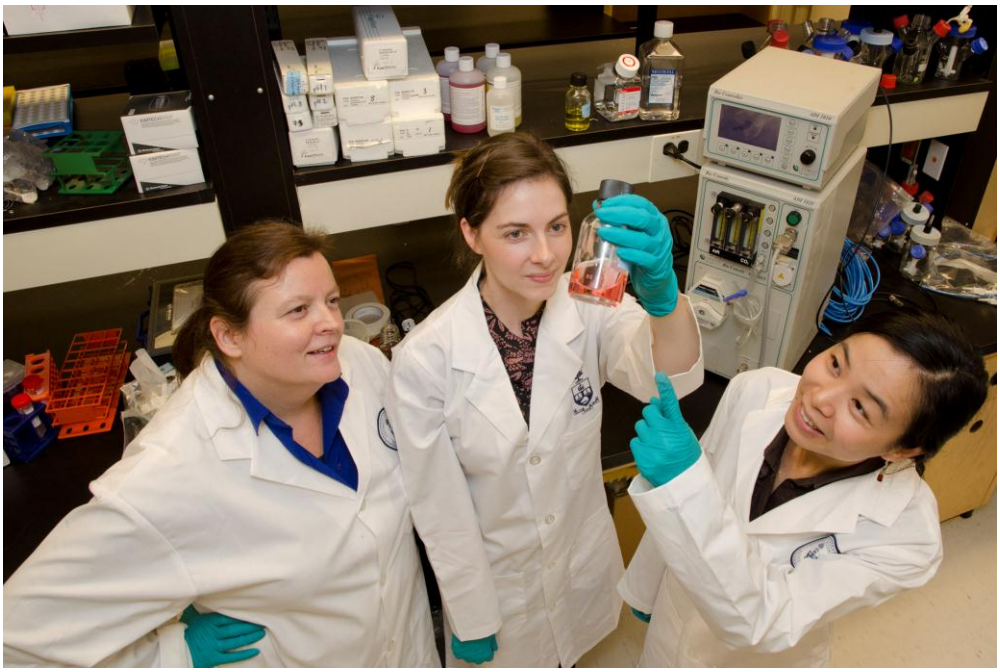
Centre for Commercialization of Regenerative Medicine

CCRM Moves Into New Facilities



The Cell Reprogramming Platform team: Sue Runciman, Development Technologist, and Development Scientists, Emily Titus and Wanyi Xiang.

CCRM has moved into its new development facilities in the historic Banting Institute at 100 College Street. Please join us for our Open House on Thursday, December 8th to meet the CCRM team, take a tour of our facilities and enjoy some refreshments. To request an invitation, please contact marion.sweeney@ccrm.ca.

Disclosures Update

CCRM has evaluated over 20 regenerative medicine disclosures from our partner institutions. Of these technologies, six are undergoing CCRM's due diligence process. This process quantifies market size and pull for the technology, product development needs and validation requirements to attract a strategic partner, alignment of these needs with CCRM capabilities and out-licensing potential. CCRM is expecting to execute it's first in-licensing deal in January 2012 and has several very promising opportunities on the horizon that are well aligned with CCRM's expertise across it's three technology platforms. CCRM will continue into the new year to meet with the TTO offices of our partner institutions, and other universities across Canada, to develop strong working relationships with their teams which will facilitate continued discussion around new technologies as they are disclosed.

Upcoming Events

CCRM is hosting an Open House on Thursday, December 8th from 2:00-4:00 p.m.

CCRM + OSCI are hosting a Holiday Poster Party on Wednesday, December 14th from 4:30-6:30 p.m.

Follow our website's Events page for details.

In this Issue

Contact CCRM

Sandra Donaldson
Manager, Communications
#110-100 College St
Toronto, Ontario, Canada
M5G 1L5
647.926.1228
sandra.donaldson@ccrm.ca

Visit us at www.ccrm.ca or follow us on Twitter.

CCRM Launch Projects

The generation of patient-specific induced pluripotent cells (iPSCs) is an important goal of regenerative medicine and the Cell Reprogramming Platform. The most common source from which to derive human iPSCs has been dermal fibroblasts but the need for both skin biopsies and the expansion of fibroblast cells for several passages in vitro, until recently, has been a major hurdle for broad application of this iPSC technology. Others have shown that peripheral blood can be easily accessed for patient tissue reprogramming and eliminates the need for extensive cell cultures, allows for access to banked blood samples and most importantly, blood sample collection is widely accepted as a minimally invasive procedure by hospitals and is well understood by patients and their families. The initial goal of this platform is to produce iPSCs, and derivatives, from blood cells for drug screening, and eventually, transplantation.

