

A Pre-Budget 2017 Submission To the Standing Committee on Finance

To Implement the Canadian Stem Cell Strategy by Establishing The Till & McCulloch Medicines of Tomorrow Innovation Fund

James Price
President & CEO
Canadian Stem Cell Foundation

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EXECUTIVE SUMMARY

Stem cells represent the biggest innovation in medicine of the last half century. These cells have the power to cure many diseases for which current medical practice can only provide symptomatic relief and chronic care – a reality that is straining health care systems in Canada and around the globe.

Stem cells are a hallmark of Canadian innovation. They were discovered in Canada and Canada is one of the top countries in stem cell R&D. Our scientists rank among the world's best and we have an emerging industrial base with a global footprint.

Recent investments, such as the Government's \$20-million commitment to establish a cell-manufacturing facility in Toronto and the \$114-million Medicine by Design grant for the University of Toronto, will help Canada move forward. However, major commitments by competitor jurisdictions — most notably California, with its investment of \$3 billion, and Japan, with an investment of more than \$1 billion in induced pluripotent stem cells — challenge Canada's leadership in this space. Moreover, Canada lacks a coordinated strategy to succeed in the regenerative medicine boom that will soon grow into a \$120-billion global market.

The Canadian Stem Cell Strategy represents a bold approach for joint action — merging the efforts of Government and the private sector — that will position Canada as a world leader in this emerging, critically important innovation sector. Created in consultation with 150 scientists, medical doctors, leaders from major health charities, industry experts, investors and philanthropists, the Strategy will:

- deliver up to 10 new curative therapies to the clinic within 10 years;
- transform health care and ease the strain on the health system; and
- attract private investment, generate 12,000 jobs and drive economic growth.

The Strategy calls for a scaled average annual Government investment of \$50 million, for a total of \$500 million in federal funds over 10 years. We know the Government cannot act alone. That sum will leverage a complementary non-federal investment of \$1 billion – more than half of which has already been pledged.

We request that the Government, as part of its Innovation Agenda, include an initial five-year commitment of \$250 million in Budget 2017 to establish the Till & McCulloch Medicines of Tomorrow Innovation Fund to implement the Canadian Stem Cell Strategy.

The Fund structure will ensure the Government's investment has appropriate governance and that monies will be strategically invested in partnership with the private sector and stakeholders.



The Canadian Stem Cell Strategy aligns with the Government's Innovation Agenda goals of investing in fresh initiatives that create sustainable growth and economic opportunities for more Canadians. It is a shovel-ready investment in health innovation that will accelerate development of a made-in-Canada industrial sector that is ready for significant growth.



INTRODUCTION

Stem cells represent the biggest innovation in medicine of the last half century. Already, they have cured thousands of patients with leukemia, multiple myeloma and other blood-based cancers.

In the next few years, stem cells will change everything. Stopping MS in its tracks is now possible. Canadian doctors are testing stem cells to heal hearts, repair severed spinal cords and fix arthritic knees. Researchers believe that diabetics soon will be freed from daily insulin injections by stem cell transplants. A cure for Parkinson's is within reach.

"Cure" is the key. Stem cells have the capacity to cure disease – not just manage symptoms. This is crucially important given that two-thirds of Canada's \$200-billion-plus annual health care bill goes to treating chronic, currently incurable conditions. With an aging population, that amount will only escalate. Unless we find a better way.

Stem cells are that better way. Not only do they represent Canada's best opportunity to cure disease and transform health care, stem cells have the power to boost our economy by creating thousands of new high-quality jobs, attracting investment, generating new companies and strengthening existing ones.

STEM CELLS ARE CANADA'S INNOVATION

Canada's expertise in stem cells is an historical point of pride. Drs. James Till and Ernest McCulloch discovered adult stem cells in the early 1960s. Their research serves as the field's foundation and has paved the way for remarkable achievements by subsequent generations of Canadian and international scientists.

Canada stands among the top two to three countries in the world in stem cell R&D. We are well positioned to succeed in the emerging cell therapy and regenerative medicine boom. As a nation, we are ready to build on our competitive advantages, optimize our expertise and excel on the global stage. What's lacking is a national plan to make it happen.

CAPITALIZING ON CANADA'S STEM CELL ADVANTAGE

Realizing this, a broad coalition led by the Canadian Stem Cell Foundation crafted a plan for the road ahead.

The Canadian Stem Cell Strategy, the product of consultations with 150 scientists, medical doctors, leaders from major health charities, industry experts, investors and philanthropists, is backed by an in-depth KPMG study and endorsed by an international panel of experts. It aligns the sector to:



- deliver up to 10 new curative therapies to the clinic within 10 years;
- transform health care and ease the strain on the health system; and
- attract private investment, generate 12,000 jobs and drive economic growth.

A PRIVATE SECTOR-LED PLAN

The Canadian Stem Cell Strategy aligns with the Government's Innovation Agenda goals: investing in pan-Canadian initiatives to create sustainable growth and economic opportunities for Canadians. It is a shovel-ready innovation-based plan for health, health care and economic growth.

The total investment is \$1.5 billion over 10 years. But the Government cannot act alone. The Strategy calls for a scaled average annual Government investment of \$50 million for a total of \$500 million in federal funds over 10 years, which will leverage a complementary non-federal investment of \$1 billion – more than half of which has already been pledged.

