



# Pioneering Targeted Scar Prevention at Wound Sites

Pulmonary Fibrosis | Burn Injuries | Surgery

## 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



Cellastra



# Scar prevention: Global unmet needs

## PULMONARY FIBROSIS

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

## DERMAL SCARRING

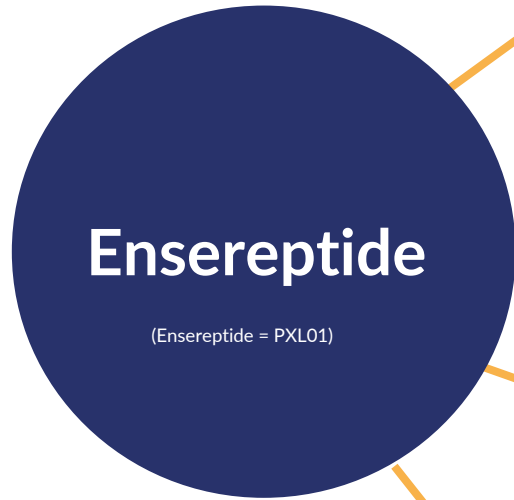
- Post-Surgery
- After Burn Injuries

## Long COVID

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

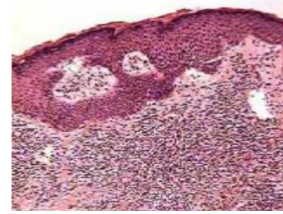
**NO EFFECTIVE DRUGS ON THE  
MARKET**

# Enseptide targets root causes of tissue injury & scarring



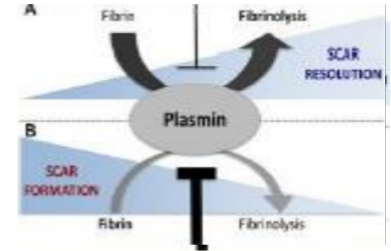
## Anti-inflammation

- Reduced cytokines
  - Reduced infiltration by white blood cells
  - Reduced tissue edema
  - Reduced blood vessel leakage



## Anti-fibrin

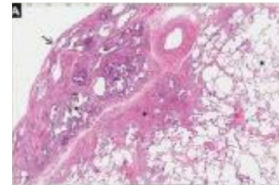
- Reduced PAI and clots
- Improved microcirculation & tissue healing



## Anti-microbial



## Anti-fibrotic



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 (Nilsson et al., 2009)
- Rabbit digit model (Hakansson et al., 2012)
- Human hand surgery (Wiig et al., 2014)

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

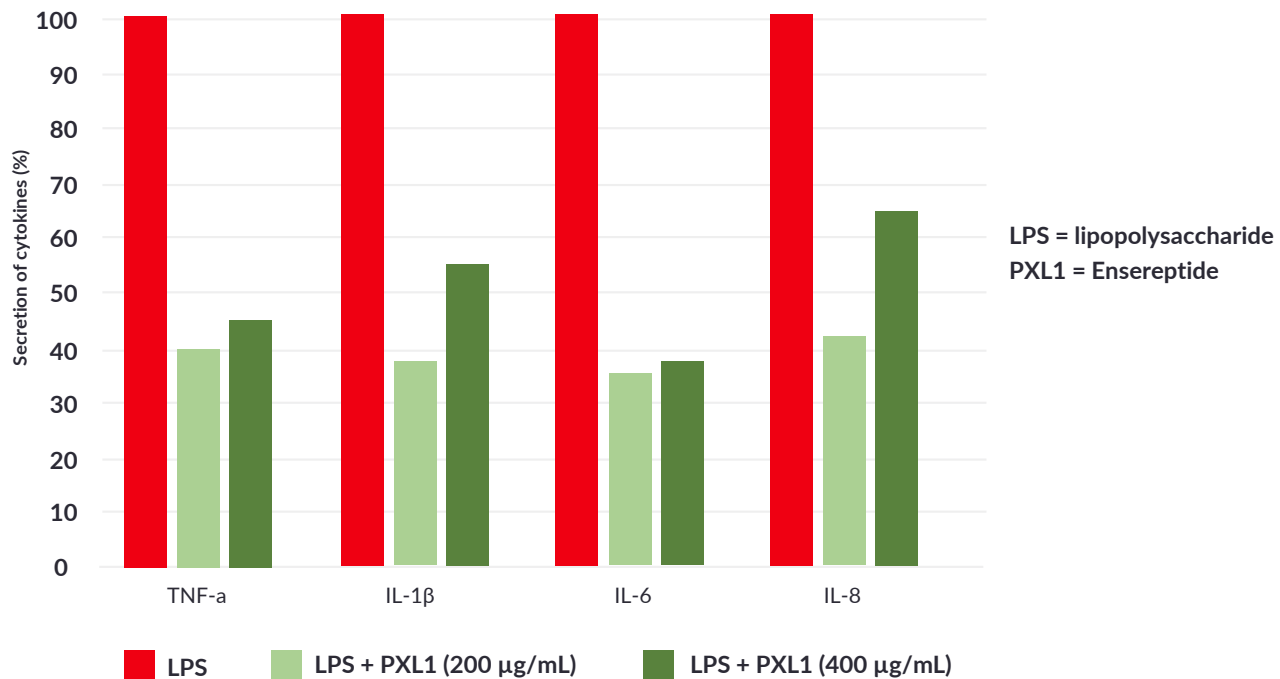
- Lower immunogenicity (van Lieshout et al., 2018)
- Higher transgenic expression in muscle (>100-fold) and lung (49-fold) at 24 hours
- Robust long-term expression of AAV6.2FF-ensereptide-Fc in mice following single intramuscular administration (Kulmala et al., 2020)
- Acute toxicity (mice, sheep) and chronic pharmacology studies (sheep) support safety of AAV6.2FF capsid (Rghei et al., 2021)

