



SCALING FOR GLOBAL IMPACT



Commercializing
Living Therapies


2024 ANNUAL REPORT

CCRM is a Canadian, public-private partnership supporting the commercialization of cell and gene therapies with strategic funding, dedicated infrastructure and specialized business and scientific expertise. By partnering with leading research institutions to launch new ventures, enabling industry by providing innovative CDMO services, scaling emerging companies by catalyzing investment, and training the workforce, CCRM is accelerating the translation of promising technologies, processes and therapies into life-changing health outcomes for patients.

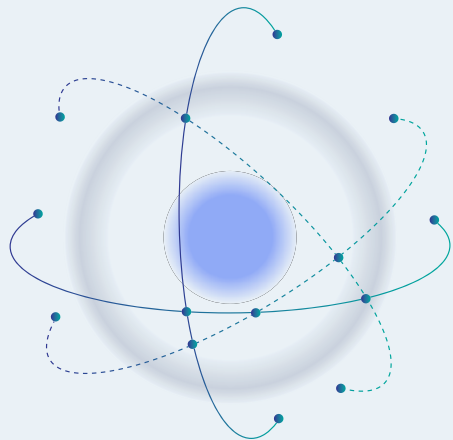


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CCRM's mission is to generate sustainable health and economic benefits through global collaboration in cell and gene therapy, and regenerative medicine.



Our Vision

To be the preferred partner for the best people, technologies, clinical trials, companies and investments in regenerative medicine.

To be the premier global enabler of clinically-tested, revolutionary new medical therapies and foundational technologies.

CCRM is revolutionizing health care by solving the big problems in regenerative medicine.

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Staying focused on the promise



Globally, the cell and gene therapy (CGT) industry is looking robust. Across North America, Europe and Asia Pacific, there were nearly 3,000 developers, almost 2,000 clinical trials underway and US\$2.9 billion invested in the third quarter of 2024¹. On the ground, the situation may feel less optimistic. Global economics, fast-changing global politics, depressed valuations for CGT start-ups, and the persistent challenges of unlocking risk capital are causes for concern. We will be watching to see whether U.S. Food and Drug Administration (FDA) approvals for CGTs continue to climb, as predicted².

2024, unfortunately, saw many layoffs in the sector. While CGTs continue to hold much promise for patients, ongoing challenges hamper progress and many therapy developers must focus on staying in business to keep the momentum going.

CCRM's 2023 annual report was full of optimism. Our funding from the Government of Canada's Networks of Centres of Excellence program had concluded, and we were thrilled to share we had several years of runway ahead of us. OmniaBio Inc., our subsidiary, was and remains integral to our sustainability, both from a financial and a mission/vision perspective. One year later, we see headwinds in the industry, but we remain confident that they are

temporary and that our industry will stay on track to revolutionize medicine. We are appreciative and grateful for the federal government's support over the years, and we are moving ahead with our strategic growth plans.

OmniaBio opened its first Phase III and commercial facility in Hamilton, Ontario, on schedule. In October, we held a grand opening ceremony and welcomed over 200 guests to our 120,000 sq. ft. building at McMaster Innovation Park (MIP). There were many speeches, tours of the facility and a networking reception. Employees across OmniaBio and CCRM worked very hard to reach that milestone, as did our construction partners Multiplex and Ellis Don, and the team at MIP. Thank you!

It's a beautiful place to work, and it's exciting to think of the impact it will have on patients in Canada and globally. Our thanks also go out to Invest Ontario, an agency of the Government of Ontario, for its funding support, and to MEDIPOST, Co., Ltd., our strategic investor and partner in this transformative venture. Turn to pages 8-10 to read more about OmniaBio's progress and achievements, including the engineering run for its first Phase III customer, MEDIPOST, and its product CARTISTEM®.

¹ <https://alliancerm.org/data>

² Cell & Gene

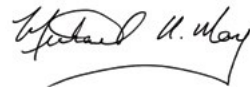
Last year, we also announced the launch of LineaBio Inc., a spin-out company from CCRM and OmniaBio. LineaBio is a cell line company manufacturing high-quality induced pluripotent stem cell (iPSC) lines that are compliant with Good Manufacturing Practices (GMP). In July 2024, LineaBio launched its catalogue of iPSC lines and a new website, and in November it submitted a Type II Drug Master File to the FDA for its flagship unmodified, off-the-shelf, GMP-compliant iPSC line, Linea 1. Read more about LineaBio on page 11.

Something else we shared in last year's annual report was that we would be making more new company announcements in the future – companies incubated at CCRM.

Apiary Therapeutics, the most recent CCRM spin-out company co-founded with Drs. Peter Zandstra (University of British Columbia and CCRM's Chief Scientific Officer) and Yale Michaels (University of Manitoba) will transform how therapeutics are delivered. Its mission is to leverage proven biology and engineered cell technology to develop safe and efficient off-the-shelf cell therapies capable of delivering targeted, long-lasting treatments to patients. 2024 has been an exciting year for Apiary. In February, the team closed its pre-seed round with investment from CCRM Enterprises and the OCI Life Sciences Innovation Fund. In May, Apiary established lab operations outside of CCRM and began building its team. Apiary is supported by two teams at CCRM,

as well as academic collaborators. The multi-site team is collaborating well and has made remarkable progress in the lab while generating enthusiasm among potential investors. We expect that 2025 will be a transformative year for Apiary – both in and out of the lab. Apiary is one of several companies that will emerge from CCRM's venture studio, incubation and investment teams this year.

