



Pioneering Targeted Scar Prevention at Wound Sites

Pulmonary Fibrosis | Burn Injuries | Postsurgical Adhesions

23 July 2025

Cellastra.com

Our Mission

Develop novel gene vector treatments that produce anti-scarring peptides at sites of tissue injury after burns, surgery and respiratory infections



Our Focus

- Expression of human lactoferrin-related peptides, part of the human innate immune system
- Primary peptide is a 25-amino acid subpeptide (ensereptide)
- The vector contains the gene sequence for ensereptide linked to a human FC IgG tag to prolong its half-life

Cellastra - key success factors



Proven executives with long industry track records



Proven concept: transfection with gene vector leads to peptide expression in vivo for months



Proven efficacy of peptide on root causes of tissue damage and scarring



Proprietary gene vectors and peptides



Promising prospects - near-term and long-term



Proven safety of lactoferrin subpeptides and viral gene vector



Profoundly unmet medical needs in tissue injuries





Scar prevention: Global unmet needs

PULMONARY FIBROSIS

- After Respiratory Infections
 - COVID 19
 - RSV
 - Influenza
 - Other pneumonia

DERMAL SCARRING

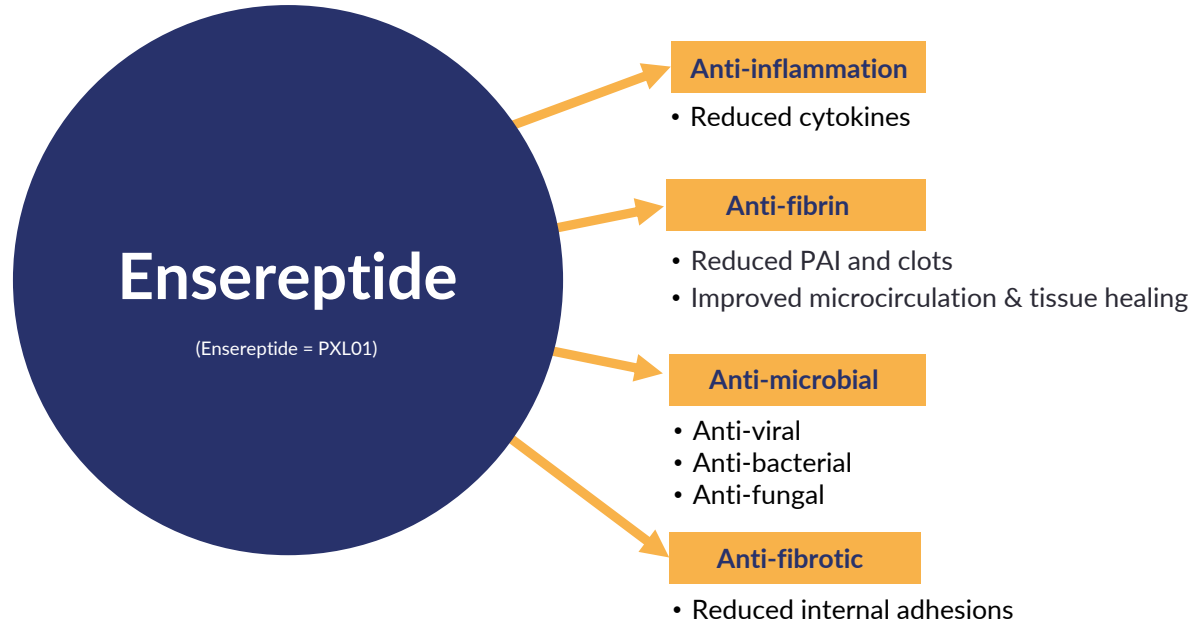
- After Burn Injuries
- Post-Surgery

BURNS

- 400,000 fire or burn injuries annually in the US, with 30,000 hospitalizations and 10,000 requiring surgery

NO EFFECTIVE DRUGS ON THE MARKET!

