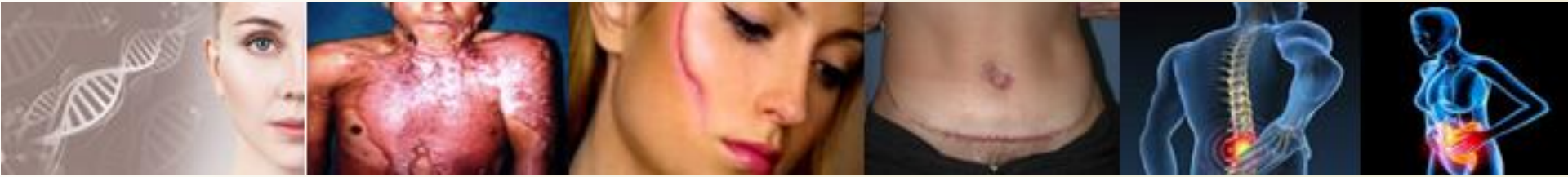
Cellastra

DELIVERING THE GENETIC CODE TO THE WOUND FOR SCAR-LESS HEALING

Global Unmet Needs in Surgery, Burns, and Trauma

www.cellastra.com



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.
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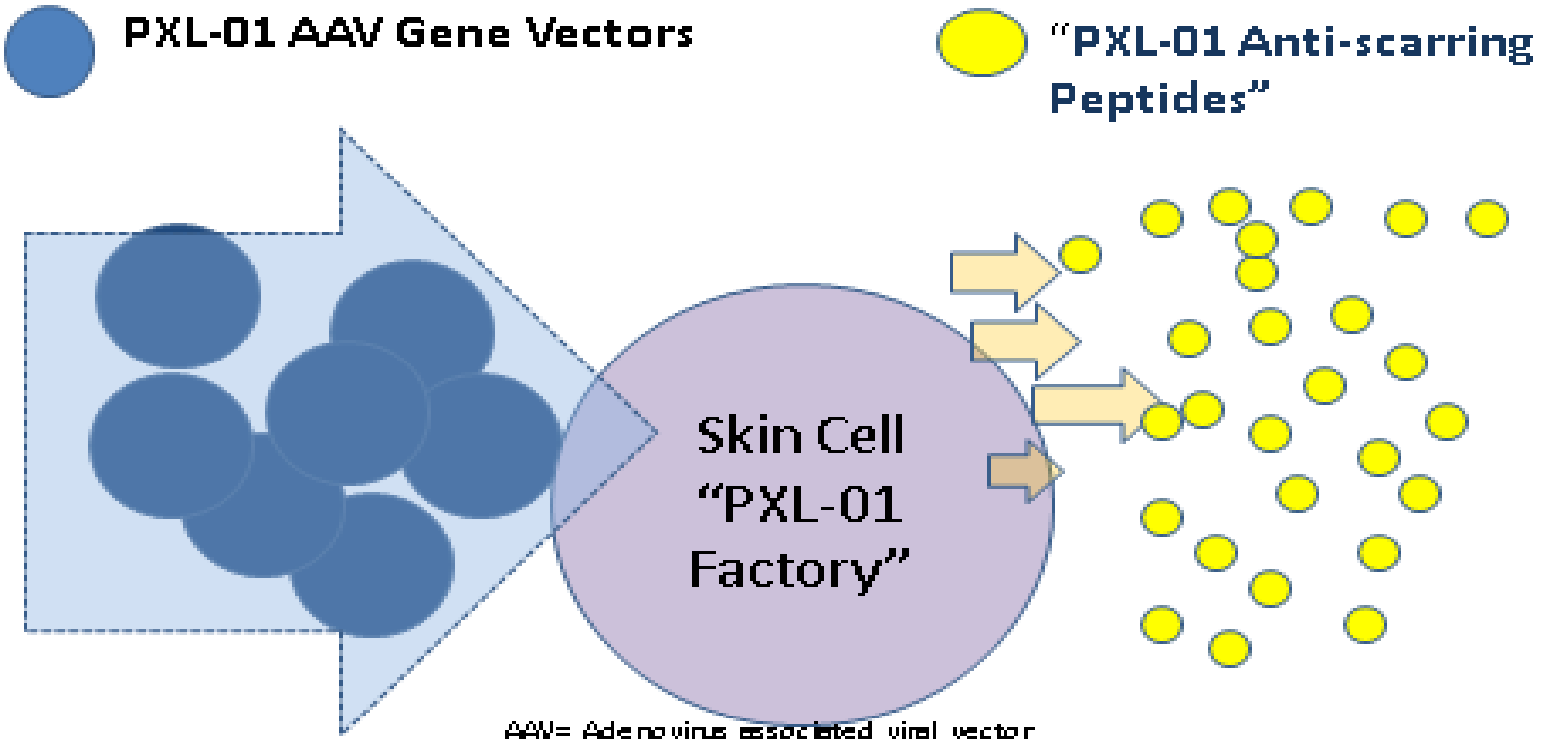
New intellectual property