We feel positive about other areas of CCRM, as you'll read in the following pages. We have demonstrated that our focus on manufacturing, access to capital, venture development, and the talent development resulting from all of these activities, drives sustainable ecosystem-building. As we look back on 2025, we hope to report that investments have flowed back into the sector and that the CCRM model continues to expand globally, impacting patients suffering from chronic disease everywhere.



Michael H. May
President and CEO

Throughout this report, all dollars are in Canadian currency unless otherwise specified.

2024 Highlights



OmniaBio's Grand Opening

Two years after putting shovels in the ground at McMaster Innovation Park in Hamilton, Ontario, OmniaBio Inc. opened its Phase III and commercial-stage facility. Politicians, media, government, industry and academic partners, as well as friends of CCRM and OmniaBio, were on hand for the grand opening ceremony on October 17. Turn to page 8 to read about OmniaBio's progress.



LineaBio Launch

Building on a decade of expertise in induced pluripotent stem cells (iPSCs), CCRM and OmniaBio launched LineaBio Inc., a cell line company that produces high-quality, off-the-shelf iPSC lines manufactured in compliance with Good Manufacturing Practices. This enables cell therapy developers to reach clinical manufacturing one year sooner and significantly reduce cell line development costs. Learn more on page 11.

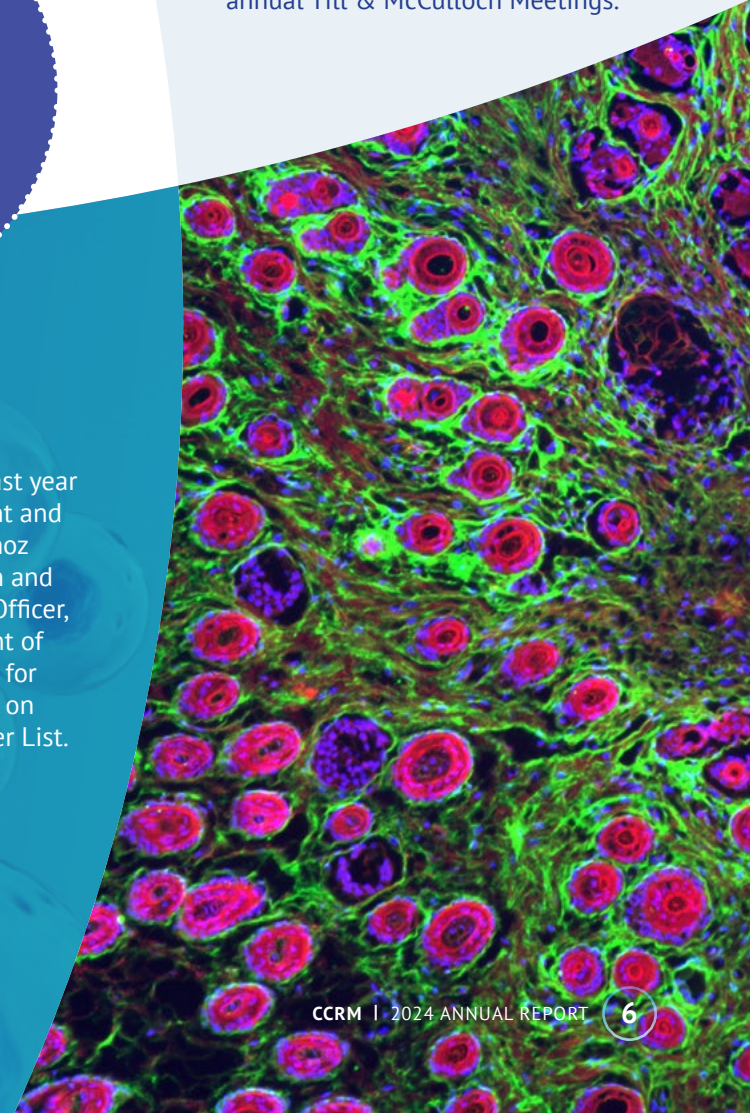


Congratulations to CCRM's Founders

Some notable highlights this past year were that Michael May, President and CEO, gave the distinguished Panoz Lecture at Trinity College Dublin and Peter Zandstra, Chief Scientific Officer, pictured above, was the recipient of BIOTECanada's Gold Leaf Award for Leadership. In April, Dr. May was on *The Medicine Maker's* 2024 Power List.

2024 Cells I See Art Contest Grand Prize Winner

Congratulations to Neha Dinesh, McGill University, winner of the Grand Prize for "The Stem Cell Peacock." This was the entry with the most votes from delegates at the annual Till & McCulloch Meetings.





New Leadership Hires

Sven Kili and Jessica Tate, pictured above, joined CCRM in 2024. Drs. Kili and Tate are well-respected leaders in the cell and gene therapy field. Dr. Kili joined as the Chief Development Officer and Dr. Tate is Vice President, Vector Platform Technology. Both are focused on strengthening our technology platforms. As well, OmniaBio hired Kenneth Harris, formerly of Amazon, as Chief Strategy Officer and Head of AI.