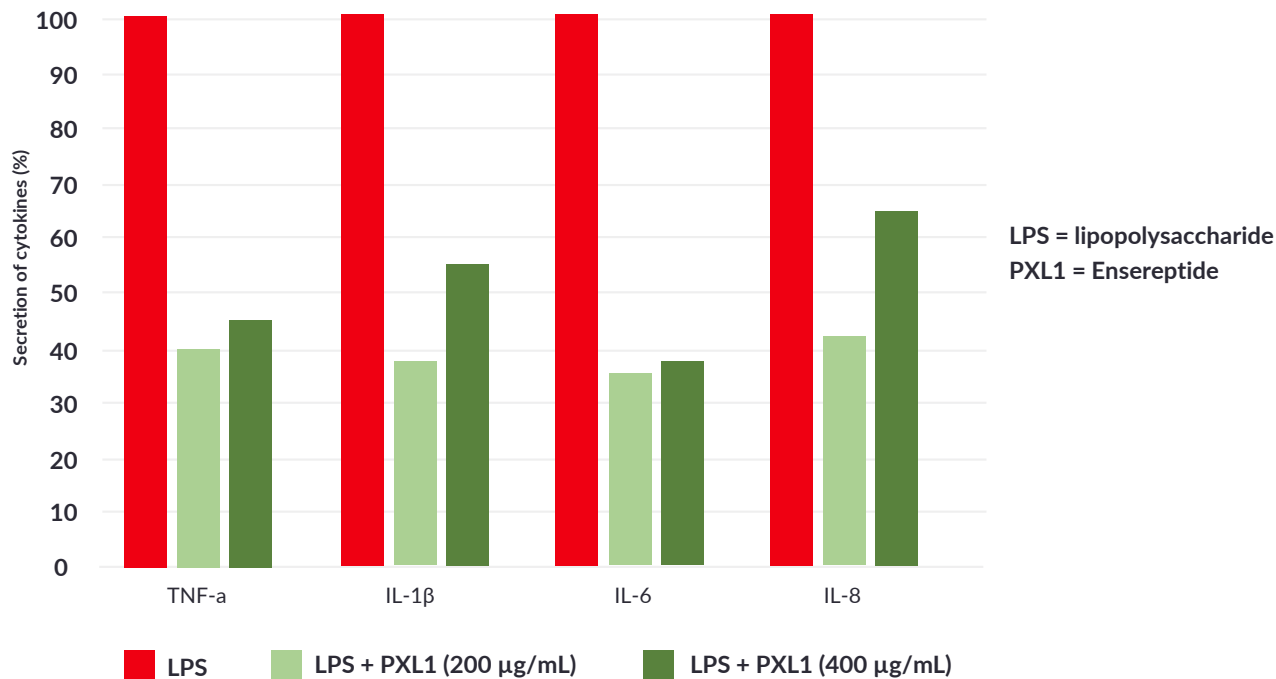
Ensereptide targets root causes of tissue injury & scarring



Nilsson E et al, Ann Surg 2009;250(6):1021-8

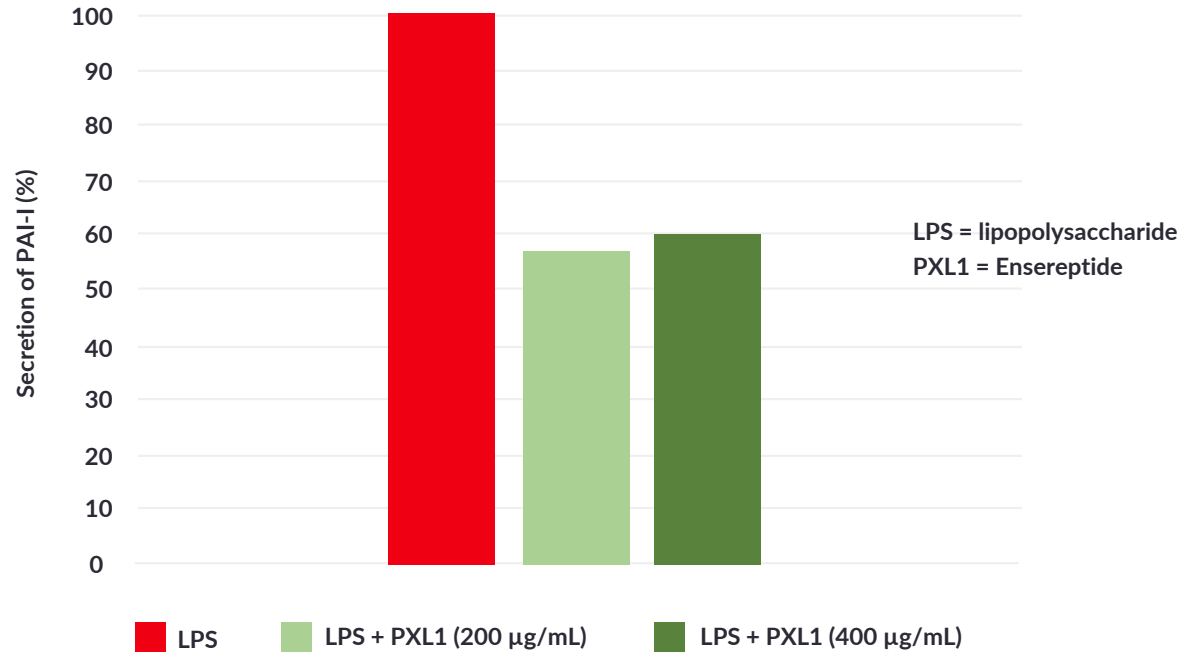
Ensereptide mitigates inflammation in vitro