”New method for endogenous production of lactoferrin derived sub-peptides (including PXL01 sequence) for prevention of scars and adhesions at the site of injury”

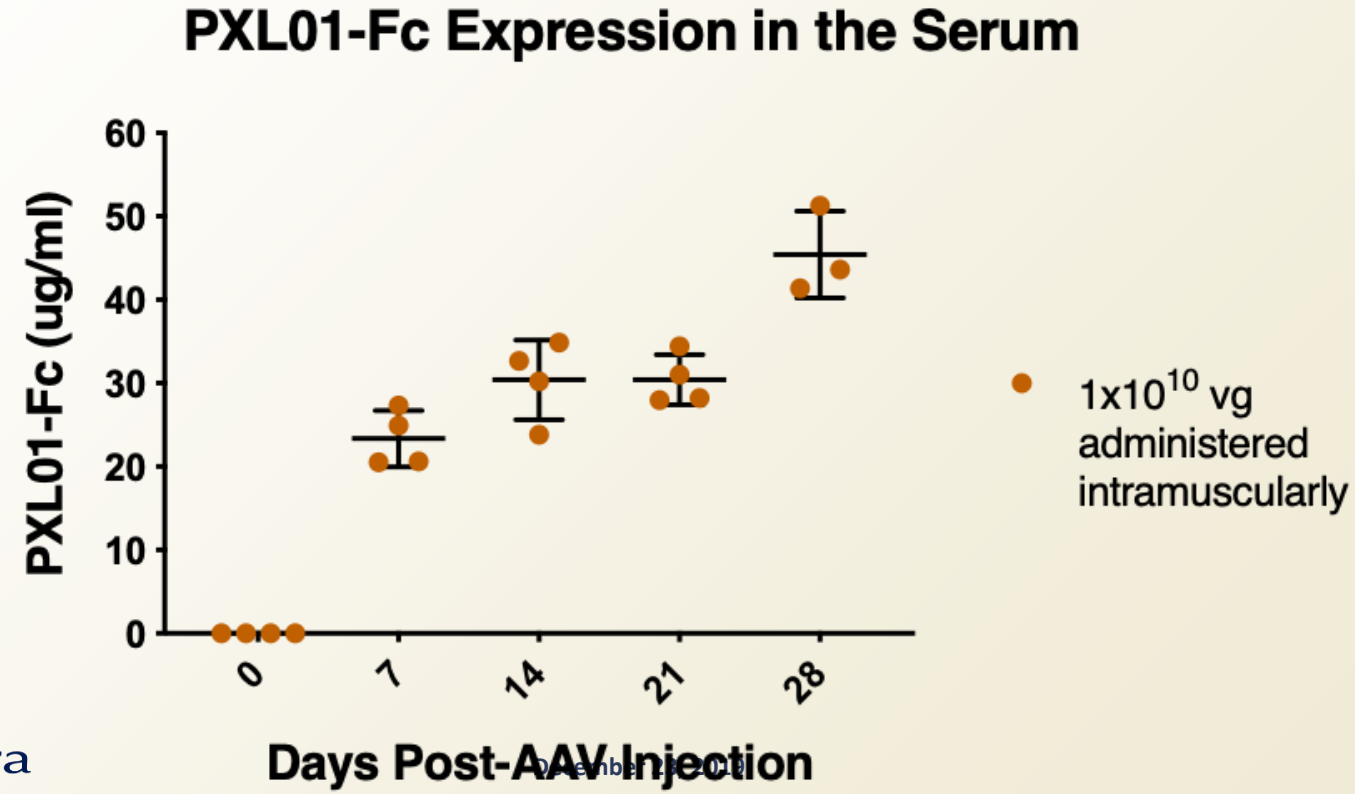
- **US patent application 16/037,769 Filed July 17, 2018**
- **PCT application 116.012WO Filed July 15, 2019**
- **Multiple uses and routes of administration of gene vector**

CELLEXA


PXL-01 AAV Gene Vectors
"PXL-01 Anti-scarring Peptides"
Skin Cell "PXL-01 Factory"
AAV= Adenovirus associated viral vector
PXL01= Lactoferrin sub peptide sequence

