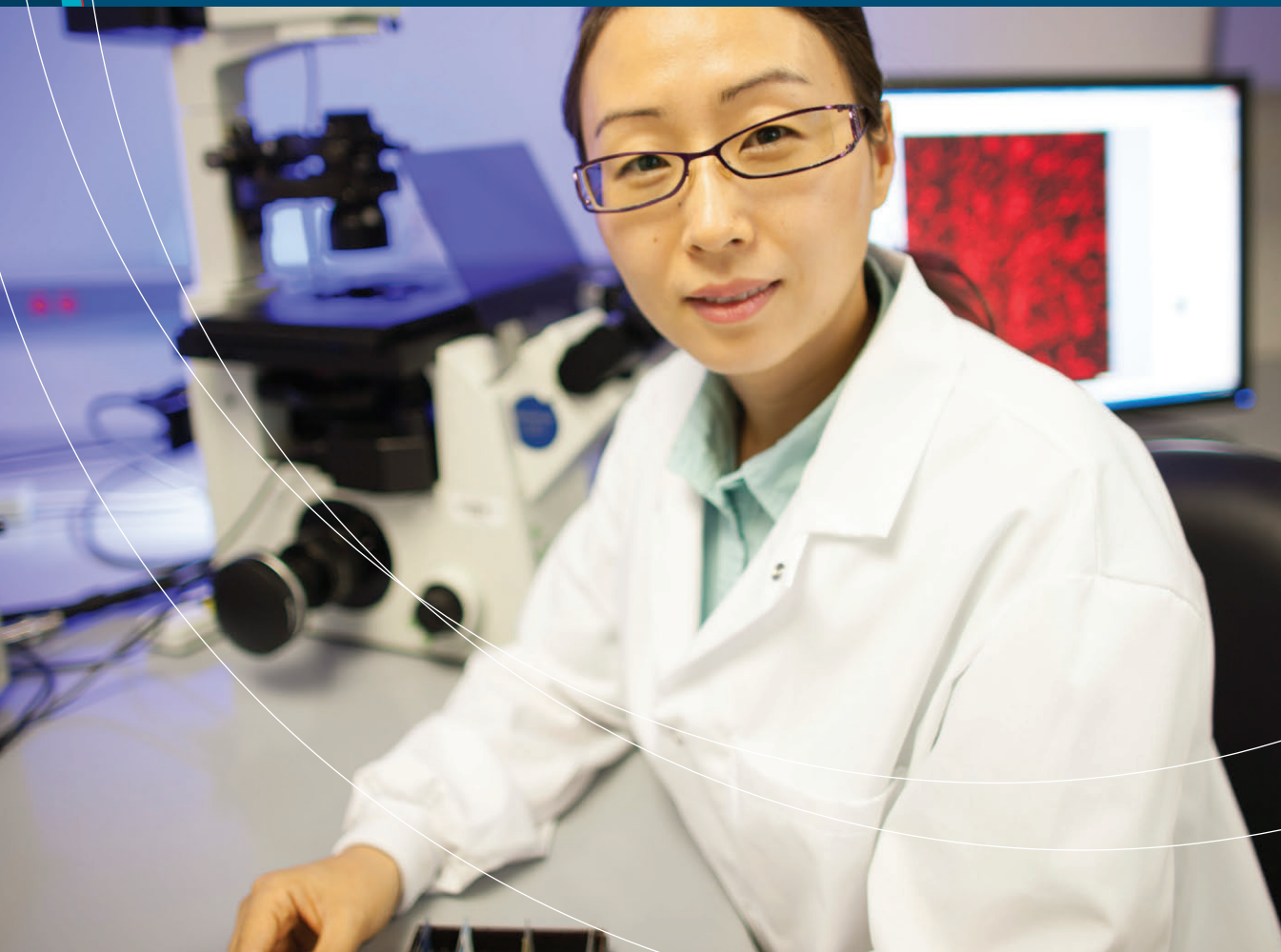


**NRC·CRRC**

# **COLLABORATING FOR INNOVATION**

●●● Human Health Therapeutics



National Research  
Council Canada

Conseil national de  
recherches Canada

**Canada** 





**Lakshmi Krishnan**

Director General

Human Health Therapeutics

## **COLLABORATING FOR INNOVATION IN BIOLOGICS AND VACCINES**

The NRC's Human Health Therapeutics (HHT) Research Centre hosts the largest R&D team dedicated to biologics development in Canada. Through fundamental research and discovery, we're dedicated to catalyzing business innovation and public health solutions for unmet medical needs. This includes:

- Multifunctional antibody-based therapeutics
- Disruptive technologies for cell and gene therapy
- Biomanufacturing platforms and automation
- Readiness innovation for emerging infections and vaccines

*On behalf of the HHT management team, I invite you to discover the impact we can have together!*

## MANAGEMENT TEAM



**Lynne LeSauteur**  
R&D Director  
Downstream Processing and Analytics  
514-283-1012  
Lynne.LeSauteur@cnrc-nrc.gc.ca



**Danica Stanimirovic**  
R&D Director  
Translational Bioscience  
613-993-3730  
Danica.Stanimirovic@nrc-cnrc.gc.ca



**Mike McCluskie**  
R&D Director  
Immunobiology  
613-993-9774  
Michael.McCluskie@nrc-cnrc.gc.ca



**Frank Van Lier**  
R&D Director  
Bioprocess Engineering  
514-496-8469  
Frank.vanLier@cnrc-nrc.gc.ca



**Kelley Parato**  
Program Director  
Cell and Gene Therapy Health Challenge Program  
613-990-1512  
Kelley.Parato@nrc-cnrc.gc.ca

## BUSINESS TEAM



**Eileen Raymond**  
Portfolio Business Advisor  
Tel.: 514-496-6349  
Eileen.Raymond@cnrc-nrc.gc.ca



**Alex Serrano**  
Client Relationship Leader  
Tel.: 514-496-6211  
Alexandre.Serrano@cnrc-nrc.gc.ca



**Daniel Desmarteaux**  
Client Relationship Leader  
Tel.: 514-496-5300  
Daniel.Desmarteaux@cnrc-nrc.gc.ca



**Stacey Nunes**  
Client Relationship Leader  
Tel.: 613-993-9212  
Stacey.Nunes@nrc-cnrc.gc.ca



**The National Research Council of Canada (NRC)  
is the Government of Canada’s largest science and  
research organization.**

The NRC’s core mandate is to foster science excellence, contribute to the public good, and promote business innovation.

Our expertise spans across a range of areas including immunobiology, translational bioscience and bioprocess engineering (bacterial, viral and mammalian cell expression platforms), as well as downstream processing and analytics to enable progression through the drug development value chain. Our aim is to build a strong pipeline of assets suitable for commercial exploitation, through collaborative research, technical advice and expertise, service agreements in bioprocess engineering, and product development and production for technology transfer to industry.

Meet with our experts today, and learn more about Canadian innovations with global impact!

## VALUE CHAIN

### OUR FOCUS

- 1 FUNDAMENTAL RESEARCH**
- 2 TARGET SELECTION AND VALIDATION**
- 3 CANDIDATE DESIGN AND OPTIMIZATION**
- 4 PRECLINICAL DEVELOPMENT**  
Milestone Investigational New Drug (IND)
- 5 CLINICAL PHASE I & II**  
Milestone Proof of Concept (PoC)
- 6 CLINICAL PHASE III**  
Milestone New Drug Application (NDA)
- 7 MARKET**

### OUR ROLE IN THE VALUE CHAIN

- Strategic R&D
- Product co-development
- Licensing
- R&D Services



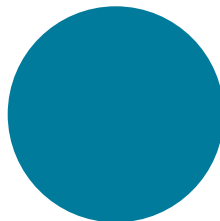
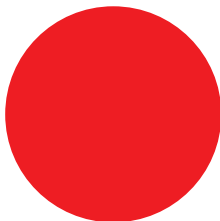




## FOCUS ON BIOLOGICS

In 2017, seven of the top 10 medicines contributing to patented drug sales in Canada were biologics.

Source: Patented Medicine Prices Review Board, Annual Report 2017 Government of Canada



### PROGRAMS

#### Multifunctional Antibody-based Therapeutics

##### Indications

- Cancer
- Neurodegenerative diseases (e.g. Alzheimer's, Parkinson's)
- Inflammatory disorders

##### Technologies

- Monoclonal, single domain, bi-specific/multi-specific antibodies
- Antibody-drug (cargo) conjugates
- Chemical conjugation or fusion to couple NRC carriers with your antibodies, peptides, and growth factors
- High-throughput cell-based assays
- *In vitro* rodent and human blood-brain barrier models
- Portfolio of carrier molecules to shuttle biotherapeutics to the brain
- Preclinical testing and imaging of blood-brain barrier penetration and efficacy
- Immune monitoring, animal model efficacy
- Imaging agents, enzymes, and nanocarriers
- 3D microfluidic bioprinting
- Humanization of antibodies and molecular modelling