CATTI Anniversary

In March, the Canadian Advanced Therapies Training Institute (CATTI) celebrated its third anniversary. In May 2023, CATTI opened the doors to a 700 sq. ft. biomanufacturing training facility at the University of Guelph in Guelph, Ontario. So far, 70 individuals – from OmniaBio and elsewhere – have received in-person training, while another 50 have been trained online. Read about CATTI on page 16.

BY THE NUMBERS IN 2024:



1,400 views

OmniaBio's [new facility video](#)



2,800 downloads

CCRM's podcast, [back for season 4](#)



23,000+ readers

[Most read blog](#) on *Signals*



24,000 followers

on LinkedIn



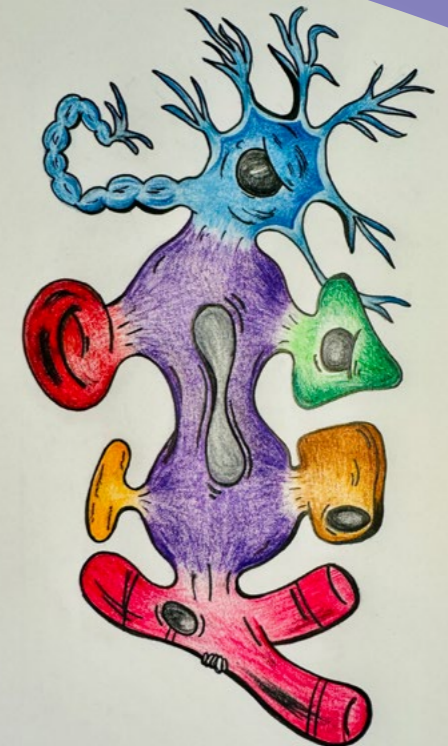
241.6M impressions

across 25 countries from OmniaBio's grand opening media outreach

2024 Cells I See Art Contest

People's Choice Award Winner

Congratulations to Sanjana Grover, University of Manitoba, winner of the People's Choice for "The Power to Produce in Assortment." The People's Choice is awarded to the entry with the highest number of likes on Facebook.



The orientation of this image has been adjusted to fit the space.

OmniaBio brings life-saving cell and gene therapies to patients through biomanufacturing innovation

CCRM's subsidiary OmniaBio Inc., a technology-focused, global cell and gene therapy contract development and manufacturing organization (CDMO), experienced a milestone year with the October 2024 opening of its new commercial-ready manufacturing facility at McMaster Innovation Park in Hamilton, Ontario.

At 100,000 sq. ft., the new state-of-the-art facility is now Canada's largest CDMO dedicated to cell and gene therapies. Building on the foundation built by CCRM, OmniaBio's opening of the facility further establishes Ontario and Canada as hubs for innovation, while increasing access and affordability to life-saving therapies across North America and globally.

The new facility is also an artificial intelligence (AI) centre of excellence. OmniaBio is among the first CDMOs globally working to integrate advanced technologies such as robotics, biosensors and machine learning to enhance process optimization, reduce costs, improve product quality and increase production rates compared to conventional CDMO approaches. OmniaBio's AI-enabled manufacturing will first focus on cellular immunotherapies and iPSC-based therapies.

This year, OmniaBio also opened a U.S. logistics hub. The hub is optimally located in Detroit, Michigan. Additional OmniaBio capacity is planned pending market demand.



OmniaBio employees working in the new facility



Highlights from OmniaBio in 2024

February

On February 8, Next Generation Manufacturing Canada (NGen) – the industry-led non-profit leading Canada's Global Innovation Cluster for Advanced Manufacturing – announced funding for a new project led by CCRM with partners OmniaBio, Cytiva, BIOVECTRA and Northern RNA. As a key partner in the project, OmniaBio is leading the transfer of immunotherapy platforms and critical supply chain materials to establish a commercial production capacity for immunotherapy biomanufacturing in Canada.

June

OmniaBio was pleased to welcome Kenneth Harris as its Chief Strategy Officer and Head of AI, strengthening its mandate of bringing maturity to cell and gene therapy through focused expertise in contract development and manufacturing.

Mr. Harris, a seasoned executive with more than 30 years of experience in the health care and life sciences technology markets, drives OmniaBio's growth and scale in his role as Chief Strategy Officer. He plays a vital part in shaping OmniaBio's corporate strategy and service differentiation, as well as in leading the formation of OmniaBio's Advisory Board. As Head of AI, Mr. Harris's expertise in this area bolsters OmniaBio's strategic interest in advancing its manufacturing automation and data-based decision-making.

September

OmniaBio publicly announced a collaboration with Somite Therapeutics, a Boston-based tech-bio company harnessing big data and AI to pioneer novel cell replacement therapies. The collaboration leverages OmniaBio's extensive iPSC experience to support Somite's development of a cell therapy that aims to restore muscle function, slow disease progression, and improve quality of life for individuals living with Duchenne muscular dystrophy, a rare genetic disorder with no known cure.