Robust Expression of PXL01 ≥ 28 Days

FcIgG tag added to measure expression



Exposure to Treatment at site of Injury

CELLEXA

- Long Term Expression enables Treatment exposure for >28 Days
- Long term exposure likely to enable more effective scar prevention

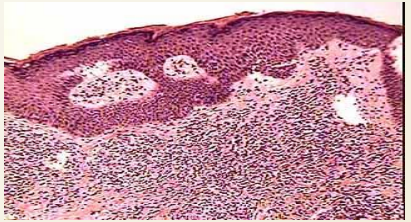
PXL01 in Hyaluronic acid

- Treatment effect < 2 Days

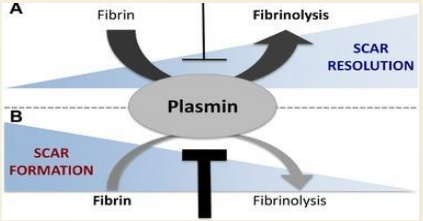
PXL-01 Anti-scarring Mechanisms

PXL-01

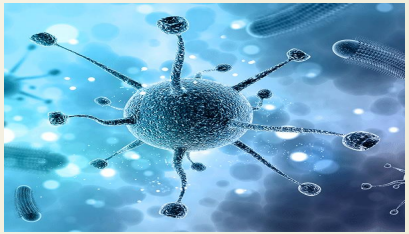
Attenuates Inflammation



Attenuates fibrin formation



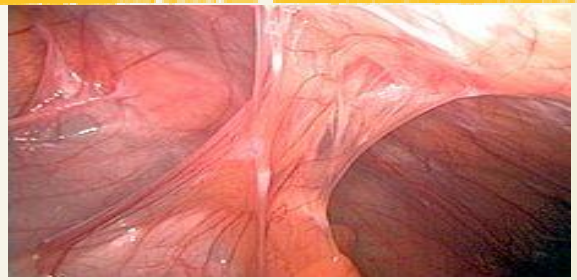
Anti-microbial

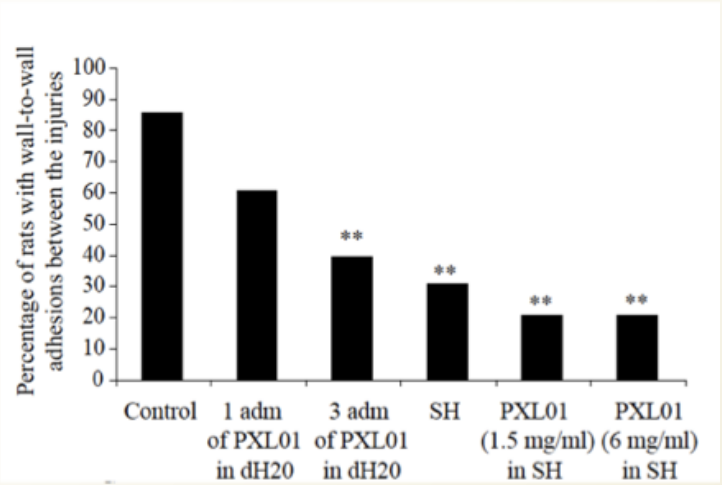


Nilsson E et al, Ann Surg . 2009,250(6):1021-8.

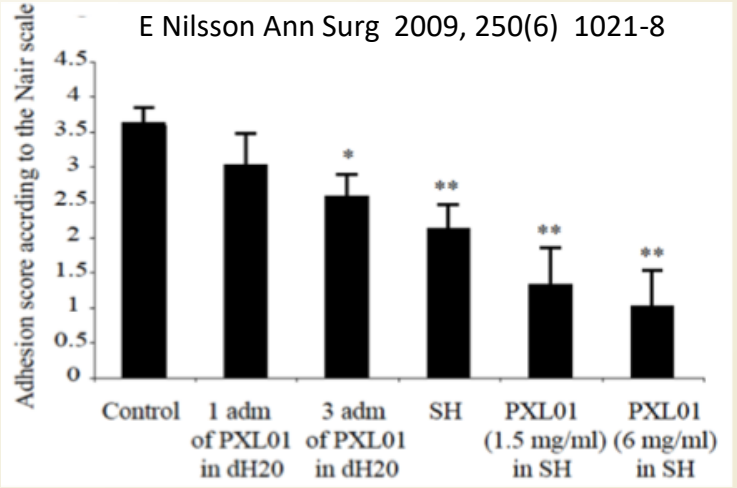
PXL-01 in Hyaluronic Acid – Proof of Concept

