed long after it has taken root. Physicians just hope to catch it in time, such as at an annual check-up or if they spot an abnormality in a brain scan.

{slide: medical challenges: treatments}

- Another challenge is that we all take basically the same medications; we all reach for the same *Aspirin*. But each of us has different metabolisms. The active ingredients in drugs respond differently to each one of us. It is no surprise, then, that nearly one third of patients do not benefit from the medicines they are taking.<sup>1</sup>

{slide: medical challenges: new drugs}

- Finally, consider the drug development process: today, it takes more than ten years and well over a billion dollars to launch a new drug.
- The search for new treatments can be exasperating. For every 5000 compounds examined, only 1 will make it to become an actual drug. This is hardly patient-friendly. It certainly is not a great business model and every time we buy a drug we are paying for the price of 4,999 failures.
- In the last few years, the promise of biotechnology advancing and knowledge about the human genome have given us hope that we can change the odds on success in drug discovery and development and being able to understand the differences in how individuals respond. But still there are definite shortcomings in the success of diagnosing and treating disease and in the efficiency of the drug discovery process. Anything we can do to speed up development, kill compounds earlier in development will allow scientists to focus on those compounds that are more likely to be good and safe therapeutics.

#### **IV. THE MEDICAL OPPORTUNITY**

{slide: biomarkers}

- Increasingly, researchers are focusing on the “pre-disease state” – knowing what is happening in the body before a disease manifests itself for example in cancer before we get tumors we get changes at the molecular level.
- In short, the focus is about “predictive medicine” and it is about personalizing medicine to select the right drug or therapy for the right individual.
- Examining an individual’s genetic make-up is pointing researchers to what is happening at the cellular and molecular activities in the body.
- Researchers are banking on “biomarkers” to unlock this information.

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<sup>1</sup> JAMA, 1998, 279:1200

- Biomarkers are the fingerprint of a medical condition. In fact, physicians have long been using them. Measuring blood pressure is one common biomarker; another is your cholesterol levels.

{slide: cell}

- Biomarkers are now being tapped to look at cell and molecular function.
- In the drug discovery process, biomarkers will be used to identify non-performing compounds earlier, allowing researchers to focus instead on those that show real promise of becoming an actual new drug.
- In the clinical setting, biomarkers are seen as improving the accuracy of diagnoses and of better targeting treatments. This is what should lead to “personalized medicine”.

## **V. OUR STRATEGIC TASKS**

- We have a meaningful role to play in all this; but to do so we have to embrace three strategic “tasks” {or, “thrusts”}:

{slide: 3 tasks – *each phrase comes sliding in*}

1. As I mentioned, the way disease is being researched, diagnosed and treated is changing. We need to become a value-added solutions provider for diagnosis and research of diseases.
  2. We need to move from being primarily a manufacturer of medical isotopes to becoming an innovator to commercialize new technology platforms.
  3. And, we need to support this approach by accelerating private-public partnerships with research institutes, academic researchers and hospitals not only here in Canada but with institutions and innovators globally.
- All three points are interrelated.

## **VI. LINKING THE STRATEGIC TASKS TO OPPORTUNITIES**

- Turning to the first task. We can improve drug development (that will lead to better diagnoses and treatments) by helping to image biomarkers.

{slide: X-ray, CT, MRI}

- Visualizing the problem has always been essential to healthcare practitioners. It is just that imaging is getting highly sophisticated and infinitely more insightful.

- Traditionally, medical imaging was mainly focused on anatomical structure. We all know that X-rays show bone structures. CT scans are employed more recently to image organs; and MRI scans reveal tissue.

{slide: cardiac scan}

- Nuclear medicine has been giving physician's information on metabolism or body functions, such as the blood flow in the heart after undergoing a stress test.
- "Nuclear medicine" has facilitated the move to a new platform: "molecular imaging".

{slide: tumour changes over timeline}

- Advancements in technology are providing even greater accuracy and sensitivity to molecular functions. Researchers, for instance, are starting to get better information on where a drug goes in the body, and how effective it is going to be.
- Confirming its importance, the US Food and Drug Administration (FDA) has publicly called upon industry to use molecular imaging and biomarkers as a tool to improve safety and speed of drug development

{slide: chemo efficacy}

- For a patient, the application could be life-saving. Why would anyone want to suffer through chemotherapy if it is not doing what it is supposed to be doing?
- Molecular imaging allows physicians can see whether the chemo is going to the right place within the body and whether it has acted on the tumor. Molecular imaging can indicate whether tumour cells are actually dividing or not – an indication of a tumour growing or dying – without waiting the weeks before seeing anatomical changes in tumour size.

{slide: PET-produced isotopes}

- An emerging technology that is facilitating such imaging improvements is called PET, or positron emission tomography. PET generates high-quality images from ultra-short-lived isotopes.
- These isotopes decay very quickly and often have half-lives of minutes, rather than half-lives of hours or days like other popular medical isotopes in use today.
- Another feature: PET isotopes are produced right in the hospital in a refrigerator-sized cyclotron.

- Our traditional medical isotopes will continue to have a role but PET could dramatically change the way traditional nuclear medicine is delivered. I'll mention how we are engaging this technology further below.
- Stem cells offer up another path to follow in this pursuit of personalized medicine. They hold promise for "regenerative medicine".

