

APS- Alimentary Protein Scaffold for Accelerated Wound Healing and Skin Regeneration

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Unmet Clinical Need

There is an unmet clinical need for simple, first-response bioactive wound dressings that would help reduce the morbidity and mortality from severe injury to the skin.

Targeting diabetic foot ulcers as first low hanging fruit, with final goals of other skin ulcerations and burn wounds (DOD).

Attributes / requirements for novel product:

- Promotes wound healing better/faster than current standard of care (good, moist wound care)
- Acts via "active wound healing" (increase in collagen + angiogenesis)
- Non-animal derived materials (allergies, religious objections)
- Significantly less expensive than current technologies

Current methods/approaches to the problem/disease

Standard of care for non-healing wounds: e.g. diabetic foot ulcers,

Conservative: dressings that keep a wound moist

e.g. Tegaderm (~ \$ 50) - limited effectiveness

Advanced: "Live" Skin Grafts / Substitutes

Acellular: Alloderm, (~\$ 750/treatment) - Cellular/TE: Apligraf, OrCel (~\$ 1,500 / 7.5 cm²) Very expensive, limited shelf life

Proposed Solution

To develop and commercialize "green" plant-derived Alimentary Soy Protein-based Scaffolds (APS) as a readily, available-off-the-shelf acellular scaffold / skin substitute which will promote accelerated wound healing.

Bioactive Wound Dressing from Electrospun Soy Protein

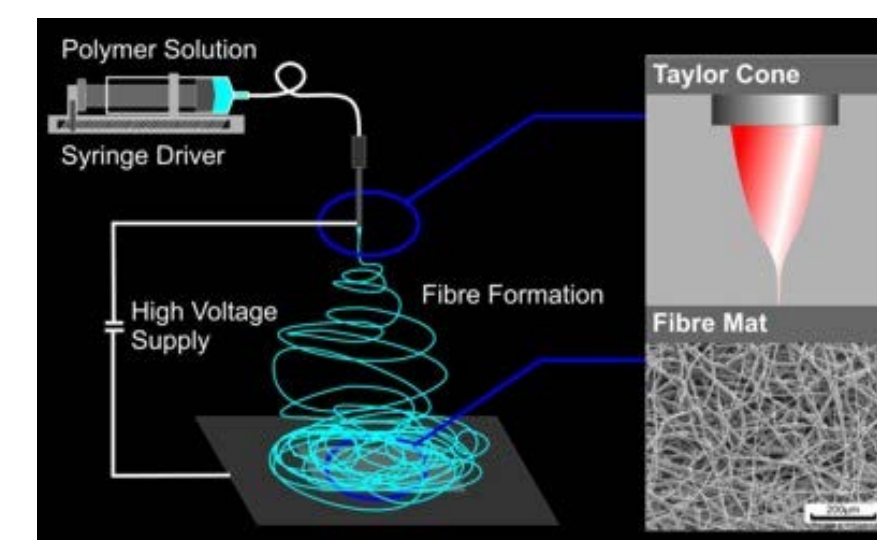
Soy beans



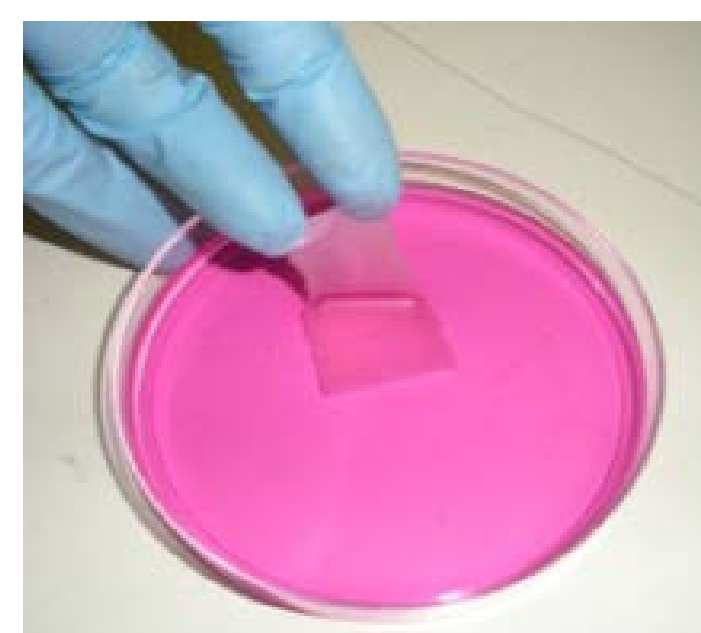
Soy protein



Electrospinning



Soy scaffold



Wound healing



Envisioned Future Health Care Product:

