

# Returning FORM

*New funding gives  
hope for 10 new  
therapies over the  
next 10 years*



■ BY DOUG WINTEMUTE

It wasn't long ago that Canada was the undisputed worldwide leader in stem cell research. Stem cells have been synonymous with Canadian science since Doctors James Till and Ernest McCulloch first proved their existence in mice at the Ontario Cancer Institute in Toronto in the 1960s. Since then, the world has caught up and is poised to leave Canada behind. Now, on the brink of a global stem cell revolution, with the promise of regenerative medicine and cell therapy seemingly more reality than science fiction, Canada aims to reclaim its status as the industry leader once again.

"If hockey is Canada's game, then stem cells is Canada's science," says James Price, President and CEO of The Canadian Stem Cell Foundation. "We've got the foundation there to build on. What we are lacking is a coherent plan for how we move the needle forward, where we place the investments. We can't be all things to all people."

This is where the Canadian Stem Cell Foundation and its partners come in. Announced late last year, *Following Through: Realizing the Promise of Stem Cells – A Canadian Stem Cell Strategy & Action Plan (2015-2025)*, looks to harness Canadian assets and investments to date, target diseases that are a priority to Canadians, align private sector and government investment, and ensure accountability so that the milestones are met and results are achieved.

"We will deliver 10 new therapies within 10 years," promises Price, the fruits of a proposed \$1.5-billion investment over the same period, of which one-third is asked of the federal government. "But, if we continue to fragment our investment into a bunch of disparate programs with conflicting objectives, were never going to reach our end goal."



Left: Michael May, CCRM President and CEO. Photo credit: CCRM



Below left: Dr. Guy Sauvageau, Excell Thera Scientific Co-Founder and CSO. Photo credit: ExCellThera

In order to compete on a world stage, Canadian stem cell science must take a unified approach. Unable to rely on raw investment alone, the Canadian Stem Cell Foundation and its partners look to target specific areas and concrete steps, taking research to clinical trials and through to commercialization. "Areas like cardiovascular disease, diabetes, neurological diseases, auto-immune disorders, these are four areas where Canada has got real strengths on an international stage," says Price. "If we focus and invest in those areas, we are going to lead in developing the therapies."

#### LEADING EDGE SCIENCE

Stem cells are unique for their ability to self-renew and differentiate. This means that a stem cell can divide into many more cells, some like itself and some with other specialized tasks. These properties make stem cells ideal for regenerative medicine and treatments. In fact, stem cell treatments for diseases such as leukemia and lymphoma have already been practiced in Canada for the last few decades, curing thousands of patients. Put simply, because chemotherapy treatments destroy cells that divide rapidly, both cancer cells

and stem cells are vulnerable to the process. By introducing donor stem cells that have been extracted from bone marrow into the body post-chemotherapy, the unique, self-renewing ability of stem cells replenishes the body's cell count.

It is in recent years, however, that stem cell research has really flourished. Research in controlling induced pluripotent stem cells (iPSCs), adult cells that can be "reprogrammed" for a new purpose, is showing enormous potential in treating a vast number of diseases. Not only will treatments of this kind increase the life expectancy and satisfaction for patients, they

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– Michael May, CCRM President and CEO.

will also serve to dismantle the massive economic burden of incurable disease treatment.

“Last year we spent \$214 billion on healthcare in Canada. Two-thirds of that \$214 billion was spent on the direct cost of treating patients with currently incurable diseases,” says Price. “When we talk about the sustainability of healthcare and how to actually do that, we believe that stem cells, and we’ve already seen this borne out though some of the existing therapies, really cure the problem and not just treat the symptoms.”

But it’s more than just reducing the exorbitant healthcare ticket. Along with an estimated 12,000 jobs created through company development and expansion, the stem cell industry represents a virtually untapped market for whomever can get safe products to commercialization first. To get there, however, requires a collaborative effort to encourage and attract investment.

“Everything we’ve done up to this point is really priming the system. We now need to fuel it with deep and meaningful investment,” says Michael May, President and CEO of the Centre for Commercialization of Regenerative Medicine (CCRM). “We need to deploy the private wealth in the country and investment from outside the country into this jewel of an asset in Canada. Regenerative medicine is a place

where we can be as much of a leader as we are in the resource sector.”

