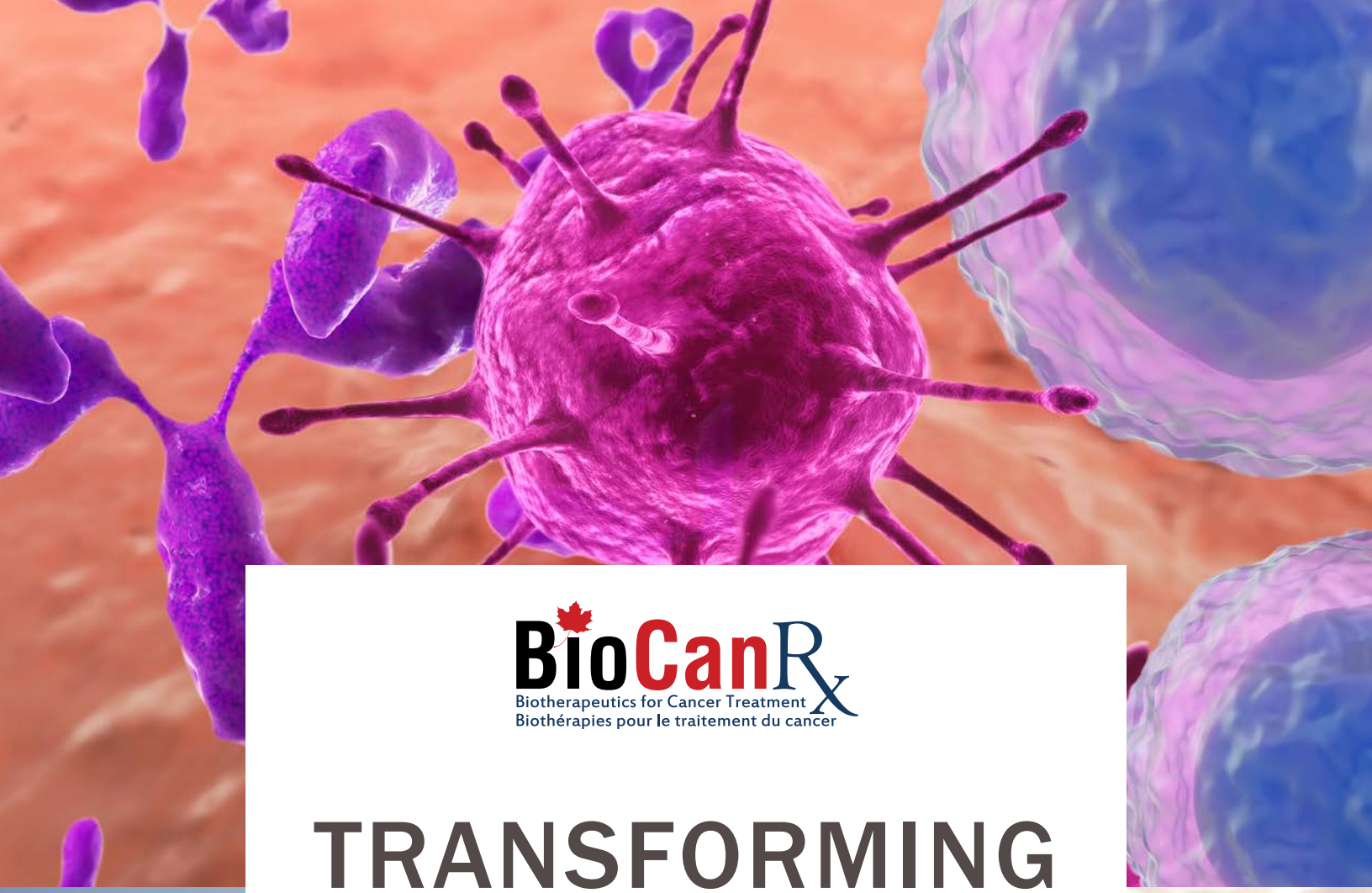
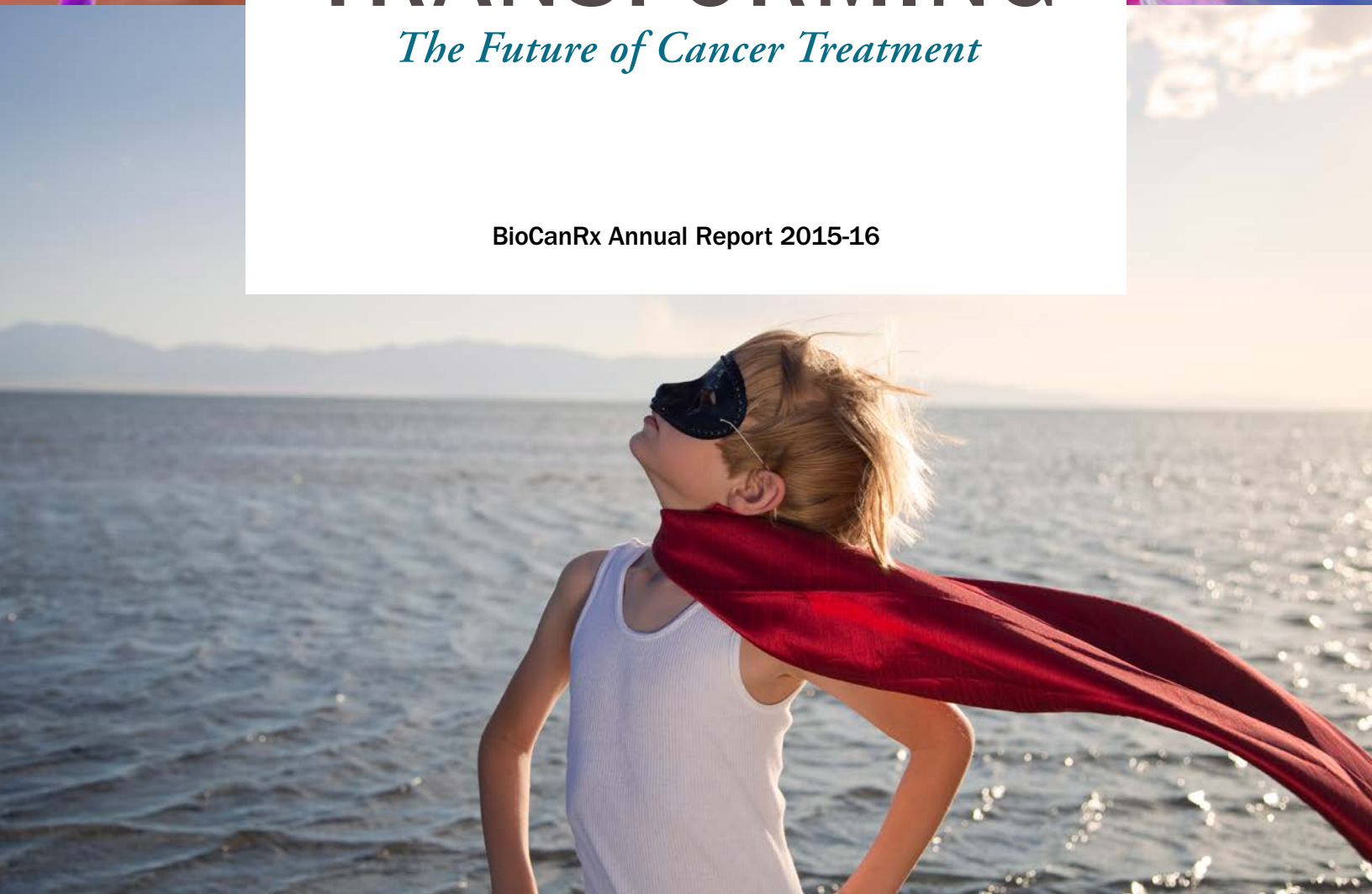


BioCanRx
Biotherapeutics for Cancer Treatment
Biothérapies pour le traitement du cancer

TRANSFORMING

The Future of Cancer Treatment

BioCanRx Annual Report 2015-16



BioCanRx is supported by the Government of Canada through the Networks of Centres of Excellence (NCE) program. This tri-agency program aims to mobilize Canada's best research, development and entrepreneurial expertise on specific issues and strategic areas of need.

