

ART: Leveraging the Power of Optical Imaging

This Montreal-based company is on the cutting edge of bio-optical diagnosis and detection

by Michael Carin



Micheline Bouchard

President & CEO

Bouchard has traced an extraordinary and high profile career as an engineer, administrator, business leader, and member of the Order of Canada. The former President and CEO of Motorola Canada, Bouchard previously left her mark at Hydro-Quebec, Hewlett-Packard, the DMR Group, and CGI. She has served as President of the Canadian Academy of Engineering, and last year the Academy awarded her its Gold Medal (the highest possible recognition for a Canadian engineer) for her inspiration to others. She came to the leadership of ART with a mandate to commercialize the company's products.

The holy grail of medical efforts is the achievement of non-invasive diagnosis or intervention. In terms of scanning technology, that goal is within grasp. The field of optical imaging promises to transcend existing technologies, and at last deliver to the medical profession a process that causes no harm to the patient's body.

We have all experienced X-rays, and many of us are familiar with CAT scans, and magnetic resonance imaging scans (MRIs). What these technologies have in common is that they produce structural or anatomical images of the body. What they fail to do is provide detailed information about how a lesion functions biologically, i.e., indicate tissue perfusion and blood oxygen content.

In recent years, positron emission tomography (PET), through its ability to provide physiological information, has advanced the evolution of scanning diagnostics. PET scan images help measure abnormal molecular cell activity, and can detect cancer, brain disorders, and heart disease. The procedure, however, begins with an injection of radioactive isotopes, which is an invasive procedure for the patient.

Optical imaging, on the other hand, requires no radiation and no use of radioactive elements. With its employment of laser light, the technology is explicitly and totally *non-invasive*. And that is why ART Advanced Research Technologies Inc. (ART) has attracted the attention of one of the key players in medical devices: GE Medical Systems. In terms of readying this new technology for the global marketplace, the Montreal-based company holds a leadership position in the growing bio-optical sector. ART

has been listed on the Toronto Stock Exchange since June 2000 (TSX: ARA).

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“Optical imaging,” explains Micheline Bouchard, ART’s President and CEO, “goes well beyond the production of an image. Laser-based, ART’s technology is unique in that it measures what is going on in the tissue and how the body is functioning, while being risk-free and tremendously cost-effective.”

The technology transcends human application. It can be used with animals, grains and liquids (to detect contaminants). In all cases, it provides insight into the biological processes and functions within tissue or matter.

Here’s how the technology works: By measuring light (absorption and scatter characteristics) in the visible and near infrared region of the spectrum, time domain optical imaging indicates tissue perfusion and metabolism, and thus allows for the detection of angiogenesis (new blood vessel formation) in biological tissue. The evidence or absence of angiogenesis relates to many diseases such as cancer and heart disease.

Additionally, with the injection of a harmless fluorescent compound, ART’s optical imaging allows specific tagging of particular receptors, antibodies, genes, or drugs. ART’s technology can measure how and to what extent a compound is operating in the body, what pathways it is taking, and the time it takes to reach where it’s going or do what it’s doing. This information in turn leads to enhanced knowledge of a disease process and the means of treating it.

“Effectively,” says Micheline Bouchard, “time domain optical imaging measures at a greater depth. It can provide quantitative information. Existing optical technologies cannot quantify as specifically; their information remains comparatively ‘blurred’ and it is only by assumption that they can indicate what is going on.”

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ART recently launched SAMI™, an innovative optical molecular imaging device dedicated to the pharmaceutical and pre-clinical research markets, and is in the process of obtaining regu-

latory approval for the commercialization of SoftScan®, an adjunct diagnostic tool for detecting breast cancer and monitoring treatment.

With respect to SoftScan®, ART is undergoing clinical trials with McGill University Centre's Royal Victoria Hospital in Montreal, and Sunnybrook & Women's Health Sciences Centre in Toronto. SoftScan® is scheduled for commercial launch in 2005, following regulatory approval from the U.S. Food and Drug Administration or Health Canada.