- 40–60% reduction of cytokines



Ensereptide mitigates fibrin formation in vitro

- 40% Reduction of Plasminogen Activator Inhibitor (PAI)



Ensereptide has antimicrobial effects

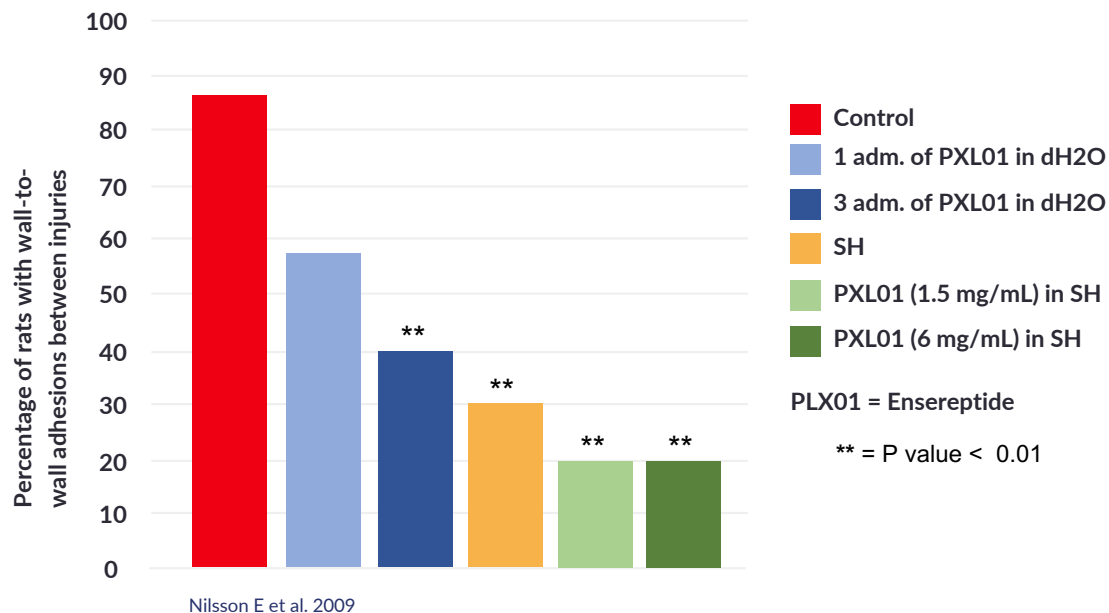
- Ensereptide (PXL01) is 40-80 X more potent antibacterial than lactoferrin in vitro

	<i>Escherichia coli</i> MMC 99%; µg/mL	<i>Staphylococcus aureus</i> MMC 99%; µg/mL	<i>Pseudomonas aeruginosa</i> MMC 99%; µg/mL
PXL01	12.5	12.5	25
Lactoferrin	>1000	>1000	>1000

Nilsson E et al., Ann Surg. 2009;250(6):1021-8.

Ensereptide anti-scar/adhesion effect (rat)

- >75% reduction of # rats with extensive adhesions
- Sustained peptide levels for 48 hrs. with SH (= sodium hyaluronate formulation) compared to distilled water (dH2O)
- No safety concerns



Ensereptide in hyaluronic acid: Clinical phase 2

Anti-scarring effect at surgical repair of ruptured hand flexor tendon

Endpoints, results at 6 months*	PXL-01 (n=68)	Placebo (n=71)	P-Value
Total active motion of the distal finger joint	60 degrees	41 degrees	p=0.016
Proportion w/good or excellent finger mobility	61%	38%	p = 0.0499
Tip-to-crease distance	5.0 mm	15.5 mm	p=0.048
Maintained/recovered Sensory function using thinnest monofilaments	74%	35%	p=0.016
At 12 Months			
Candidate for tenolysis, re- surgery	12%	30%	p = 0.086