NCE RCE

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A Message from the Scientific Director and Chair of the Board of Directors

On behalf of the Board of Directors, we are very pleased to present this report on the achievements of BioCanRx in 2015-2016 – its first full year of operation as a Network of Centres of Excellence.

Cancer patients are desperately seeking new and more effective treatments for their disease. The remarkable advances in biologically-based therapies are among the most promising cancer treatment regimens to emerge over the last ten years. In just over a year, we have watched the rapid development of cancer biotherapeutics – including oncolytic viruses, immune cell therapies and synthetic antibodies. Globally, research has reached a tipping point in the development of these therapeutics and we are now beginning to witness the stories of patients whose lives have been transformed by the power of these emerging therapies.

BioCanRx has an incredible opportunity to advance novel, life-saving Canadian biotherapeutics that could significantly improve the outcomes for cancer patients in Canada. BioCanRx, a leader in Canada's cancer biotherapeutics sector, is taking full advantage of this country's unique expertise to extend progress in this field to Canadians. The network is a thriving community that will accelerate the arrival of these benefits into the clinic. The promise of cancer biotherapeutics and the amazing achievements of the research community involved in the BioCanRx network are simply impressive.

One of the many achievements of this network in 2015-2016 was the establishment of a strong research program. BioCanRx awarded $4.7 million in funding to pan-Canadian projects that are truly innovative and ground-breaking. These funds were leveraged with partner dollars at a ratio of 2.2:1 over the life of the projects, strengthening existing partnered relationships and bringing forward new relationships to the network. While the strength of the research program is rooted in the tremendous work being done in Canada, the high-quality of the projects selected for funding is also a direct result of the expertise and engagement shown in the deliberations of our Research Management Committee (RMC), whose voting members are 80% international.

After year one, BioCanRx has laid a strong foundation for the network's success. Canada is well positioned to play a leading role in establishing immunotherapy and biotherapeutics as the fourth pillar of cancer treatment and providing better therapies for patients. We congratulate all of the BioCanRx network on a successful and productive inaugural year. Please enjoy reading about our accomplishments and connect with us to learn more.

John C. Bell, PhD
BioCanRx Scientific Director

Ken Newport
BioCanRx Chairman

A Message from the President and CEO

I am delighted to present my first annual report as President and CEO of BioCanRx, a role I assumed in March 2016.

A tremendous amount of work has been accomplished by our Board and staff, and by our network during our inaugural year of operations. This would not have been possible without the engagement of the partners and community that make up Canada's cancer enterprise.

The BioCanRx network has established unprecedented national-level, multi-disciplinary collaboration in the cancer biotherapy space, and in so doing, is positioned to deliver cutting-edge outcomes as the funded projects progress. Our research funding model integrates partners through all stages of research and product development. We are developing innovative combination biotherapies, many centred around internationally recognized Canadian-made discoveries, such as the oncolytic virus vaccine platform. Our investigators have engaged regulators at Health Canada in a collaborative and transparent manner, resulting in the appetite of Canadian regulators for these progressive approaches to cancer treatment and paving the way for our network to conduct more innovative clinical testing of promising cancer therapies.

As you will see throughout this report, there are many positives to the first year of BioCanRx, but there have been challenges. The most significant operational challenge was the end-stage cancer and subsequent death of the network's founding President and CEO, Drew Lyall. Drew instilled a vision of what a network could be and the value it could bring to cancer patients. So keen was his desire to see this network succeed, he set up a fund to support BioCanRx. We are confident Drew has seeded a vision for the network which has put it on a path for success. Drew's passing in early 2016 from cancer strengthened the team's resolve and commitment to deliver on BioCanRx's mandate. On a more personal note, Drew was a friend. I am both humbled and honored to have been entrusted with this great responsibility. It is my intention to always reach for the very high bar of excellence set by Drew for all activities that will bear the name of BioCanRx.

I would like to thank all involved in the BioCanRx network for their support and involvement during our start-up year, notably those who have volunteered their leadership and expertise to serve on our Board and committees. We extend our thanks to The Ottawa Hospital Research Institute who has been a generous host. I'm truly impressed by the collaborative nature of this community and it's welcome of BioCanRx into the ecosystem of cancer research in Canada. I look forward to continuing to work together to improve the quality of life for Canadians living with cancer.

Stéphanie Michaud, PhD
President and CEO

About BioCanRx and its Mission

Success requires a strong foundation

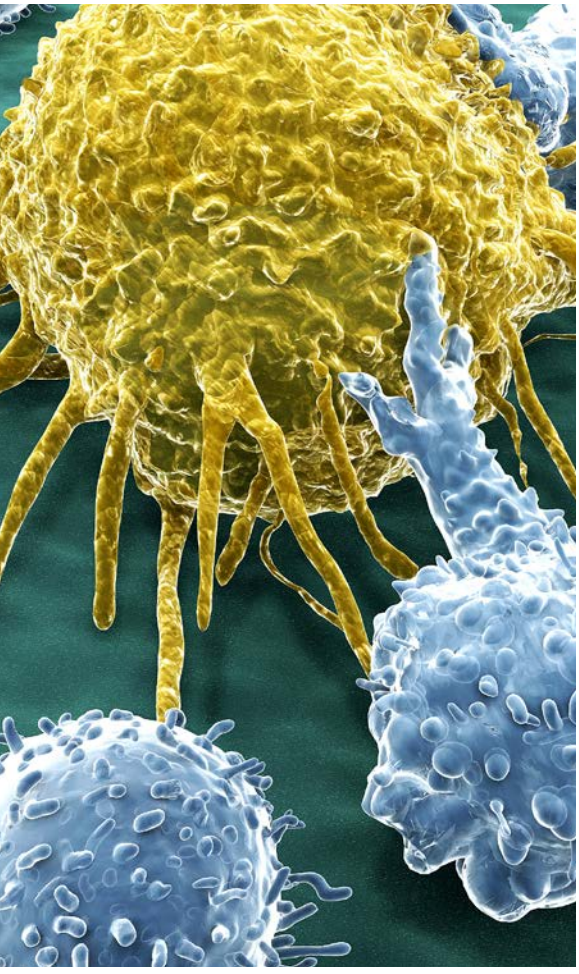
VISION

To cure patients and enhance the quality of life of those living with cancer.

MISSION

To accelerate to the clinic, the most promising cancer biotherapeutics designed to save lives and enable a better quality of life.

Biotherapeutics for Cancer Treatment (BioCanRx) is a not-for-profit network funded by the Government of Canada's Networks of Centres of Excellence (NCE) program, Canada's flagship science and technology granting program. The goal of the NCE program is to mobilize Canada's research talent to create new jobs, stimulate growth and improve the quality of life for Canadians.



The BioCanRx network aims to be a global leader in the translation, manufacture and adoption of innovative cancer biotherapeutics for the benefit of all cancer patients. At BioCanRx, we support research that is difficult to fund in the translational phase of development. To achieve this, BioCanRx works in partnership with academia, industry, government, patients, charities and NGOs to build upon the existing research excellence in Canada so that we may identify, develop and de-risk promising cancer biotherapies. The network will place Canada at the forefront of biotherapeutic cancer treatment by translating research evidence into the clinic through our multidisciplinary research program, multi-sectoral partnerships, and high-impact training program focused on developing the next generation of Canadian scientists and clinicians.

