personalized skin

CUTISS AG

Personalized skin tissue therapy to treat large and deep skin defects

Vision & Mission

We are an innovative, Swiss life-science 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

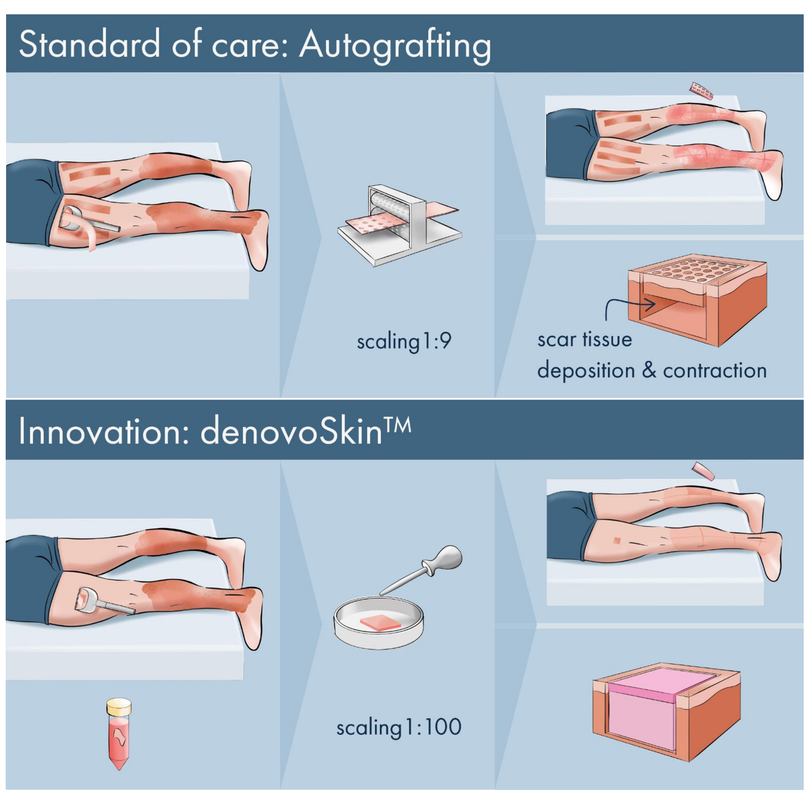
SWISS TECHNOLOGY AWARD 2019 · TOP 1 SWISS BIOTECH 2018/2019 · W.A. de Vigier Foundation · venture TOP1 · CNN Money Switzerland · Forbes

Profile

CUTISS AG is a Spin-off (2017) from University of Zurich / University Children's Hospital Zurich, and is a current member of Wyss Zurich, a start up accelerator born from the idea of Hansjörg Wyss together with the University and the ETH in Zurich. CUTISS has currently 20 employees at its offices, Good-Manufacturing- Practice (GMP) facility in Zurich, and its research lab at the Bio-Technopark in Schlieren-Zurich. A new GMP facility is being built at the Bio-Technopark.

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.



Our Solution

After more than 15 years of research, CUTISS can now bio-engineer large quantities of individually customized human skin grafts (1:100), denovoSkin™. Starting off from a very small piece of healthy patient's skin, denovoSkin™ is bio-engineered with a thick, double layer, robust structure. Because of those intrinsic characteristics, denovoSkin™ is expected to be mechanically stable and result in a minimally scarring outcome after transplantation onto the patient's 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 30 days.

***Meuli M., et al. Plast Reconstr Surg. 2019 Jul;144(1):188-198**
5 year follow up data available

Development Stage

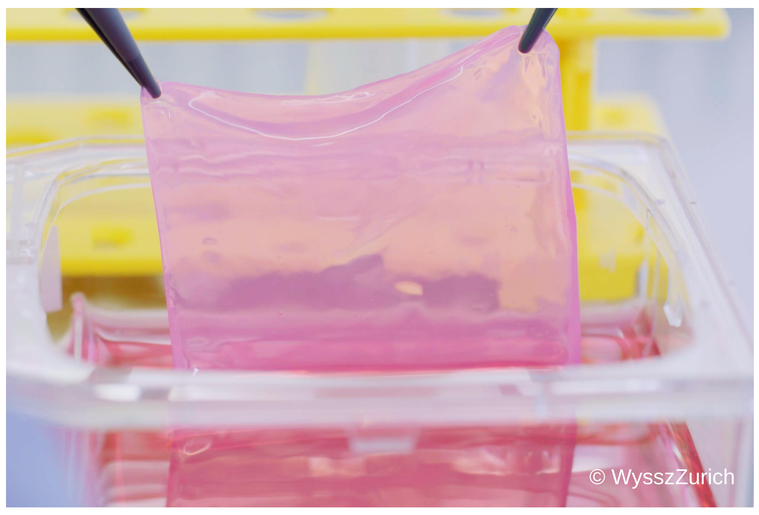
Phase I safety trials for denovoSkin™ are completed and published**. denovoSkin™ has received the Orphan Drug Designation for the treatment of burns from Swissmedic, EU EMA, and US FDA. It is currently tested in three European multi-centric Phase II efficacy clinical studies (NCT03227146, NCT03229564,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

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 one. The automate is being developed in collaboration with Zühlke Engineering and CSEM, supported by H2020 EU and Innosuisse grants. A first prototype is expected by Q4 2020. Automated skin tissue production, first in class, is expected to 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 very dynamic and 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 denovoSkin™ in EU in 2022/2023 and starting with the automated serial GMP production soon after. At CUTISS we also work on the pigmentation of denovoSkin™, 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 epidermal cell spray (e.g. ReCell®). Three bio-engineered grafts are being developed in US, CA and AU. As compared, denovoSkin™ possesses unique features that promise improved quality of life in patients, and support scale-up. Furthermore, CUTISS is most advanced in clinical development, regula-tory and reimbursement strategies.