We request that the Government, as part of its Innovation Agenda, include an initial five-year commitment of \$250 million in Budget 2017 to establish the Till & McCulloch Medicines of Tomorrow Innovation Fund to implement the Canadian Stem Cell Strategy. The Fund structure will ensure the Government investment has appropriate governance and that monies are strategically invested in partnership with the private sector and stakeholders.

We anticipate that following a successful review of the Fund's performance in Year 5, an additional \$250 million will be invested by the Government in partnership with the private sector for the final five-year term of the Strategy.

THE INVESTMENT, IN CONTEXT

In mid-January, Prime Minister Justin Trudeau announced \$20 million in federal funding to help establish a new cell manufacturing facility at the Centre for the Commercialization of Regenerative Medicine in Toronto. Recently, the Government announced a \$114-million grant for a stem cell research hub at the University of Toronto called Medicine by Design. According to a CBC report, the Government has invested about \$705 million in stem cell research through the Canadian Institutes of Health Research since 2001, including \$64.5 million in 2014-15.

In comparison, the State of California — with a population similar to Canada's — committed \$3 billion in funding over 10 years, with almost \$900 million earmarked for new projects in the next four years alone. Japan has invested more than



\$1 billion in induced pluripotent stem cells and revamped its regulatory framework in the expectation that substantial domestic profits will accrue. These competitor country investments challenge Canada's leadership in the sector.

While recent investments have been encouraging, Canada lacks a national strategy to succeed in the global regenerative medicine boom set to unfold over the next decade. The Canadian Stem Cell Strategy represents a bold approach for joint action – merging the efforts of Government and the private sector – that will position Canada as a leader in this emerging, critically important innovation sector. The Strategy provides a coordinated pan-Canadian approach to align and integrate the efforts of:

- researchers and medical professionals who will conduct the clinical trials;
- industry players who will both fund and commercialize the R&D;
- philanthropists prepared to support stem cell R&D; and
- health charities that will support and champion the work on behalf of their patient stakeholders.

Without such an organized, coherent and effective national plan, Canada will be left behind and miss this opportunity to save lives, realize substantial economic growth and create thousands of high-value jobs.

The potential economic impact is tremendous. Bloomberg News reported in July that Japan is preparing to tap a global market for regenerative medicine that will grow to \$120-billion by 2030 and set off "a medical and industrial revolution." The Centre for the Commercialization of Regenerative Medicine projects that the Strategy could generate in excess of 12,000 jobs for Canadians via the growth of existing companies and the development of new enterprises.

BUILDING CANADA'S COMPARATIVE ADVANTAGE

Canada is an enticing place for clinical research and has created a burgeoning industry over the last few decades. We offer exceptionally qualified clinicians supported by experienced research staff, cutting-edge research facilities, a varied patient population, and a range of incentives. These features make our country a competitive and relatively cost-efficient destination of choice for trials. The Strategy will ensure that:

- existing investments can be capitalized upon;
- thousands of jobs will be created and retained;
- financial pressure on the health care system will be reduced; and
- patients in Canada and across the world will overcome their illnesses, injuries and conditions via access to therapies.



INVESTMENT, JOBS & THE ECONOMY

The Canadian Stem Cell Foundation represents a broad national coalition of scientists, clinicians, health charities, industry leaders, philanthropists and the investment community. We have already secured private sector commitments of more than \$500 million to partner with the Government of Canada to implement the Canadian Stem Cell Strategy. As an indication, Vancouver-based STEMCELL Technologies Inc. has pledged more than \$350 million over 10 years toward R&D as part of the plan.

AN OUTCOMES-DRIVEN APPROACH

The Strategy brings together current stem cell assets and mobilizes further resources through a novel operating model to:

- target high-impact diseases that are a priority for Canadians and match Canadian research strengths;
- coordinate and harness existing and new stem cell assets (discoveries, infrastructure, technologies, intellectual property and networks);
- align private and public sector investment to move new therapies and technologies through all stages of research, clinical and commercial development; and
- ensure accountability so that milestones are met and results are achieved.

To operationalize the Strategy we propose the establishment of the Till & McCulloch Medicines of Tomorrow Innovation Fund, a strategically aligned, nationally coordinated family of funds that will:

- implement the Strategy;
- manage the overall funding; and
- safeguard that targeted health and commercial outcomes are achieved.

The Fund will invest in a highly integrated portfolio of three sub-funds that will maximize private investment in projects along the development continuum from research to clinical validation to commercialization. They consist of:

- Capital Mobilization & Commercialization Fund to mobilize private capital and create companies to commercialize world-class products, therapeutics and technologies;
- Clinical Advancement & Technology Development Fund to fund and attract leading-edge clinical trials and technology development; and
- Multi-Disciplinary R&D Fund to build a strong multi-disciplinary R&D pipeline.

A competitive, merit-based funding process will mean the most promising projects are supported. A rigorous ongoing external review process employing



industry and scientific experts will ensure that projects meet expectations and investments are allocated to projects with the greatest potential positive impact.

CONCLUSION

A true reflection of the Government's Innovation Agenda, the Canadian Stem Cell Strategy will deliver up to 10 new therapies to the clinic within a decade. It will transform health care by easing the burden of having to provide continuous treatments to currently incurable conditions and generating long-term savings in the health care system. It will attract private investment, create thousands of jobs and drive economic growth.

CONTACT

James Price, MBA
President & CEO
Canadian Stem Cell Foundation
6 Gurdwara Road, Suite 101
Ottawa, ON K2E 8A3
Office: 613-239-2148

japrice@stemcellfoundation.ca

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