By the end of this fiscal year, the BioCanRx network had enrolled 33 of Canada's best and brightest cancer researchers and clinicians across 14 institutions. The network is headquartered at The Ottawa Hospital, the home institution of BioCanRx's Scientific Director and world-renowned expert in oncolytic viruses, Dr. John Bell. The Administrative Centre (Appendix I) is now fully functional with the arrival of Dr. Stéphanie Michaud as President and CEO in March 2016. The administrative team has also integrated foundational policies and processes to support the functions of the network including conflict of interest, finance and administrative functions. BioCanRx's world-class Board of Directors (Appendix I) includes a robust 12-member group of experts. Directors include a broad and comprehensive range of specific senior executives with knowledge and expertise in the areas of industry, finance, cancer research, health policy and patient groups. In addition to the Board of Directors, BioCanRx has established five subcommittees – the Research Management Committee (RMC), the Executive Committee, the Governance and Nominating Committee, the Finance and Audit Committee and the HQP Development Committee. Their support, along with that of the cancer research community and partner organizations, is ensuring that BioCanRx is an important contributor to Canadian cancer research.

Network Facts (2015-2016)

Location: The Ottawa Hospital, Ottawa, ON

Administrative Centre: 11 staff

Research Projects: 12

Core Facilities: 4

Network Investigators: 16

Network Members (Institutions): 8

Highly Qualified Personnel receiving funding from BioCanRx: 50

Partners: 43

Network Achievements and Impacts

- Established the Research Management Committee (RMC) with world leaders in the field of biotherapeutics and subsequent launch of BioCanRx's research program.
- Completed two research calls and successfully launch a national rolling, open call process.
- Funded 12 high-impact, world-class research projects, totalling $15.5 million in research investment from BioCanRx and partners. These research projects respond to existing gaps, provide strong financial leveraging for public, private and industry investment and will bring trials to over 54 patients across 5 sites in Canada.
- Through our projects, recruited additional expertise and core facilities to the network, broadening the disciplines necessary for advancing the development and innovation of the BioCanRx technologies.
- Established a unique HQP program that welcomes partners at all levels and satisfies the needs of the cancer research ecosystem.
- Enabled privileged access to the BioCanRx core facilities for network investigators.
- Established a collaborative voice for the patient community by bringing together the Cancer Stakeholder Alliance (CSA).

Research Program

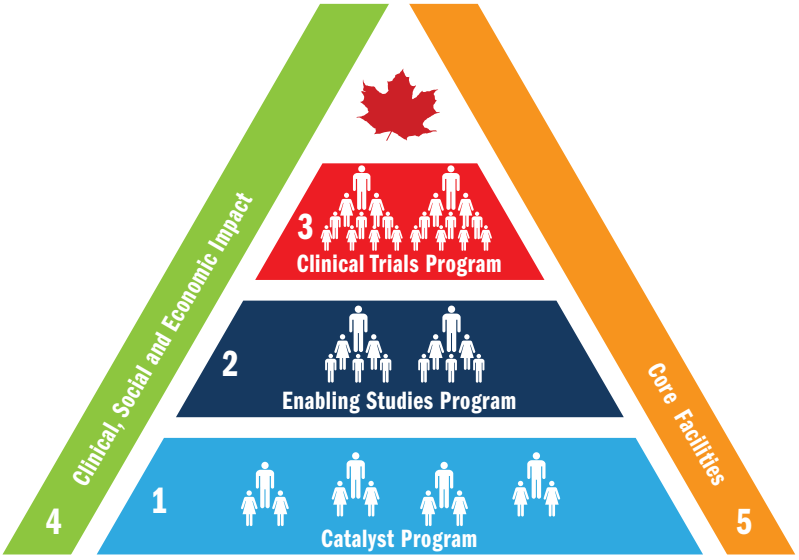
Ground Breaking Cancer Research to Drive a New Era for Cancer Treatment

Two in every five Canadians will develop cancer in their lifetime, with more than half of all new cases estimated to be prostate, breast, lung and colorectal cancers, according to *Canadian Cancer Statistics 2015.* Those diagnosed face months of aggressive treatment – surgery, chemotherapy and radiation. What if there was another option? What if a virus could cure cancer? What if our immune system could be trained to fight and destroy cancer, so it can't spread? What if we could outsmart and outwit cancer for good?

Cancer research in Canada is a well-established field driven by world-class investigators with a long history of success in innovative and ground breaking research. Canada's strength in biotherapeutics has signalled a new era for cancer patients and through the work of BioCanRx real change is inevitable.

In 2015-2016, BioCanRx successfully developed and launched its research funding program, which invests in activities that support the application of mature and validated technologies, and enables the translation of novel and promising technologies into clinical testing – a space traditionally not funded through Canada's regular grant funding mechanisms. The BioCanRx research program takes a pipeline approach to biotherapeutic product development and delivery, meaning that we invest in projects that have a clear path to the clinic and result in innovative clinical trials. In addition, we fund research projects that will improve the path of promising therapies to the clinic by addressing potential barriers in the process of therapeutic development, clinical testing, regulatory approval and system acceptance.

Our Research Investment Program



In keeping with our mission to accelerate Canadian cancer biotherapeutics discoveries from the laboratory into clinical testing, BioCanRx provides research grant funds through five research programs:

1. Catalyst Program

This program provides support for short-term, collaborative projects that are early stage. Project deliverables must result in an application to the next stage in the BioCanRx research pipeline, or generate scientific tools and methods that can be used by other BioCanRx network researchers;

2. Enabling Studies Program

This program provides support for critical resources to bridge the funding gap between the laboratory to clinical testing for innovative cancer biotherapeutics. The outcomes of this program will prepare and position biotherapeutic products and platforms for clinical testing in patients. Data collected in these projects will enable completion of a clinical trial application (CTA);

3. Clinical Trials Program

This program provides support for early phase clinical trials in Canada of novel biotherapeutics products and platforms that have been substantially developed in Canada.

4. Clinical, Social and Economic Impact (CSEI) Program

This program will develop potential solutions to social, legal, ethical, economic or health-systems barriers facing BioCanRx biotherapeutic products and platforms as they progress through the translational pipeline from preclinical research to clinical trials to implementation by health care systems.

5. Core Facilities

To further support the innovation taking place within the network, BioCanRx provides a baseline level of support to core facilities. Our core facilities are shared research resources that provide world-class infrastructure for a number of services required to develop and execute clinical trials. These services include the manufacturing of clinical grade therapeutic viruses and vaccine vectors, and sophisticated methods of monitoring immune-system response to the biotherapeutics being tested. These facilities are available to every project funded by BioCanRx. Additionally, BioCanRx supports cell therapy manufacturing through clinical trial project funding.

Transformational Research Projects

Through to March 31, 2016, BioCanRx funded 12 research projects and four core facilities in two rounds of proposals. Through those calls and through the leadership of our Research Management Committee (RMC), BioCanRx committed $4.7M in research funding across our four funding programs.

BioCanRx also committed $893K in critical funding to four core facilities. In 2015-16, BioCanRx approved support for one additional Core Facilities, one additional CSEI project and one additional Clinical Trial, with funds set to start flowing in April 2016.

In early 2016, BioCanRx launched a rolling, open call process with a letter-of-intent phase and invited existing and new researchers to build our research community and align their collective expertise to further develop cancer biotherapeutics.