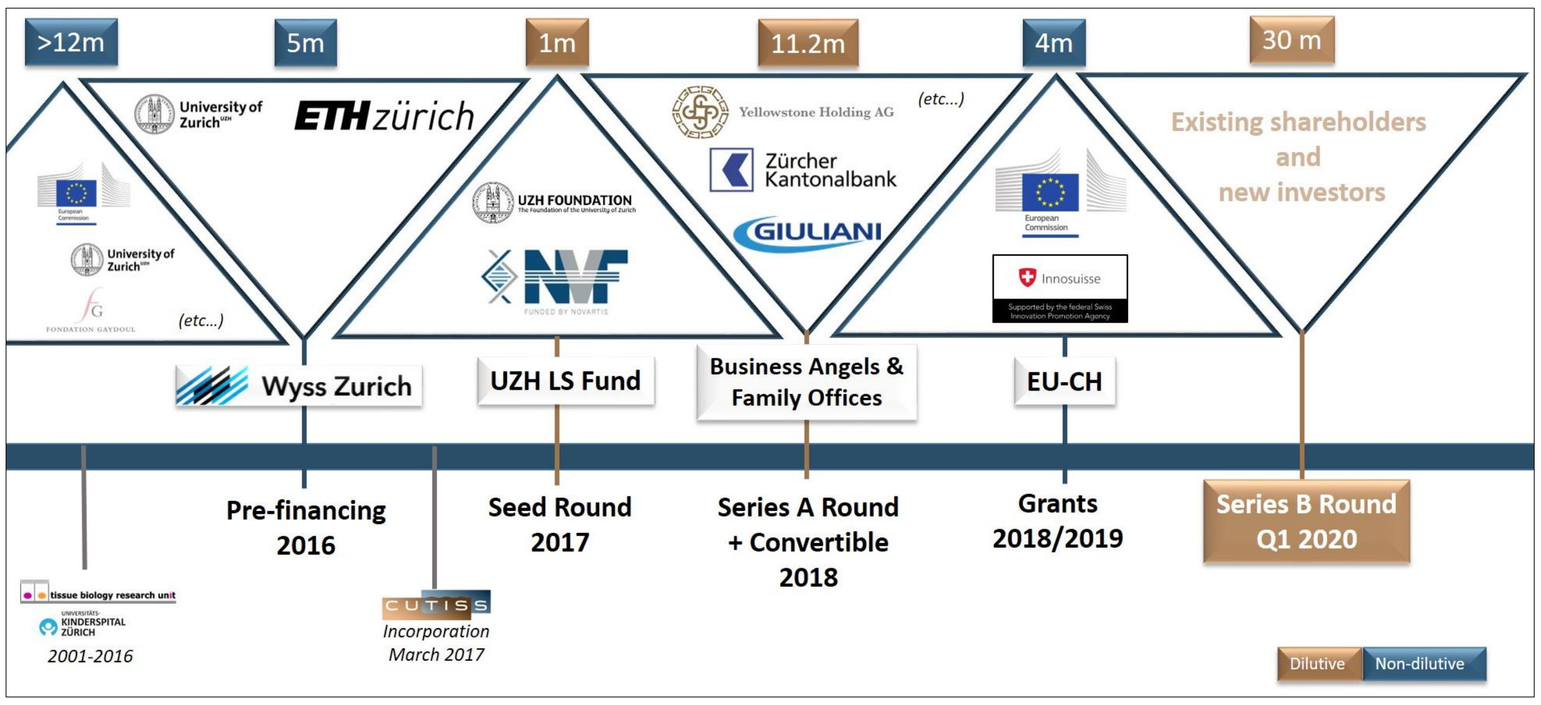
Intellectual Property

A. Patents

- Exclusively licenced to CUTISS by University of Zurich
  - Device and method for compression (2013), WO 2014/207251, Granted.
  - Tissue graft (2014), WO 2016/015754
- Patents by CUTISS
  - Skin biopsy carrier (filed, 2019)
  - Automation process (to be filed 2019)
  - Disposable compression (to be filed 2019)

B. Trade secret of production process

Company Financing ($)



Financing Round B

With this capital increase, CUTISS AG intends to further progress all ongoing activities of the Company until 2023. Major milestones are:

- GMP manufacturing scale-up
- Orphan Market Authorization dossier submission in CH/EU/US
- Automation dossier finalized
- Advance the pigmentation program

Management Team

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

✓ >100 cumulative years of international experience in skin bio-engineering in academia, small companies and corporates

Board of Directors

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

✓ Gerard Ber,
Entrepreneur
Independent Member proposed to join in Q1 2020

Contact

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