Schlieren - April 2021

D. Marino, CEO

CUTISS AG

Personalized skin tissue therapy to treat large and deep skin defects

Vision & Mission

We are an innovative, Swiss life-science Clinical Stage Company aiming to provide patients that suffer from large and deep skin defects with the first automate-produced, personalized skin tissue therapy, denovoSkin™ - a safe, effective and accessible therapy for children and adults.

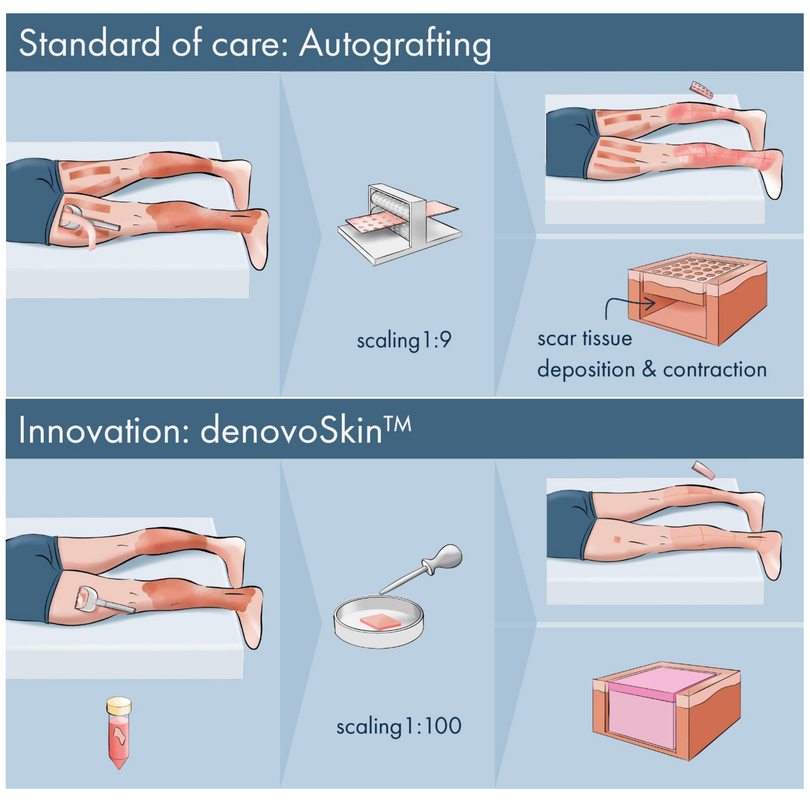
Awards & International Media

Clinical Challenge

Worldwide, at least 50 million people suffer from severe, large skin defects that require surgical interventions to restore skin function. Standard of care treatment is often scarce and leaves these patients with permanent, painful, disfiguring and debilitating scars. Scars may impair mobility and growth, require several follow-up surgeries, intense homecare and psychosocial rehabilitation. Standard of care today is meshed autografting: thin sheets of healthy skin from the patient body are harvested, meshed (≤1:9), and transplanted on the deep wounds.

Current Manufacturing Process

Skin is composed by two main layers: Epidermis and Dermis. To bio-engineer denovoSkin™, patient's epidermal and dermal cells are isolated in our GMP facility from a thin, small biopsy. The cells are expanded in vitro in 2D, and thereafter used in combination with a compressed hydrogel to create a personalized dermo-epidermal 3D skin graft, then transplanted on the patient's wound. The current manual process takes about 3-4 weeks.



***Meuli M., et al. Plast Reconstr Surg. 2019 Jul;144(1):188-198**

5 year follow up data available

Profile

CUTISS is a spin-off (2017) from University of Zurich (UZH) / University Children's Hospital and is currently a member of Wyss Zurich, an accelerator born from the idea of Hansjörg Wyss together with the University and the ETH in Zurich. CUTISS has 36 employees, and headquarters at the Bio-Technopark in Zurich-Schlieren with offices, a Good-Manufacturing- Practice (GMP) facility (not yet approved) and research labs. Current GMP manufacturing for clinical trials is at Wyss Zurich.