Research Program: In Review

2014

December 13, 2014
NCE announces $25.5 million over 5 years in funding for BioCanRx

December 17, 2014
BioCanRx is federally incorporated as a non-profit organization

2015

January 5, 2015
Inaugural meeting of the Board of Directors is held approve the strategy for BioCanRx research program and approve terms of reference for BioCanRx governance committees

March 4, 2015
Launch of inaugural research call for proposals

April 29, 2015
Inaugural meeting of the Research Management Committee (RMC) to review research proposals submitted by founding network investigators

June 9, 2015
Board of Directors approve funding for inaugural research projects, operational plan and budget for FY 2015-16

September 24, 2015
BioCanRx hosts workshop to further develop research program for social sciences

September 29, 2015
Board of Directors meet to approve further funding for research projects and core facilities submitted to BioCanRx's inaugural research call for proposals

October 1, 2015
BioCanRx launches its Clinical, Social and Economic Impact program

2016

January 6, 2016
Board approves the rolling, open call concept inviting the research community at large to submit applications to BioCanRx

March 29, 2016
Inaugural rolling, open call for proposals closes and 20 LOIs are received

$4.7M
In research funding

$893K
In critical funding to four core facilities

BioCanRx has an incredible opportunity to advance novel, life-saving Canadian biotherapeutics that could significantly improve the outcomes for cancer patients in Canada

Core Facilities

Virus Manufacturing Facilities

Ottawa Virus Manufacturing Facility (OVMF)

The Ottawa Hospital, Ottawa
A grade-B compliant GMP facility:

- designed to manufacture oncolytic viruses for human clinical trials
- with infrastructure, management and expertise to manage multi-stage projects, manufacture pathogens, and to develop and validate processes and assays

Robert E. Fitzhenry Vector Laboratory

McMaster University, Hamilton
A GMP facility:

- designed to manufacture viral vectors for human clinical trials, with separate cell laboratory and vector laboratory production suites
- managed through strict quality assurance practices, laboratory surveillance, and research and development

GLP Immune-Monitoring Facilities

Human Immune Testing Suite (HITs)

McMaster University, Hamilton
A self-contained research laboratory that:

- specializes in the immunological analysis of human clinical samples
- measures a patient's immune response as part of treatment
- uses standardized methods and robotic technology to minimize error in analyses for cancer immunotherapy studies
- can isolate lymphocytes from whole tissues

Molecular and Cellular Immunology Core (MCIC)

Deeley Research Centre, BC Cancer Agency, Victoria
A state-of-the art facility that:

- assesses a patient's immune response as part of a clinical trial
- offers assays designed to monitor the patient's immune function throughout the course of treatment
- develops cutting-edge technology, such as their multi-colour immunohistochemistry (mcIHC) imaging platform, which can visualize functional relationships between immune cell populations
- Is Canada's leading centre for analyzing the tumour microenvironment using mcIHC

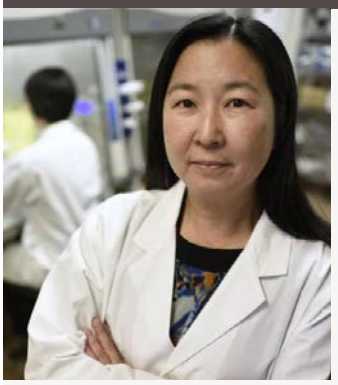
BioCanRx's Inaugural Research Projects

Clinical Trials

Clinical trial to test the oncolytic vaccine approach in combination with checkpoint inhibitor antibodies

Dr. Marcus Butler
Princess Margaret Cancer Centre, University Health Network

This phase 1 combination trial will treat lung cancer patients with advanced tumours that express a protein called MAGE-A3. The MAGE-A3 protein, or antigen, is tumour-specific and has been identified on many solid tumours, which makes it an excellent candidate for targeting numerous cancer types. The project team has engineered the oncolytic vaccine platform to target the MAGE-A3 antigen—a technology that primes the immune system, attacks cancer cells directly and stimulates an immune system response. Onto this, they will layer an antibody therapy in the form of an immune checkpoint inhibitor. These inhibitors remove the brakes on the immune system, which are often engaged by cancer cells and allow the cancer to escape detection as a threat. It is anticipated that this combination approach will deliver a one–two punch—attacking the cancer and training the immune system with its own cancer-killing ability.



Evaluating adoptive cell therapy to treat ovarian cancer using TILs conditioned with dendritic cells

Dr. Pam Ohashi
Princess Margaret Cancer Centre, University Health Network

This cell therapy trial for ovarian cancer brings an innovative, made-in-Canada biotherapeutic approach that uses T-cells, a population of cells from the immune system, to treat this deadly disease. T-cells are white blood cells that have the ability to seek out and destroy tumours. When found within a tumour, these cells are called tumour-infiltrating lymphocytes, or TILs. Known as adoptive cell therapy, this approach to cancer treatment takes a patient's own TILs and re-activates them in the laboratory before giving them back to the patient. This therapy has been tested in patients with metastatic melanoma and shows promise. This is the first trial to test the approach in ovarian cancer, a difficult cancer to treat that has one of the highest mortality rates.

Clinical, Social and Economic Impact Project

Towards rational design of policies and practices to enable clinical translation of novel cancer biotherapeutics in Canada

Dr. Tania Bubela
University of Alberta

Dr. Bubela's project team will provide critical intelligence to BioCanRx to inform the policy direction, regulations and systems innovations required to bring novel biotherapies to cancer patients in the clinic. This multifaceted project will:

- address significant economic, legal and health-system challenges that face the translation of cancer biotherapeutics into the clinic,
- help position BioCanRx-developed biotherapeutics for uptake into the health-care system,
- integrate understanding of regulatory and reimbursement challenges, and
- provide patient information on reputable clinical trials of cancer biotherapeutics in North America.

Catalyst Projects

Development of an oncolytic vaccine for brain cancer

Dr. David Stojdl
CHEO Research Institute / University of Ottawa

Dr. Stojdl and his team are evaluating two viruses that would adapt the Canadian innovation of oncolytic vaccines to a potential treatment for glioblastoma multiforme (GBM). These viruses are engineered to express a protein found in GBM tumours. If successful, the identified virus will move toward a clinical trial for GBM patients, a cancer population that has seen no significant treatment improvements since the 1980s.

Novel anti-tumour antibodies isolated from cancer patient immune b-cell repertoires

Dr. Brad Nelson
University of British Columbia

Dr. Nelson's team has developed a way to cultivate natural antibodies directly from the B cells of cancer patients. B cells are the immune cells that produce antibodies and the repertoire of antibodies they produce varies from person to person. This project will isolate the B cell antibody repertoires derived from patients to identify a panel of the best tumour-targeting antibodies. These antibodies can be further enhanced with Dr. Nelson's proprietary technology for turning them into antibody–drug conjugates (ADCs) by arming them with anti-cancer toxins. By isolating a repertoire of antibodies directly from human cancer patients, this method significantly improves upon the current technique of deriving antibodies through the vaccination of mice.

Development of a bioreactor system to automate T-cell manufacturing

Dr. Jonathan Bramson & Dr. Raja Gosh
McMaster University

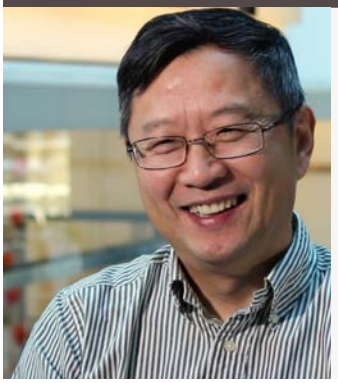
Early results from clinical trials of engineered T-cells (a type of white blood cell) have resulted in powerful anti-tumour responses. Industry's enthusiasm for this approach is high, resulting in major investment across the world. However, the cost of manufacturing clinical-grade, engineered T cells remains a major hurdle to be overcome. Dr. Bramson's team will create an automated, table-top manufacturing solution that can be deployed in any hospital currently performing bone marrow transplants. This technology capitalizes on existing infrastructure and could significantly increase the production capacity of current GMP facilities.

Creating T-cell receptors that react to specific tumour antigens for improved adoptive T-cell therapy

Dr. Naoto Hirano
Princess Margaret Cancer Centre, University Health Network

Adoptive T-cell therapy—a treatment using immune cells from a patient—is an emerging cancer immunotherapy that has shown great promise in recent early phase clinical trials. For any given cancer, only a small proportion of T-cells within the tumour are actually programmed to recognize the cancer as a threat. Dr. Hirano's lab has developed a technology to improve the cancer-killing quality of T-cells by cloning T-cell receptors (TCRs) found to be very sensitive to specific antigens found on a cancer—even more so than the T cells that naturally occur in a tumour. After creating these super cancer-sensitive TCRs, they will be combined with T cells to create a fresh and active population of cancer-fighting T-cells for delivery into a patient—providing more effective anti-tumour response with less toxicity for multiple forms of cancer.