- **Rat multiple abrasion model**
  - **Gold standard for the assessment of scar prevention**
  - **Abrasion of cecum is combined with a full thickness injury on the lateral abdominal wall**





E Nilsson Ann Surg 2009, 250(6) 1021-8



PXL-01 in Hyaluronic Acid: Clinical Phase 2

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

Gene therapy – The new race

- 12/2017 First gene therapy approved by FDA: Luxterna from Spark Bio -RPE mutation associated blindness (retinal defect)
- 2018: Gene therapy companies raised > $9B, up 64%
- 2018-19: several companies acquired for 800M – 7B USD
- 7/2018: FDA released 5 new draft gene therapy Guidelines
- 2019 FDA announced 50 new hires to expedite review

ONE SINGLE TREATMENT MAY HAVE LONG-TERM BENEFIT

Scarring/Adhesions - Global Unmet Needs

- Dermal severe (“hypertrophic “) scarring <35 % in Caucasians and 65 % in Chinese / Asians
- Burn injuries: 70-90%
- Back surgery (Lumbar laminectomy): 20-40 % failure often due to adhesions/scarring /pain – may require new surgery
- Abdominal and gynecological (pelvic) surgery – adhesions in 50-90% - may cause bowel obstruction, infertility and death
- MULTIBIOLLION DOLLAR MARKETS - NO EFFECTIVE TREATMENT OR PREVENTION ON THE MARKET

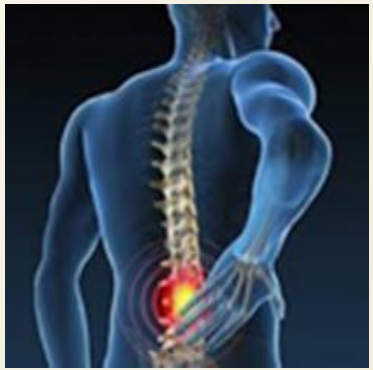
CELLEXA Product Candidates

CLX-001
Topical Spray or Gel

Burn injuries

CLX-002
Topical Gel or Injection

Scars after surgery - face, neck, mammoplasty, C-section



CLX-003
Injection

Adhesions, orthopedic, hand and abdominal surgery

CELLEXA

- CELLEXA: Disruptive gene therapy to prevent pathological scarring without interfering with normal wound healing and hemostasis.
- AAV vector with genetic program – turns target cells (e.g. skin cells) into “factories” to produce the lactoferrin anti-scarring sub-peptide, PXL01
- IP filed July 17, 2018 and July 15, 2019
- Swedish MPA and FDA (“Pre-IND”) meeting to define preclinical and studies
- Formulation for topical use or injection in wound
- Applied once in the wound area – Long term prevention of excessive scar
- Phase 1 dose finding followed by phase 2-3 clinical studies