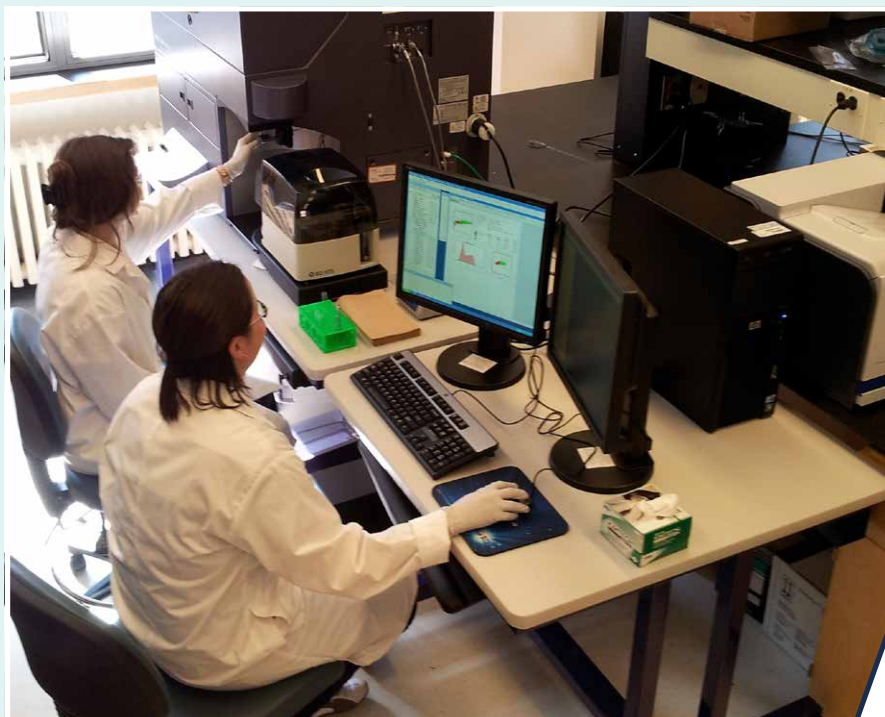
The CCRM, partner of the Canadian Stem Cell Foundation, tasks itself with accelerating the translation process from the excellent research and development in

Canadian stem cell science to commercialization as well as stimulating company creation and investment. Already it has 10 proto-companies built around bundles of technologies that are to be supported, incubated and launched. By leveraging Canada’s strong clinical infrastructure and its positive regulatory environment, working toward harmonizing regulatory approval and reimbursement, and building up Canada’s product manufacturing capabilities, the CCRM aspires to turn Canada into a global hub for cell manufacturing, drawing in national and international companies and investment dollars.

### NEW BLOOD

On June 15, 2015, the launch of ExCellThera was announced, a spin-off company fueled by a partnership between the CCRM and IRICoR (Institute of Research in Immunology and Cancer – Commercialization of Research). As the first of the CCRM’s proto-companies leaves the nest, the Canada-strong vision starts to take shape. ExCellThera looks to make its mark on the global stage by bringing its best-in-class process of cord blood stem cell transplantation to the world and the world to Canada. With the technology to expand the amount of stem cells in umbilical cord blood (UCB), ExCellThera plans to position itself as a world leader in the development, manufacturing, and distribution of hematopoietic stem cells.

“Although umbilical cord blood (UCB) is indeed a rich source of stem cells, in absolute numbers it is very low,” says Steven Klein, President and CEO of ExCellThera and V.P. of Business Development with IRICoR. “In terms of transplanting, transfusing, or infusing stem cells from UCB into a recipient, the success of that transplantation is directly proportional to the number of stem cells that the recipient receives. So that’s really been a blockage to the



CCRM staff working in the development facility.. Photo credit: CCRM.

widespread usage of UCB for stem cell transplantation.”

With a concerted focus being placed on stem cell technologies, the hope is that more companies like ExCellThera will begin to sprout. And, for a country that has not, historically, been very strong in translating research into clinical trials or commercial products, this is significant. Overall, this is another forward step in strengthening Canada’s industrial and clinical development, proof positive that the Canadian stem cell coalition is already making an impact.