Our Solution

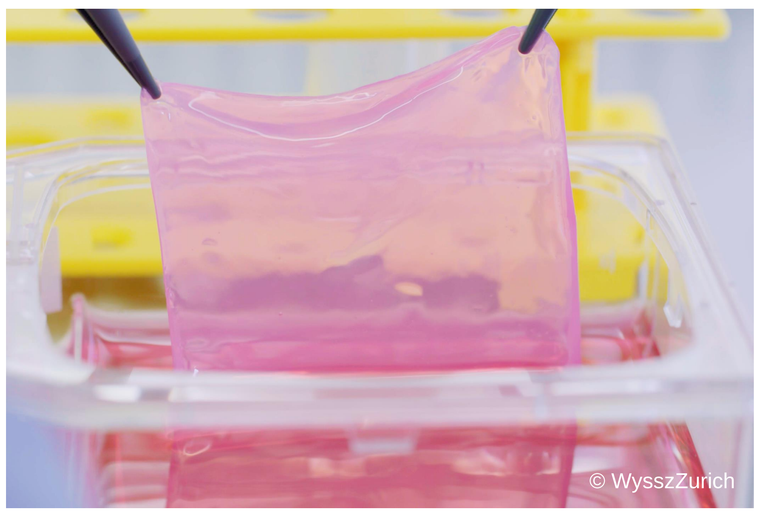
After more than 15 years of research, CUTISS can now bio-engineer an personalized dermo-epidermal skin graft, denovoSkin™. Starting off from a very small piece of healthy patient's skin, denovoSkin™ is bio-engineered with in large quantities (≥1:100) with a thick, double layer, robust structure. Because of its intrinsic characteristics, denovoSkin™ is expected to be mechanically stable and result in a minimally scarring outcome after transplantation onto the patient's wounds.

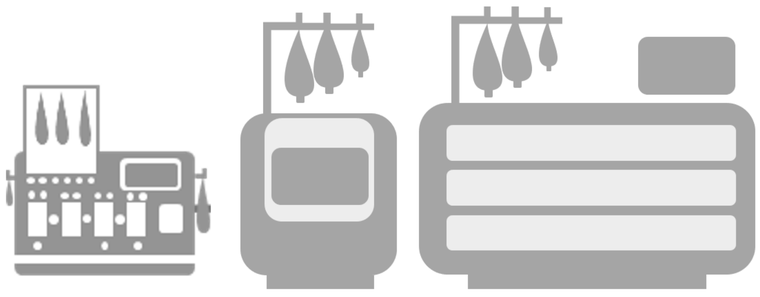
Development Stage

Phase I safety trial for denovoSkin™ is completed and results are published**. denovoSkin™ has received the Orphan Drug Designation for the treatment of burns from Swissmedic, EMA, and US FDA. It is currently tested in three European multi-centric Phase II efficacy clinical studies (NCT03227146, NCT03229564, NCT03394612). Both acute (burn) and elective patients (scar reconstruction, plastic surgery, etc.) are enrolled in the current studies. Burn compassionate patients have also been treated with promising results.

Automated Manufacturing

Skin is our largest organ. The bio-engineering of personalized skin tissue therapy faces scale-up challenges. At CUTISS we work on the translation of the current manual process into an automated, fully closed one. The three automates were developed (2020) in collaboration with Zühlke Engineering and CSEM, supported by H2020 EU and Innosuisse grants. Automated skin tissue production, first in class, is expected to among others, decrease production costs and time, ensure robustness of the process and allow for the de-centralization of manufacturing.





Market for denovoSkin™

The global market for large burns is 10 bn$, 2bn$ in EU/US. The reconstructive market is vast. The market for burn scar reconstruction alone is >5 bn$ in EU/US. It is CUTISS' ambition to generate first sales for burns with the manually produced denovoSkin™ in Switzerland and EU. Automation would then gradually replace the manual process. At CUTISS, we also work on pigmentation which would be great benefit for patients and open up new markets' opportunities.

Competitive Landscape

As of today, there is no direct competitive technology on the market. Large and deep skin defects are treated by meshed autografting. In severe cases, autografting can be combined with acellular dermal templates (e.g. Integra®), epidermal sheets (e.g. Epicel®, Holoderm®), or cell spray (e.g. ReCell®). Two autologous bio-engineered dermo-epidermal grafts are being developed CA and AU. As compared, denovoSkin™ possesses unique features that promise wound closure and improved quality of life in patients, and support scale-up. Furthermore, CUTISS is most advanced in clinical development, regulatory and reimbursement strategies.