3-4 years to market - $24M estimated development cost

Opportunity

CELLEXA Clinical studies

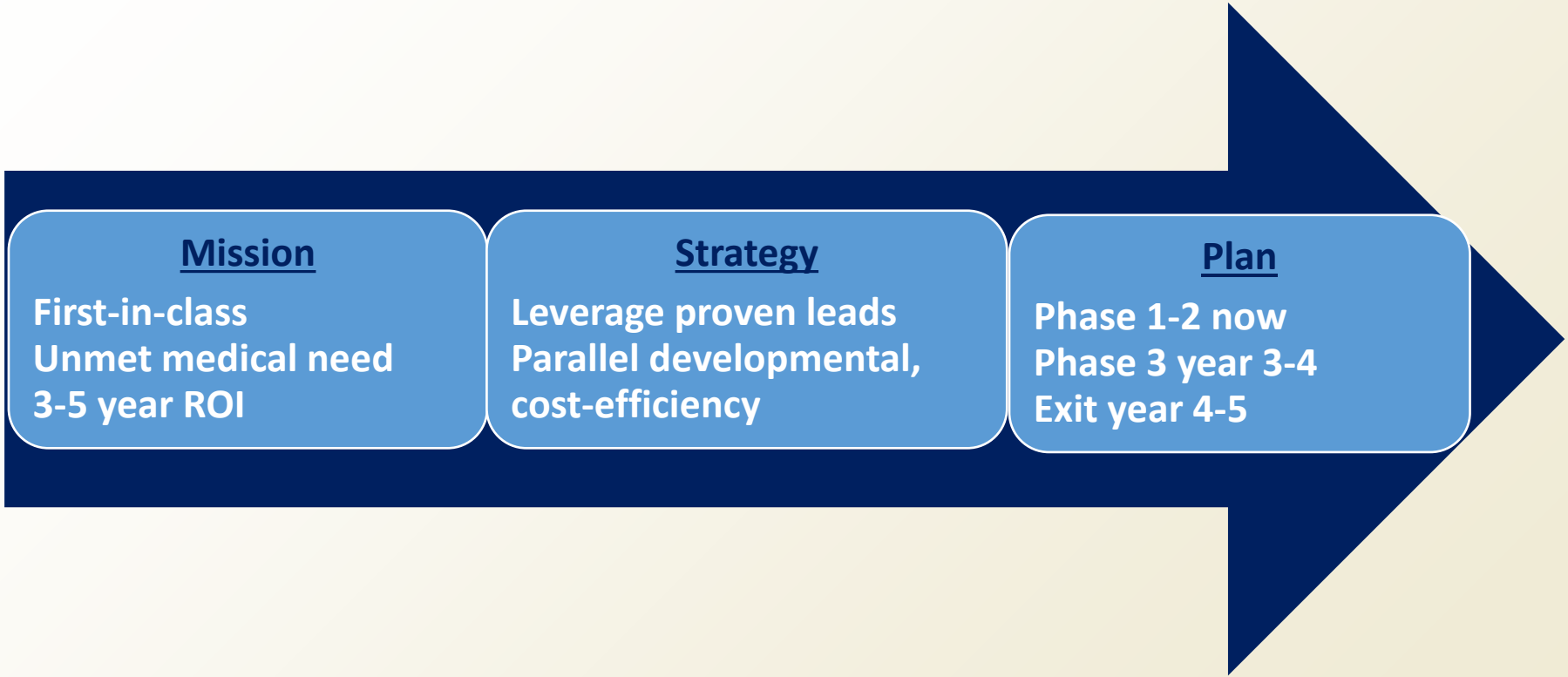
- Formulation for topical use or injection in wound as applicable
- Burn injuries: Apply thin layer once by spray or ointment immediately prior to skin grafting
- After surgery or other injury: Apply immediately as gel in wound area before wound closure or as subcutaneous injection within 3-4 days
  - Phase 1 proof of concept: Dose-ranging (n = 30)
  - Randomized, blinded, placebo-controlled, phase 2-3 study (n = 120)
  - Randomized, blinded, placebo-controlled, phase 3 study (n = 240)

CELLASTRA Preliminary budget ($1,000)

	2019	2020	2021	2022	Total
Preclinical	950	750			**1,700**
Drug/CMC	400	1200	1,800	1,800	**5,300**
Clinical					
Phase 1	700				**700**
Phase 2		1,800	1,800		**3,600**
Phase 3			3,600	3,600	**7,200**
Total study	**2.150**	**3,750**	**7,200**	**5,400**	**18,500**
Total operations	**750**	**1750**	**1,750**	**1,750**	**6,000**
Grand total	**2.900**	**5,500**	**8,950**	**7,150**	**24,500**

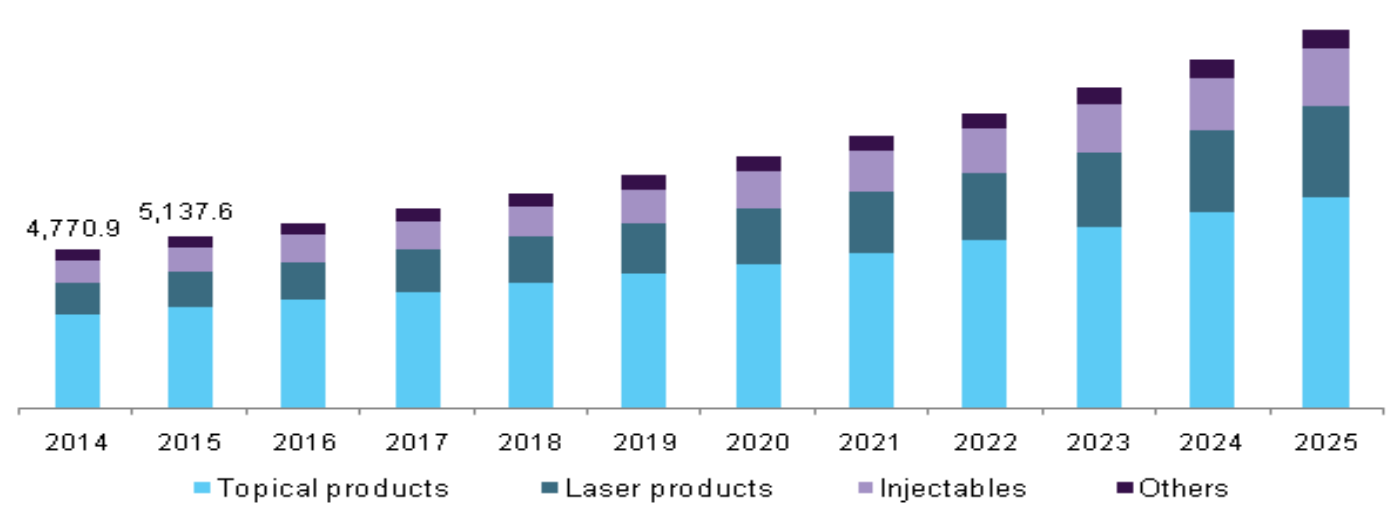
- **Limited toxicology needed – natural lactoferrin derived anti-scarring peptides already found to be safe**
- **Gene vector IMP 10k/patient**
- **Clinical CRO study cost 15k/patient**
- **Site cost 15k/patient including long term follow up**
- **Operation costs for administration, fund raising, IP, coordination of CROs, and business development**

