

Delivering Canadian Stem Cell Research Excellence in the Twenty-First Century

Submission to the House of Commons Standing Committee on Finance

August 6 2014



About the Stem Cell Network

<u>The Stem Cell Network (SCN)</u> is a not-for-profit organization created by the Government of Canada in 2001, and funded with a mission to act as a catalyst for enabling the translation of stem cell research into clinical applications, commercial products and public policy.

In 13 years, SCN has completely transformed stem cell research in Canada and established an outstanding international reputation. SCN has engaged in innovative research to push the boundaries of basic research towards real and commercialized new therapies.

SCN's research investments have catalyzed 12 clinical trials, enabled 11 start-up companies, trained over 1,800 highly qualified personnel, incubated several international and Canadian research networks and organizations, and established the Till & McCulloch Meetings, Canada's premier stem cell research event.

Through strategic investments and a focus on collaboration, SCN has expanded Canada's capacity to conduct stem cell research while engaging over 120 biologists, clinicians, bioengineers, lawyers, ethicists and social scientists from 27 Canadian universities and hospitals, and international collaborators from 39 institutions in eight countries. These stakeholders have worked closely together within the Stem Cell Network to bring rigour and innovation to Canadian stem cell research and to improve the welfare of Canadians.

SCN is a member of the <u>Network of Centres of Excellence</u>, Canada's flagship science and technology program.

Executive Summary

The Stem Cell Network (SCN) was founded with the assistance of the Government of Canada, and will cease to be funded in 2015. Its mandate is to catalyze innovative stem cell research and development in Canada. Its work has been successful and has catalyzed ground breaking research, made-in-Canada biotech start-up companies, and has trained many hundreds of highly-trained, high-value personnel. The original policy decision and investment, which foresaw both the development of a highly-skilled economic sector and a high-value health care contribution, was well-placed.

We are at a tipping point in Canada. Either we invest to consolidate and build upon our international leadership in stem cell research and regenerative medicine, or we pass on the opportunity and allow others to take the lead. We propose that Canada undertake a transformative next step to deliver on the promise of stem cell research, and to maintain Canadian scientific leadership – along with the high-value jobs and biotech industries that go along with it – in this field that Canada pioneered.

To move forward and fully realize the economic, health care, and science & technology benefits of the momentum that has been built, we are requesting a two-year pilot project that would transform the Stem Cell Network into a body that could also fund clinical trials on humans – a critical next step in realizing a new generation of life-saving and quality-of-life-enhancing therapies for people suffering from a range of chronic illnesses.

Over the past year SCN has consulted with over 50 representatives from Health Charities, Industry, Academia, and Finance, as well as International experts in the field. This has led to their endorsement of a ten-year action plan, of which we are asking the Government to fund, on a trial basis, the first 2 years. All sectors have given their support and indicated they would be willing partners, indeed, since 2010, over \$40M was invested by our partners in research, led by the Stem Cell Network. This investment is poised to continue to grow, given the appropriate framework.

The Stem Cell Network is proposing a two-year federal government investment, along with a two-year mandate extension of the Stem Cell Network, as a proof of concept for a longer-term Stem Cell Action Plan that would include accelerated clinical trials, and a focus on the most productive kinds of clinical trials, while fostering a robust biotech industry in Canada, creating high-value jobs, and contributing to faster development of new therapies for Canadians. The Stem Cell Network has a track record of leveraging dollars; over the past 5 years it has leveraged over \$40M. Going forward, we would operate on a guaranteed minimum matching requirement of 1:1, ensuring that federal dollars are leveraging non-federal investments to generate a robust research ecosystem.

The request of the Government of Canada is for an allocation of \$10 million a year over two years on a trial basis, after which time the Government of Canada would assess whether to continue the Stem Cell Network project. If deemed successful, in accordance with mutually-agreed outcomes and objectives, the Stem Cell Action Plan would continue as a longer term scale-up that positions Canada to:

- Grow the Canadian biotech industry
- Provide patients across Canada with the latest therapies
- Create and catalyze hundreds of high-value jobs in Canada
- Support a robust health sciences ecosystem for the establishment of small and medium-sized businesses in a field of medical science that will be increasing in importance in the decades to come.