Enabling Studies Projects



Combining oncolytic vaccine therapy with adoptive cell therapy to target cancers expressing MAGE-A3

Dr. Yonghong Wan
McMaster University

This project prepares an exciting combination of technologies that have a clear mechanism for working together to kill cancer cells—adoptive cell therapy and the oncolytic vaccine platform. Dr. Wan and his team will prepare the two platform technologies to work in combination by engineering them both to target the MAGE-A3 antigen. The project will enable a clinical trial application to undertake for a world-first study combining adoptive cell therapy with the internationally recognized Canadian innovation of oncolytic vaccines.

Advanced preclinical development of the oncolytic vaccine platform to prepare requirements for a clinical trial of patients with HPV-associated cancers

Dr. Brian Lichty
McMaster University

Human Papilloma Virus (HPV) causes about 5% of the world's cancer burden and every year it results in more than 250,000 deaths globally. In addition to its association with virtually all cases of cervical cancer, many head and neck cancers are often caused by HPV, which in North America amounts to more cases than cervical cancer. This project proposes using another virus, called Maraba, to attack and kill HPV+ cancer. The very fact that HPV+ cancers are caused by a virus makes them more sensitive to killing by the therapeutic Maraba virus. More importantly, the cancer-killing Maraba virus is also designed to educate the patient's immune system to find and kill cancer cells that it is unable to kill directly. This project will: adapt the Maraba oncolytic virus vaccine approach for an HPV+ antigen, undertake toxicology studies and manufacture the product required to submit a clinical trial application to Health Canada.

Development of immune regulating antibodies for use in companion animal clinical trials

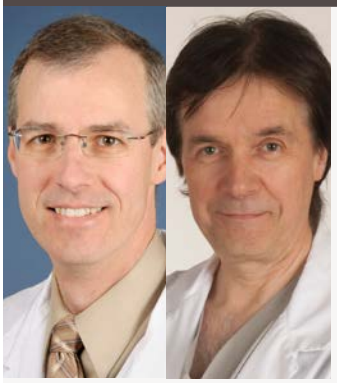
Dr. Jason Moffat
University of Toronto

This project provides an innovative approach to accelerating the development of combination cancer biotherapies by using clinical trials for companion animals—cancer patients themselves that spontaneously develop cancer and could benefit from clinical application of novel experimental therapeutics. Dr. Moffat and his team will develop canine-active synthetic antibodies that bind to key immune-modulatory molecules that are in development for use in human cancer patients. This project will test the ability to rapidly assess combinations of antibodies with other innovative therapies (e.g., oncolytic viruses, T cells) in a clinical setting, thereby speeding up therapeutic development and making it more cost effective.

Development of antibody-based platforms that specifically target cancer cells

Dr. Steven Jones
BC Cancer Agency, University of British Columbia, Simon Fraser University

Antibodies have the ability to bind to specific proteins found on cancer cells. As a result, antibodies can target cancer with incredible accuracy. Antibodies armed with drugs, called antibody-drug conjugates (ADCs), can deliver cancer-killing compounds directly to a cancer cell, requiring less drug and potentially resulting in a more potent effect. Under the guidance of Dr. Jones, the project team will sequence samples from cancer patients to identify six new antibody targets and then create corresponding antibodies that can be armed with a drug (as an ADC), or with a radioisotope that can deliver hyper-targeted radiation therapy or be used to image the activity of the antibodies.



Developing T-cells that target antigens specific to lymphoid cancers

Dr. Denis Claude-Roy & Dr. Claude Perreault
Centre de recherche hôpital Maisonneuve-Rosemont, Université de Montréal

In Canada, approximately half of the 16,000 people annually diagnosed with blood cancers develop resistance to chemotherapy and succumb to their cancer. For these patients, allogeneic hematopoietic cell transplantation (AHCT)—a transplant using stem cells from a healthy person—is the sole potentially curative treatment available. However, AHCT has two major and devastating drawbacks—the risk of graft-versus-host disease (in which the donor cells attack the patient) and its variable anti-cancer effect. Research shows that AHCT is effective when immune cells recognize and target a certain group of cancer antigens called MiHAs, or minor histocompatibility antigens. Studies suggest that using T cells primed against a single MiHA can cure blood cancers without causing graft-versus-host disease. Using a proteomic approach, the project team has identified 39 MiHAs expressed by hematopoietic cells using samples from 1,000 patients with hematologic cancers (e.g., non-Hodgkin's lymphoma and chronic lymphocytic leukemia, but not acute leukemias). In this project they will identify and validate a handful of the best candidates for a clinical trial, and develop a protocol for submission the Health Canada.

HQP Training Program

Retaining and Training the Next Generation

Canada has pockets of expertise in cancer biotherapeutics, but to enable the development and eventual adoption of these emerging technologies across the country requires cultivating a cadre of highly qualified personnel (HQP). Launched in 2015-16, BioCanRx's HQP Training Program aims to provide a multidisciplinary, multisectoral and networked training environment that will also expose HQP to the clinical, social and economic impact of cancer biotherapeutics.

Through the recruitment of a Manager of HQP Training Program and with the establishment of the HQP Development Committee, the network's training program was designed and implemented. This program offers learning opportunities that are specifically created to address network needs, and strengthen the knowledge and expertise within the Canadian cancer biotherapeutics community through workshops, peer-to-peer training, travel awards, partnerships and outreach programs. These programs will benefit highly qualified personnel, which include graduate students, postdoctoral fellows, research associates, technical and clinical research staff, as well as Core Facility staff.

HQP Training Program Highlights

Preclinical Experimental Design and Reporting Workshop
Ottawa, March 4, 2016

The rate of successful translation of preclinical cancer therapies is generally considered low. One reason for this may be the irreproducibility of preclinical experiments. The National Institutes of Health (NIH) have identified two themes underlying the lack of reproducibility and poor translation of preclinical research in general: a lack of training in research design; and deficiencies in the reporting of research. To address these issues, NIH developed new guidelines that are being implemented by funding agencies, universities, publishers and journals.

Because BioCanRx is dedicated to translating the most promising cancer biotherapeutics, it is imperative for our network members to understand the importance and value of transparent, accurate reporting in their preclinical cancer research. The strength, growth and promise of the cancer biotherapeutics field depend on this. To help preclinical researchers implement these new guidelines, BioCanRx co-developed a one-day pilot workshop for network HQP (post-doctoral fellows, senior graduate students) in Ottawa. The aim of the workshop was to introduce researchers to the core reporting items proposed by the NIH: standards of reporting, replicates, statistics, randomization, blinding, sample size estimation, and inclusion/exclusion criteria.

All surveyed participants found the content in the workshop to be relevant to their preclinical research. Additionally, 100% of the surveyed participants agreed that they could immediately put the lessons learned from this workshop into practice.

Clinical Application of Tumour-infiltrating Lymphocyte Therapy Workshop Toronto, March 30, 2016

This workshop highlighted, connected and disseminated Canadian knowledge and expertise in tumour-infiltrating lymphocyte (TIL) research and clinical testing led by Dr. Pamela Ohashi's group at the Princess Margaret Cancer Centre. Importantly, this workshop convened the Terry Fox Research Institute's immunoTherapy NeTwork (iTNT) TIL Working Group, whose members are working to advance Canada's clinical testing of TIL therapy.

This workshop introduced topics and perspectives not immediately on the radar of Canadian TIL therapy researchers. The day first looked at the international landscape of TIL therapy clinical testing and manufacturing (with speakers from NIH, Manchester University and the Amsterdam BioTherapeutics Unit), and the Canadian regulatory issues for TIL manufacturing and clinical trials. It then broadened the discussion on promising cell therapies in Canada by addressing: health technology assessment of novel biologics; provincial payer considerations for novel therapies; medical barriers in Canada for wider clinical testing and adoption of TIL therapy; and the value of registries in adoptive cell therapies clinical testing as evidenced from the field of regenerative medicine.

This forum for knowledge exchange was critical toward creating awareness around the future opportunities and challenges for Canadian researchers and clinicians advancing the development of TIL therapy. Following the meeting, all surveyed participants indicated that they had a better understanding of TIL therapy clinical expertise within Canada and internationally.