{slide: cell view }

- Being so-called unspecialized cells, stem cells have the ability to transform into specific cells such as blood, brain, heart or liver. The hope is that these will repair damaged organs by transplanting new cells obtained from stem cells.
- Imagine eliminating the need for insulin injections for diabetics, regenerating heart muscle after it fails, or repairing nerve damage in the brain. Some have said that the treatments yielded by stem cells will replace many drugs and surgery.
- This is moving beyond theory. Since 2003, researchers have successfully transplanted retinal stem cells into damaged eyes to restore vision.
- Regenerative medicine just may be the sword to battle chronic disease.
- Imaging techniques are needed to see what happens to stem cells in use: Do the cells target the right tissue? How many cells get there? How long do they stay? Are the cells functional?
- What's our role in this exciting area?
- We are exploring how new research isotopes could be applied to enhance imaging capabilities for researchers.
- We are also looking to partner with research institutes to see how we can jointly offer technology and services to the pharmaceutical industry in their quest for new drugs.

{slide: irradiator }

- To support stem cell research, we have expanded the use of our small scale irradiator technology.
- Another opportunity: regenerative medicine could increase the demand for sterile biologically-active medical devices. We could be uniquely positioned to help here as well by developing new radiation based sterilization technologies for use in regenerative medicine.

- By the way, with this latter point in mind, I mentioned earlier about the importance of cobalt-60 in sterilizing materials. We just need to ensure that we can get our hands on more cobalt-60 – the demand is there. We need more CANDUs...!
- A key theme should be evident. We need to be more innovative, nimble and responsive to the incredible opportunities in the evolving medical field.

{slide: TheraSphere vial}

- TheraSphere, I am pleased to say, is a case in point. This is a proprietary product of ours.
- We are infusing millions of tiny glass spheres with radiation to treat liver cancer – a “nano-treatment” that is establishing itself as a best-practice therapy worldwide.

{slide: microscopic spheres}

- No bigger than a human hair, these spheres are injected into an artery leading to the liver where they get lodged in the capillaries that feed the liver tumour.

{slide: liver cancer}

- The radiation emitted from the spheres is highly localized. It delivers the therapeutic radiation to the tumour cells while minimizing the radiation dose to the healthy cells. For the patient, the procedure is done on an out-patient basis and has minimal side-effects.
- TheraSphere is a product that is being rolled out globally, starting with the U.S., and only recently to India and Europe.
- Its use in India is particularly interesting. India has positioned itself as a “medical tourism” destination – attracting patients from all over the world to be treated at world class medical facilities. In fact, the largest hospital group in Asia is now centered in New Delhi and it has now added TheraSphere as a cancer treatment option.
- Canadian technology and innovative techniques are being used to improve cancer care in other respects.

{slide: antibody/radioimmunotherapy}

- We’ve been part of the first-ever approved “radioimmunotherapy” – a new class of targeted cancer therapy. This is another example of nano-technology at work. That is, attaching (or what is known as “labeling”) radioisotopes to antibodies to

treat cancer from within the body, such as for non-Hodgkin's lymphoma, a devastating blood-borne cancer.

- We are actively involved in finding new ways to label other molecules to treat other conditions.

{slide: Innovation to Commercialization}

- We need to push this innovation frontier further. That is why we are looking to new partnership models.
- Historically, it has been estimated that 80% of innovation in life sciences has come from academia. The role of companies was devoted largely to commercializing products. Increasingly, major breakthroughs are coming from collaborative partnerships between these sectors.
- Our business model must adapt but I am confident that we know how to do so.
- We've built our business on a successful partnership with many of you in the isotope-generation business. We need to sustain these links.
- To grow beyond single-digit growth, though, we need to do more. We need to associate ourselves with new world class leaders. We are doing our part here: we've hired key talent from the U.S.; and, we need to build our own intellectual capital. But we can't do it alone. We need to more fully engage the medical research, hospital and university community worldwide.
- The ball is in motion. In Europe, we are collaborating with the Université de Liege. We are helping this university commercialize and distribute PET isotopes to European hospitals
- I referred to PET earlier. These ultra-short-lived isotopes were initially produced in the university's own cyclotron for medical research purposes. Our partnership has brought them to physicians to enhance patient care.

{slide: OHI}

- Ground-breaking work is also taking place at institutions across Canada, including just a few kilometers from here, such as at the University of Ottawa and its cardiac academic health centre – the University of Ottawa Heart Institute. It, too, is working with PET technology and we are exploring how we can work more closely with this fine institution.

{slide: improving commercialization}

- We shouldn't forget that this region is blessed with opportunity. There are over 40 research centres and institutions in the Ottawa region, alone.<sup>2</sup> A number of these have a stake in the life sciences, such as the National Research Council and the Ottawa Health Research Institute.
- We need to establish centres of excellence to commercialize molecular medicine technologies both here in Ottawa and abroad. (I'd encourage you to watch this space for some upcoming announcements.)
- This is how we need to leverage our franchise. Partnerships are needed so we can collectively innovate and commercialize products faster. We no longer can afford to be just a manufacturer of isotopes.

## **VII. CONCLUSION**

{slide: MDS Nordion}

- I mentioned that we had three strategic tasks to pursue. In summary: we need to be a technology and service enabler for new diagnostics and therapeutics. We need to move from being a manufacturer to an innovator. And, we need to develop new forms of private-public partnerships.
- Combined, these are mission-critical because we now want to do in the next 4 years what took us decades to get to this spot: I expect us to double our revenue by 2010 as a minimum.
- We have occupied a leading isotope supplier position up to this point today – and we're proud of that. Now we need to be a leading innovator in molecular medicine for tomorrow. Canada has the potential to be a global leader in applying molecular medicine and we are positioning MDS Nordion to be a catalyst in getting us there.
- In conclusion, just as software tools and the internet have become essential to our information economy, molecular medicine will be essential to health innovation. With this, the promise of personalized medicine is within reach.

{slide: thank you}

Thank you.

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<sup>2</sup> *The Ottawa Partnership, April 2006*