Much excitement surrounds the potential use of pluripotent stem cells (PSC) as a limitless source of cells for therapeutic use and in drug discovery and development. Routine use in such applications requires large quantities of cells that are well characterized and consistent. Unfortunately, current methods produce only relatively small quantities of cells at great cost and are usually poorly controlled and resource intensive. The Cell Manufacturing Platform is undertaking the development of an efficient and robust method for scalable manufacture of PSC, and demonstrating bulk production of human cardiomyocytes. The platform team will apply expertise in cell culture bioprocess development and employ bioreactor technologies to enable production in substrate-free suspension cultures under optimized conditions. This technology will enable routine production of high quality PSC in large quantities, facilitating clinical and commercial development of PSC derived products.

The Biomaterials and Tissue Mimetics Platform will focus on tailored biomaterials substrates for stem cell maintenance and differentiation. Material characterization data will be archived to produce a *biomaterials bank*. The project will bring both novel substrates and detailed material characterization information that will serve as a resource for future product development activities within all CCRM platforms. In the first phase of the project, non-proprietary and commercially available reference substrate materials and critical material characteristics will be identified. Characterization methods will be developed and validated and the biomaterials bank database structure will be established. The second phase will focus on the production and characterization of proprietary biomaterial substrates sourced from member institutions using the test methods established in the first phase.

Viewpoint

Michael May, CEO, CCRM

Thanks to the support of our host institution, the University of Toronto, CCRM has moved into its permanent home in the historic Banting Institute, across the street from MaRS. With a team of 15 full and part-time staff, development labs receiving equipment, fully renovated administrative offices, 3 launch projects ready to start and 6 industry projects in various stages of development, CCRM has achieved a number of key milestones in its first year start-up plan.

While the platform managers have been preparing their teams and facilities for project execution, the business development team has been ramping up interactions with Member Institutions (Technology Transfer Officers and Researchers) and our Industry Consortium (now 20 companies). Although we are still refining core agreements, diligence processes and information sharing, I remain confident that we will commence “deal flow” (new funding, in-licensing, out-licensing and company creation) by the end of our first year. Congratulations to the CCRM team on getting us through the first phase of start-up!

Strategic Advisory Board

CCRM's SAB is composed of world-leading experts in stem cell and biomaterials technologies. CCRM shares its SAB with the Ontario Stem Cell Initiative (OSCI).

The SAB is co-chaired by **Peter Zandstra** and **Janet Rossant**. Janet is the Chief of Research at the Hospital for Sick Children Research Institute in Toronto, Director of OSCI and Vice President of the International Society for Stem Cell Research. Peter Zandstra is the Chief Scientific Officer of CCRM, Professor at the University of Toronto's Institute of Biomaterials and Biomedical Engineering, and holds the Canada Research Chair in Stem Cell Bioengineering.

The members of the Board include **George Daley** who is an Associate Professor of Pediatrics in the Division of Hematology/Oncology at the Children's Hospital and Dana Farber Cancer Institute and Associate Professor of Biological Chemistry and Molecular Pharmacology at Harvard Medical School. **Jeffrey Hubbell** is a Professor at the École Polytechnique Fédérale de Lausanne, Switzerland and also holds the Merck Serono Chair in Drug Delivery. **Douglas Lauffenburger** is a Professor and Head of the Department of Biological Engineering and is also the Ford Professor of Bioengineering at the Massachusetts Institute of Technology. **Chris Mason** is a Professor of Regenerative Medicine Bioprocessing in the Department of Biochemical Engineering at University College London (see side bar). **Shin-Ichi Nishikawa** is the Deputy Director at the RIKEN Center for Developmental Biology, Group Director of the Laboratory for Stem Cell Biology and Vice Program Director, Drug Discovery and Medical Technology Platforms in Japan. **Kathrin Plath** is an Associate Professor, Biological Chemistry at the David Geffen School of Medicine at University of California Los Angeles. **Michael Sefton** is a Professor at the Institute of Biomaterials and Biomedical Engineering and the Michael E. Charles Professor of Chemical Engineering at the University of Toronto. **Fiona Watt** is the Deputy Director of the Wellcome Trust Centre for Stem Cell Research, Herchel Smith Professor of Molecular Genetics and Deputy Director of Cancer Research UK at the Cambridge Research Institute. **Shinya Yamanaka** is a Honourary Member of the SAB and is a Professor at the Institute for Integrated Cell-Material Sciences and Director of the Center for iPS cell Research and Application (CiRA) at Kyoto University in Japan.