“ExCellThera would not exist without IRICoR or the CCRM,” says Klein. “From the business point of view, the ability of the CCRM and IRICoR to identify the right Intellectual property to protect, the technologies with the proper patent filings, to bring the scientists together, to prepare the business case, to work together and have a shared vision, I think these are all critical elements in being able to create ExCellThera. And I hope, for other groups in Canada, that this can be a model that they can look at.”

**SNAKE OIL TREATMENTS**

Unfortunately, for therapies with such great potential comes significant danger: stem cell tourism. However, by building a self-sustaining stem cell industry here in Canada, it is expected that the tourism allure will be effectively negated. There are a number of unsavoury clinics that find loopholes in international government language and law allowing them to practice unproven, expensive, and often dangerous treatments that may not be therapies at all, preying on the desperation of sick people and their loved ones. Much of this is done in the name of stem cell therapy without the backing of proper safety precautions.

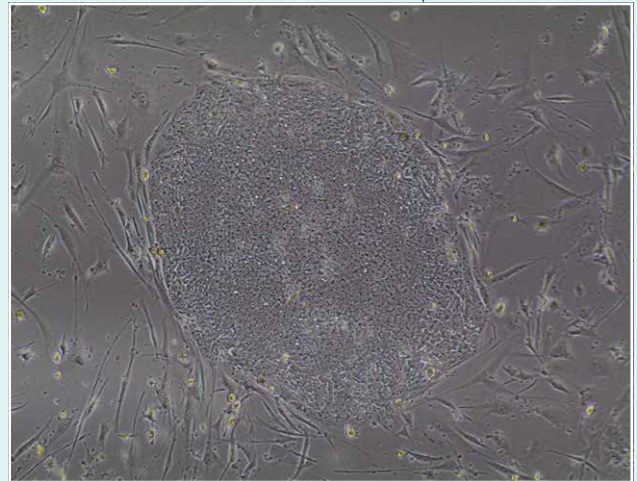
“This always happens at the leading edge of medical treatments. There are bad people who take advantage of hope and very sick people to dupe them. It happens. It happens all over the world,” says May. “People are sucking fat out of a person and saying it’s full of stem cells and putting the fat back into another place and claiming they’re going to cure blindness or going to make them walk again. This is just hocus-pocus.”

Both the Canadian Stem Cell Foundation and the CCRM believe that if Canada was to position itself as a stem cell leader, it would not only stop the vast majority of stem cell tourism, but it would also become a global destination for stem cell therapy. As of today, Canada appears on the verge of breaking through. The foundation is built; Canada houses excellent science, a strong regulatory system, and great clinical infrastructure. So what is next? What is needed for Canada to take major strides toward implementation?

**CANADIAN STEM CELLS**

“This is a private sector-led plan and it’s got a lot of merit on its own,” says Price of the Canadian Stem Cell Strategy & Action Plan. “But, at the end of the day, our private sector partners are looking for a signal from the federal government that they’re committed to this area, in terms of providing important seed funding but also in terms of a commitment to work in partnership with the investment and industrial community to streamline some of the regulatory pathways so that Canada becomes a destination.”

The strategy leading up to October’s federal election was clear: seek a commitment in the various election platforms.



Induced pluripotent stem cell (iPSC) colony from patient fibroblast. Photo credit: CCRM.

Those involved in the Canadian stem cell industry are asking that the Canadian federal government send a clear message to Canadians that it is serious about stem cell therapy and regenerative medicines, that it is doing everything possible to ensure that, once treatments are shown to be safe, they will be made available to Canadians in a timely matter. Adding political partnership to the already burgeoning Canadian stem cell industry will bring it one step closer to a national brand and one step closer to regaining its status as global leaders in stem cell technologies.

“We’re the discoverers of stem cells. We need to capture the nation’s imagination and vision, and we need to produce a national Canadian cell therapy company,” says May. “This is a field and a strength in Canada where we can not only be the scientific leaders, but we should be the leaders, delivering leading-edge technologies to patients around the world. We can do this and should do this.” **BB**

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