- Double- blind, randomized, multicenter study
- Significant clinical benefit in 4 of 5 endpoints (PPAS)
- Good safety profile

Wiig M et al., PLOS One 9(10): e110735

Peptide Biology

- The human body (and all mammals) contains many proteins and peptides intended to function in host defense (innate immune system).
- Lactoferrin is a large protein with numerous functions including host defense; for example, it's present in breast milk and provides immune protection to nursing infants.
- Lactoferrin itself was tested for numerous immune properties with oral administration.
- A subpeptide of lactoferrin called **ensereptide**, of **25 amino acids length**, has many of **the same properties as the parent molecule** and is more potent for many.

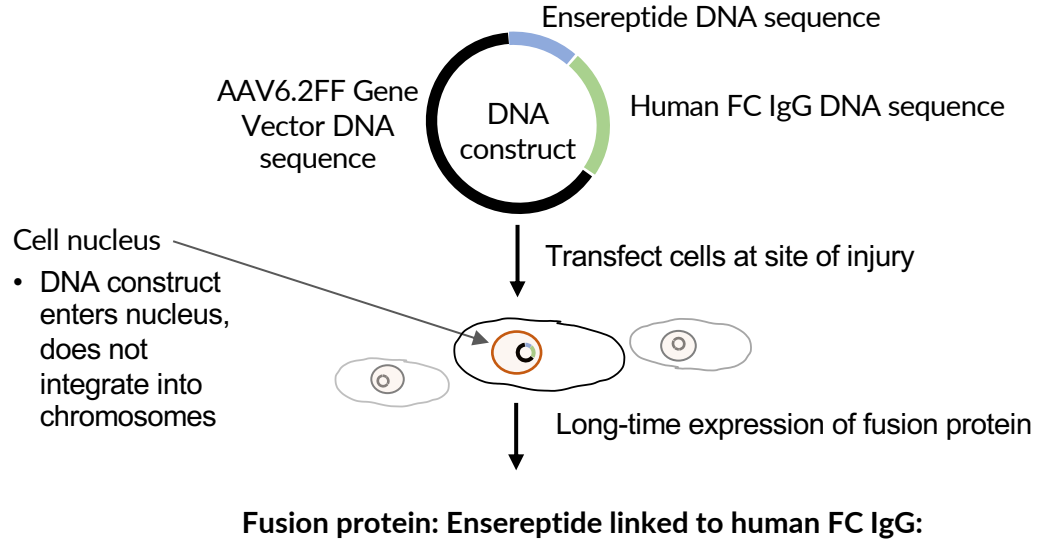
Peptide Biology (cont.)

- Ensereptide demonstrated **numerous properties useful in wound healing and host defense** (based on published work)
- Ensereptide is a naturally occurring peptide and probably an initial product from the metabolism of lactoferrin - a **similar active peptide is found in cows as bovine lactoferrin metabolite**
- Peptides are difficult to turn into drugs – they have a **very short half-life in the body**
 - Enzymes **rapidly degrade** peptides (and proteins)
 - Peptides are **rapidly filtered out** of the blood by the kidneys

Ensereptide alone vs. Cellastra's Novel Gene Vector Approach

Ensereptide peptide itself:

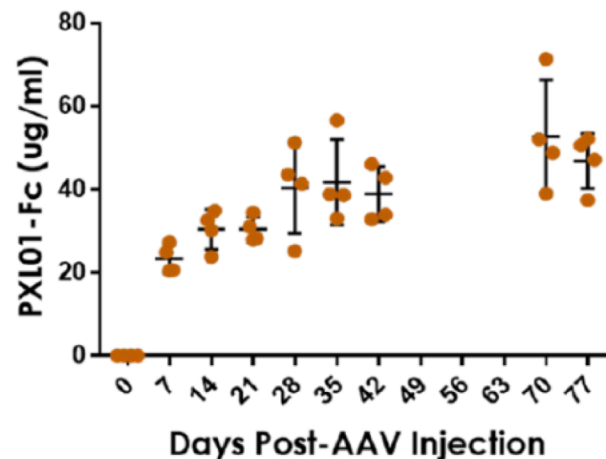
- Treatment at wound area
- Small molecule, only 25 amino acid
- Short half-life in human body
- Single exposure insufficient



