MEDILIGHT: Miniaturized smart system for light stimulation and monitoring of wound healing

MNBS 2015 – Technology Translation into Usable & Marketable Systems & Services session

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Project Idea & Consortium

- Induction of "healing" for chronic wounds by individualized light therapy using red and blue LEDs.
- Specific monitoring and evaluation of the healing process using sensor data from the wound area.

Partners and budget

Total Budget: 2,988,033 Euro / Max. EU Contribution: 2,485,593 Euro
Project Goals

- **Ambition**
  - Advanced system integration in wound dressing, adding intelligence, adapting its therapeutic behavior
  - In specific: realisation of waveguide structures and printed sensors, miniaturisation of electronic module/control unit for the wound care device
  - Smart device and monitoring software for evaluation of the healing process and adjustment of optical parameters for optimum wound healing

- **Main technical goals**
  - Develop a disposable wound dressing with integrated light structures and electronic sensors (18cmx18cm)
  - Develop a highly integrated electronic module (5cmx5cmx0.7cm) (data acquisition, light sources & detectors, etc.)
  - Develop various light schemes, optimisation of the light therapy
  - A wireless device and software, recording the history of wound healing and provision of an individualised therapy
  - Testing prototypes animal in-vivo models (pre-clinical studies) and perform first human tests
Urgent patient needs

- Chronic wounds = non healing wounds
  - Chronic wounds reduce quality of life and may lead to infections, amputations and even death!
  - Increasing with ageing population.

- Common chronic wounds
  - Diabetic foot ulcers,
  - Pressure ulcers,
  - Leg ulcers (venous stasis ulcers),

- Burns
Users' Needs and Unique Value (Cont.)

• Improve scientific knowledge in wound healing,
• Design safe and efficient solutions in professional and consumer wound care
• Advanced wound care through new technology with much less pain and better effectiveness ("Cleaner treatment" is highly desirable)
• Bring significant advantages for the physician and benefits for the patient.
  ➢ Patient: Less time spent in the hospital after the diagnosis and the first phase of treatment and testing
    ▪ Comfortable treatment, continuation at home
    ▪ Less interaction with Doctors; Feedback provided to doctors automatically or few visits to the doctors (medical economics studies have been already performed by URGO; preferred also by health insurances)
• Unique value: Unique "All-in-one product" in the advanced wound care market because it can be deployed for all different healing stages!
• Very advanced wound treatment (dry treatment) (without silver particles in some healing stages), easy and comfort for the patient, cost savings through shorter stay at hospital, reported treatment efficiency, etc.)
Users' Needs and Unique Value (Cont.)

- **Users' needs: what are they?**

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<tr>
<th>EFFICIENCY</th>
<th>SAFETY</th>
<th>COMFORT</th>
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<tbody>
<tr>
<td>➢ Improve healing process</td>
<td>➢ Be comfortable to the patient</td>
<td>➢ Avoid side-effects</td>
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<td>➢ Control / limit the infection risk</td>
<td>➢ Control / limit the infection risk</td>
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<tr>
<td>➢ highly advanced wound therapy without chemical treatment, improved comfort</td>
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**Patient**

**Health Professionals**

- **INSURANCE**
  - Be efficient, fast
  - Have a technical assistance
  - Be reimbursed

**Caregiver**

- **HANDLING**
  - Can be adapted to each wound and localizations

- **MONEY SAVINGS**
  - Money savings
  - Time saving
Users' Needs and Unique Value (Cont.)

• **How do we know them? validate them? contact and involve the users?**
  – Key Opinion Leader (Health care professional; Medical sales expert visiting hospitals, private doctors, patients)
  – Clinical studies
  – Nurses panels

• **How do you explain the potential advantage of your product to the users**
  – Key Opinion Leader during clinical studies overtakes the communication role
  – Medical sales representatives

• **Why the technology under development has a unique value for the market users?**
  – All-in-one solution for Advanced wound care market: promote healing and avoid risks of infection

• **What position your users have in the value chain (final, OEM, integrator)?**
  – Final

• **Why the technology under development has a unique value for the market users?**
  – “All-in-on” product for all healing stages, infected or not infected. Unique in the advanced wound care market.

• **How do you know it?**
  – IN-vitro studies done during the H2020 project MEDILIGHT
  – In-vivo will be performed in MEDILIGHT project and Clinical studies will be done after MEDILIGHT project

• **How the users' needs are addressed in the innovation process?**
  – User specification and requirements
  – External Advisory Board (Dermatologist) and getting always feedback from clinical and private physicians
Innovation process and Technology Translation

• Our wish is to implement MEDILIGHT product as a disruptive technology that could address all healing stages (infected or not infected) (All-in-on product)

• The targeted market is the global market. Profitable market perspective in western countries is expected through public and private health care systems and private patients in emerging countries.

• We believe that MEDILIGHT will create a strong technological platform that could lead to several « product generations » in the future (Product diversification based on LED cycle, treatment etc.). For URGO, this project fits into the internal strategy to increase the market shares and to maintain its global competitiveness.

• **Road to technology translation and partners enabling this:**

  After MEDILIGHT:

  **Electronic Module:**
  
  ➢ (1) Microsemi or other EMS to fabricate the electronic module (for TRL>6)

  **Disposable part:**
  
  ➢ (2) CSEM transferring flexible WG technology to a main flexible manufacturer (e.g Contaq, ANDUS, Flextronics, etc.) to fabricate the flexible WGs
  
  ➢ (3) URGO to integrate the WG in the patch
    
    ▪ URGO’s subcontractor for the sterilisation of the patch

  *It will be possibly explored by URGO to undertake also step (2) and in this way control the whole disposable part, influencing significantly the value chain.*

• What investment is needed for TRL>6: An estimate number will be provided in the oral presentation.
A New Industrial Transposition Unit in 2013

A few figures

- A dedicated industrial area of 1,400m² for prototype manufacturing
- A « bridge » facility between R&D and the main URGO’s manufacturing facilities
- Demonstrators for Medilight and later for the clinical studies (TRL 6 and TRL>6)
- A global budget of 7,5M€
  - 3,5M€ dedicated to construction and renovation of the building
  - And 4M€ dedicated to mechanical devices
- A dozen people dedicated to this industrial unit
  - 6 engineers, 6 technicians
Road to Exploitation and distance to the market

IN VITRO proof of concept (UHEI)
Product Design
In-vivo, Clinical Studies / Medico-economical study
Regulatory / Health authority issues
Industrial scale up

*About 4.5-5 years after MEDILIGHT
The following additional issues considered:

**IP**
- Does your consortium have already an agreement for the exploitation of the IP after the project?
  - Consortium Agreement has been done

**Manufacturing**
- Do you know who and how can be manufactured all the components of your systems?
  - Urgo converting and assembly into plasters
  - A preliminary plan has been drawn in Foil 8

**Access to the market**
- Does any of the partners in the consortium has direct access to the intended market?
  - URGO has direct access to the Advanced Wound Care Market
THANK YOU FOR YOUR ATTENTION

http://www.medilight-project.eu/

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