Stem Cell Network
Réseau de cellules souches

Catalyzing Tomorrow's Breakthroughs

The House of Commons Standing Committee on Finance

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Executive Summary

The Stem Cell Network (SCN) was created by the Government of Canada in 2001, and is a member of the Networks of Centers of Excellence.

As a national not-for-profit organization, the SCN's mission is to act as a catalyst for enabling the translation of stem cell research into clinical applications, commercial products, and public policy. The SCN engages in innovative and goal-directed research to push the boundaries of basic research towards real and commercialized new therapies. Canada is truly an international leader in stem cell research, third in the list of global stem cell scientific output.

> *For over 14 years, the SCN has invested in excess of $85 million of taxpayer dollars and leveraged over $80 million from stakeholders and partners. The Network has invested in over 120 researchers and trained more than 2,500 students from 30 Canadian institutions. We have enabled partnering with 39 international institutes in eight countries, and facilitated exchanges, workshops, and collaborations with China, Japan, the United Kingdom, Australia, and India. SCN successes include catalyzing 12 clinical trials from translational research, forming the International Consortium of Stem Cell Networks (2004), helping create the Canadian Center for Commercialization of Regenerative Medicine, and providing funding for the development of Toronto's Medicine by Design team. The SCN was a catalyst for the creation of the knowledge mobilization network CellCAN, and provided seed funding for the Canadian Stem Cell Foundation.*

However, the previous government did not extend funding for the next generation of stem cell research, leaving researchers with no dedicated funding. Consequently, researchers are now struggling to find grants on an individual basis, and many laboratories are considering staff cuts or have begun to downsize. The SCN itself will have to shut its doors entirely in 12 months unless the federal government renews its commitment to this field of scientific research.

In Canada, incurable diseases consume 67 percent of all direct health care costs and their burden on the health care system continues to outpace the country's economic growth. Of the $190 billion annual costs related to chronic diseases, approximately $68 billion is directly attributed to treatment expenditures. Stem cell therapies promise to more effectively treat many of those chronic illnesses.

Globally in 2011, despite the relatively early stage of maturity of the industry, the market for stem cell and regenerative medicine therapies was estimated at $3.8 billion (USD). The market is expected to grow to surpass $20 billion by 2025.

From Vancouver to Edmonton in the West, Winnipeg and Regina in the Prairies, Ottawa, Toronto, Montreal, and Halifax in Eastern Canada, SCN has an impact across Canada. Should the government choose to invest in this life changing research SCN would work with the government to select the most suitable funding profile, which may include level funding over the five (5) years or a front-end loaded profile.

If funded, the SCN would be able to deliver multiple announcements across the country to show the Canadian public where and when this money was being invested.

Forty years ago, Canadian researchers were the first to prove the existence of stem cells and their seminal studies launched the international field of stem cell research. Now, other countries recognize that becoming leaders in this field produces benefits to the economy and the health of populations. Canada's rivals for leadership in stem cell research and manufacturing include the United States, Japan and the United Kingdom – all of whom employ a combination of innovative policies and practices.

The Stem Cell Network is asking the Government of Canada to invest $10 million per year for five (5) years to enable continued progress in stem cell research in Canada. SCN is requesting that its mandate be renewed for five (5) years beyond 2016, and updated specifically to drive regenerative medicine research from the lab to the translational phase and into human clinical trials.

For this investment the Stem Cell Network would:

1. Fund large-scale multi-disciplinary translational research ($22.5M)
2. Invest in Stage 1 clinical trials of regenerative medicine based therapies to get the treatments to patients earlier ($15M)
3. Invest in the next generation of scientists by offering ongoing workshops and co-op placements as well as international exchanges to the next generation of Canadian scientists ($5M)

The Stem Cell Network

The primary service of the SCN is to offer an independent peer review process for selecting the best stem cell research in Canada, to fund that research, and to track and report on its outcome.

Stem cells are unique due to their capacity to develop into any cell, and repair any damaged or 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 research can help:

- Increase understanding of how diseases occur;
- Generate healthy cells to replace diseased cells (regenerative medicine); and
- Test new drugs for safety and effectiveness.

Stem cell therapies are already used to treat leukemia, multiple myeloma, and other blood cancers. Bone marrow transplants are a routine procedure with 45,000 people globally receiving such treatments every year. Drugs such as erythropoietin, that target stem cell differentiation, are also widely used in clinics.

Our Strengths:
SCN's strengths rest in its reputation as a well-established and respected organization. A large network of world-class scientists is essential to SCN's success on the international stage.

With the ability to make major breakthroughs in health research – impacting the lives of thousands of Canadians – SCN is part of making Canada a world leader in the area of stem cell research.

But:
The current lack of funding for stem cell research creates the real possibility the best and brightest scientists in Canada may leave for other countries.