- Our fusion protein has increased half-life
- Increased half-life promotes healing
- Increased exposure of peptide promotes healing

Robust expression of Ensereptide (in mouse)

- Robust expression in mouse plasma until sacrifice on Day 77
- Intramuscular admin. of encoded vector for ensereptide (PXL01)
- Fc (human IgG constant domain) tag added to the gene construct
 - Enables quantification expression
 - Prolongs half-life in plasma



Balb/c mice were intramuscularly administered 1×10^{10} vector genomes of AAV6.2FF expressing PXL01 fused to the Fc domain of human IgG1 (PXL01-Fc). Plasma levels of PXL01-Fc were measured over time until the **experiment was terminated at 77 days post AAV-administration.**

Intellectual Property

Oct 20, 2020 (Univ. of Guelph)

A: US patent 10,806,802 B2

Adeno-associated virus particle with mutated capsid and methods of use thereof

- Also allowed in Canada
- Licensed from U. of Guelph

Feb 6, 2024 (assigned to Cellastra)

B: US Patent 11,891,429 B2

Recombinant Gene Vectors Encoded to Regulate Endogenous Production of Anti Scarring/Adhesion Lactoferrin Biomolecules

A+B combined cover

- Composition of matter
- Broad range of recombinant vectors expressing lactoferrin and subpeptides
- Multiple uses and routes of administration



Scientific basis for Cellastra development program

Anti-adhesion efficacy of ensereptide in hyaluronic acid

- Rat model of intestinal abrasions
- Rabbit digit model
- Human hand surgery

(Nilsson et al., 2009)

(Hakansson et al., 2012)

(Wiig et al., 2014)

AAV6.2FF Gene Vector compared with natural AAV6

- Lower immunogenicity
- Higher transgenic expression in muscle (>100-fold) and lung (49-fold) at 24 hours
- Acute toxicity (mice, sheep) and chronic pharmacology studies (sheep) support safety of AAV6.2FF capsid

(van Lieshout et al., 2018)

(Rghei et al., 2021)

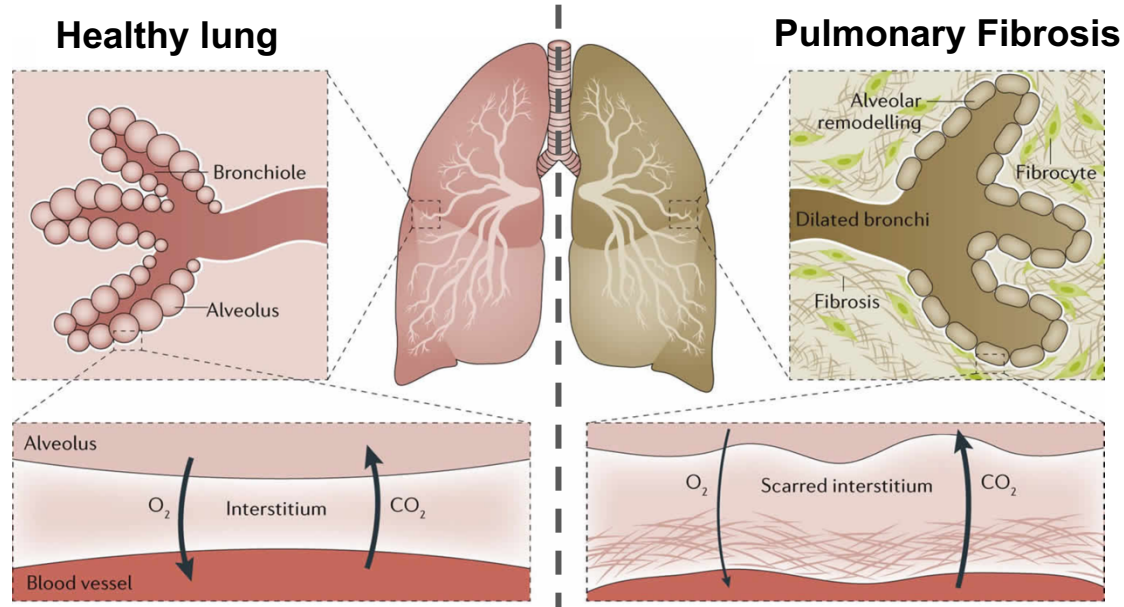
Transfection of cells in vivo

- Long term expression of ensereptide fusion protein (in mice)
- No safety issues with regard to the vector