Background

Stem cells are unique due to their capacity to develop into any cell, and repair any damaged and diseased tissue or organ in the human body. These cells, and the broader regenerative medicine field, hold enormous potential for societal benefit from both health and economic perspectives. Stem cell therapies are already being used to treat leukemia, multiple myeloma and other blood cancers. They hold a tremendous potential to do even more, including treating people suffering from respiratory diseases, heart disease, other cancers, ocular disease, diabetes, spinal cord injury, MS, Crohn's disease, auto-immune disorders, Parkinson's and to reverse tumor growth. The potential is enormous, given the right conditions and resources to invest adequately in stem cell research, and in the commercialization and availability of stem cell based therapies.

Stem cells were discovered in Canada. The earliest stem cell research was pioneered in this country, but other countries have since established robust stem cell research systems. Our competitors recognize the benefits to the economy and the health of the population in countries that lead in this field. The rivals for leadership in stem cell research and manufacturing include California, Japan and the United Kingdom – all of whom employ a combination of innovative policies and practices.

Canada has an opportunity to affirm its position of leadership in this field, which will be the most exciting frontier of science, applied science, bioeconomy, and applied new therapies over the next century.

Since its foundation in 2001, the Stem Cell Network has engaged in innovative multidisciplinary and multi-sectoral research programs. We now have the potential to undertake transformative clinical trials to treat devastating illnesses. For example, to grow blood stem cells in bioreactors for transplantation into leukemia patients, to target cancer stem cells in childhood brain cancer, to stimulate brain repair for children with brain injuries, to stimulate recovery after heart attack, to treat diabetes, to repair damaged eyes, and more. All of these trials are in our pipeline and ready to proceed.

Through strategic investments and a focus on collaboration, SCN and its partners have expanded Canada's capacity to conduct stem cell research, while engaging over 120 biologists, clinicians, bioengineers, lawyers, ethicists and social scientists from 27 Canadian universities and hospitals and international collaborators from 39 institutions in eight countries. These stakeholders have worked closely together within the Stem Cell Network to bring rigour and innovation to Canadian stem cell research and to improve the health of Canadians.

Stem Cell Network's Proposal

The Stem Cell Network is calling upon the Government of Canada to implement a Stem Cell Research Action Plan – an integrated set of conditions for Canada to reclaim this country's position of leadership in this field of growing importance in health research:

- ✓ Extend the Stem Cell Network's mandate for an additional two years, beyond 2015, with expanded flexibility to fund human clinical trials to test truly revolutionizing next generation therapies.
- ✓ Allocate a federal contribution of \$10 million a year for two years to continue to fund the translational research it has been funding, while adding human clinical trials.
- ✓ Require a guaranteed minimum matching requirement of 1:1, ensuring that federal dollars are leveraging non-federal investments to generate a robust research ecosystem.
- ✓ Work with Health Canada to streamline the regulatory environment to facilitate successful establishment of biotech start-ups, so that the business side of the equation stays in Canada, and does not flee to more SME-friendly jurisdictions.
- Assess the pilot project after two years, against jointly-defined and predetermined performance measures, including the number and type of clinical trials, the success rate in commercialization of research, and an assessment of the overall contribution to future health outcomes.

Conclusion

A properly designed, integrated set of policies would do the following:

- Affirm Canada's global leadership in this cutting-edge and increasingly important field of health research;
- Translate and commercialize Discovery Research into clinical therapies;
- Improve health outcomes for patients in Canada, giving Canadians first access to ground-breaking therapies for a multiplicity of chronic illnesses;
- Support jobs and economic prosperity for Canadians by creating an environment that fosters highskilled research jobs and biotech SMEs.

The Stem Cell Network's proposal requests a modest federal investment, in recognition of the need to balance the budget and sustain a responsible fiscal framework.

This proposal would sustain an environment that has already spawned eleven biotech startups, hundreds of high-value research jobs, and the creation of a world-class annual conference that generates economic activity in addition to the research excellence it catalyzes.

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We would welcome an opportunity to appear before the Standing Committee during in-person deliberations.

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