

Our Mission

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
 - o COVID 19
 - o RSV
 - o Influenza
 - o Other pneumonia

DERMAL SCARRING

- After Burn Injuries
- Post-Surgery

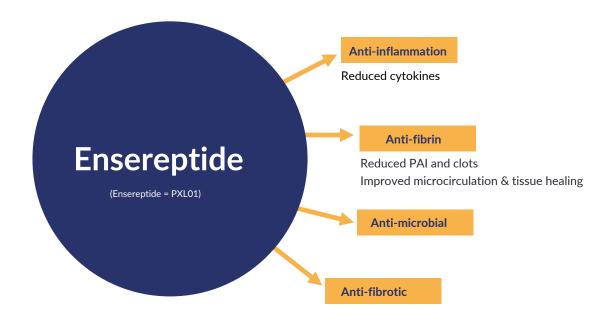
BURNS

 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



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

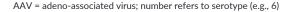
 Robust long-term expression of AAV6.2FF-ensereptide-Fc in mice following single intramuscular administration

 Acute toxicity (mice, sheep) and chronic pharmacology studies (sheep) support safety of AAV6.2FF capsid (van Lieshout et al., 2018)

(Kulmala et al., 2020)

(Rghei et al., 2021)

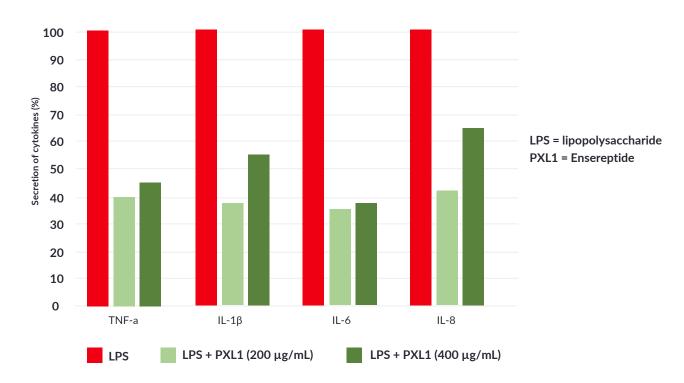






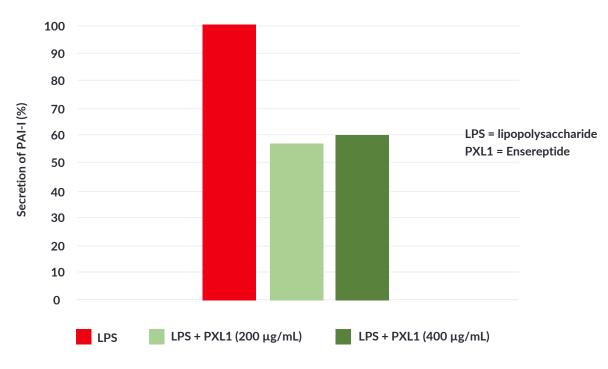
Ensereptide mitigates inflammation in vitro

40-60% reduction of cytokines



Ensereptide mitigates fibrin formation in vitro

40% Reduction of Plasminogen Activator Inhibitor (PAI)





Ensereptide has antimicrobial effects in vitro

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

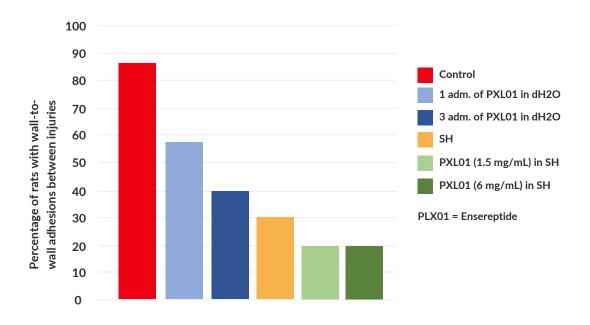
	Escherichia coli MMC 99%; μg/mL	Staphylococcus aureus MMC 99%; μg/mL	Pseudomonas aeruginosa MMC 99%; μg/mL
PXL01	12.5	12.5	25
Lactoferrin	>1000	>1000	>1000

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



Ensereptide antiscar/adhesion effect (rat)

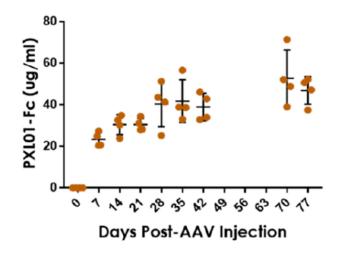
- >75% reduction of # rats with extensive adhesions
- Sustained peptide levels for 48 hrs. with SH (= sodium hyaluronate formulation) compared to distilled water (dH2O)
- No safety concerns





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
 - O Enables quantification expression
 - Prolongs half-life in plasma



Balb/c mice were intramuscularly administered 1x10^10 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.