October

OmniaBio held a public grand opening event to celebrate its new commercial manufacturing facility in Hamilton. In attendance were Ontario government stakeholders such as Premier Doug Ford, Hon. Vic Fedeli (Minister of Economic Development, Job Creation and Trade), Hon. Sylvia Jones (Deputy Premier and Minister of Health) and Mayor Andrea Horwath of Hamilton. Special guests included Antonio Lee and Edward Ahn from OmniaBio's investor and client MEDIPOST, along with members of their team.

It was announced at the event that MEDIPOST, a recognized innovator in stem cell therapeutics, is the new facility's first commercial-stage customer, with plans to manufacture CARTISTEM® for North American osteoarthritis patients.

Guests heard firsthand from cancer survivor and patient advocate Laurie Adami, who shared how the work of organizations like OmniaBio has a life-changing impact on patients in need of advanced cell and gene therapies.

The opening event also generated significant media coverage to announce the new facility, an important addition to the Canadian and global biomanufacturing landscape.

OmniaBio is grateful to CCRM, MEDIPOST, Next Generation Manufacturing Canada (NGen) and Invest Ontario for their support of its new facility.



L-R: Mitchel Sivilotti, OmniaBio, Hon. Sylvia Jones, Hon. Vic Fedeli and Premier Doug Ford, Government of Ontario, Andrea Horwath, Mayor of Hamilton, MPP Donna Skelly, Michael May, CCRM

LineaBio's off-the-shelf, GMP-compliant iPSC lines enable the CGT industry

In 2023, CCRM and OmniaBio spun out LineaBio Inc., a cell line company providing access to high-quality, off-the-shelf, Good Manufacturing Practices (GMP)-compliant induced pluripotent stem cell (iPSC) lines that streamline drug product manufacturing.

LineaBio's off-the-shelf iPSC lines enable cell therapy developers by accelerating time to GMP by 12 months and reducing cell line development costs by up to 60 per cent. LineaBio's vision is to make cell therapy universally accessible and affordable.

LineaBio's proprietary GMP iPSC lines are based on more than a decade of iPSC platform expertise honed at CCRM, including reprogramming 200+ iPSC lines. LineaBio's affiliation with CDMO OmniaBio provides its clients a seamless path to the manufacturing of master and working cell banks, process and analytical development, and ultimately clinical and commercial GMP drug products.

2012-2022+

CCRM invests more than a decade into developing a leading reprogramming and gene editing platform.

July 2024

LineaBio releases Linea 1, its flagship GMP iPSC line that serves as the parental line for subsequent lines.

2025 (expected)

LineaBio's secondary GMP iPSC line, Linea 2, is currently in development and is expected to be released in 2025.

2023

LineaBio is founded by CCRM and OmniaBio to leverage expertise and build a series of off-the-shelf GMP iPSC lines.

November 2024

LineaBio submits a Drug Master File (DMF) for Linea 1 to the U.S. Food and Drug Administration (FDA). The DMF submission allows clients using the Linea 1 line to incorporate a standardized, comprehensive chemistry, manufacturing and controls (CMC) data package into their regulatory submissions to the FDA.

Empowering talent and enriching culture at CCRM



In a competitive market like ours, talent retention is paramount. Over the years, CCRM has been building its team and developing programs to provide an employee-centric culture. Here are some of our initiatives.

CEO Culture Council

The CEO Culture Council is a group that meets regularly to assess and improve the culture at CCRM. For example, we offer training and development programs and promote organizational culture through volunteerism, mentorship and diversity initiatives.

Volunteer Committee

In 2024, the Volunteer Committee hosted several initiatives to support WoodGreen Community Services, a leading Toronto social services agency. Again this year, CCRM volunteers worked with Visions of Science. We organized STEM workshops for students in Grades 8-10, at three locations across the GTA. To support Canadian Blood Services for the second time, we partnered with OmniaBio, BlueRock Therapeutics and Notch Therapeutics for a December Blood Drive.

CCRM Connect

We launched CCRM Connect in 2023 to bring together current and former employees of CCRM and our Board of Directors. We expanded the network to include OmniaBio Inc., LineaBio Inc., CCRM Australia, CCRM Nordic and the Canadian Advanced Therapies Training Institute. This network aims to spark conversations, collaborations, relationships and mentoring. 2024 saw us hosting a number of dinners at conferences, as well as a special screening of the documentary *Of Medicine and Miracles*.

Mentorship Program

Now in its second year, CCRM's Mentorship Program pairs mentors and mentees for year-long mentorship relationships, enabling employees to enhance skills, establish networks and develop their careers.

EPIC

The Equality, Professionalism and Inclusion Council (EPIC) celebrates CCRM's diversity and facilitates the professional development of employees. In 2024, EPIC organized cultural events and hosted informational sessions to acknowledge Pride Month and the National Day for Truth and Reconciliation.

Staff participating in cultural events

Driving innovation to market: How CCRM Enterprises has advanced regenerative medicine solutions



Panel (above) and networking (right) at the “Future of Regenerative Medicine” event, November 5



CCRM Enterprises Inc. is our for-profit venture investment arm. It makes early-stage investments in regenerative medicine and cell and gene therapy companies, while leveraging CCRM’s sector-specific expertise and highly specialized infrastructure.