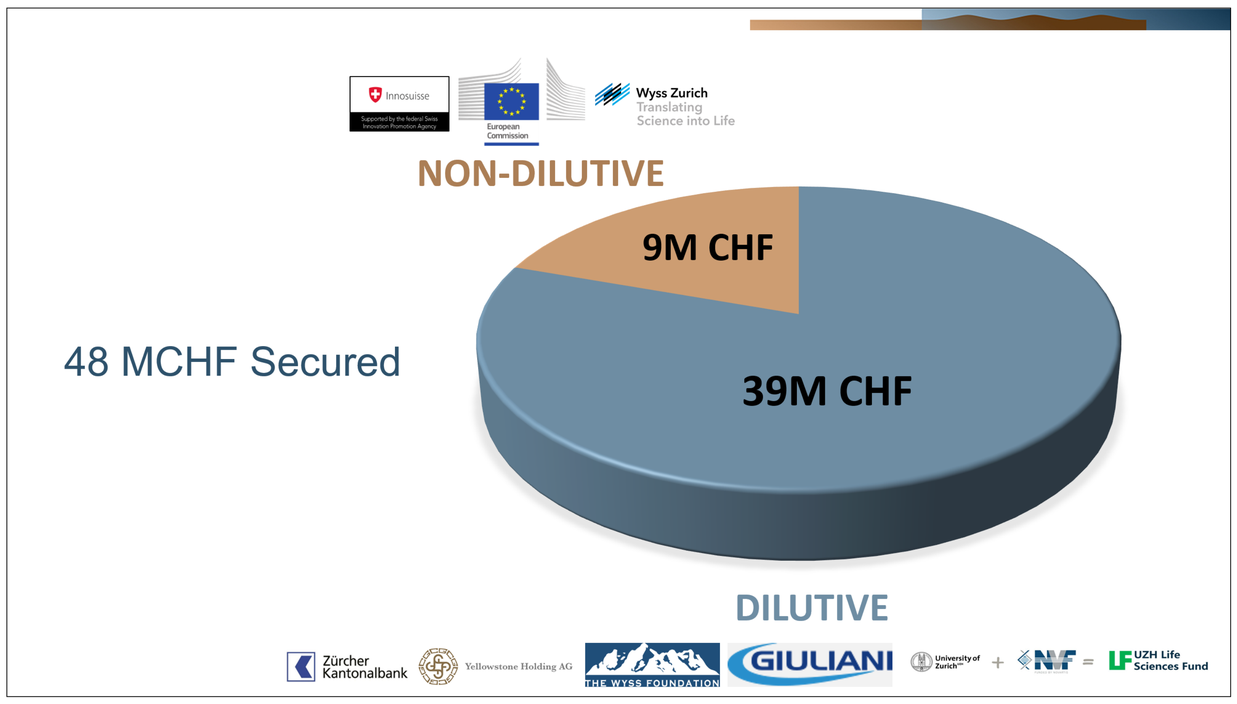
Intellectual Property

A. Patents

- Exclusively licence by UZH
  - Method for compression (2013), WO 2014/207251. Granted.
  - Tissue graft (2014), WO 2016/015754. Granted.
- Patents owned by CUTISS
  - Automation patents (2019/2020), Filed and in national phase.

B. Trade secret of production process

Company Financing



Use of Proceedings

A Series B Financing Round was closed in February 2021 with >28MCHF. These proceedings provide financing up to at least Q2 2023. Until then, CUTISS plans to further progress all ongoing activities of the Company:

- Clinical Validation
- GMP manufacturing scale-up
- Orphan Market Authorization dossier
- Automation of cell expansion
- Pigmentation
- IP portfolio

Management Team

- **Daniela Marino,** Dr.
  Chief Executive Officer and Co-Founder
- **Fabienne Hartmann-Fritsch**, Dr.
  Chief Clinical Officer and Co-Founder
- **Vincent Ronfard**, Dr.
  Chief Innovation Officer
- **Kathi L. Mujynya**,
  Chief Operation Officer
- **Peter Harboe-Schmidt,**
  Chief Financial Officer

✓ >100 years of international experience in academia, SMEs & corporates

Board of Directors

- **Martin Meuli**, Prof. Dr. med.
  Chairman, Medical Advisor and Co-Founder
- **Daniela Marino**, Dr.
  CEO and Co-Founder
- **Ernst Reichmann**, Prof. Dr.
  Scientific Advisor and Co-Founder
- **Giammaria Giuliani**,
  Investor
- **Gerard Ber**
  Independent board member

Contact

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