New patents + freedom to operate

Oct 20, 2020 (Univ. of Guelph)

A: US patent 10,806,802 B2

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

Feb 6, 2024 (assigned to Cellastra)

B: US Patent 11,891,429 B2

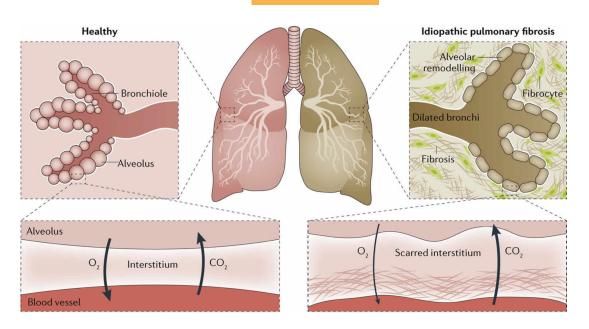
A+B combined cover

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





Fibrexa for mitigation of respiratory infections



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



Scarlexa to prevent scarring or adhesions after surgery

For prevention of scarring or adhesions after surgery, Scarlexa is applied before wound closure or injected subcutaneously into the wound area.

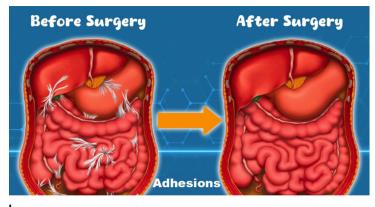
Shown is adhesions of the lung (a).

Surgery is often used to remove adhesions (b).

Treatment with Scarlexa prevents the return of adhesions.



а









Scarlexa for burn injuries

- Burn Injury Indication would be explored by a Swedish Consortium
- In vitro treatment of keratinocytes (and other skin cells) 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





Karl Mettinger, MD, PhD

Chairman & CEO

- 35+ vrs. 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



- 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 BIOTECanada
- CEO Oncolvtics, Wyvern, Kickshaw Ventures
- Inventor of several gene therapy patents



Daniel Quintero, Esq.

- General Counsel, Secretary

 20+ yrs. incl Founding Partner Prometheus Partners
- 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
- Astra7eneca



Emma Ye. MD Cand Scientific Advisor, Comms

- Vanderbilt University
- **UC** Berkeley



Prof Christopher Evans, PhD

Advisor, SAB

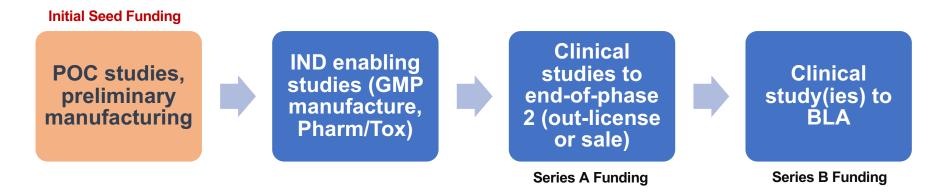
- Prof of Orthopedics at Mayo Clinic
- Head of the Musculoskeletal Gene Therapy Research Laboratory



Core Team

& Advisors

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 \$1 million

- Conduct POC in vivo and in vitro studies to define mechanism of action
- Define indication(s) to be pursued initially and later

Step 2 - to IND

 Secure funding to complete an IND submission Q4 2025 \$4.8 million

- Start preliminary GMP manufacturing and GLP Pharm/Tox
- Submit an IND for initial indication
- Manufacture a Phase 1 GMP batch

Step 3 - IND Opened

 Initiate first-in-humans study 2026 \$1.3 million Q1



Budget to IND

Univ. Of Guelph manufacturing and testing	\$100,000
Manufacturing engineering batch	\$350,000
Nonclinical POC studies	\$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

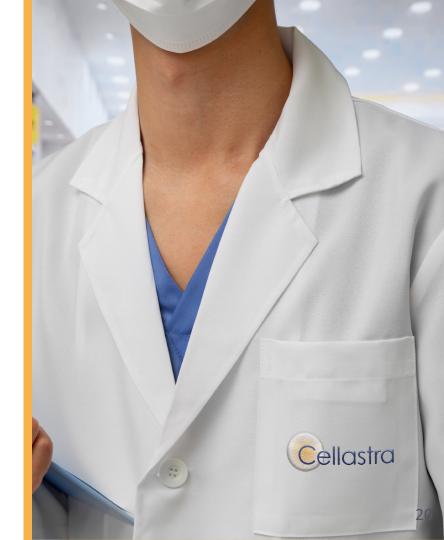
Formulation and delivery system development: \$300,000

Pharm/Tox studies: \$1 million



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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