Partnerships for Impact:

Recognizing the wider need for educational resources in clinical translation, BioCanRx led the creation of a strategic partnership bringing together eight biomedical research organizations to co-develop and deliver educational programming in this area. These organizations include: Stem Cell Network (SCN), Ontario Institute for Cancer Research (OICR), Ontario Institute for Regenerative Medicine (OIRM), Centre for Commercialization of Regenerative Medicine (CCRM), CellCAN, Foundation Fighting Blindness and the University of Toronto's Medicine by Design.

To inspire the next generation of highly qualified personnel, BioCanRx partnered with Let's Talk Science Ottawa to co-develop a youth outreach program aimed at educating Canadian high-school students on cancer biology and biotherapeutics. Let's Talk Science is a national, charitable organization that promotes STEM (Science, technology, engineering and mathematics) education and youth development.

Additionally, BioCanRx launched its partnership with Mitacs to offer their popular *Accelerate Internships* to the Canadian cancer biotherapeutics community. This national internship program connects companies and other organizations with the research expertise in academia. These opportunities allow HQP from academia to work on exciting research and development projects and add value to the partnered organizations and academic institutes.

> *"As a network HQP, I have attended the full-day TIL workshop, which was educational in updating me on the frontiers of cellular biotherapeutics, and allowed me to network with others in the community. In addition, serving as a member of the HQP Development Committee, I had the opportunity to learn from and contribute to BioCanRx's leadership in delivering exciting training programs. Overall, these experiences have undoubtedly better prepared me for a career in this sector."*
>
> *Tim (Tingxi) Guo, PhD Candidate*

HQP Numbers for 2015-2016:

260
HQP registered within the BioCanRx HQP network

70
Workshop attendees representing 16 Canadian institutions

1,313
High school students educated through BioCanRx – Let's Talk Science youth outreach programs

12
Undergraduate Summer Studentships funded

17
HQP Travel Awards awarded for 3 HQP related events in Canada

Partnerships and Public Engagement

A Collective Approach For Those Who Need it Most – Patients.

As a network, one of BioCanRx's primary objectives since its inception has been to bring together all like-minded organizations and agencies involved in the funding and support for novel biotherapeutics to treat cancer. With the goal of establishing a national research agenda for this field, together with our partners, we are striving toward better outcomes for cancer patients globally.

The BioCanRx Cancer Stakeholder Alliance (CSA)

To successfully translate research benefits to patients, it is important for BioCanRx to work with cancer NGO partners. The BioCanRx Cancer Stakeholder Alliance (CSA) comprises charities and foundations that have supported the overall project of the BioCanRx network and/or are interested in partnering where priorities align. The CSA provides valuable input to BioCanRx regarding the patient perspective; as well, some members support projects in their cancer indications.

In advance of BioCanRx's successful application to the Networks of Centres of Excellence, a precursor group came together in April 2014 to hear about the BioCanRx proposal, resulting in numerous participants' formal support for the BioCanRx application. That meeting sparked the creation of the CSA, with its first official meeting held in June 2015 as BioCanRx was just getting off the ground.

In June 2015, BioCanRx hosted its first CSA event where BioCanRx presented its mandate, structure, funding programs, review process and the research projects funded in its first round of funding. BioCanRx explored possible areas of collaboration, including ways to partner on R&D projects and opportunities for knowledge exchange partnerships with the participants. Three CSA members who had actively highlighted the importance of patient engagement in clinical development planning were invited to attend a subsequent BioCanRx workshop, which shaped the development of the Clinical, Social and Economic Impact research program. The CSA meeting also helped to establish and build relationships with several organizations that have contributed funds to BioCanRx research projects or may do so in the future.

BioCanRx maintains regular communications with these organizations to inform them of research projects that fall within their specific areas of interest and to leverage each other's networks and communication capabilities to announce and promote activities of mutual interest.

"For patients, the promise of biotherapeutics means that a day when the disease can be effectively treated without the threat of debilitating side-effects is getting closer. It is through true collaboration that we can realize these novel therapeutics and make a difference in the lives of patients around the world".

Dr. Stuart Edmonds, Vice-President, Research, Heath Promotion and Survivorship
Prostate Cancer Canada

Demanding research that is industry-ready

BioCanRx is steadfastly committed to fostering industry relationships that will improve outcomes for cancer patients. BioCanRx funding has increased the participation and interest from industry in the development of these biotherapeutics. Our pipeline approach to development provides an attractive leveraging opportunity for industry investment in early stage biotherapeutics. This is bolstered by the strong international review and oversight provided by our Research Management Committee, providing the confidence that BioCanRx is funding the best science with the greatest potential to move into clinical trials and provide benefits to patients.

BioCanRx is making research industry-ready and our activity in 2015-2016 has attracted significant industry investments, both financial and in-kind, in BioCanRx-funded projects, programs and events.

For example, a BioCanRx project led by Dr. Jonathan Bramson at McMaster University is addressing a significant concern regarding cell therapies for cancer—the cost of manufacturing human-grade engineered T cells. The project will develop a Canadian-based technology that would create a desktop GMP laboratory-

in-a-box and greatly increase the number of clinical sites capable of performing T-cell therapy for cancer treatment, while also dramatically reducing the cost of preparing engineered T cells for cancer therapies. The successful development of this technology could move beyond T-cell manufacturing and have significant global impact. This project involves partnerships with the Canadian company called Octane Medical Group and has resulted in a spin-off company, Triumvira Immunologics, which will commercialize T-cell technologies.

As a result of outreach efforts, industry partners were lined up to play significant roles in the 2016 BioCanRx annual scientific conference, whether as a sponsor, lead presenter, panellist or exhibitor. In addition, to strengthen our understanding of industry interests, we have appointed additional industry representatives to our Board of Directors and Research Management Committee.

> *"BioCanRx has been an invaluable partner in helping the founding scientists and academic institutions advance the technology to a point where investors could be brought in. We look forward to continue working with BioCanRx as we begin to test this combination therapy, which could provide new hope to patients with lung cancer, but also prove useful for all forms of cancer".*
>
> *Sammy Farah, CEO, Turnstone Biologics Inc.*

Communications and Public Outreach

BioCanRx has engaged in a number of networking opportunities and developed communication tools in order to promote activities and collaborations within the network. During our first full year in operations we developed and launched our overall visual branding, a bilingual website, social media channels, newsletters from the Scientific Director, a corporate brochure, a partnership brochure and project dashboards. BioCanRx also engaged in media and social media outreach, including media releases, events and awareness campaigns with partners. Plans are underway to develop other tools to present patient friendly information about our clinical trials and to market the unique capabilities of our core facilities.

Council of Academic Hospitals of Ontario's (CAHO's) Healthier, Wealthier and Smarter Initiative (#onHWS)