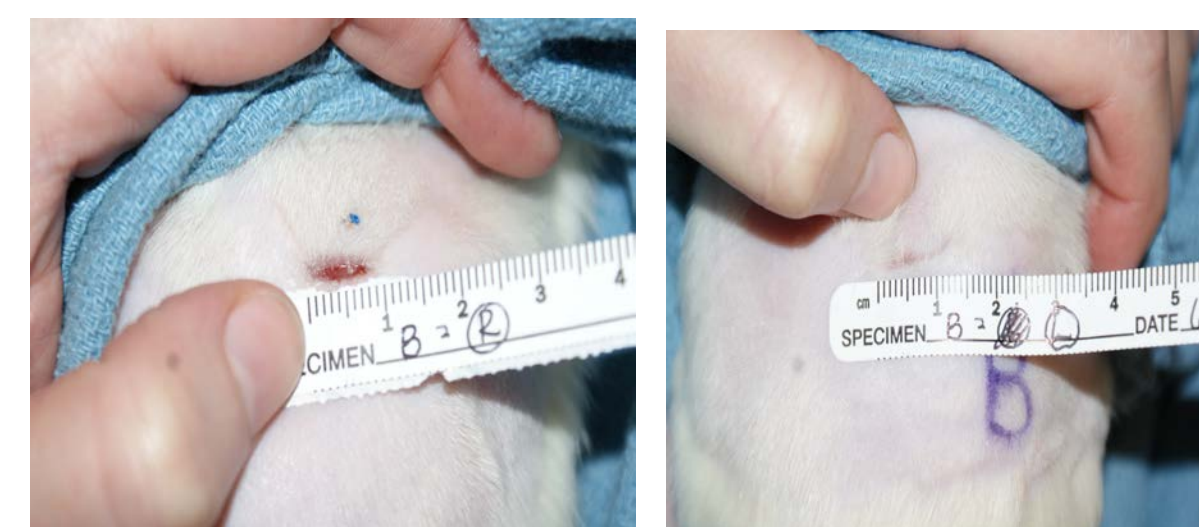
APS Scaffolds will:

be available as off-the shelf available, sterile packaged, affordable wound dressing that will enhance / accelerate wound healing over current standard of care

circumvent current and emerging problems with animal protein-based skin substitutes

meet an unmet clinical need, i.e. to provide an affordable, bioactive scaffold for wound healing.

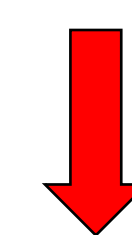
Delayed wound healing: novel rat ring model