(Kulmala et al., 2020)

AAV = adeno-associated virus; number refers to serotype (e.g., 6)

Fibrexa for mitigation of lung infections / fibrosis



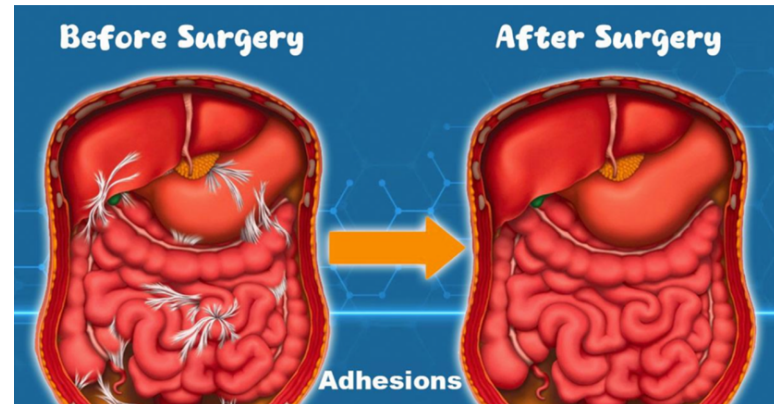
- FIBREXA is a formulation for inhalation
- Intended for high-risk patients e.g., elderly or other patients with risk factors for developing long-term complications with fibrosis after respiratory infections (e.g., Influenza, RSV and COVID-19).

Scarlexa may prevent new adhesions after surgery

- For prevention of scarring or adhesions after surgery, SCARLEXA is applied before wound closure or injected subcutaneously into the wound area.
- Shown is adhesions of the lung (a).
- Surgery is often used to remove adhesions (b).
- Treatment with Scarlexa prevents the return of adhesions.



a



b

Scarlexa for burn injuries



- Complications of burns are many:
 - Disrupted skin barrier function – dehydration, infection
 - Aesthetically displeasing, reduced quality of life
 - Stiff scars hinder movement and facial expression
 - Pain is often present and can be severe
 - Lung damage is common from heat, flames, or chemical
- Burn Injury Indication would be explored with a Swedish Consortium
- In vitro treatment of keratinocytes (and other skin cells) with SCARLEXA after collection from burn patient and expansion in cell culture
 - Production of ensereptide-linker-Fc by transplanted keratinocytes would decrease scarring in treated burn wounds
- Clinical studies may be funded by government (US, Sweden, EU/EC)
- Great humanitarian & military interest
- Cost of burn care >\$18 B/year in US alone

Core Team & Advisors



Karl Mettinger, MD, PhD

Chairman & CEO

- 35+ yrs. biotech exp
- Kabi Pharmacia, IVAX, Supergen, Oncolytics, Pharmacyclics
- 3 multi-BN\$ exits
- Karolinska Institute
- Co-Founder/President Swedish Stroke Society



Sven Andreasson, MSc

Vice Chairman

- 40 yrs. exp. incl leadership positions Kabi, Pharmacia
- Active Biotech, Isconova, Novavax,



Vinod Kumar, MD

CMO, EVP

- 30 years exp from U. Illinois, U Miami, Lilly,
- Novartis, Section Head/Global Program Medical Director



Henrik Kulmala, PhD

EVP Product Dev/Regulatory

- 35+ yrs. exp
- Marion Merrell Dow, Fujisawa, Genix
- 75 drugs (INDs, NDAs, BLAs)



Brad Thompson, PhD

CTO, Chair SAB

- 35+ yrs. , incl BIOTEC Canada
- CEO Oncolytics, Wyvern, Kickshaw Ventures
- Inventor of several gene therapy patents



Daniel Quintero, Esq

General Counsel, Secretary

- 20+ yrs. incl Founding Partner Prometheus Partners LLP
- Sony Optiarch / Electronics



Bruce Phillips CPA

CFO

- 30+ yrs. exp incl Arthur Young, HPC, Xero, Aprio



Kent Persson, PhD

Co-Founder, Advisor

- 25+ yrs. exp. incl UCSF, Bio-Rad
- Octapharma
- AstraZeneca



Emma Ye, MD Cand.