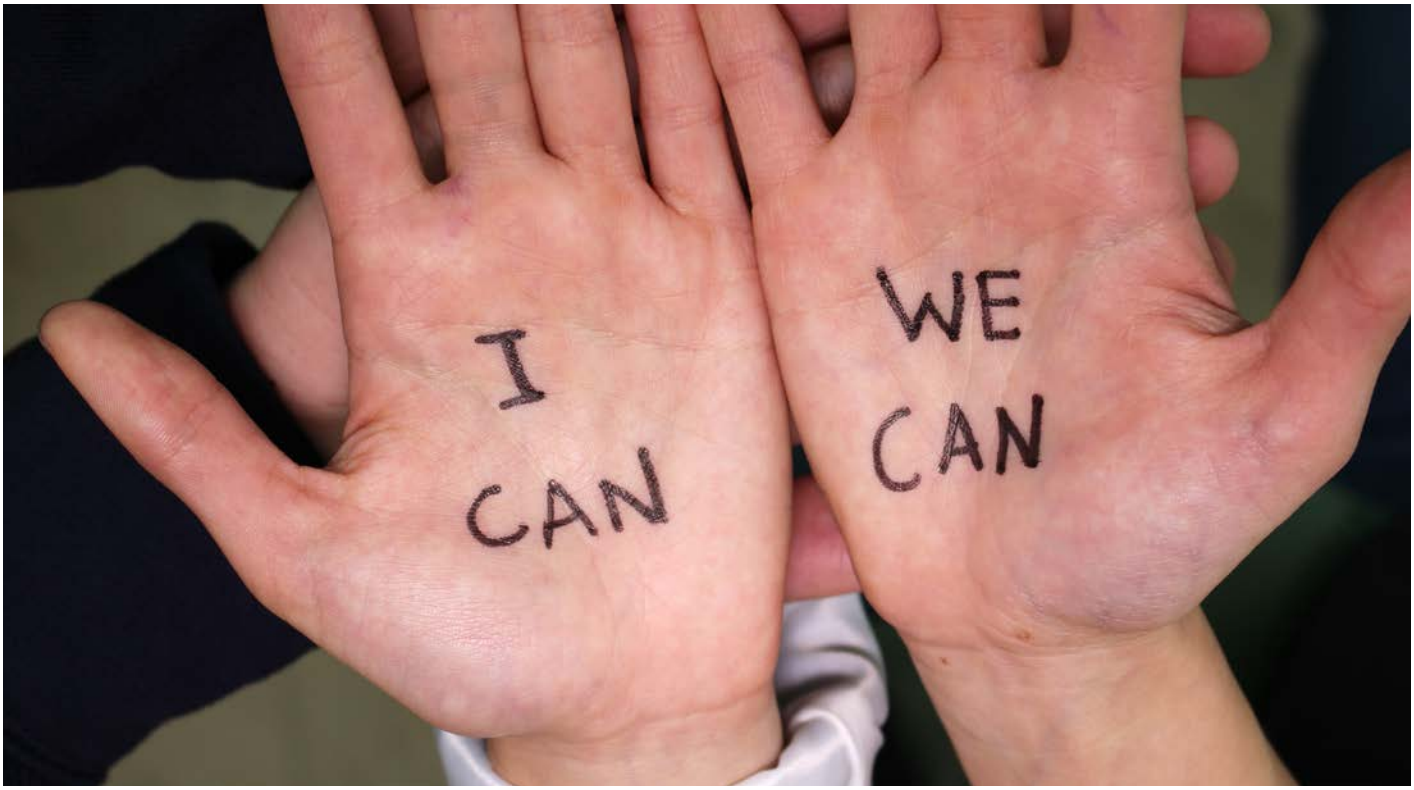
Dr. John Bell and an HQP associated with a BioCanRx Core Facility participated in the Council of Academic Hospitals of Ontario's (CAHO's) Healthier, Wealthier and Smarter initiative (#onHWS), which was dedicated to educating provincial politicians about the health science that is happening in Ontario hospitals. The Ottawa Virus Manufacturing Facility was a prominent part of the event, which took place at Queen's Park in Toronto. Along with the knowledge transfer and exchange that took place, the goal of this event was to demonstrate how science is advancing the knowledge economy and demonstrate the return on investment in science.

Drew Lyall Legacy Fund

Drew Lyall was the founding President and CEO of BioCanRx. He was unwavering in his commitment to advance health research into the clinic and was remarkably good at convincing people of its importance. He demonstrated this in his successful tenure with the Stem Cell Network and was deeply looking forward to doing the same with BioCanRx. He had a profound belief that productive collaborations were the best way to advance excellent science and make gains, ultimately, for patients.

These attributes, along with his experience and vision seeded a strong foundation for BioCanRx. This spirit continues to drive BioCanRx, and his passing in January 2016 has intensified the determination and commitment to make this network a success. In January 2016, the BioCanRx Board of Directors unanimously approved the following motion:

On behalf of the Board of Directors of BioCanRx, we would like to thank Drew Lyall for his dedicated leadership as the BioCanRx CEO and for setting a standard of determined spirit and courage that the organization will try to uphold.



A Message From Drew:

"This is not a message I thought I would ever have cause to write - none of us ever would! As many of you know, just over seven years ago I was diagnosed with melanoma, the deadliest form of skin cancer.

If caught early, the 10-year survival rates are quite high - over 95% - but if even a little too late, the long-term prognosis is grim. Unfortunately, despite the incredible care I received in Ottawa, my melanoma passed a point of no return.

Those of you who knew me well knew how passionately I felt about health research and how much more quickly and effectively I felt clinical trials can be initiated by bringing together experts across all fields to collaborate from the outset of projects. With that in mind, as one of my final acts, I started a fund with a pledge of $10,000 from my estate dedicated to supporting BioCanRx, the cancer research organization I helped to found. My goal, and my belief, is that if this fund can make a critical difference to BioCanRx and the people whose lives they are working to save, both now, and in the coming years.

We concentrate so much at work on tasks and accomplishments, yet really it is the people we interact with along the way that makes the journey itself so worthwhile, and the final outcomes we achieve so much the greater. You were absolutely a key part of my journey, and I wanted to let you know that you made my life all the richer for it.

My own story, although the end is not what I had hoped, still left me with so much faith and belief in what can be done. But my pledge alone will not be enough. Together we can help bring focus to novel and less toxic cancer treatments for hard to treat cancer such as melanoma. It was a cause and a calling dear to my heart. Will you help me?"

- Drew

For more information, visit the Ottawa Regional Cancer Foundation's webpage for the fund: http://ottawacancer.kintera.org/faf/home/default.asp?ievent=1152116.

Financial Statements for Fiscal Year 2015-16

Snapshot of Year 1

LOGAN KATZ LLP SRL | chartered professional accountants | comptables professionnels agréés

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AGN Member/membre

INDEPENDENT AUDITORS' REPORT

To the Members of
BioCanRx: Biotherapeutics for Cancer Treatment:

Report on the Financial Statements
We have audited the accompanying financial statements of BioCanRx: Biotherapeutics for Cancer Treatment (the "Organization"), which comprise the statement of financial position as at March 31, 2016, and the statements of revenue and expenditures, changes in net assets, and cash flows for the period from date of incorporation, December 17, 2014 to March 31, 2016, and a summary of significant accounting policies and other explanatory information.

Management's Responsibility for the Financial Statements
Management is responsible for the preparation and fair presentation of these financial statements in accordance with Canadian accounting standards for not-for-profit organizations ("ASNFPO") and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility
Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with Canadian generally accepted auditing standards. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditors consider internal control relevant to the Organization's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Organization's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion
In our opinion, the financial statements present fairly, in all material respects, the financial position of the Organization as at March 31, 2016, and its results of operations and its cash flows for the period from date of incorporation, December 17, 2014 to March 31, 2016, in accordance with ASNFPO.

Logan Katz LLP

Chartered Professional Accountants
Licensed Public Accountants

Ottawa, Canada
May 26, 2016

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BioCanRx: Biotherapeutics For Cancer Treatment

Statement of Revenue and Expenditures

PERIOD FROM DATE OF INCORPORATION, DECEMBER 17, 2014 TO MARCH 31, 2016	
REVENUE	
Networks of Centres of Excellence grant	$ 3,343,216
Contributed services in-kind	82,500
Recognition of deferred capital contributions	25,500
Event registration fees	2,550
Miscellaneous	3,329
	3,457,095
EXPENDITURES	
Mission Fulfillment:	
Research grants	2,474,651
Research travel	24,176
Training	14,592
Thematic workshop	39,052
Cancer summit	49,754
Communications	200,973
	2,803,198
Governance and Administration:	
Amortization	28,467
Operating	126,052
Professional and consulting fees	59,218
Salaries and benefits	68,905
Subcontractors	246,429
Recruiting	1,136
Travel	118,996
	649,203
	3,452,401
EXCESS OF REVENUE OVER EXPENDITURES	$ 4,694

Appendix I: 2015-16 Board of Directors, Committees and Administrative Centre

2015-2016 BOARD OF DIRECTORS

Ken Newport, Chair

Dr. Lorne Babiuk
Vice-President, Research,
University of Alberta

Dr. John Bell
Scientific Director, BioCanRx
Senior Scientist,
The Ottawa Hospital
Professor, University of Ottawa

Dr. Heather Bryant
Vice-President, Cancer Control,
Canadian Partnership Against Cancer

Dr. Elizabeth Douville
Founder and Managing Partner
AmorChem Venture Fund

Darrell Fox
Board Member and Senior Advisor,
Terry Fox Research Institute

Bruce Galloway
Former Chair,
Ovarian Cancer Canada

Dr. Tom Hudson
President and Scientific Director,
Ontario Institute for Cancer Research (OICR)

Kendra MacDonald
Partner, Deloitte

Dr. Duncan Stewart
President and CEO, Ottawa Hospital Research Institute (OHRI)

Dr. Augusto Villaneuva
Business Unit Head, Oncology,
Merck Canada

Dr. David Young
Life Science Entrepreneur
and Founder/CEO of Actium
Research Inc.