Bouchard explains how SoftScan® works in largely layman's terms: "If there is a suspicion of cancer after a mammogram, the patient will go to a second step, an ultrasound or an MRI, for a better assessment. It is at this stage that SoftScan® can play a critical role as an adjunct to mammography. Whereas ultrasound and MRI provide only structural images of what is going on in the breast, Softscan® provides a crucial functionality: the ability to determine if a breast lesion is benign or malignant (cancerous). It can detect the presence of angiogenesis: the creation of small blood vessels that are indicative of the presence of cancer. If there is an increase in volume around the tumour, namely perfusion, SoftScan® measures that, and SoftScan® then goes a step further. Typically the small blood vessels that did not previously exist were created because the tumour needs oxygen to survive, and will draw the oxygen from these blood vessels. SoftScan® measures the metabolism, the oxygen content of the vessels, and thus the activity, the virulence, of the cancer. If, on the other hand, SoftScan® sees a lesion but with physiological processes around it that are identical to the rest of the breast, then the lesion is not cancerous."

Additionally, SoftScan® is also positioned to be an aid in decision-making during breast cancer treatment, such as chemotherapy and radiotherapy. Physicians will use SoftScan® to validate treatment, making adjustments where necessary to improve efficacy. If treatment success is more rapid than expected, the physician can stop treatment earlier, thus eliminating the often distressing side-effects associated with chemotherapy and radiotherapy.

Unlike X-ray mammography, SoftScan®'s laser imaging does not expose patients to radiation, nor to painful compression of the breast. Furthermore, it can be used as often as needed.

Apart from the potential reduction in human suffering and death that SoftScan® can bring, this technology will help reduce costs to the medical system by millions of dollars in breast diagnoses, assessments and treatments. SoftScan® addresses a global available market projected to reach US\$1 billion by 2008.

ART is well poised for commercial success since it signed an agreement in October 2002 whereby GE Medical Systems will manufacture and distribute the SoftScan® breast imaging device after the clinical and pre-production phases have been completed. GE Medical Systems' sales and distribution expertise will play a major role as it occupies a leadership position in the medical devices market, with a 40% market share.

In August 2003, ART reached a similar agreement with GE Medical Systems, whereby GE will act as worldwide distributor for ART's Small

Animal Molecular Imaging (SAMI™) technology, which is ready for market. In fact, commercialization efforts have already begun. SAMI™ will dramatically reduce costs and speed up research in the biotechnology and pharmaceutical markets. Designed to help drug developers monitor physiological changes in small laboratory animals, SAMI™ provides information that has previously been difficult to obtain by other imaging devices. It provides access to physiological and quantitative *in vivo* images. The unique advantage of SAMI™ is its rapid demonstration of a drug's efficacy, toxicity and side effects on organs not targeted by the drug treatment, all in real time.

SAMI™ was just an idea in June of 2002. A year later, ART was



Softscan® is an optical imaging device for the detection of breast cancer, the flagship product of ART. ART has also developed a pre-clinical optical molecular imager—SAMI™—designed to assess new drug candidates in small animals *in vivo*, reduce drug development costs and accelerate time-to-market of new drugs.

launching the product, which certainly impressed investors and boosted the company's stock. The current market for this type of device is estimated at more than US\$700 million, growing to US\$1.5 billion in the next five years. Over 7,000 pharmaceutical companies, laboratories and other research centers could benefit from the technology immediately.

As SAMI™ begins its commercialization and SoftScan® goes through clinical trials and the regulatory approval process, ART will continue to leverage the potential of its innovative time domain optical imaging technology platform to generate short-term revenues. A wide range of applications are possible: a device, for example, that fuses SAMI's fluorescent imaging capability with SoftScan's functional imaging to measure the efficacy of new drugs in humans or applications for prostate cancer detection. In the agro-food sector, a device built on ART's technology platform would enable the control of contaminants or other unwanted substances such as bacteria in food, detect genetically modified food, and control quality. Such a device would not require regulatory approval, while generating new revenues.

"A number of parties are interested in leveraging the capabilities of our technology platform," says Micheline Bouchard. "We are now beginning to assess those opportunities, as we remain focused on our initial two applications. We will look at options like sharing both risk and opportunity with a partner, while always maintaining ownership of our platform's intellectual property. This is ART's strategy and what lies ahead is a promising and profitable future." □