

## Quick Facts on Regenerative Medicine & CCRM

Regenerative medicine and cell therapy harness the power of stem cells, tissue engineering and biomaterials to repair, regenerate or replace diseased cells, tissues and organs. These technologies have the potential to treat, manage and perhaps cure some of the most debilitating and costly diseases in the world today, such as heart disease and diabetes.

### The Industry

- The current global market for regenerative medicine is USD\$36B and forecasted to grow to reach USD\$49.41B by 2021.<sup>1</sup>
- The current global market for cell therapy is USD\$6B<sup>2</sup> and the industry is expected to grow to over USD\$8B by 2018 at an annual growth rate of 21 per cent.<sup>3</sup>
- Approximately 100,000 patients will be treated with CAR-T immunotherapies by 2021.<sup>4</sup>
- There are over 1,900 active cell therapy clinical trials, targeting indications such as cancer, heart disease, diabetes, chronic wounds, neurodegenerative disease, stroke, spinal cord injury, vision impairment and severe burns, amongst others.<sup>5</sup>
- There are 574 active industry-sponsored cell therapy clinical studies, including 50 in Phase 3 development.<sup>5</sup>
- Canada ranks second in cost competitiveness for biomedical R&D compared to other industrialized nations.<sup>6</sup>

### There is increased intensity of regenerative medicine industry activity. So far in 2016 we've seen the following:

- With \$40M in funding from the Government of Canada and GE Healthcare to establish a Centre for Advanced Therapeutic Cell Technologies (CATCT), referred to as BridGE@CCRM, CCRM is building a team, acquiring state-of-the-art equipment and attracting partners for co-development projects to solve technical challenges in cell manufacturing.
- Juno added single cell antibody sequencing capabilities through its acquisition of Harvard spin-out, AbVitro, for USD\$125M upfront.
- The FDA granted Adaptimmune's TCR product targeting NY-ESO a Breakthrough Therapy Designation in Synovial Sarcoma.
- Japanese biopharma Astellas acquired Ocata Therapeutics.
- Vericel announced positive topline results from its Phase 2b study investigating Ixmyelocel-T in patients with heart failure due to dilated ischemic cardiomyopathy.
- Caladrius Biosciences subsidiary PCT entered into a global collaboration and licensing agreement with Hitachi Chemical.
- Cellectis and MabQuest formed an immunotherapy partnership investigating a new class of checkpoint inhibitors in the treatment of cancer.
- NantKwest partnered with the NCI to develop engineered NK cells and antibody combination therapies for oncology.
- Juno Therapeutics and WuXi Apptec announced the formation of a new immunotherapy company in China.
- Editas Medicine and Intellia Therapeutics, both focused on developing CRISPR/Cas9 technologies, went public and raised over USD\$200M.
- Kite Pharma and Cell Design Labs announced a collaboration to develop "on/off" switches for engineered T cell immunotherapies.

<sup>1</sup> Regenerative Medicines Market by Therapy (Cell Therapy, Gene Therapy, Immunotherapy, Tissue Engineering), Product (Cell-based, Acellular), Application (Orthopaedic & Musculoskeletal Spine, Dermatology, Cardiovascular, Central Nervous System), Region - Global Forecast to 2021. marketsandmarkets.com. Website, July 2016

<sup>2</sup> Masoc C, Brindley DA, Culme-Seymour EJ, Davie NL. Cell therapy industry: billion dollar global business with unlimited potential. 2011. Regen Med 6(3), 265-72

<sup>3</sup> Global Cell Therapy Market & Pipeline Insight, Kuick Research, 2014

<sup>4</sup> Kitamura, Makiko. GE Sees Cell Therapy Industry's Sales at \$10 Billion by 2021. Website, 2015

<sup>5</sup> Alliance for Regenerative Medicine, website

<sup>6</sup> KPMG Competitive Alternatives, 2012



## Quick Facts on Commercialization & CCRM

### Commercialization

Commercialization is the process of bringing a new product to market. CCRM specializes in developing and commercializing cell and gene therapies and regenerative medicine technologies.

### CCRM's Commercialization and Scientific Strengths

- CCRM is the commercialization partner for the Ontario Institute for Regenerative Medicine (OIRM), a network of over 175 research programs<sup>1</sup> that was awarded \$25M from the Ontario government.
- CCRM is the commercialization partner of Medicine by Design, a regenerative medicine centre at the University of Toronto that will design and manufacture molecules, cells, tissues and organs that can be used to treat degenerative diseases. It was awarded \$114M from the Government of Canada.
- CCRM was awarded \$2M from the Ministry of Research and Innovation to support bioprocess optimization and clinical translation through a new GMP facility in downtown Toronto. It is building and operating the new GMP facility in partnership with University Health Network.
- In June 2015, CCRM launched its first company, ExCellThera, in partnership with IRICoR.
- CCRM is creating an investment fund that will finance the commercialization of regenerative medicine and cell therapy technologies.
- CCRM has built an industry consortium of more than 45 companies and launched more than 10 co-development projects with industry partners to commercialize regenerative medicine and cell therapy technologies.
- CCRM has assessed over 50 technologies for their commercialization merit.
- CCRM's product and development team has delivered over 90 iPSC lines, completed over 30 projects, and has a pipeline with more than 15 additional projects.
- CCRM is collaborating with translation centres around the world to support the commercialization of IP stemming from regenerative medicine and cell therapy, including the Cell Therapy Catapult (UK), the California Institute for Regenerative Medicine, the Karolinska Institute (Sweden), and Stem Cells Australia.

### CCRM's Network

- The University of Toronto and Mount Sinai Hospital rank second and fourth respectively, in the world in terms of scientific stem cell publications.<sup>2</sup>
- Canada ranks third in the world for percentage concentration of patent activity in regenerative medicine (1991-2011).<sup>3</sup>

For more information on CCRM, please contact [stacey.johnson@ccrm.ca](mailto:stacey.johnson@ccrm.ca) or call 647-309-1830. Visit us at our website at [www.ccrm.ca](http://www.ccrm.ca).

*\* Dollar amounts are CAD unless otherwise stated.*

<sup>1</sup> Ontario Institute for Regenerative Medicine, June 2016

<sup>2</sup> Translational Regenerative Medicine: World Market Prospects 2014-2024

<sup>3</sup> Regenerative Medicine – The Patent Landscape 2011. Intellectual Property Office (UK)