#### Disruptive Technology Solutions for Cell and Gene Therapy

##### Indications

- Cancer
- Genetic diseases
- Rare disorders

### Technologies

- Synthetic biology-driven precision editing for universal cell platform
- Precision targeting for accurate and effective delivery at site(s) of disease
- Capacity-building for Canadian biomanufacturing and clinical pipeline
- Gene therapy vectors (genetic switches for controlled expression and process scale-up)

### INITIATIVES

#### Biomanufacturing – Platforms and Automation

- Protein and vector production
- Process development and scale-up (up to 500 L)
- Purification
- Biophysical characterization

#### Vaccines and Emerging Infections – Readiness Innovation

- Carbohydrate, protein and lipid antigen target identification
- Virus, virus-like particle, vector, protein, and bacteria production
- Microbial expression systems (1500 L pilot plant)
- Immunomodulation: carriers, adjuvants and delivery systems
- Human immunology: high throughput, multiplex assays
- Multi-color flow cytometry
- Emerging infections animal models (BSL3)



●●● "Our ability to innovate is founded in collaboration.

The NRC's broad range of expertise gives our partners access to a full suite of assets, from research and discovery to biomanufacturing, purification and characterization, through to downstream analytics, technology transfer and IP management.

We deliver impact for Canadians and global partners."

– Lakshmi Krishnan, Director General, Human Health Therapeutics, NRC



Cell Culture  
**Stainless**

500L

50L

20L

7L

3L

Cell Culture  
**Single use**

200L

Microbial fermentation  
**Stainless**

1500L

750L

150L

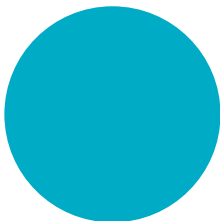
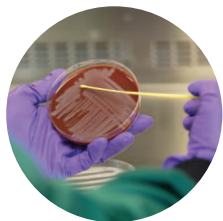
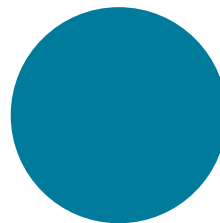
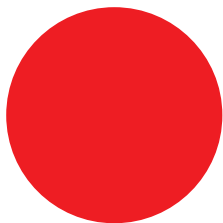
75L

20L

14L

3.5L





## FACILITIES

### Advanced analytical platform

#### Biophysical characterization

- Molecular weight and charge heterogeneity
- Post-translational modifications
- Purity
- Stability
- Solubility
- Aggregate formation

#### Mass spectrometry (MS)

- Structure and function analysis
- Post-translational modifications
- Carbohydrate and lipid moiety identification

#### Other services

- Targeted biomarker quantification and mass spectrometry "omics" approaches
- Development of novel methods for bioanalysis
- Advanced nuclear magnetic resonance (NMR) structural analysis of proteins and carbohydrates

### Microbial fermentation pilot plant

- Production of peptides, proteins, enzymes, nutraceuticals, organic acids, polymers, polysaccharides and probiotics
- Bioprocess optimization and scale up to 1,500 L
- Bacteria and yeast systems: *E. coli*, *M. extorquens*, *Pichia*, *Saccharomyces*

- Pathogen cultivation facilities up to BSL 2
- Handling of methanol-oxidizing microorganisms
- Testing of new monitoring/control equipment and reagents
- Purification and analytical services
- Tech transfer to contract manufacturing organizations (CMOs)

### Cell culture pilot plant

- Production of antibodies, proteins, viruses, and virus-like particles
- Proprietary suspension and serum-free cell expression systems for transient and stable production: HEK293, CHO, A549, VERO
- Process optimization and scale up of batch, fed-batch, and perfusion cultures up to 500 L
- In-process assay development
- Purification and analytical services
- Tech transfer to contract manufacturing organizations (CMOs)

### Preclinical *in vivo* facility

- Validation of therapeutic targets and biomarkers for peripheral and central diseases
- Pharmacokinetic and pharmacodynamics studies in animal models
- *In vivo* vaccine safety and efficacy studies for infectious diseases (level 2 & 3)
- Efficacy and immune mechanism of action testing in syngenic, xenogenic, orthotopic and transgenic cancer models
- Development of novel *in vivo* imaging methods and contrast agents for molecular imaging
- Data packages to enable Investigational New Drug (IND) submissions