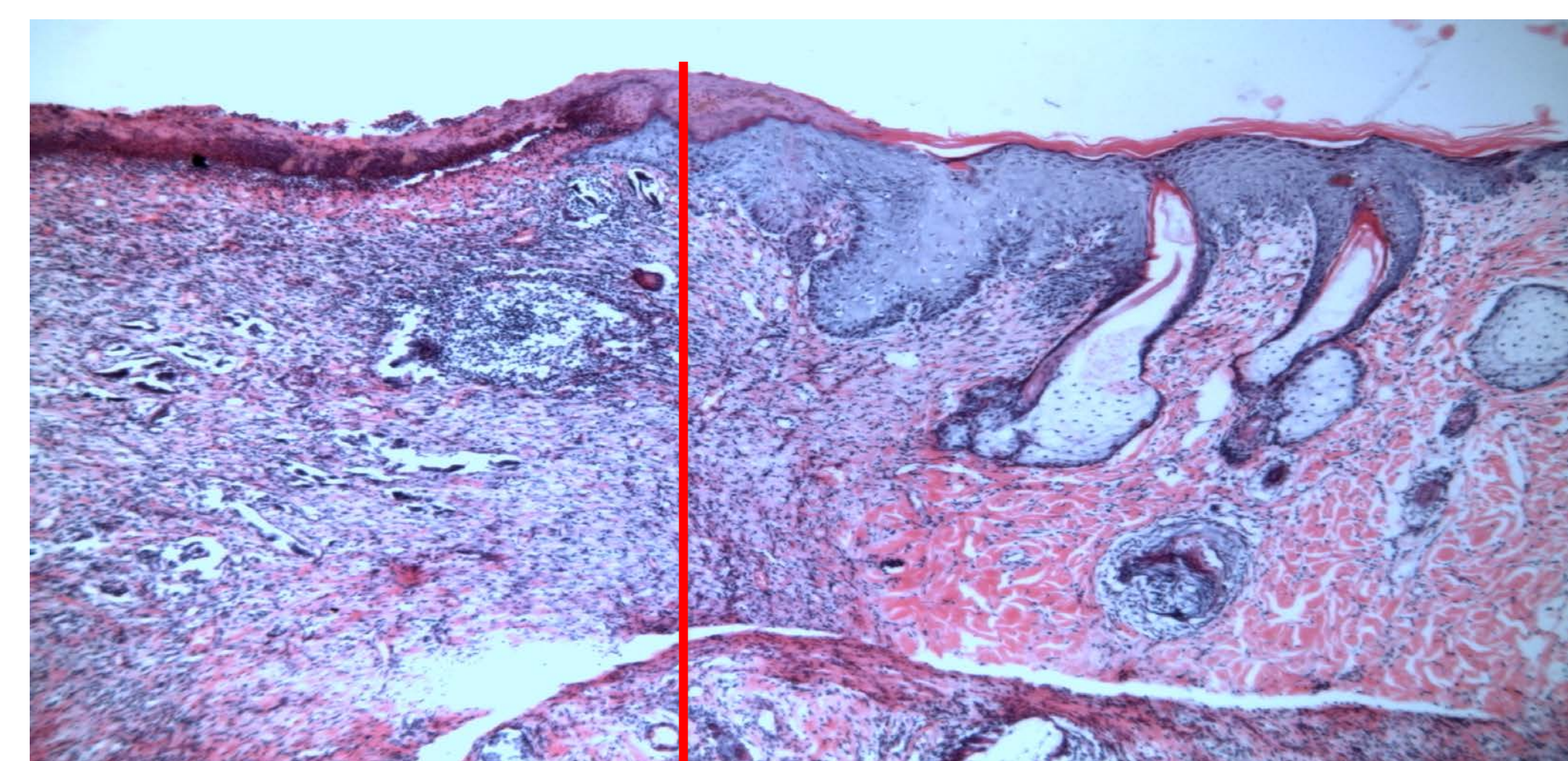
"Normal" wound healing in rats at day 18 post surgery.
Left: untreated (Tegaderm covered) control wound,
Right: wound covered with APS.



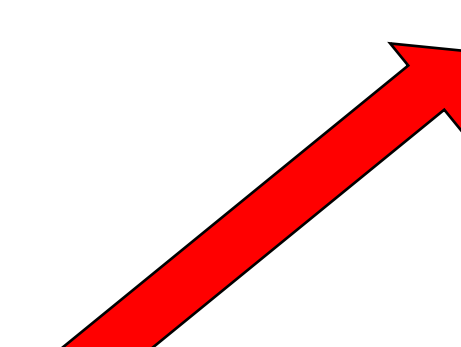
Novel ring model for delayed wound healing in rats at day 18 post surgery.
Left: untreated (Tegaderm covered) wound,
Right: wound covered with APS.