In 2024, CCRM Enterprises was proud to support some of its portfolio companies with follow-on investments. Recent successes include a \$200 million partnership between Aspect Biosystems and the governments of Canada and British Columbia to develop bioprinted tissue therapeutics. Kisoji Biotech, a company developing multi-specific antibodies, announced a major partnership with Cancer Research UK to advance its first clinical program. Another highlight was the US\$40 million in Series A financing raised by Morphocell, a Montreal-based company developing transformative treatments for liver diseases.

CCRM Enterprises added to its team in 2024, which expanded its deal sourcing and diligence efforts as it explores new investment vehicles and funding models.

This year, the team participated in panels and talks emphasizing the promise of regenerative medicine and advanced therapies. Of note was Cynthia Lavoie’s moderation of the “Future of Regenerative Medicine” panel, hosted by CCRM. Dr. Lavoie is the

Chief Investment Officer and President of CCRM Enterprises. Panelists included experts in academia, commercialization, regulatory affairs and innovation. (See page 17 for more details.) The team also participated in local and international conferences, like the J.P. Morgan Healthcare Conference, Biotech Showcase, OBIO Investment Summit, Mintz Investor Conference, Bloom Burton & Co. Healthcare Investor Conference, SickKids Innovation Showcase, BIO International, Cell & Gene Meeting on the Mesa, Sweet Biopharma Day, UHNLeashed and BioFuture.

Involvement in pitching competitions, including joining CCRM Nordic and CCRM Australia to host the International Regenerative Medicine SuperPitch VII, enabled the team to engage with and advise early-stage companies while expanding its network of investor syndicates. These efforts achieve CCRM Enterprises’ objective of supporting the cell and gene therapy ecosystem locally and beyond to ensure promising therapeutics get to market.

In 2025, the team is excited to build on these efforts as it continues to support its portfolio companies, while expanding its funding models and investment vehicles to boost the regenerative medicine ecosystem.

Shaping tomorrow's cures: The CCRM Foundation will drive the future of medicine

Through collaboration with globally leading experts and ecosystem partners, including CCRM and Medicine by Design, The CCRM Foundation supports the advancement of potentially curative cell and gene therapies. A registered charity, its goal is to improve the quality of life for countless patients and usher in the future of medicine.

While many cell and gene therapies have reached the clinic, there remain several barriers to commercialization. Although billions of dollars of research have led to incredible breakthroughs in the field, there is limited funding to get these breakthroughs to the clinic. It is often at the early translation stage that research discoveries become stuck – when more research is needed to attract investment, but research funding is scarce.

The CCRM Foundation aims to solve this issue by using strategic philanthropy to address unmet medical needs and bridge the research commercialization gap.

Over the past year, The CCRM Foundation has been developing its first strategic plan, entitled “Powering a revolution in regenerative medicine.” By forming a working group consisting of executives from key partner organizations, as well as engaging with prospective donors and volunteers, The CCRM Foundation is actively seeking input on its strategy and developing a robust case for support to advance fundraising efforts over the coming year.

The CCRM Foundation has defined four major fundraising priorities to bring its vision to life:

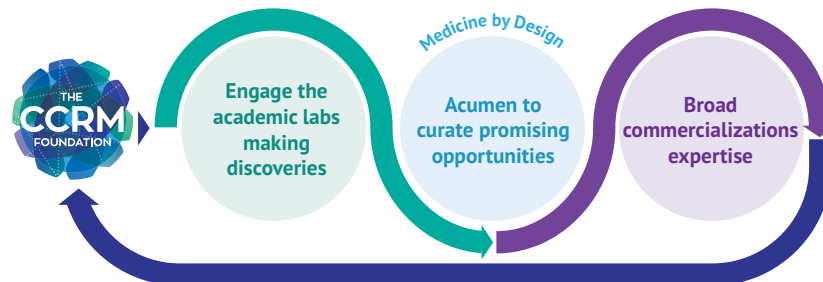
Curating high-potential projects: Accelerating discoveries into lifesaving and life-changing cell and gene therapies through [Medicine by Design's Pivotal Experiment Fund](#).

Strategic ideation to drive innovation: Advancing the frontiers of regenerative medicine by aligning the “pull” of the market with academic invention through CCRM's [Venture by Design](#).

Preparing for a new paradigm in medicine: Supporting and co-developing stakeholder forums that focus on including all patient perspectives in the design, development and clinical implementation of cell and gene therapies.

Training the next generation: Delivering sector-specific training and mentorship programs to educate a diverse generation of leaders and workers with skills in translational research, entrepreneurship and biomanufacturing.

Using **strategic philanthropy** to solve the lack of early-stage translational funding and expertise, to address unmet medical need.



Outcome: Patient impact and the potential for cures

Global innovation in CGT: Progress from CCRM Australia and CCRM Nordic



Australian trade mission to BIO Korea



GoCo Health Innovation City

In 2024, CCRM Australia and Sweden-based CCRM Nordic made significant progress to drive innovation in cell and gene therapy (CGT).

Highlights from CCRM Nordic

Founded in 2023, CCRM Nordic has established itself as a regional nexus for the commercialization of advanced therapies. It has launched its process development (PD) lab and enabled its first customer.

Its focus has been on oncology, where the PD team has set up both automated and modular processes, as well as analytical development. The team has also begun projects focusing on scaling iPSCs and closing steps of an advanced therapy manufacturing process.

