

Problem

Sepsis is an exaggerated, systemic, immune response to an infection that often leads to multiple organ failure. Patients with sepsis-induced cardiac dysfunction experience high mortality rates (50% increase), lengthy recovery times and serious long-term effects. The current standard of care is supportive - antibiotics or antivirals are given to deal with the source of infection, then supportive care is used, such as mechanical ventilation and fluid management, which requires (at least) days of bedside care and frequent assessment. Furthermore, these therapies may have harmful cardiac effects.

Solution

From prior work in mesenchymal stem cell therapy for sepsis, we have determined the key components responsible for the therapeutic effects and refined them into a stable, synthetic, and scalable package. miRNA regulates protein synthesis, some associated with disease. We have identified miRNAs that are decreased in the hearts of septic patients. Lipid nanoparticle (LNPs) delivery of miRNA ensures the efficacy of the therapy. NM-001 has been shown to be anti-inflammatory, anti-microbial and protects organs from injury.

NorthMiRs Inc.

80 Saint George Street, Toronto ON,
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Samantha McWhirter, CEO

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Market Opportunity

The sepsis therapeutic market is set to grow from \$3.48B in 2020 to \$7.51B in 2030 at a CAGR of 8.0%. It is the most common cause of death in critically ill patients and is the most expensive reason for hospitalization, \$1B/year in Ontario alone and \$1.7B in Canada. Worldwide, the cost of hospitalization for each septic patient is over \$32K USD.

Sepsis-induced cardiomyopathy, the target indication for NM-001, is present in up to 70% of septic patients. Norepinephrine (LEVOPHED, Hospira/Pfizer) and dobutamine (DOBUTAMIN, Sandoz/Novartis) are two leading treatments, but are undesirable due to increased myocardial demand and the risk of arrhythmias.

Competitive Advantage

Our team has filed two US provisional patents in the last 8 months: 1) Novel set of miRNA used to treat sepsis 2) miRNA inhibitor/mimic delivery for treatment of ARDS. Our team provides comprehensive expertise from benchtop to clinic. Our therapeutic is the most effective and comprehensive solution, because we use unique microRNAs to regulate the immune response of the host.

Go-to-market Strategy

With numerous therapeutically validated miRNA and miRNA inhibitors in our pipeline, we aim to have a clinical trial application (CTA) filed for our lead candidate by 2025. Currently, we are engaging with strategic partners in regulatory affairs (WeCANreg), business development (Janus Life Sciences Consulting) and LNP production to develop strategies to de-risk, scale-up, and commercialize our therapeutics, as we collect the required data to apply for clinical trials.

Developing nanotechnology-enabled gene therapies to address the underlying immune dysregulation of sepsis.

Product: NM-001 is using miRNA to heal the hearts of septic patients at risk of multi organ failure.

Funding status

\$150K: Private investment **\$400K:** NanoMedicines Innovation Network
\$150K: Mitacs **\$400K:** CIHR partner funding

Estimated funds required

\$1M to prepare a pre-clinical dossier for Phase 1 clinical trial application
\$2M to support Phase 1 clinical trial

Mentor co-founders



Gilbert Walker
U of T Chemistry
expert in nanoparticle design



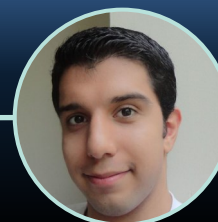
Claudia dos Santos
U of T Medicine
critical care physician & expert in acute lung injury



Samantha McWhirter
CEO, Formulation Scientist



Logan Zettle
Formulation Scientist



Amin Ektesabi
Pre-clinical scientist



Chirag Vaswani
Pre-clinical scientist

Student co-founders

An NMiN spin-off company **NMiN**
NANOMEDICINES INNOVATION NETWORK
REGULATORY STRATEGISTS

PhD Candidates at U of T Chemistry or Medicine



NorthMiRs, Inc.

Developing nanotechnology-enabled gene therapies to address the underlying immune dysregulation of sepsis

Company Overview

Product:

NM-001 is using miRNA to heal the hearts of septic patients at risk of multi organ failure.

Mentor co-founders:

Prof. Gilbert Walker
U of T Chemistry, expert in nanoparticle design

Prof. Claudia dos Santos, MD
U of T Medicine, critical care physician and expert in acute lung injury

Student co-founders:

Samantha McWhirter
CEO, Formulation Scientist

Logan Zettle
Formulation Scientist

Chirag Vaswani
Pre-clinical Scientist

Amin Ektesabi
Pre-clinical Scientist

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Founded June 2022

Contact

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NorthMiRs



NorthMiRs Inc.

Vision

To treat sepsis using miRNA in a lipid nanoparticle-based delivery system.

Products & Services

Our products and services can support and accelerate the drug delivery efforts of your pharmaceutical company, industrial biotech company, or academic lab.

NorthMiRs' lead candidate, NM-001, is a miRNA replacement therapy for sepsis to regulate the dysregulated immunological response of the host. It is anti-inflammatory, anti-microbial and protects organs from injury.

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We provide expertise from benchtop to complete preclinical execution of a protocol for treating patients based on their personal challenges with sepsis, from diagnosis to therapy.

MiRNA hinders protein synthesis that can be involved in disease. Compared to traditional therapeutics that target specific receptors or proteins, the strategy of using miRNA has additional novelty since miRNAs typically affect the expression of more than a single protein and influence multiple biochemical pathways, a useful trait in a complex illness like sepsis.

Our miRNA replacement therapy, NM-001, offers a solution by acting on various important aspects of lung and heart injury and extrapulmonary inflammation.

TREATING SEPSIS >> SAVING LIVES

Creating point-of-care, personalized medicine for the specific underlying disease and immune dysfunction mechanisms of the individual patient.

Leadership



Gilbert Walker
Co-Founder



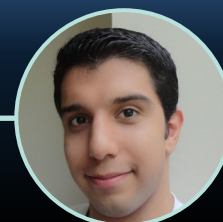
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