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



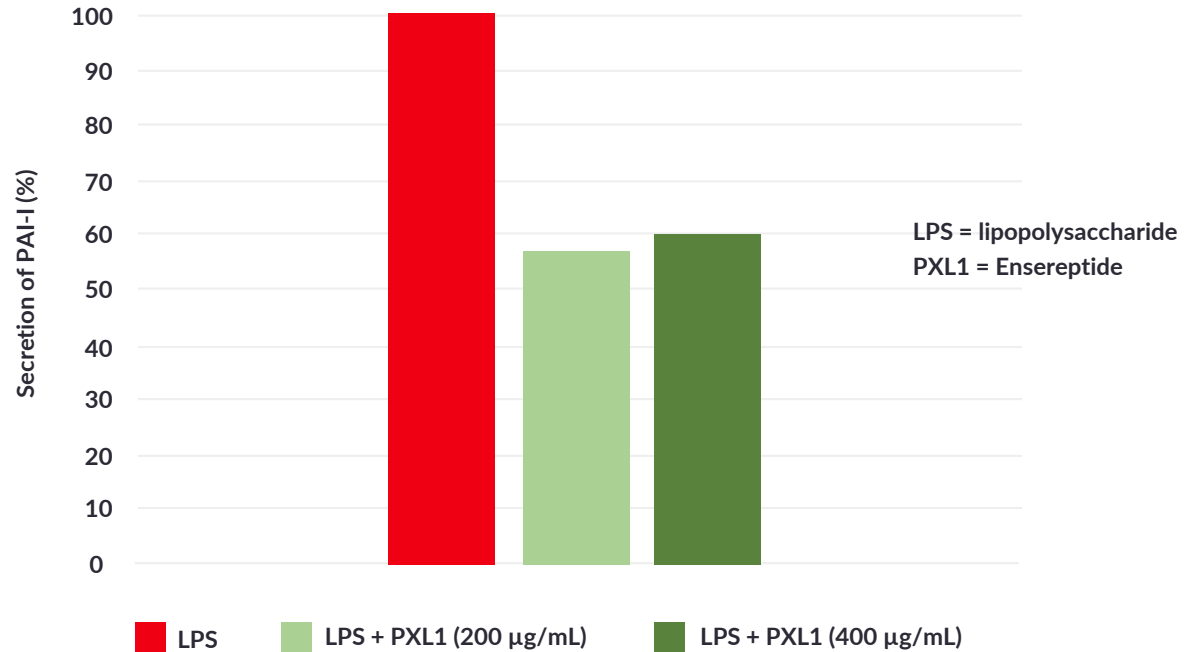
# Ensureptide mitigates inflammation in vitro

40–60% reduction of cytokines



# Ensureptide mitigates fibrin formation in vitro

40% Reduction of Plasminogen Activator Inhibitor (PAI)





# Ensereptide has antimicrobial effects in vitro

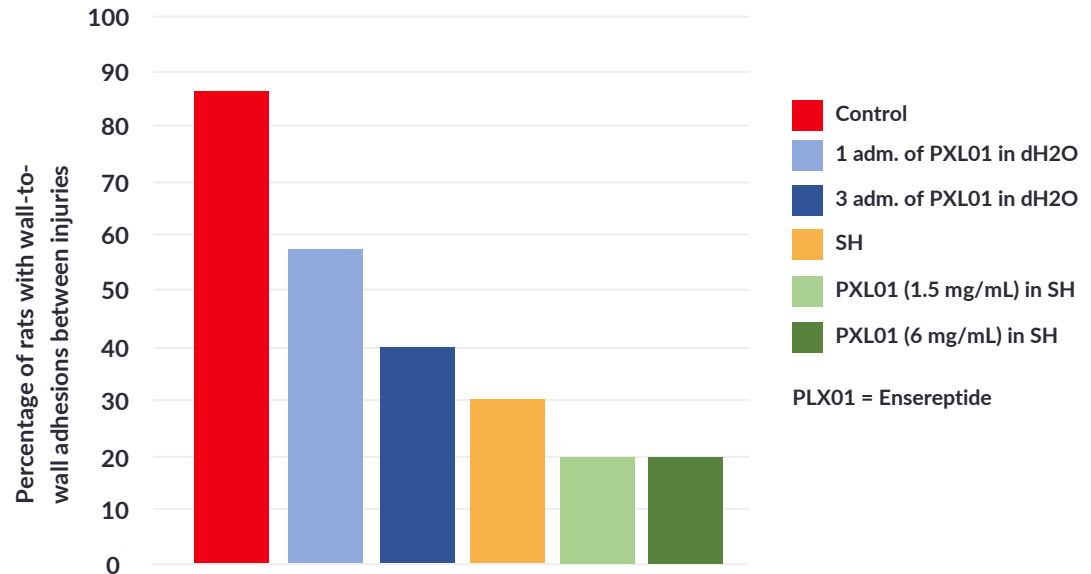
Ensereptide (PXL01) is 40-80 X more potent antibacterial than lactoferrin in vitro

	<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.)