A major milestone was January's groundbreaking ceremony at GoCo Active lab in Gothenburg, Sweden, which will house CCRM Nordic's future Good Manufacturing Practices production and PD facilities. Handover is expected in 2026.

In November, CCRM Nordic's Director of Venture Development was seconded to work with CCRM's Technology Sourcing and Venture Development team in Toronto to collaborate on a project and share best practices.

Led by Anna Falk, Chief Scientific Officer, a Scientific Advisory Board launched in April. Fulfilling the Nordic name, it has representation from Sweden, Denmark, Norway and Finland.

Highlights from CCRM Australia

With the University of Queensland (UQ), CCRM Australia is co-leading a sector-wide application for government funding for new biomanufacturing platform technologies, and it has signed a letter of intent to establish a PD facility at UQ. Further, it is leading a consortium to develop a CGT company incubator that will adopt the principles of CCRM's Venture by Design in Toronto.

CCRM Australia participated in international events in the U.S. and Korea to foster collaboration and commercial engagement. It coordinated an Australian delegation visit to Toronto to tour CCRM's operational facilities and attend stakeholder meetings.

Alice Pébay, Chief Scientific Officer, presented at the La French MedTech Australia Forum and the Australasian Society for Stem Cell Research Meeting 2024. The first Friends of CCRM Australia Advisory Network reception took place, bringing together key representatives from academia, industry and clinical sectors.

Global hubs converge for SuperPitch

As part of the CCRM International Regenerative Medicine SuperPitch VII, four shortlisted biotechnology companies from Canada, Europe and Australia pitched to a panel of international venture firms in November. Originally an Australian initiative, SuperPitch is now a partnership with CCRM Nordic and Canada's CCRM Enterprises Inc.

Upskilling for the future: How CATTI drove innovation in biomanufacturing training in 2024

In addition to celebrating its third anniversary in March, the Canadian Advanced Therapies Training Institute (CATTI) also announced several significant collaborations to advance its mission of developing a Good Manufacturing Practices (GMP)-trained workforce in Canada.

In May, CATTI and the U.K.'s Cell and Gene Therapy Catapult announced a strategy to provide aligned training and assessments for the advanced therapies manufacturing industry. It is an important first step towards developing shared standards that will help the growing industry access a skilled workforce.

A new collaboration with the McGill Regenerative Medicine Network (MRM) at McGill University resulted in a hands-on GMP training session pilot, which launched in June. It focused on pluripotent stem cell-derived products, and enhancing participants' aseptic processing and clean room skills. Moving forward, CATTI and MRM will offer sessions regularly.

In November, OBIO and CATTI announced a partnership to deliver the Biomanufacturing for Advanced Therapies Training Program, funded by Upskill Canada [powered by Palette Skills] and the Government of Canada. This highly subsidized program is for all Canadian companies and individuals

looking to upskill their competencies in advanced biomanufacturing. Its goal is to train 280 people by March 2026.

Ushering in a new era in biomanufacturing training, CATTI and Ouat! announced a partnership, in December, to bring innovative virtual reality training solutions to the Canadian biomanufacturing industry. CATTI will use HakoBio, Ouat!'s web-based platform, to create 3D biomanufacturing environments to test real-world situations in a de-risked environment.

To date, 70 individuals have received between one and five weeks of practical training in Guelph or McGill's Montreal facility. CATTI has also trained an additional 50 individuals through online courses, live online webinars (with the Stem Cell Network), and during Medicine by Design's Summer by Design program.



Participants in CATTI's training programs



Highlights from CCRM-led training and education initiatives



CCRM's Mohad Mehrabian presenting at Summer by Design 2024



Participants in Summer by Design 2023

From tried and true to brand new, CCRM hosted and participated in a variety of training and educational opportunities to support trainees to industry leaders in the cell and gene therapy (CGT) field.

Future of Regenerative Medicine Event

Kicking off the discussion with the Gartner hype cycle and debating whether the CGT field is currently in the “trough of disillusionment” or the “slope of enlightenment,” CCRM hosted a lively panel discussion on the future of regenerative medicine in November in Montreal.

The panel of thought leaders drew from their own experiences to comment on where the field is heading, what opportunities they see and what challenges the sector still faces. The speakers were Cynthia Lavoie (moderator), President & Chief Investment Officer, CCRM Enterprises Inc.; Benjamin Haley, Professor, University of Montreal and FRQ Chair in Genomic Engineering; Emily Titus, Senior Vice President, Technical Operations, Notch Therapeutics; Patrick Bedford, Vice President, Regulatory Affairs, Morphocell Technologies, and Founder & Managing Director, weCANreg Consulting Group, Inc.; and Rob Quirk, Vice President, Technology Sourcing and Venture Development, CCRM.

Summer by Design

From June 10-19, 35 regenerative medicine PhDs and postdoctoral fellows from Canada and around the world arrived at the University of Toronto to participate in the 2024 edition of Summer by Design. They spent 10 days learning about the commercialization of cell and gene therapies, participating in interactive sessions and building their international networks.

CCRM supported the development of the program's curriculum and led sessions. Beginning with a welcome from CCRM's President and CEO, and followed by talks from experts on CCRM's Technology Sourcing and Venture Development team, and Process and Analytical Development team, as well as from CCRM Enterprises Inc., the group learned about the multifaceted considerations that go into commercializing a discovery.