Getting to Know

Chris Mason
Strategic Advisory Board, CCRM

Chris Mason holds a Clinical Sciences degree from Imperial College London, a Medical degree from King's College London and a PhD in tissue-engineering bioprocessing from University College London (UCL).

Chris is a Professor of Regenerative Medicine Bioprocessing in the Department of Biochemical Engineering at University College London (UCL). Chris also holds a Personal Chair in Regenerative Medicine Bioprocessing, leads the Regenerative Medicine Bioprocess Group in the UCL Advanced Centre for Biochemical Engineering and is on the Steering Committee for the UCL Centre for Stem Cells & Regenerative Medicine.

With a background in basic science, clinical medicine, bioprocessing and business, Chris is internationally recognized to be at the forefront of the emerging field of cell therapy and regenerative medicine translation and commercialization. He is a member of the ISSCR Industry Committee and the Alliance for Regenerative Medicine Communication & Education Committee.

The CCRM Team

CCRM has rounded out its start-up team with a few recent hires. On the science side of things, the Cell Reprogramming Platform, managed by **Kamal Garcha**, has two new Development Scientists, **Emily Titus** and **Wanyi Xiang**, and a Development Technologist, **Sue Runciman**. In the Cell Manufacturing Platform, **Nick Timmins** was recently recruited from Australia to manage this platform and **Céline Bauwens** is on board as a Development Scientist. The Biomaterials and Tissue Mimetics Platform, managed by **Gary Skarja**, now has **Joanna Fromstein** and **Roshan Yoganathan** as Development Scientists. **Sowmya Viswanathan** is CCRM's Regulatory and Clinical Translation Manger.

On the business and administration side, **Allison Brown** joins CCRM as Manger of Commercialization working alongside **Rahul Sarugaser**, Manger of Business Development. **Sandra Donaldson** is Manager of Communications and Program Manager for the **Ontario Stem Cell Initiative**. **Mary Babyn-Baena**, Office Manager, and **Marion Sweeney**, Administrative Assistant, round out the administrative side of our team. **Joanne Thomsen** is Director of Human Resources at MaRS Innovation and provides CCRM with expertise in this area.

Michael May leads the executive team as Chief Executive Officer, **Peter Zandstra** is the Chief Scientific Officer and **Alan Stratton** is the Chief Financial Officer.

CCRM Activity

Nick Timmins, Cell Manufacturing Platform Manager at CCRM, and CEO Michael May, a keynote speaker, will be attending the Stem Cell Biomanufacturing Conference hosted at the Georgia Institute of Technology in Atlanta on December 14-16/11.

Nick Timmins and Peter Zandstra (CSO) will be attending an Engineering Conferences International (ECI) conference, Scale-Up and Manufacturing of Cell-Based Therapies in San Diego on January 11-13/12.

Michael May will also be in California in January as he is a member of the Institute of Medicine panel reviewing the California Institute of Regenerative Medicine (CIRM). The primary objective of the review is to ensure that all of the CIRM's operations are functioning at peak performance. Michael's insight will be key to evaluating the commercialization aspects of the institute.❖

www.ccrm.ca

Meet the CCRM Team

Allison Brown
Manager, Commercialization

Allison completed her BASc followed by a PhD in Chemical Engineering and Applied Chemistry at the University of Toronto at the Institute of Biomaterials and Biomedical Engineering.

Allison is the Manager of Commercialization for the Centre for Commercialization of Regenerative Medicine. Most recently, Allison was the Senior Market Research Manager at Nycomed Canada Inc. where she worked on the brand team responsible for the Canadian product launch of DAXAS™. In this role, Allison designed and managed the pre- and post-launch market research strategy that included analysis of unmet therapeutic needs/opportunity, market competitors/dynamics, product positioning and measures of commercial success. Prior to this, Allison was a Project Manager for Therapeutic Biomaterials for Regenerative Medicine at the University of Toronto where she was responsible for operational management and scientific co-ordination of a public-private partnership focused on commercialization of novel therapies for chronic inflammatory conditions.