

**FOLLOWING
THROUGH** REALIZING
THE PROMISE
OF STEM CELLS

**A Pre-Budget Submission to the
House of Commons Standing Committee on Finance**

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

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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 in countries around the globe.

Stem cells are a hallmark of Canadian innovation. They were first discovered in Canada and Canada is one of the top three countries in stem cell R&D, with our scientists ranking among the best in the world.

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 \$1 billion in stem cells and regenerative medicine -- challenge Canada's leadership in this sector of the knowledge economy. Moreover, Canada lacks a national plan to succeed in the coming cell therapy and regenerative medicine boom.

The Canadian Stem Cell Strategy -- created in consultation with 150 scientists, medical doctors, leaders from major health charities, industry experts, investors and philanthropists – will:

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

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. That sum will **leverage a complementary non-federal investment of \$1 billion – half of which has been pledged.**

We request that Budget 2016 include an initial commitment of \$250 million 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 reflects the Government's Innovation Agenda for investing in initiatives that create sustainable growth and economic opportunities for more Canadians. It is a shovel-ready investment in health innovation and will accelerate development of a made-in-Canada industrial sector 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 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, 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 paved the way for remarkable achievements by subsequent generations of Canadian scientists. To quote Prime Minister Justin Trudeau, “Regenerative medicine is the future and we're quite good at it in Canada.”

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 been lacking, however, 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, along with public and private investments, to:

- deliver up to 10 new curative therapies within 10 years;
- transform health care; and
- generate 12,000 jobs for Canadians.

A PRIVATE SECTOR-LED PLAN

The Canadian Stem Cell Strategy reflects the same approach as the government's Innovation Agenda: investing in initiatives that 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 private and public investment is \$1.5 billion over 10 years. 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 – half of which has already been pledged.

We request that Budget 2016 include an initial commitment of \$250 million 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 will be 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 Trudeau announced \$20 million in federal funding to help establish a new cell manufacturing facility for 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 the 2014-15 fiscal year.

In comparison, the State of California — with a population similar to that of Canada — 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 and revamped its regulatory framework, with the expectation that significant domestic profits will flow as a result. These competitor

country investments challenge Canada's leadership in the sector – especially given that no national plan is in place.

The Strategy provides a coordinated pan-Canadian approach to align and integrate the efforts of researchers, medical professionals who will conduct the clinical trials, industry players who will both fund and commercialize the R&D, philanthropists prepared to support it, and health charities that will help 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. The global market for stem cells is expected to exceed \$170.15 billion USD by 2020, according to a 2014 study by Grand View Research, Inc. Market growth is being driven by the rise in chronic diseases such as cardiovascular and liver disease, diabetes and cancer.

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 projects, 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 R&D tax credits. These features make our country a competitive and relatively cost-efficient destination for trials. The Strategy will ensure that:

- existing investments can be capitalized upon;
- thousands of jobs will be both 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 new stem cell cures.

INVESTMENT, JOBS & THE ECONOMY

We represent 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 of the private sector support, Vancouver-based STEMCELL Technologies Inc. has pledged \$350 million over 10 years toward R&D as part of the plan. The company, which employs almost 800 workers who manufacture

over 2,000 products for scientists in more than 70 countries, is now Canada's biggest biotech company and growing at a rate of 20% per year.

AN OUTCOMES-DRIVEN APPROACH

The main goal of the Canadian Stem Cell Strategy is to deliver up to 10 new curative therapies for disease. Achieving this goal will establish a sustainable and commercially successful stem cell, cell therapy and regenerative medicine industry in Canada that will generate 12,000 new jobs. It will also help transform health care by easing the burden of providing continuous care for currently incurable conditions.

The Strategy is based on bringing together current stem cell assets and mobilizing further resources through a novel operating model that will:

- 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 Till & McCulloch Medicines of Tomorrow Innovation Fund will invest in a highly integrated portfolio of three sub-funds that will attract and enable 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 that 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 that investments are strategically allocated to projects with the greatest potential impact and highest probability of success.

CONCLUSION

The Canadian Stem Cell Strategy will deliver up to 10 new therapies within a decade of its implementation. It will transform health care and ease the burden of providing continuous treatments for currently incurable conditions. It will attract private investment and generate 12,000 new jobs.

CONTACT INFORMATION

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(See Appendix for Coalition Supporters and the Board of Directors of the Canadian Stem Cell Foundation)

APPENDIX

Coalition for the Canadian Stem Cell Strategy

Business Leaders and Philanthropists

VANCOUVER

Peter J.G. Bentley, OC, LL.D
Chair Emeritus, Canfor Corporation

Allen C. Eaves, MD, PhD, FRCPC
Founder & CEO, STEMCELL Technologies

Martha Piper, PhD, OC, OBC
Corporate Director, BMO Financial Group,
TransAlta, Shoppers Drug Mart

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N. Murray Edwards, OC, LL.D
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Randy and Claudia Findlay
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Retired President & CEO, Nexen Inc.

James K. Gray, OC, AOE
Chair, Energy, Brookfield Asset Management

Richard Haskayne, OC, AOE, FCA
Chair, Haskayne & Partners

Stephen Snyder
Retired President & CEO, TransAlta Corp.

James Stanford, OC
Retired CEO, Petro Canada

Rick and Donna Sukovieff
Co-Founder, Solex Energy Ltd.

Don and Ruth Taylor, CM
Taylor Family Foundation

Michael and Renae Tims
Vice-Chair, Matco Investments

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Senior Advisor, Bennett Jones; Corporate
Director, Cameco and Agrium

Eric P. Newell, OC, AOE
Chancellor Emeritus, University of Alberta

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Gerald Grandey
Retired CEO, Cameco Corporation

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Randy and Janis Benson
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David Hennigar
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John Risley
President and CEO, Clearwater Fine Foods

Jim Spatz
Chairman & CEO, Southwest Properties

Coalition Organizations

Canadian Stem Cell Foundation

Health Charities Coalition of Canada

CellCAN Regenerative Medicine and Cell Therapy Network

Ontario Bioscience Innovation Organization

Centre for Commercialization of Regenerative Medicine

Ontario Institute for Regenerative Medicine

Stem Cell Network

Canada's Health Charities (Health Charities Forum)

Alzheimer Society of Canada

Kidney Cancer Canada

Canadian Breast Cancer Foundation

Lymphoma Foundation Canada

Canadian Cancer Society

Multiple Sclerosis Society of Canada

Canadian Diabetes Association

Muscular Dystrophy Canada

Canadian Liver Foundation

Prostate Cancer Canada

Crohn's and Colitis Canada

The Arthritis Society

Cystic Fibrosis Canada

The Asthma Society

Health Charities Coalition of Canada

The Foundation Fighting Blindness – Canada

Heart and Stroke Foundation

The Kidney Foundation of Canada

JDRF Canada

The Rick Hansen Institute

Other Stakeholders

In addition to the above, more than 100 other stakeholders -- representing researchers, medical professionals, industry leaders and finance experts took part in the national dialogue to create the Canadian Stem Cell Strategy & Action Plan.

Canadian Stem Cell Foundation Board of Directors

Alan Bernstein, OC, PhD, FRSC (Chair)
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