Scientific Advisor, Comms

- Vanderbilt University
- UC Berkeley



Prof Christopher Evans, PhD

Advisor, SAB

- Prof of Orthopedics at Mayo Clinic
- Head of the Musculoskeletal Gene Therapy Research Laboratory



Folke Sjoberg MD, PhD

Advisor, Tissue Repair, Burn Injuries

- Prof. at Burn surg./ Crit. care at Linköping Univ. and the Burn Ctr. Depts. of Hand, Plastic Surg. and Intensive Care, Linköping Univ. Hospital
- Mbr. Of Exec. Comm. of Internatl. Soc. For Burn Injuries

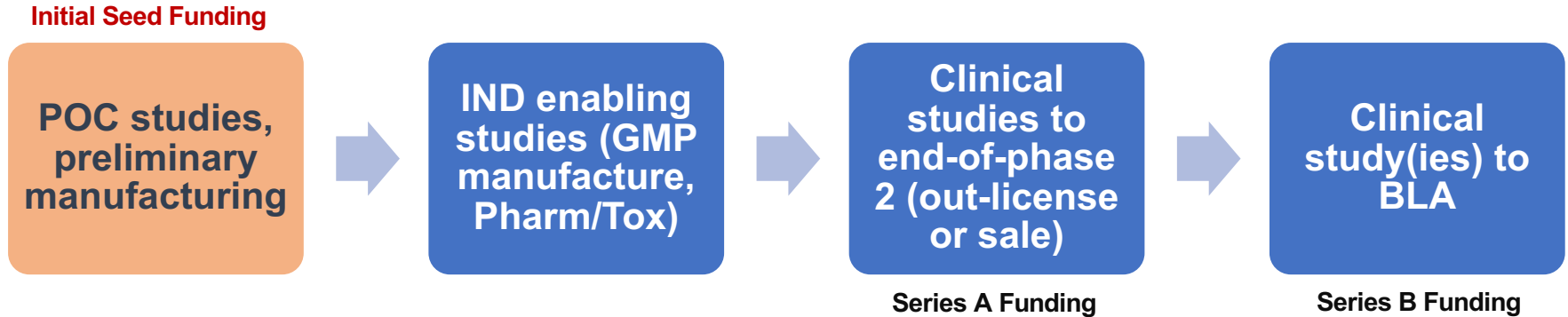


Magda Forsberg, PhD

Advisor, Orthopedic & Medical Devices

- Background at Karolinska Institute, focusing on stem cell biology and clinical applications
- President & CEO of DVL-op MEDICO Inc, involved in the prod. and comm. Ortho. and medical devices

Cellastra Funding – 4 stages



POC = Proof of Concept; **IND** = Investigational New Drug exemption **GMP**; = Good Manufacturing Practice; **BLA**= Biologics License Application

Cellastra Priorities

Step 1 - POC

- Secure initial funding for proof of concept (POC) studies
Q3 2025
- Conduct POC in vivo and in vitro studies to define mechanism of action
- Define indication(s) to be pursued initially and later

\$1 million

Step 2 – to IND

- Secure funding to complete an IND submission
Q4 2025
- Start preliminary GMP manufacturing and GLP Pharm/Tox
- Manufacture a Phase 1 GMP batch
- Submit an IND for initial indication

\$4.8 million

Step 3 – IND Opened

- Initiate first-in-humans study
Q1 2026

\$1.3 million

Budget to IND

• Univ. Of Guelph manufacturing and testing	\$100,000	} \$1 million
• Manufacturing engineering batch	\$350,000	
• Nonclinical POC studies (total)	\$203,000	
• Material characterization	\$85,000	
• POC SARS-CoV-2 in vivo study	\$115,000	
• Potency and gene product assays	\$150,000	

• GMP Manufacturing of vector:	\$3.5 million
◦ 20 L to 50 L initial batch	
• Formulation and delivery system development:	\$300,000
• Pharm/Tox studies:	\$1 million

Lower funding level alternatives

- For \$100,000 – lab manufacturing of vector and in vitro studies
- For \$250,000 lab manufacturing, in vitro studies, and 1 or more in vivo POC studies
- For \$500,000 – manufacture small-scale exploratory batch and conduct in vitro and in vivo POC studies

Cellastra

Value Proposition

- ✓ Proven management team
- ✓ Potentially revolutionizing new treatment paradigm:
Encoding scarless healing at injury sites
- ✓ First-in-class proprietary gene vector, shown to be safe and active in pharmacology-toxicology studies
- ✓ Proof-of-Concept established for peptide in animals and clinical Phase 2, double-blind, placebo-controlled, study (n=138)
- ✓ Near-term exit opportunity



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