Without question, the increasing rate of discovery in stem cell research will result in many new treatments reaching medical clinics over the next decade. Cardiac damage, multiple sclerosis, type 1 diabetes, Parkinson's disease, spinal cord injuries, macular degeneration, and cancer are only a few examples of the diseases studied by SCN scientists with the goal of developing new therapies. 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.

Recent federal investment in regenerative medicine has seen a boost to the University of Toronto's Medicine by Design program. However, SCN funds a broader range of research and provides financial support to projects heading to or in clinical trials.

SCN trains knowledge workers and captures the benefits through commercialization and other knowledge translation activities. The SCN funds peer-reviewed research through hubs in Vancouver, Calgary, Edmonton, Regina, Saskatoon, Winnipeg, Ottawa, Toronto, Hamilton, London, Quebec City, Montreal, and Halifax.

The Stem Cell Network, with its hub system, has the ability to harness the opportunities found across Canada, focusing research and clinical trials to achieve maximum benefits. The SCN targets Canadian researchers, and junior researchers, involved in cutting-edge translational work at over 30 institutions across the country. With over 120 principal researchers at these institutions, SCN has a long reach.

See Appendix I for a list of participating institutions.

Canada's Economic Opportunity

With world-class research hubs located in Toronto, Ottawa, Montreal, Edmonton, Calgary, and Vancouver, SCN seamlessly links colleagues across the country. This provides a pan-Canadian approach to advancing new therapies for treating diseases. The potential for stem cell therapeutics and regenerative medicine to mitigate or cure disease represents an enormous economic opportunity – estimates value the total global market at $3.8 billion.

New therapeutic approaches such as stem cell therapies play a significant role in improving patient outcomes and assisting the long-term financial stability of the healthcare system. Stem cell research has the potential to alleviate or even cure many of today's most devastating diseases, such as diabetes, heart disease, cancer, liver and lung disease and many more. Canada has a unique opportunity to affirm its position of leadership in a field that represents one of the most exciting frontiers of science, applied science, bio-economy, and applied new therapies over the next century.

Benefits of investing in the Stem Cell Network:

Two clinical trials were launched last year: Dr. Duncan Stewart at the Ottawa Hospital Research Institute (OHRI) is using gene-enhanced stem cells to restore heart function and, at Toronto's SickKids Hospital, Dr. Freda Miller is testing the capacity of the drug metformin to instigate brain repair in children recovering from brain cancer.

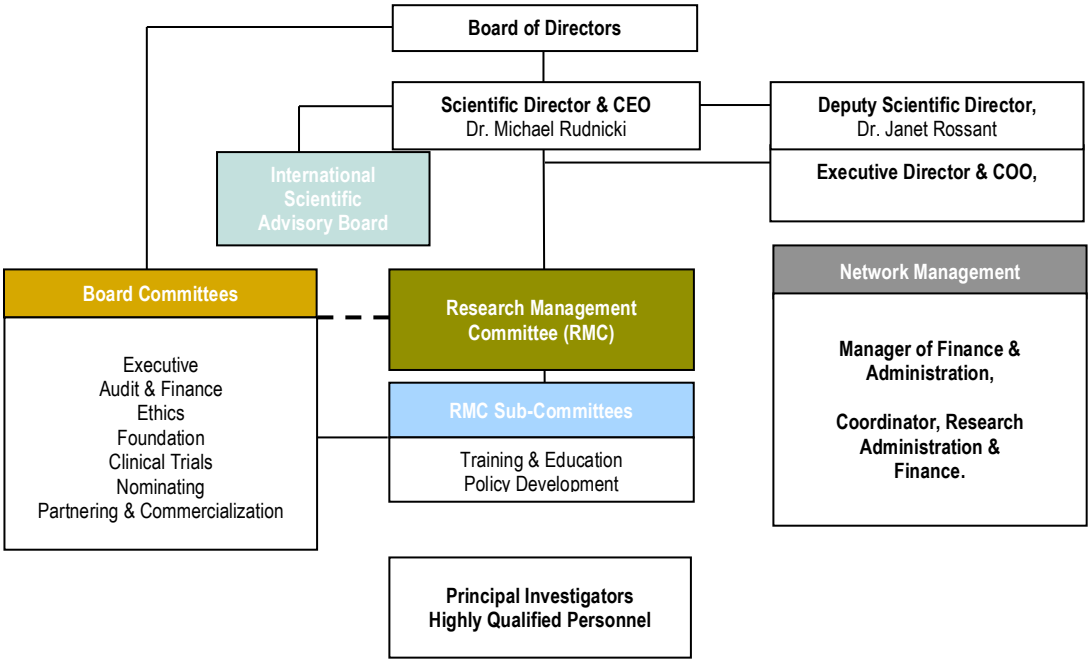
A reinvestment in SCN would underscore the value of the science and the synergies achieved through its investment model. This would undeniably result in greater achievements at a faster rate than traditional funding mechanisms. SCN is not a granting agency; it is an investment fund, monitoring each investment for outcomes, achievement of milestones, and works as an effective steward of public funds as demonstrated over a 14-year track record.

