

### **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
  - Other pneumonia

#### **DERMAL SCARRING**

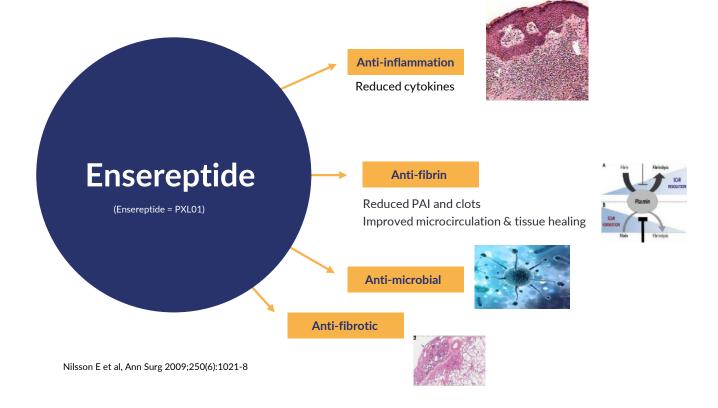
- Post-Surgery
- After Burn Injuries

### Long COVID

- 60 million globally including ~16 million in US
- More cases added daily; ~10% of Omicron infections

## NO EFFECTIVE DRUGS ON THE MARKET

# Ensereptide targets root causes of tissue injury & scarring





# Basis for Cellastra development program

## Anti-adhesion efficacy of ensereptide in hyaluronic acid

• Rat model of intestinal abrasions

 Rabbit digit model 2012)

Human hand surgery

(Nilsson et al., 2009) (Hakansson et al.,

(Wiig et al., 2014)

## AAV6.2FF Gene Vector compared with natural AAV6

Lower immunogenicity

(van Lieshout et al., 2018)

- 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

(Kulmala et al., 2020)

(Rghei et al., 2021)

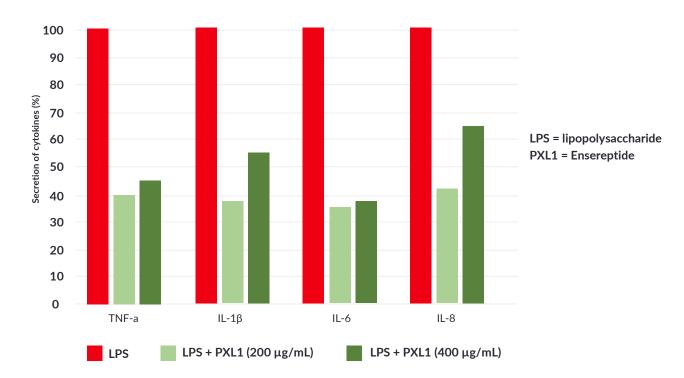
AAV = adeno-associated virus; number refers to serotype (e.g., 6)





# **Ensereptide mitigates** inflammation in vitro

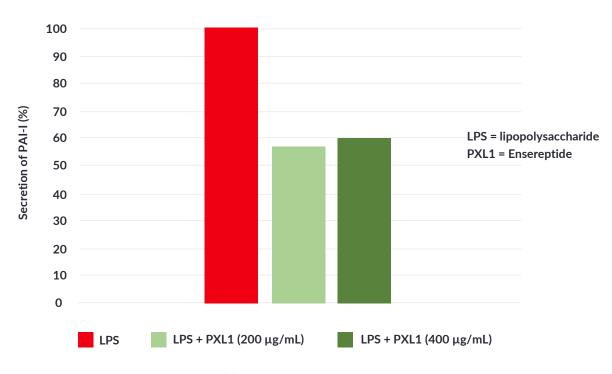
40-60% reduction of cytokines





## **Ensereptide mitigates fibrin formation in vitro**

40% Reduction of Plasminogen Activator Inhibitor (PAI)





# Ensereptide has antimicrobial effects in vitro

Ensereptide (PXLO1) is 40-80 X more potent antibacterial than lactoferrin in vitro

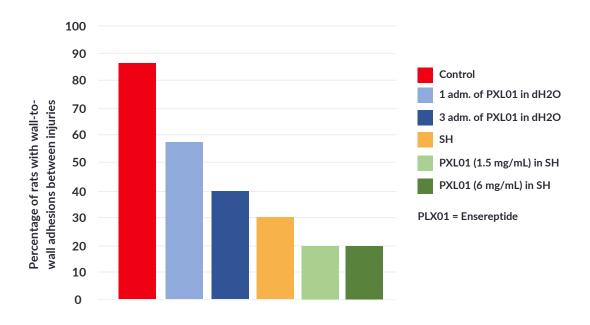
	Escherichia coli MMC 99%; μg/mL	Staphylococcus aureus MMC 99%; μg/mL	Pseudomonas aeruginosa MMC 99%; μg/mL
PXL01	12.5	12.5	25
Lactoferrin	>1000	>1000	>1000

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



## Ensereptide antiscar/adhesion effect (rat)

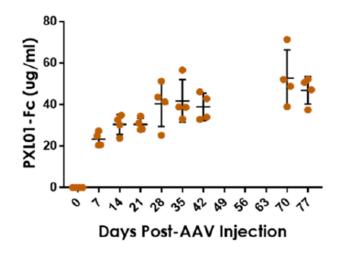
- >75% reduction of # rats with extensive adhesions
- Sustained peptide levels for 48 hrs. with SH (= sodium hyaluronate formulation) compared to distilled water (dH2O)
- No safety concerns