Tegaderm-treated wounds: massive inflammation and scarring



Wounded area inflammation, granulation tissue
Healthy border zone epithelial layer



Target Market / Patient Population

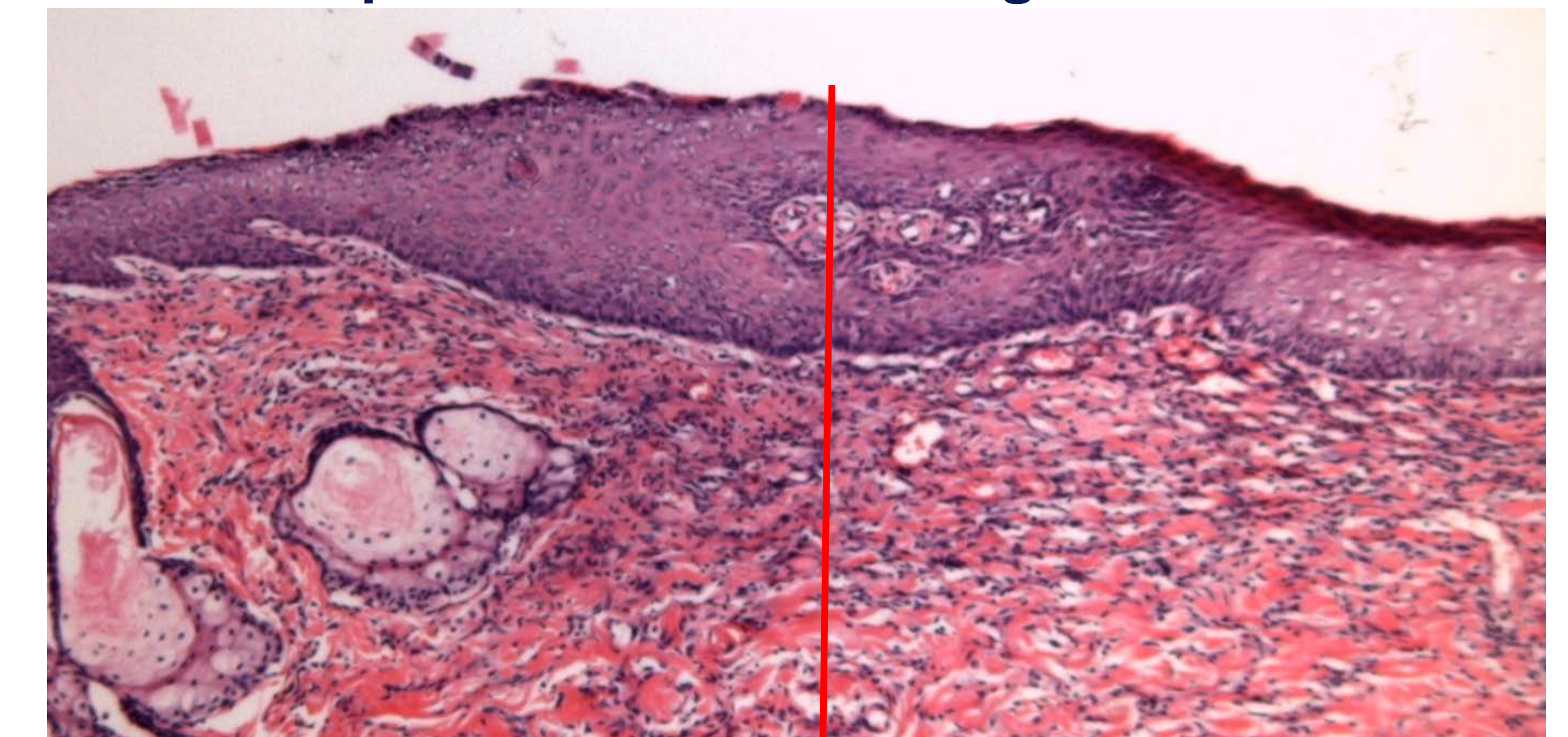
Non-healing skin wounds afflict nearly 5 million Americans each year.

US market for tissue-engineered skin replacement products for the treatment of traumatic skin lesions and non-healing diabetic skin ulcers exceeds \$500 million per year.

Worldwide the number of potential users for such products would, conservatively estimated, exceed several hundred thousand patients each.

Potentially multibillion dollar market, provided that health care providers world-wide have access to simple yet effective products with extended shelf lives at an affordable price.

APS-treated wounds: Re-epithelialization: and regeneration



Healthy border zone Epithelial layer

Wound Epithelial layer

Commercialization/Licensing Strategy

APS is licensed to:



Affiliations

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