Monocyte and Macrophage Transplantation to Improve Cutaneous Wound Healing (OTL 14-118)

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Invention Summary

- Technology to utilize patient-derived (autologous) immune cells (macrophages, monocytes) in a biocompatible matrix (hydrogel) to improve healing at wound site

- Normal wound healing processes can be substantially and chronically hindered in patients suffering:
  - Burns
  - Diabetes
  - Chronic infection
  - Peripheral vascular disease
Existing wound care technologies include:

**Traditional/basic (dressings, adhesives)**

**Advanced (foams, collagen)**

**Bioactive (artificial skin and substitutes)**

**Therapy devices (NPWT, UV)**
Bioactive Wound Care Market

Bioactive wound care market expected to reach $4.9 billion by 2020

(Total wound care market $18.5 billion by 2021)
Introduction to the Wound Care Market

Chronic wound conditions are a tremendous burden on the health care system. While a little more than half of diabetic foot ulcers heal within 12 weeks, 13% remain unhealed a year after presentation. Approximately 900,000 Americans experience diabetic foot ulcers each year, corresponding to an annual healthcare expenditure of $10 to $15 billion dollars. Three million Americans experience venous leg ulcers each year, adding an additional $2 billion to the nation's healthcare bill. (source: ISPOR, AAFP)

<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>Wound Type</th>
<th>No. of Patients/Year (millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underlying Illness</td>
<td>Venous ulcers</td>
<td>1.60</td>
</tr>
<tr>
<td></td>
<td>Arterial ulcers</td>
<td>1.70</td>
</tr>
<tr>
<td></td>
<td>Diabetic foot ulcers</td>
<td>1.30</td>
</tr>
<tr>
<td>Long-term Immobility</td>
<td>Pressure ulcers</td>
<td>2.50</td>
</tr>
<tr>
<td>Surgical Processes</td>
<td>Surgical wounds (major)</td>
<td>36.00</td>
</tr>
<tr>
<td></td>
<td>Surgical wounds (minor/moderate)</td>
<td>31.00</td>
</tr>
<tr>
<td>Trauma</td>
<td>Burn injuries</td>
<td>1.30</td>
</tr>
<tr>
<td></td>
<td>Amputations</td>
<td>0.15</td>
</tr>
<tr>
<td></td>
<td>Traumatic wounds/lacerations</td>
<td>16.30</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>92.00</td>
</tr>
</tbody>
</table>
Reaplix’s LeucoPatch

- Separates and concentrates cells onto a patch for application to a wound
- Conducting clinical trials in diabetic foot ulcer patients
- Patents granted by most global patent offices

WO2010020247A1 - “Multilayered blood product”
+ Additional patent on blood centrifugation
Discussions With Inventors

- New research related to this technology is in pipeline for publication
- Ideally the technology should be developed as a self-contained kit
- Wound therapy should be effective on infected wounds - still needs to be verified experimentally
- Optimization of product (dosing, formulation, etc) needs to be conducted in a large-animal model (pig? rabbit?)
- Controlled clinical trial in human subjects?
SWOT Analysis

**STRENGTHS**

- Unmet medical need – room for dramatic improvement in $20B market
- Could leverage Stanford’s strong prototyping and CT capabilities
- Technology could be expanded to other applications with similar product lines – burns, reconstructive/cosmetic surgery
- Utilize Stanford SPARK or other Stanford translational grants to complete robust pre-clinical work

**WEAKNESSES**

- Little precedent for regulatory approval of related technologies
- Early stage – need animal model to proceed
- Hospital-based technology – reimbursement barriers
- Advanced wound care has traditionally been a hard market to enter – high barriers for preclinical work

**OPPORTUNITIES**

**THREATS**
Potential Partners

1) **OSNovative Systems, Inc. (US):** ENLUXTRA “any wound” self adaptive wound dressing; located in Santa Clara

2) **Mölnlycke Healthcare (SE):** “Advance Solo” - vacuum with a canister attached to collect the waste liquid that is removed from a wound

3) **Smith & Nephew (UK):** large product line covering wound healing area; “PICO” - has no canister but absorbs the fluid in an absorbent layer within the dressing

4) **Acelity|KCI, Inc. (US):** “Nanova” - activated negative pressure wound therapy

5) **MLM Biologics, Inc. (US):** “bio-ConneKt” (horse plaster): sterilized collagen matrix

*Why would these partners be a good fit for the technology?*

*Smith & Nephew:* Well-established in the field; has the financial resources to develop the tech.

*OSNovative Systems Inc.:* Also has expertise in the field and might be willing to pursue this type of ground-breaking product
The technology has great potential to lead to an innovative product, but needs some more foundational exploration before advancing to human Clinical Trials:

1) Need to optimize and test the efficacy of this product on both infected non-infected chronic wounds (e.g. diabetic and multiple sclerotic wounds), ideally in a large-animal model like pig. Optimization of progenitor cells composition and formulation “biocompatible materials that supports survival of progenitor cells and aid wound healing” required before conducting clinical trials in humans.

2) This technology itself would not lead directly to a final commercialized product, but combined with other relevant patents or follow-up preclinical work, it should be attractive for large company to invest or to buy a startup

3) Technology pre-clinical optimization could be pursued with Stanford-based seed funding: SPARK, Biodesign, etc
Technology Summary and Recommendation

- OUTSTANDING Science to technology to great product POTENTIAL.
- Further science and technology development to optimize for infected/old wounds
- Attractive if it offers significant clinical and/or reimbursement/cost advantage as compare to classical (non cell product) wound healing product.
- Prototype product - tested on large animal
- Attempt for veterinary use: Proof of concept in relatively easy regulatory landscape.
- Exit: sell to large pharma/ small pharma/ Startup