## 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
  - 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)

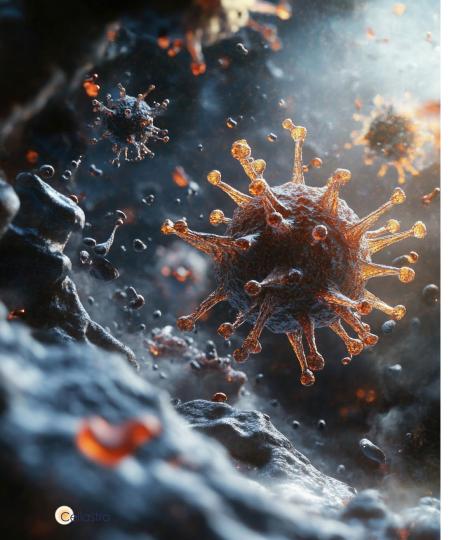
B: US Patent 11,891,429 B2

#### 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







## **Pulmonary Fibrosis**

Virus or other factor leads to inflammation which causes vascular endothelial damage, microthrombi formation, complement activation, and tissue damage

- Initial inflammation leads to immune system activation, excess cytokine formation and release, immune cell and fibroblast migration into site
- Tissue damage in alveoli and other lung tissues leads to acute respiratory distress syndrome or ARDS; secondary infections common in ARDS
- Fibroblast and myofibroblast activation contribute to fibrotic changes in lungs
- Pulmonary fibrosis and lung tissue damage lead to respiratory failure

## Scarlexa for prevention of hypertrophic scarring

### **Breast implants**



- Globally 1.5 M pts/year. About 10-15% of subjects with implants develop capsule contracture, often requiring re-surgery
- Subjects also can develop a hypertrophic scar at the incision site (often under the breast)

### **C-Sections**



- Globally 35 M (US 1.6 M) procedures/year.
   Hypertrophic scarring develops in up to 60% of subjects in China; less in US
- Adhesions (internal scars) can lead to sterility and bowel obstruction, which can be fatal











### 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 & CFO

- 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

#### CMO. FVP

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



Henrik Kulmala, PhD

#### EVP Product Dev/Regulatory

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



**Brad Thompson, PhD** CTO, Chair SAB

- 35+ vrs. . 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 HP
- Sony Optiarch / Electronics



**Bruce Phillips CPA CFO** 

30+ vrs. 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



**Core Team** 

& Advisors

# Cellastra Pipeline (incl. potential partnering)

Tech- nology	Product	Indica- tion	Preclinical	Phase 1-2	Phase 3	Comment
AAV Vector for Inhalation	Fibrexa	Respiratory infections / fibrosis		Emergency Use Year	3?	BLA Year 4
AAV Vector for Injection	Scarlexa	Dermal scar Breast Implant				BLA Year4
		Dermal Scar C-Section* Burn injuries**				BLA Year 4

<sup>\*</sup>May include other surgical indications if Agencies agree

BLA = Biological License Application



<sup>\*\*</sup>External explorative study by Swedish Consortium

## **Preliminary Budget (\$1,000)**

Product	Year 1	Year 2	Year 3	Year 4	Total
Fibrexa	5,550	5,550	6,400	6,800	24,500
Scarlexa	950	7,050	9,450	11,200	28,650
Total External	6,500	12,550	15,850	18,000	53,150
Operations	1,560	3,012	3,804	4,320	12,696
Total Cost	8,060	15,562	19,654	22,320	65,846
Revenue Fibrexa			187,000*	2,500,000 **	

<sup>\*</sup>Assuming Emergency Use Authorization in the US by Q4 Year 3

<sup>\*\*</sup>Assuming Full Approval by Q4 Year 4



# **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
- Market Projections of \$2.5 B by Year 4





## Market Projections (\$1,000)

Product	Year 3	Year 4	Year 5	Year 6	Year 7
Fibrexa EUA *	187,000				
Fibrexa		2,500,000**	7,750,000	7,750,000	7,750,000
Scarlexa				7,141,000	7,450,000
	187,000	2,500,000	7,7500,000	14,900,000	15,200,000

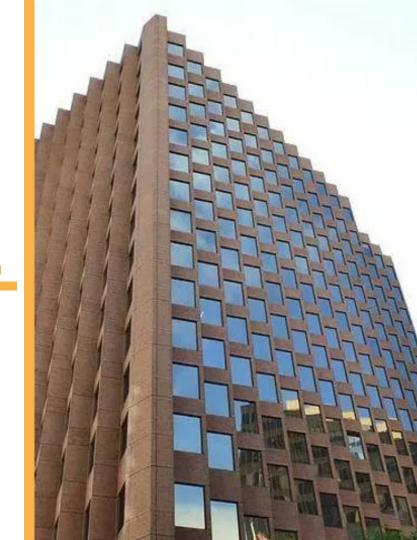
Potential EUA (Emergency Use Authorization) in the US Year 3



<sup>\*\*</sup> Full approval by Q4 Year 4

### Series A Offer

- \$25 M in year 1\*
- Manufacturing, Formulation,
   Preclinical Studies
- GMP Manufacturing
- IND (pre-IND conference)
- Phase 1-2 clinical trials
- Followed by Series B or Exit Year 2-3



Cellastra\* May include a Seed Round of 1+5= 6M

### **Forward Looking Statement**

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