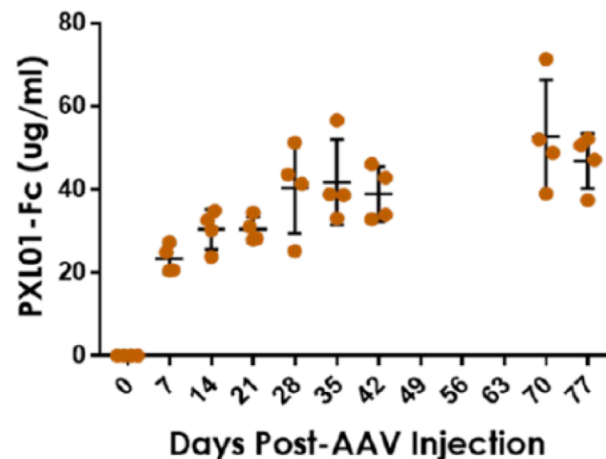
# Enserpeptide anti-scar/adhesion effect (rat)

- >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



# Robust expression of Enseptide (in mouse)

- Robust expression in mouse plasma until sacrifice on Day 77
- Intramuscular admin. of encoded vector for enseptide (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  $1 \times 10^{10}$  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.**



# 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 can develop a **hypertrophic scar** or **Keloid** at the incision site (often under the breast, as shown in image above).

## 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 enserpeptide-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

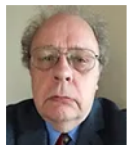
- 40 yrs. exp. incl leadership positions Kabi, Pharmacia
- Active Biotech, Isconova, Novavax,



## 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

- 35+ yrs. , incl BIOTECCanada
- 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 C and

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

# Cellastra Pipeline

## (incl. potential partnering)

Tech-nology	Product	Indica-tion	Preclinical	Phase 1-2	Phase 3	Comment
AAV Vector for Inhalation	<b>Fibrexa</b>	Respiratory infections / fibrosis	<p><i>Possible Emergency Use Year 3</i></p>			BLA Year 4
AAV Vector for Injection	<b>Scarlexa</b>	Dermal scar Breast Implant				BLA Year 4
		Dermal Scar C-Section <sup>b</sup> Burn injuries <sup>c</sup>				BLA Year 4

<sup>a</sup> Only single Phase 3 required hence the shorter time in Phase 3

BLA = Biological License Application

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

<sup>c</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
<b>Total Cost</b>	<b>8,060</b>	<b>15,562</b>	<b>19,654</b>	<b>22,320</b>	<b>65,846</b>
Revenue Fibrexa			187,000*	2,500,000 **	

\*Assuming Emergency Use Authorization in the US by Q4 Year 3

\*\*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	7,750,000	14,900,000	15,200,000

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

\*\* 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





# Forward Looking Statement

- Certain information set forth in this presentation contains “forward-looking information”, including “future oriented financial information” and “financial outlook”, under applicable securities laws (collectively referred to herein as forward-looking statements). Except for statements of historical fact, information contained herein constitutes forward-looking statements and includes, but is not limited to, the (i) projected financial performance of the Company; (ii) completion of, and the use of proceeds from, the sale of the shares being offered hereunder; (iii) the expected development of the Company’s business, projects and joint ventures; (iv) execution of the Company’s vision and growth strategy, including with respect to future M&A activity and global growth; (v) sources and availability of third-party financing for the Company’s projects; (vi) completion of the Company’s projects that are currently underway, in development or otherwise under consideration; (vi) renewal of the Company’s current customer, supplier and other material agreements; and (vii) future liquidity, working capital, and capital requirements. Forward-looking statements are provided to allow potential investors the opportunity to understand management’s beliefs and opinions in respect of the future so that they may use such beliefs and opinions as one factor in evaluating an investment.
- These statements are not guarantees of future performance and undue reliance should not be placed on them. Such forward-looking statements necessarily involve known and unknown risks and uncertainties, which may cause actual performance and financial results in future periods to differ materially from any projections of future performance or result expressed or implied by such forward-looking statements.
- Although forward-looking statements contained in this presentation are based upon what management of the Company believes are reasonable assumptions, there can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. The Company undertakes no obligation to update forward-looking statements if circumstances or management’s estimates or opinions should change except as required by applicable securities laws. The reader is cautioned not to place undue reliance on forward-looking statements.





 Cellastra

[cellastra.com](https://cellastra.com)