Execution


Mission
First-in-class
Unmet medical need
3-5 year ROI
Strategy
Leverage proven leads
Parallel developmental, cost-efficiency
Plan
Phase 1-2 now
Phase 3 year 3-4
Exit year 4-5

Global Dermal Scarring Market

- **Dermal scarring market 2015-2025 (from $13.8B to $34.5B)**



- **Large unmet need – mainly topical OTC products with low level of demonstrated benefit in meta analysis of 1,703 pts in 39 studies**

Sidgwek et al., Arch Dermatology Res, 2015, 307:461-477)

Offer

- **Series A**
  - **$10M in year 1 (Ongoing)**
  - **Dermal scarring Phase 1-2 clinical trials**
- **Series B**
  - **$7.5M in year 2**
  - **Dermal scarring phase 2 -3 clinical trials**
- **Series C**
  - **$7M in year 3**
  - **Dermal scarring phase 3 clinical trials**

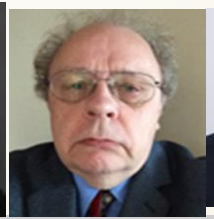
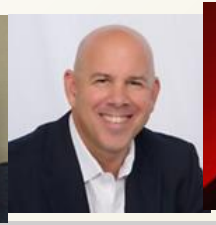
Value proposition

- Proven management team
- First-in-class, disruptive anti-scarring gene therapy - ”targets root causes”
- CELLEXA has potential for long-term effect after single dose
- Preclin. & clinical Phase 2 Proof of Concept for the peptide established
- Huge unmet need -No effective pharmaceuticals for scar prevention on the market
- Dermal scar market projected to reach 34.5 B USD by 2025
- Follow-on products for burn injuries, orthopedic , abdominal / pelvic adhesions: Multi-$B potential markets expansion
- Attractive early exit opportunity and valuation in 1-5 years

Back Up Slides

Team, Product Label and Market Projections

Management team

Karl Mettinger KMD, PhD President / CEO Director, Cofounder	**Brad Thompson** PhD CTO, Director	**Henrik (Hank) Kulmala ,** PhD	**Bruce Phillips.** CPA CFO	**Daniel Quintero Esq**. General Counsel, Corporate Secretary	**Kent Persson** PhD Exec. Advisor, Swedish Coordinator
30+ years Biotech • Ass Prof Karolinska Dep. Gen Mgmr Kabi Cardiovascular, • Exec Dir IVAX • CMO Supergen, Oncolytics, • Consult Pharmacyclics, Tissue Genesis	• 30 years Biotech • Chair CANADABiotec, • Head Biotech Alberta Res. Council, • CEO Oncolytics Biotech, • Cpfounder, CEO KickShaw	30+ Years Biotech • Ass. Prof NW Ohio Univ College • NDAs, MAAs, INDs for 75 drugs • Marion Merril Dow, Fujisawa, Curatek, VP RA Quark, Genix.	1. 30+years Ernst & Young, Founding Partner, and CEO of HPC (Harshman, Phillips & Company), 2. Merged with Aprio in 2019,.	• 20 Yyrs. legal experience • Gen Councel ,Corp Secretary Sony Optiarch, Sr Managing Councel, Dir Sony Electron. • Founding Partner Prometheus	20 years Biotech • Post Doc UCSF, • Sr. Scientist Bi- Rad, Octaphama, • Co-organizer Swed. American Stem Cell Conference, SF