# IMPACT

## OUR CLIENTS

82%	Found unique offerings at the NRC
54%	Submitting IND next 3 years
56%	Pre-revenue
74%	< 50 employees
\$16.4M	Increased investments since interaction with the NRC
\$108M	Increased market valuation since interaction with the NRC

## HHT IN NUMBERS

~340	Experts	4	Sites
2	Programs	3	Initiatives
35+	Candidates in the pipeline	3	Biosafety levels

> \$45M

INVESTED IN HUMAN  
HEALTH BY THE NRC  
EACH YEAR



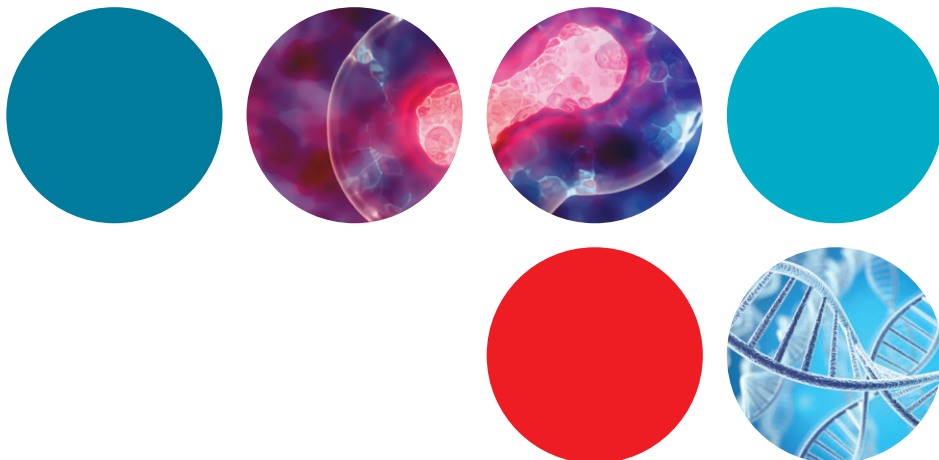
“Investments in foundational research today form the cornerstone of tomorrow’s breakthroughs. [Our] collaboration with the NRC should serve as a template—only through a combination of vision, expertise and teamwork will we arrive at the next generation of cancer therapies...”

- Dr. Ali Tehrani, President and CEO, Zymeworks

**MILESTONES – PROJECTS WITH THE NRC**

Year	Milestone	Company	Molecule/ Technology	Indication/ Application
2018	Licensed	Cansino	Ad5-based vaccine (NRC HEK293)	Ebola
2018	Phase 1-2a	VBI	Virus-like particle	Glioblastoma
2017	Phase 1	Forbius	Antibody-drug conjugate	Solid tumours
2016	Phase 1	Zymeworks	Bi-specific antibody	Breast, gastric, and ovarian cancer
2016	Phase 1	VBI Vaccines	Virus-like particle	Cytomegalovirus
2016	Phase 2	Alethia Biotherapeutics	Monoclonal antibody	Metastatic carcinomas
2015	Phase 1	PREVENT	Vaccine	Streptococcus Group A
2015	Market	NPS Biopharmaceuticals	Hormonal therapy	Hypoparathyroidism
2012	Phase 3	Oncolytics	Oncolytic virus	Cancer





### WHY PARTNER WITH THE NRC?

- Recognized expertise in biotechnology
- Track record of industry collaborations
- Extensive science & technology infrastructure
- Innovative health solutions for unmet medical needs

### PARTNERING FOR IMPACT

- Enhanced ability to attract investment
- High-quality job creation
- Progression of products and technologies towards commercialization
- Increased business expenditures on R&D (BERD)

## IDEAL PARTNER FOR SMALL AND MEDIUM-SIZED ENTERPRISES (SMES)

Our aim is to build a strong pipeline of assets suitable for commercial exploitation. When you collaborate with the NRC, you can look forward to working with an experienced team that's backed by extensive technology and infrastructure assets. We work with firms of all sizes, with a particular focus on SMEs.



[www.canada.ca/nrc-human-health-therapeutics](http://www.canada.ca/nrc-human-health-therapeutics)

© (2019) Her Majesty the Queen in Right of Canada, as represented by the National Research Council of Canada.  
Paper: Cat. No. NR16-277/2019E, ISBN 978-0-660-30899-9 • PDF: Cat. No. NR16-277/2019E-PDF, ISBN 978-0-660-30898-2  
May 2019 • Également disponible en français