Summer by Design is hosted by the University of Toronto's Medicine by Design, in partnership with CCRM, the Rotman School of Management and the Stem Cell Network.

Till & McCulloch Meetings

The Till & McCulloch Meetings (TMM) enable Canadian and global trainees, researchers and industry representatives to network and learn about advances in research techniques and other developments in the regenerative medicine field. TMM took place from November 4-6 in Montreal. As a gold-level sponsor this year, CCRM was involved in several ways.

CCRM was pleased to sponsor the trainee pre-conference workshop called “Talk Nerdy to Me: Mastering the Art of Explaining your Research to any Audience,” which armed participants with the core science communication skills needed to enhance presentations and adapt research for different audiences.

The patient talk is always a highlight at TMM, as it reminds trainees and professionals of the huge impact their research efforts can make in people’s lives. CCRM had the opportunity to support the session and introduce Vancouver’s Joshua Robertson, who recounted his journey living with type I diabetes. He shared his experience as the first Canadian patient to participate in a pioneering stem cell therapy clinical trial.



Joshua Robertson,
diabetes patient

Webinars

Allogeneic natural killer (NK) cell therapies

CCRM’s Tey Irrazabal, Manager, Technology & Venture Development, presented a webinar called “Mastering allogeneic NK cell therapies: Flexibility, robustness, and speed to clinic.” Dr. Irrazabal discussed industry challenges and opportunities around NK cell therapy development and robust manufacturing preparation and infrastructure. She presented new, customizable and scalable manufacturing platforms, along with a case study about an NK cell therapy platform with supporting data to streamline time to the clinic while mitigating challenges in manufacturing at a commercial scale. [Watch it here.](#)

Lentiviral vectors

A new member of CCRM’s team, Jessica Tate, Vice President, Vector Platform Technology, led an insightful virtual presentation called “Enhancing lentiviral vector (LVV) stability and recovery: Optimizing buffer formulation.”

Attendees learned how Design of Experiments can be utilized to optimize buffer formulations that enhance LVV stability, and the key factors affecting LVV stability, including buffer composition, additives and virus concentration. Dr. Tate also discussed testing conditions for analyzing short-term and long-term LVV stability. [Watch it here.](#)

Both webinars were hosted by *Cell & Gene Therapy Insights*, in partnership with OmniaBio, CCRM’s CDMO subsidiary.

BY THE NUMBERS

This year, CCRM’s experts and leaders shared their insights and expertise, along with discussions of our work, with audiences at conferences, meetings and events all over the world. This included, at least:

 **3 webinars**

 **17 panels**

 **21 presentations**

Portfolio company highlights

 CLICK THE BOXES TO GET TO THEIR WEBSITES!

Through CCRM Enterprises Inc., CCRM provides tailored support to advance promising discoveries from lab to market, supporting the launch and development of 20 companies which have collectively raised over \$1 billion. Here are some key accomplishments from select portfolio companies in 2024.*



Apiary

Toronto, Preclinical

Apiary Therapeutics leverages proven biology and engineered cell technology to develop safe and efficient off-the-shelf cell therapies capable of delivering targeted, long-lasting treatments. See the Executive Message on page 5 for the launch announcement.



Aspect Biosystems

Vancouver, Preclinical

In 2024, Aspect Biosystems announced a \$200 million partnership with the governments of Canada and British Columbia to advance the development of bioprinted tissue therapeutics for people with serious metabolic and endocrine diseases. Aspect was also named Life Sciences BC Company of the Year, as well as BIOTECanada's Biotech Company of the Year.

**Past exits: AVROBIO and Empirica Therapeutics*



ExCellThera

Montreal, Phase 2

ExCellThera Inc., CCRM's first spin-off company (2015), demonstrated its status as a world leader in enhanced blood stem cell therapies, namely through its publication in *Blood*, highlighting the potential of its proprietary UM171 small molecule to result in efficient stem cell expansion for therapeutic use, as well as presentations at EBMT 2024 Annual Meeting, 2024 Cell & Gene Meeting on the Mesa conference, and ASH 2024. The company's commercialization efforts reached key milestones, including obtaining an International Non-Proprietary Name and New Orphan Drug Designation for its UM171 Cell Therapy, and European Medicines Agency acceptance under accelerated assessment of Market Authorization Application for patients with hematological malignancies lacking an available donor.



Feldan

Quebec City, Clinical

Feldan Therapeutics became a clinical-stage company with the initiation of a Phase 1/2a study for FLD-103, a first-in-class intralesional treatment for basal cell carcinoma. The company completed a US\$21 million Series B financing round co-led by Genesys Capital and Fonds de Solidarité FTQ. Feldan expanded its patent portfolio with the granting of five new patents, bringing the total to 25 issued patents and over 50 applications worldwide. Also, Feldan published three proof-of-concept articles in prestigious journals and received over US\$1 million in grants to optimize its intracellular delivery technology, the Feldan Shuttle, further supporting innovation and pipeline expansion opportunities.