Board & Scientific Advisory Board

Board

- **Alan Lewis, PhD,** Exec Chair, 40+ yrs., Wyeth, Celgene, NovoCell, JDRF, Ambit, MediStem DiaVacs, BOD BioMarin
- **Karl Mettinger MD, PhD,** 30+ yrs exp., President & CEO of Cellastra, see above
- **Sven Andreasson,** 35+ yrs, Kabi, Pharmacia, Active Biotech, NovaVax
- **Brad Thompson, PhD**, 35+ yrs exp, see prev
- **Dan Quintero., Esq,** 20+ yrs, see above
- **Kent Persson, PhD**, 20+ yrs. exp, see prev

Scientific Advisory Board (SAB)

- **Larry Couture, PhD,** NIH, Genzyme, City of Hope, CEO Orbsen Pharma Arrogen Inc
- **Christopher Evans, PhD,** Professor Harvard, Mayo Clinic
- **Folke Sjoberg, MD, PhD,** Professor Burn Center LIU, Sweden, International KoL
- **Kent Persson, PhD,** Molecular Biologist, Cofounder of Cellastra, UCSF, Bio-Rad,, Octapharma
- **Magda Forsber, PhD,** Karolinska Institute, CEO Device company DVL-Op

CELLEXA Proposed initial product label

- **Indications and usage**
  - **CELLEXA is indicated for topical treatment or injections to prevent dermal scarring after burn injury, surgery or trauma in patients 18 years of age or older with a risk of developing hypertrophic or disfiguring scarring**

- **Dosage and administration**
  - **Apply a thin layer of CELLEXA by spray or gel after burn injury/surgery or inject subcutaneously or intra dermally to affected wound areas**
  - **CELLEXA is for topical use or subcutaneous/intradermal injections only**
  - **Not for ophthalmic, oral or intravaginal application**

Surgery: Dermal scarring market N. America*

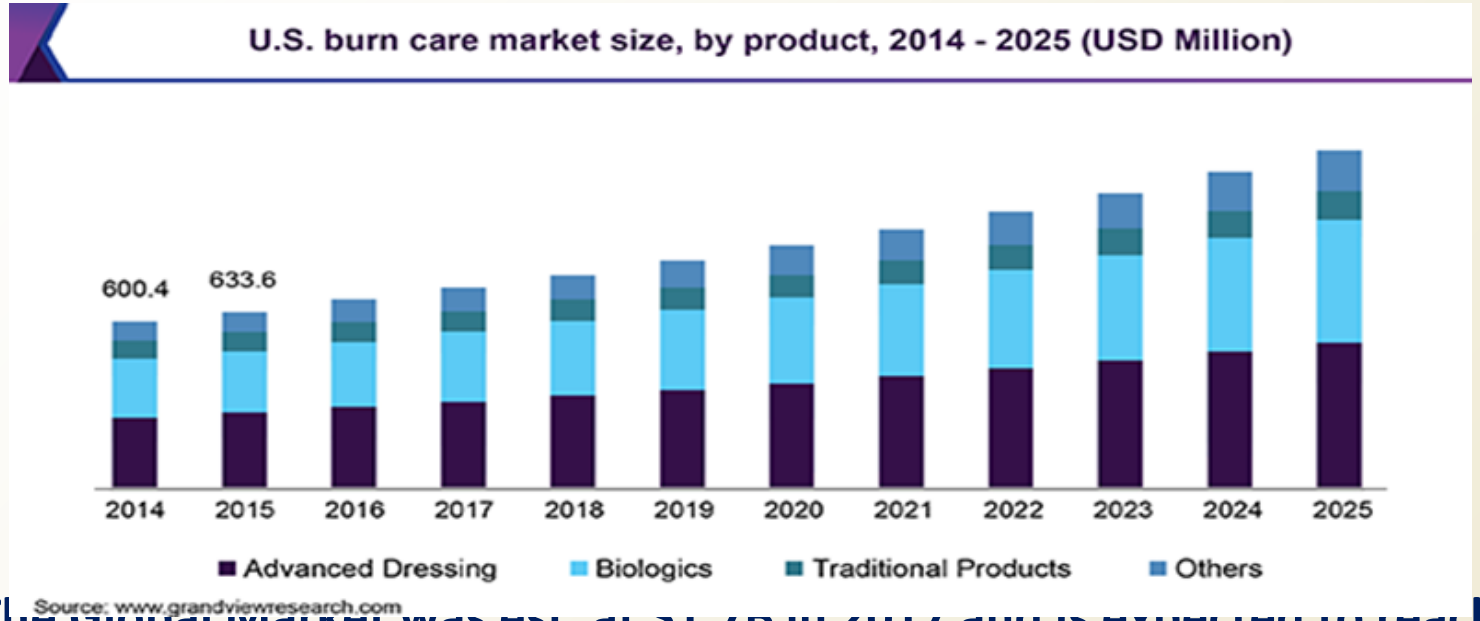
	USA	Canada	Patients
Tendon Repair			
Hand Injuries	250,000		
Ob/Gyn			
C section	1,242,000	102,300	1,344,300
Hysterectomy	193,440	25,484	218,924
Abdominal			-
Inguinal Hernia	390,630	56,881	447,511
Colorectal resection	306,000		306,000
Orthopedic			-
Knee arthroplasty	752,000	63,000	815,000
Outpatient	571,000		571,000
Hip Replacement	522,000	53,000	575,000
Bone part. excision	358,000		358,000
Spinal laminectomy	468,000		468,000
Spinal fusion	438,000		438,000
Plastic Surgery			
Breast Augment.	290,000	279,000	569,000
Breast Reduction	39,000		39,000
Nose Reshaping	223,000	218,000	441,000
Abdominoplasty	127,000	128,000	255,000
Facelift	131,000		131,000
Total Patients	**6,301,070**	**925,665**	**6,976,735**