The development of new drugs that act on stem cells will also become an important component of the regenerative medicine market. As an example, one Canadian company, STEMCELL Technologies, based in Vancouver, BC, delivers over 1,500 products to more than 70 countries worldwide.

Operations and Management Structure

The Stem Cell Network is a non-profit organization and incorporated under the Not-for-Profit Corporations Act. It has an independent Board of Directors and a Research Management Committee to make peer review decisions.

The SCN Board of Directors boasts a diversity of experience in managing and overseeing many companies ranging from research labs, private companies, non-profit organizations and associations.



The Executive Director is in charge of the day-to-day management with specialized support from 5-10 qualified individuals in the areas of: finance, communications, office management, and scientific policy. The Executive Director reports to the Board of Directors through the CEO who is also the Scientific Director.

Financial Situation

SCN funding has been the only dedicated funding available to Canadian stem cell researchers, specifically targeted at regenerative medicine researchers across the country. If the Government of Canada does not continue this important investment, Canada will lose the momentum it has, and will likely lose some of the brightest minds in the country.

The SCN flows funds in an efficient way to connect research monies to researchers. With only minimal capital assets (i.e., computers and office equipment), SCN is able to monitor research, keeping it on target and on budget. No funds go towards bricks and mortar. The primary service of the SCN is to offer an independent peer review process for selecting the best stem cell research in Canada, to fund that research, and to track and report on it. Of note, any patents generated by the research will belong to the researcher and the institution of their employment. SCN will not take a position on that research.

Work plan: Timelines for these projects would begin immediately upon receipt of funding:

Q1 2016:

- Upon announcement of funding SCN would immediately launch a call for proposals for ($22.5M) Pan-Canadian Collaborative research projects.
- Launch a call for proposals for clinical trials that have Health Canada approval for Phase I ($15M).
- Launch a call for abstracts from junior researchers to attend the 2016 Till and McCullough Stem Cell Conference – Canada's premier Stem Cell Conference ($1M for training).

Immediate Clinical Trials

Below is a list of clinical trials ready for implementation over the next two years. These are all either in the very early stages and looking for funding to treat more patients or are currently looking for investors. Evident from this list are the potential range of medical conditions for which cell therapies are becoming available, and the range of investigators involved from across Canada. Furthermore a search of Clinicaltrials.gov for stem cell based technologies reveals over 5,000 registered clinical trials have been, or are currently being, conducted around the world.

1. Sauvageau Global Project "Novel Strategies to Expand Human Hematopoietic Stem Cells for Clinical Use"
   - This group is currently putting together a clinical trial application for Health Canada, and fundraising for a potential trial.

2. Miller Global Project "Regenerative Networks: Recruiting Adult Stem Cells for Tissue Repair"
   - Health Canada approved the metformin clinical trial for children who underwent radiotherapy for brain cancer.

3. JS Delisle/DC Roy Cell Therapy Accelerator Grant "Regenerating anti-viral immunity after hematopoietic stem cell transplantation through adoptive T-cell transfer"
   - The group has met with Health Canada to discuss a pre-clinical trial application.

4. Stewart Cell Therapy Accelerator Grant "Developing an optimized mesenchymal stem cell product for cellular immunotherapy for septic shock trial (CISS)"
   - This group is in the process of submitting a full clinical trial application to Health Canada.

5. Dr. Tim Keiffer in partnership with ViaCyte is using a proprietary pancreatic endoderm cell product and an encaptra drug delivery system which has the potential to be a virtual cure for diabetes

Appendices

Appendix I – List of Participating Institutions

The Hospital for Sick Children
Ottawa Hospital Research Institute
Dalhousie University
Institut de recherches clinque de Montréal
McMaster University
Memorial University of Newfoundland
Sunnybrook and Women's College Health Sciences Centre
University of Alberta
University of British Columbia
University Health Network
University of Lethbridge
University of Ottawa
University of Saskatchewan
University of Calgary
Queen's University
John P. Robarts Research Institute
St. Michael's Hospital
University of Toronto
University of Waterloo
Hopital Masionneuve-Rosemont
McGill University
Montréal Heart Institute
Lady Davis Institute of the Jewish General Hospital
Université Laval
Mount Sinai Hospital, Samuel Lunenfeld Research Institute
University of Manitoba
University of Montréal
University of Regina
University of Western Ontario
York University
University of Ottawa Heart Institute
Research Corporation
Simon Fraser University