KisoJi

Montreal, Preclinical

KisoJi continued to make strides in 2024, advancing its highly differentiated antibody discovery platform using AI-based paratope mapping and sampling. The company announced a partnership with Cancer Research UK, where the latter will be designing and funding a 100-patient Phase 1/2 clinical study of KisoJi's KJ-103 drug candidate, the only naked antibody against TROP2 to have potent antitumor effects and not requiring a cytotoxic payload. In December, KisoJi announced the raising of \$41 million in equity to advance KJ-103 into the clinic. Funds will also be used to deploy its antibody discovery platform towards new multi-specific therapeutic antibody drugs in cardiometabolic disease, immunology and inflammation.



Mediphage Biocenticals

Toronto/Boston, Preclinical

Mediphage continues to advance the capabilities of genetic medicine with its high-fidelity msDNA™ cargo and non-viral gene therapy programs. In 2024, Mediphage secured an undisclosed seed round with participation from existing investors, including CCRM Enterprises, Riverine Ventures and Bio Med Ventures. The company appointed Dr. Vincent Ling to the Advisory Board, who brings over 30 years of experience in gene and cell therapy, biological modalities and drug delivery systems. Mediphage published a paper in *Molecular Therapy*, highlighting the manufacturing process impact on the fidelity of the final product, and helping differentiate msDNA™ from other linear DNA produced *in vitro*. After publication, Mediphage advanced conversations with three of the top 10 pharmaceutical companies to test msDNA™ in a variety of applications.



Notch Therapeutics

Toronto, Vancouver/Seattle, Preclinical

In 2024, Notch built an allogeneic T-cell pipeline using unique genome editing that generates uniformly engineered therapies, allowing the more economical generation of large quantities of potent and persistent cells. Additionally, Notch demonstrated readily scalable T cell manufacturing in small footprint bioreactors. By developing a proprietary strategy, Notch's universal T cells (UNi-T cells) were protected from multiple mechanisms of patient immune cell clearance, aiming to enhance cell persistence and durability of patient response. Through creating a proprietary engineered cytokine technology, which eliminates the need for helper cells or exogenous cytokines, Notch offers the potential to deliver off-the-shelf T-cell therapies without requiring toxic lymphodepleting chemotherapies as pretreatment. Finally, Notch demonstrated preclinical proof-of-concept data in mouse models, supporting the development of its products for treating cancer and autoimmune conditions. Notch is the first company to go through CCRM's incubation program.



Pluristyx

Seattle, Clinical

Pluristyx launched its first clinical-grade iPSC lines for customers to use as starting material for further manufacturing. Cell line variants with hypoimmune features and the FailSafe safety switch are available, with clinical-grade versions on the way. Strategic licensing and distribution agreements with ARMI and Charles River have further expanded customer access to cell lines. Pluristyx also launched PluriFreeze, a cryopreservation media for R&D and clinical use.

Transforming ideas into impact: Medicine by Design's role in advancing regenerative medicine

In 2015, the Canada First Research Excellence Fund (CFREF) invested \$114 million to launch [Medicine by Design](#) as a regenerative medicine hub within the Toronto Academic Health Sciences Network (TAHSN), which includes the University of Toronto (U of T) and its affiliated hospitals.

The transformative investment provided a once-in-a-generation opportunity to build on Toronto's legacy in regenerative medicine, sharpen its peaks of excellence, and push the frontiers of the field. Medicine by Design invested more than \$77 million into 180 convergent research projects led by investigators who have secured over \$975 million in additional research funds, including more than \$41 million from industry partners.

In addition, the CFREF funding supported the recruitment of 17 new faculty and the training of more than 2,000 graduate students and postdoctoral fellows. These investments have ensured that the impact of CFREF's funding will continue for many years. One of Medicine by Design's flagship programs is the Pivotal Experiment Fund. It is an early-stage commercialization fund that is advancing a pre-clinical pipeline of regenerative medicine-based therapies with strong potential for clinical and/or commercial impact.

Having reached the end of its CFREF funding, Medicine by Design is now turning its focus to the sustainability of the regenerative medicine community it has built. The strategic alliance with CCRM builds upon a long-standing partnership between the two organizations and capitalizes on their respective strengths: bridging transformational research to industry expertise and biomanufacturing infrastructure. The goal of the alliance is to overcome gaps and fund opportunities within the regenerative medicine research and translation ecosystem based on the integration of a commercial perspective and the academic community.

Medicine by Design will also work closely with The CCRM Foundation, a new charity advancing education, research and patient impact in the field of cell and gene medicines. The CCRM Foundation is using strategic philanthropy to bridge the research commercialization gap for the advancement of academic-led innovations that address unmet medical needs through critical, but underfunded, stages of development. Turn to page 14 to read more about The CCRM Foundation.



Packed auditorium at Medicine by Design's 9th Annual Symposium, December 9



Michael May, CCRM, and Allison Brown, Medicine by Design, during a fireside chat at the 2024 Annual Symposium

Key Funders



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Founding Institutional Members



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Current and Former Portfolio Companies

Current



Former



Collaborative Partners



Industry Consortium

CCRM has established a consortium of more than 100 companies that represent key sectors of the regenerative medicine industry, including therapeutics, devices, reagents, and cells as tools. These companies range from multinational corporations, to small-medium enterprises, to emerging start-ups. They have utilized the translational platforms developed by CCRM to enable new opportunities and address real-life bottlenecks in their businesses.

CCRM would like to acknowledge the valuable relationships that have been fostered with these companies.



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