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Canada's emerging cell therapy biotech industry

CANADIAN COMPANIES DRIVING GLOBAL BREAKTHROUGHS IN REGENERATIVE MEDICINE

By KATHRYN BOOTHBY

Rapid advances in regenerative medicine are bringing the promise of curative solutions for chronic conditions closer to reality. Canadian companies are at the forefront of this revolution, paving the way for this country to be a standard-bearer of breakthrough treatments for patients around the globe.

Therapies using cells are potentially improving outcomes and reducing or eliminating side effects for such devastating diseases as diabetes, hemophilia, and critical limb ischemia, as well as conditions such as chronic tendinitis, damaged skin, and pattern baldness. New tools and technologies are also helping to put an end to bulky, obtrusive mechanisms to deliver life-saving treatments.

"We are at a powerful leading edge for medicine," says Michael May, president and chief executive officer of the Centre for Commercialization of Regenerative Medicine (CCRM) in Toronto. "The ability to regenerate tissue will transform the treatment of diseases, quality of life, and the economics of health care."

"Billions are being spent globally in the field of regenerative medicine on investment, research, development and sales," says May. "Now, with clinical efficacy being demonstrated, we're seeing more regulatory approvals and resulting mega-deals between small companies and large corporations."

But where does Canada fit in the global picture? The discovery of stem cells in Canada in the 1960s sparked the worldwide use of bone marrow transplants for patients with leukemia and aplastic anemia. "This spawned an incredible research machine that made some important discoveries over the ensuing years. We are at a similar junction today," he says. "We're leading the science and have begun to leverage commercialization around the globe. The system is primed; we now need to fuel it with private investment to ensure Canada is at the centre of this emerging industry."

CCRM is actively working to achieve that goal by coordinating access to bundles of technologies from around the globe; creating and supporting companies to further develop and commercialize those discoveries; and establishing relevant industry networks and accessible infrastructure. CCRM currently works with a 50-member industry consortium that includes therapeutic innovation companies, multinational pharmaceutical organizations such as Pfizer and Amgen, and infrastructure and tool companies such as GE Healthcare and Stemcell Technologies.

"Access to strong academic and industry networks en-



IMAGE CREATED BY TAMMI HALL

CCRM: helping position Canadian companies at the centre of regenerative medicine around the world.

ables us to now build a third key stakeholder group — an investor network," says May.

That strategy is beginning to pay off for some of Canada's cell therapy companies, including RepliCel Life Sciences Inc., Hemostemix Inc., and Sernova Corp.

RepliCel (TSX.V: RP) is driving multiple products in the regenerative medicine arena with three cell therapy products in clinical development, and a dermal injection device that promises to change the way any product is delivered in or under the skin, including the over \$2 billion worth of dermal fillers injected annually.

"2015 is a pivotal year for the company," says Lee Buckler, RepliCel's vice-president, business and corporate development. "This is the year we moved all our cell therapy assets forward in clinical development, which sets us up for transformative catalysts over the next 18 months." Earlier this year, RepliCel launched a Canadian trial for chronic tendinitis and just recently announced the launch of a dermatology trial in Germany. Topping off the trio is a trial for pattern baldness with commercialization partner Shiseido Company, which is expected to launch in Japan shortly.

RepliCel is one of a handful

of foreign cell therapy companies with an active partnership in Japan. "Having Shiseido, one of the world's largest cosmetic firms, as RepliCel's partner for its pattern baldness product, has given us notable credibility in that market," says Buckler, "and we are now engaging other companies in Japan about partnerships for our other products."

"Partnering in Japan is at the top of our list because the government has expedited the process of developing cell-based therapies, making it

disease, and 25% will die from it. Currently, the only treatment is amputation.

The process involves collecting cells from a patient's blood that are then manufactured into a cell therapy and delivered back to the patient. The company believes the re-introduced cells create new blood vessels that restore blood flow and could save the limb from amputation.

"CLI is a severe disease, threatening millions of people's lives worldwide. We are running our clinical trials

immune-protected therapeutic cells into an implanted pre-vascularized medical device. The company believes the Cell Pouch System, about the size of a business card, creates a natural organ-like environment when placed under the skin, and the cells release required proteins or hormones such as insulin, or Factor VIII potentially eliminating the need for chronic injections or infusions.

For diabetes, Sernova's product — the device and cells implanted in humans — is being designed to mimic the pancreas where cells (islets) read blood sugar levels then release both insulin and other hormones into the bloodstream. The company has recently become a fully integrated pharmaceutical company as it has gained worldwide exclusive rights to a glucose responsive insulin-producing stem cell technology from University Health Network (UHN). The company has received grants from the National Research Council, Juvenile Diabetes Association and support from both the Canadian and Ontario governments to assist with its activities.

"If Sernova's treatment leads to patients no longer having to take injections or deal with a cumbersome device, this could improve the quality of life for millions of

people, reduce the debilitating side-effects of the disease, and cut health care system costs significantly," says Dr. Philip Toleikis, Sernova's president and chief executive officer.

"Canada imports close to 100 per cent of our medical treatments," notes May. "It would be much more exciting to be exporting our treatments and using our health care system to develop and deliver those products to patients around the world, all while improving the health of Canadians here at home."

Canadian companies working in regenerative cell therapy have globally competitive technologies and great science. RepliCel, Hemostemix, and Sernova are all moving products through clinical trials at a time when big industry players are making investments in manufacturing, therapeutics and tools to facilitate the production of cells.

"While every company's corporate strategy is different," concludes RepliCel's Buckler, "it is our corporate intention to build sufficient value in our assets, licenses, and royalty streams so that the company becomes a home-grown acquisition target thus contributing valuable assets to the growing appetites for regenerative medicine among the global multinational players."

WE ARE AT A POWERFUL LEADING EDGE FOR MEDICINE

possible to bring cell therapies to market faster there than any other regulated market in the world," says Buckler.

Hemostemix (TSX.V: HEM) is currently undertaking an international phase-two, double-blind, randomized, placebo-controlled clinical trial to test the efficacy of a cell therapy to treat critical limb ischemia (CLI). CLI is characterized by insufficient blood flow to the lower limbs caused by blockages in small blood vessels. In North America alone, some four million people have the

in leading international centers, including Canada, the U.S., South Africa, and soon in Taiwan," says Dr. Elmar Burchardt, Hemostemix' president and chief executive officer and former vice-president of regenerative medicine at Pfizer.

Sernova (TSX.V: SVA), a clinical stage company, is treating chronic, debilitating diseases such as insulin-dependent diabetes, hemophilia A and thyroid disease using a regenerative medicine approach through the placement of im-

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