*Figures represent major target indications out of more than 22 million surgical procedures annually in US alone

Surgery Market Assumptions N. America

- Annual number of surgeries in target indications: 6,976,000
- 10 percent (low estimate) with hypertrophic scarring (HTS): 697,600
- 5 percent with previous history HTS : 348,800
- Year 1 Market penetration 5 %: 17,440
- Year 5 Market penetration 25 % : 87,200
- Year 5 est. price of 25k to 50k per patient represents est. annual revenue of 2.18 – 4.36 B USD

US Burn Injury Market



- The Global Market was est. at $1.7B in 2017 and is expected to reach $2.98B by 2025.

Burn Injury Statistics US

- > 1.25 million burn injuries annually
- 4th leading cause of accidental death
- 600,000 Emergency Room visits
- 486,000 requiring complex medical treatment
- 40,000 hospitalizations / 30,000 at 127 specialized burn centers
- > $18 B spent on specialized care

American Burn Association 2018

Burn Market Assumptions US

- Annual number of burn injuries receiving medical attention: 486,000
- 70 percent with hypertrophic scarring (HTS): 340,200
- Year 1 Market penetration 10 %: 34,020
- Market penetration 25 % Year 5 on market: 85,050
- Year 5 est. price of 25k to 50k per patient represents est. annual revenue of 2.13 – 4.26 B USD
- TOTAL REVENUES SURGERY AND BURN INDICATIONS: 4.31 – 8.62 B USD

Gene Therapy - Successful Exits

Company	Founded	Funding	Main Asset	Exit	Price USD)	Acquirer
Kite	2009	• 4 funding rounds raised 8.3 M • IPO 6/2014 raised 127M	CAR T Yescarta approved lymphoma	**2017**	**30B**	Gilead
Juno	2013	• 3 rounds: 310 M IPO 12/2014 raised 264M	CAR-T NHL BLA	**2018**	**9B**	Celgene
Avexis	2010	• 4 rounds raised 75M • IPO 02/2016 raised 95M	AVX-101SMA -Spinal Muscle Atrophy	**2018**	**8.7B**	Novartis
Spark	2013	• Series A and B raised 122.8M	Luxterna approved	**2019**	**4.8 B**	Roche
NightStar	2013	• Raised total 174.6 M incl. • IPO 09/2017 $76.9M	Geneti cblimdness	**2019**	**800 M**	Biogen
Audentes	2013	Raiseed 137.5 M Ser A.B,C IPO 2016 75 M USD	Rare muscle doseases	**2019**	**3 B**	Astellas

Incidence & Risk Factors of hypertrophic scars

- Caucasians
  - Up to one third
  - More than two thirds in burns
- Afro Americans and Latinos
  - Increased incidence
- Chinese /Asians
  - Up to two thirds after surgery
- *Ri*sk Factors include
  - Darker skin color / Depth of injury / Stretching / Bacterial infections
  -

Hypertrophic Scars vs. Keloids

- May get more elevated in first six months
- Rarely genetic (Ehlers – Danlos syndrome)
- Located on shoulders, neck, sternum, knees, ankles
- More common in darker skin populations

- More elevated / extends (“claw”)
- Genetic – difficult to prevent
- Chest, shoulders, ear lobes, arms, cheeks
- High Recurrence rate (70-90%) after resection