Observers on BioCanRx Board of Directors and respective subcommittees

Dr. Stéphanie Michaud
President and CEO, BioCanRx

Kim Douglas
NCE Liaison,
Networks of Centres of Excellence

EXECUTIVE COMMITTEE

Ken Newport, Chair

Dr. John Bell
Scientific Director, BioCanRx
Senior Scientist,
The Ottawa Hospital
Professor, University of Ottawa

Dr. Elizabeth Douville
Founder and Managing Partner
AmorChem Venture Fund

Dr. Duncan Stewart
President and CEO, Ottawa
Hospital Research Institute

Kendra MacDonald
Partner, Deloitte

AUDIT AND FINANCE COMMITTEE

Kendra MacDonald, Chair
Partner, Deloitte

Robert Hanlon
Chief Operating Officer, Ottawa
Hospital Research Institute

Bruce Galloway
Former Chair, Ovarian Cancer
Canada

Ken Newport
Chair, Board of Directors

GOVERNANCE AND NOMINATING

Ken Newport, Chair

Dr. Lorne Babiuk
Vice-President, Research,
University of Alberta

Dr. John Bell
Scientific Director, BioCanRx
Senior Scientifist,
The Ottawa Hospital
Professor, University of Ottawa

Dr. Heather Bryant
Vice-President, Cancer Control,
Canadian Partnership Against
Cancer

Darrell Fox
Board Member and Senior Advisor,
Terry Fox Research Institute

RESEARCH MANAGEMENT COMMITTEE

Dr. Stephen Russell, Chair
Oncologist and Professor, Mayo
Clinic, Rochester MN (USA)

Dr. Alan Melcher
Professor of Clinical Oncology and
Biotherapy, Leeds University (UK)

Dr. Bruce Seet
Director, Medical Affairs, Sanofi-
Pasteur (Canada)

Dr. Cliona Rooney
Professor, Baylor College of
Medicine (USA)

Dr. Chris Klebanoff
Assistant Clinical Investigator, NCI
Surgery Branch, NIH (USA)

Dr. Grant McFadden
Professor, Department of
Molecular Genetics and
Microbiology, University of Florida
(USA)

Dr. Ira Mellman
Vice-President, Cancer
Immunology, Genentech (USA)

Dr. Len Seymour
Founder and Chief Scientific
Officer, Oxford Genetics (UK)

Dr. Robert Coffin
Entrepreneur, BioVex founder (USA)

Dr. Steven Xanthoudakis
Director, Licensing and External
Research, Merck Research
Laboratories (Canada)

Observer

Dr. John Bell
Scientific Director, BioCanRx
Senior Scientist,
The Ottawa Hospital
Professor, University of Ottawa

HQP DEVELOPMENT COMMITTEE

Dr. Harold Atkins, Chairman
Clinician Scientist,
The Ottawa Hospital

Dr. Raja Ghosh
Professor, McMaster University

Dr. Bruce Seet
Director, Medical Affairs,
Sanofi Pasteur

Dr. Linh Nguyen
Scientific Associate,
University Health Network

Dr. Julia Pomeransky
Research and Operations Manager,
Turnstone Biologics Inc.

Tim Guo
PhD Candidate,
University of Toronto

Dr. Carolina Ilkow
Research Associate,
The Ottawa Hospital

Dr. Kelley Parato
Director, Scientific Affairs,
BioCanRx

Jovian Tsang
Manager, HQP Training Programs,
BioCanRx

ADMINISTRATIVE CENTRE

Dr. Stéphanie Michaud
President and CEO

Dr. John Bell
Scientific Director

Dr. Kelley Parato
Director, Scientific Affairs

Christian Carswell
Director, Business Development

Paddy Moore
Director, External Affairs

Amanda Devost
Manager, Communications and
Corporate Affairs

Jovian Tsang
Manager, HQP Training

Shannon Sethuram
Manager, Finance and
Administration (P/T)

William Read
Manager, Systems Implementation
and Operational Planning (P/T)

Linda Nong
Associate, Business Development
and Digital Marketing

Rebecca Cadwalader
Program Officer, Research and
Training (P/T)

Appendix II: Funded Network Investigators

John Bell
The Ottawa Hospital, University of Ottawa

Jonathan Bramson
McMaster University

Bryam Bridle
University of Guelph

Tania Bubella
University of Alberta

Marcus Butler
Princess Margaret Cancer Centre, University Health Network

Raja Ghosh
McMaster University

Naoto Hirano
Princess Margaret Cancer Centre, University Health Network

Brian Lichty
McMaster University

Andrea McCart
Princess Margaret Cancer Centre, University Health Network

Jason Moffat
University of Toronto

Pamela Ohashi
Princess Margaret Cancer Centre, University Health Network

Christopher Paige
Princess Margaret Cancer Centre, University Health Network

Claude Perreault
Université de Montréal, Hôpital Maisonneuve-Rosemont

Denis-Claude Roy
Université de Montréal, Hôpital Maisonneuve-Rosemont

David Stojdl
Children's Hospital of Eastern Ontario, University of Ottawa

Yonghong Wan
McMaster University

Appendix III: Network Members

Ottawa Hospital Research Institute
Children's Hospital of Eastern Ontario
Hôpital Maisonneuve-Rosemont
McMaster University
Simon Fraser University
University Health Network
University of Guelph
University of Toronto

Appendix IV: Collaborators

NOT-FOR-PROFIT PARTNERS

BC Cancer Foundation
Canadian Cancer Society
Cure: Blood Cancer
Fondation de l'Hôpital Maisonneuve-Rosemont
Hair Donation Ottawa
Krembil Foundation
McMaster Boris Family Fund
Ottawa Regional Cancer Foundation
OVC Pet Trust Fund
Pancreatic Cancer Canada
Prostate Cancer Canada
The Lung Association
The Ottawa Hospital Foundation
The Princess Margaret Cancer Foundation UHN

INDUSTRY PARTNERS

Celgene
Merck
Miltenyi
Takara
Turnstone Biologics
Zymerworks

INSTITUTIONS/ACADEMIC PARTNERS

Ottawa Hospital Research Institute
BC Cancer Agency
CHEO Research Institute
Hôpital Maisonneuve-Rosemont
Jewish General Hospital
Johns Hopkins University
Juravinski Cancer Centre
McMaster University
University of Alberta
University of Guelph
UHN Toronto General Hospital
Université de Montréal
University of Ottawa
University of Toronto

GOVERNMENT PARTNERS

Canadian Institutes of Health Research
Health Canada
Genome British Columbia
Government of Ontario
Michael Smith Foundation for Health Research
Natural Sciences and Engineering Research Council
Networks of Centres of Excellence
Ontario Institute for Cancer Research
Social Sciences and Humanities Research Council

For more information, please contact Amanda Devost,
Manager, Communications and Corporate Affairs
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at adevost@biocanrx.com

BioCanRx
Biotherapeutics for Cancer Treatment
Biothérapies pour le traitement du cancer

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