

## INVESTMENT OPPORTUNITY TO TRANSFORM SKIN SURGERY



CUTISS AG is an innovative, late-stage clinical company focusing on precision regenerative medicine. Having secured >CHF 67M, CUTISS is now raising its Series C to advance towards commercialization and liquidity event.

- Zurich University (UZH) spin-off, incorporated in 2017, TOP#1 Swiss start-up 2020
- Headquartered at the Bio-Technopark in Zurich-Schlieren
- ~45 employees, top notch senior executives, advisors and investors
- Own labs and Good Manufacturing Practice (GMP) facility certified by Swissmedic
- A fully owned subsidiary working on an innovation portfolio for future pipelines

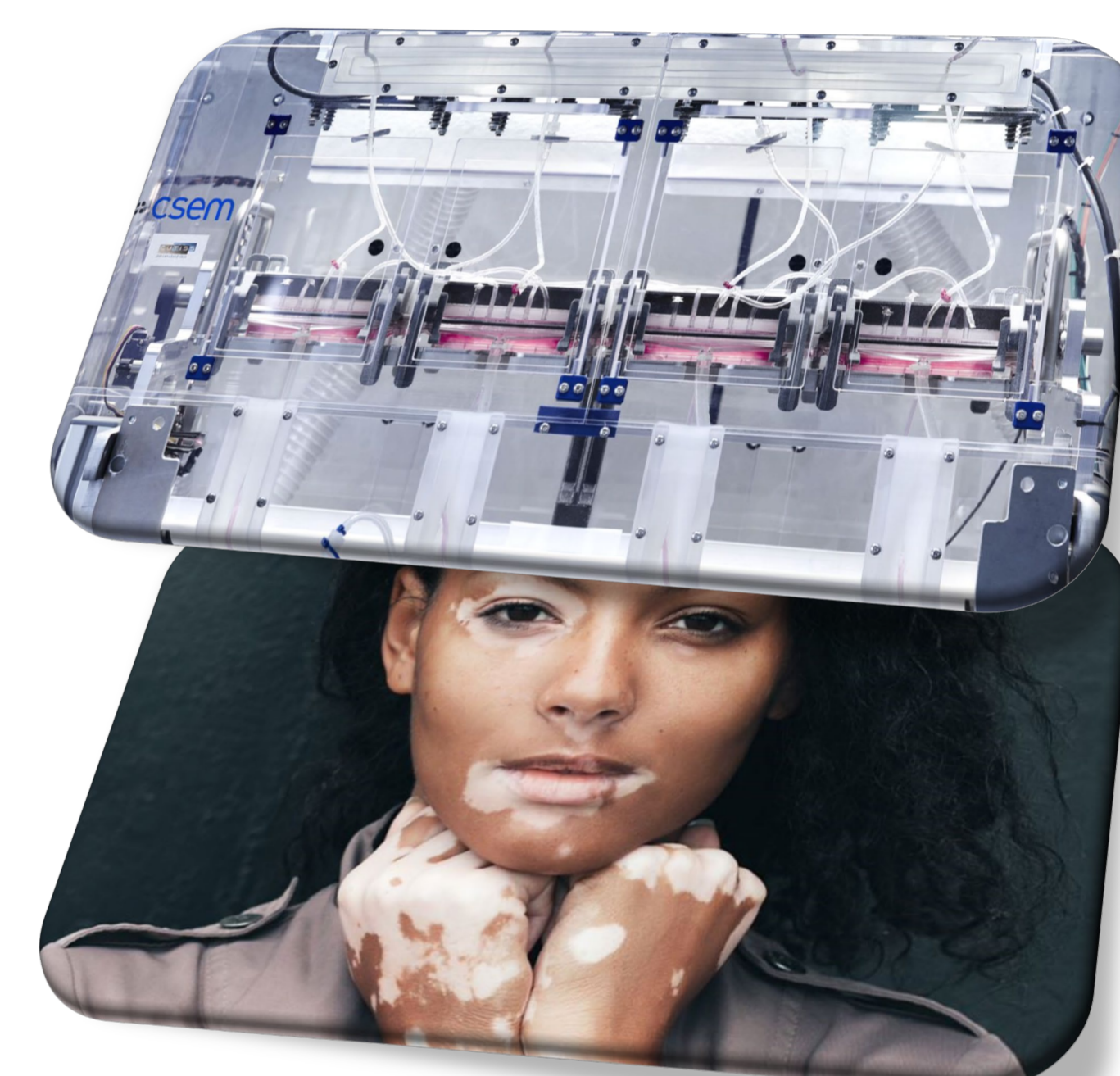
### CURRENT ACTIVE AREAS

**SKIN REPLACEMENT SURGERY** - Standard of care in burn and reconstructive surgery (e.g. trauma, scar and cancer resection etc.) is scarce, leads to severe scarring and is costly. CUTISS aims to transform skin surgery with denovoSkin™, a personalised, bio-engineered skin graft. Classified as an advanced therapy medicinal product (ATMP), it can be bio-engineered in large quantities using a stamp-sized sample of patient's own skin. To date, our clinical data confirm long-term safety, demonstrate efficacy vs standard of care, promise significant improvement in patients' quality of life by minimizing scarring, while lowering total healthcare costs. Importantly, burns are classified as a rare (orphan) in CH-EU-US, offering attractive fast track options towards market authorization.

**AUTOMATED TISSUE BIO-ENGINEERING** - To secure scale-up, allow decentralization and achieve relevant cost reduction for the in-house manufacturing of denovoSkin™, CUTISS is developing first-in-class automated bio-reactors with leading Swiss and international engineering partners.

This pioneering, proprietary platform could be used beyond skin for the next-priority human tissues (muscle, gums, etc) and beyond medicine in agritech and foodtech (leather, meat).

**DERMATOLOGY** - Skin color restoration in vitiligo, dyspigmented scars and grafted denovoSkin™, with innovative medical devices for personalized, precision cell therapy at point-of-care.



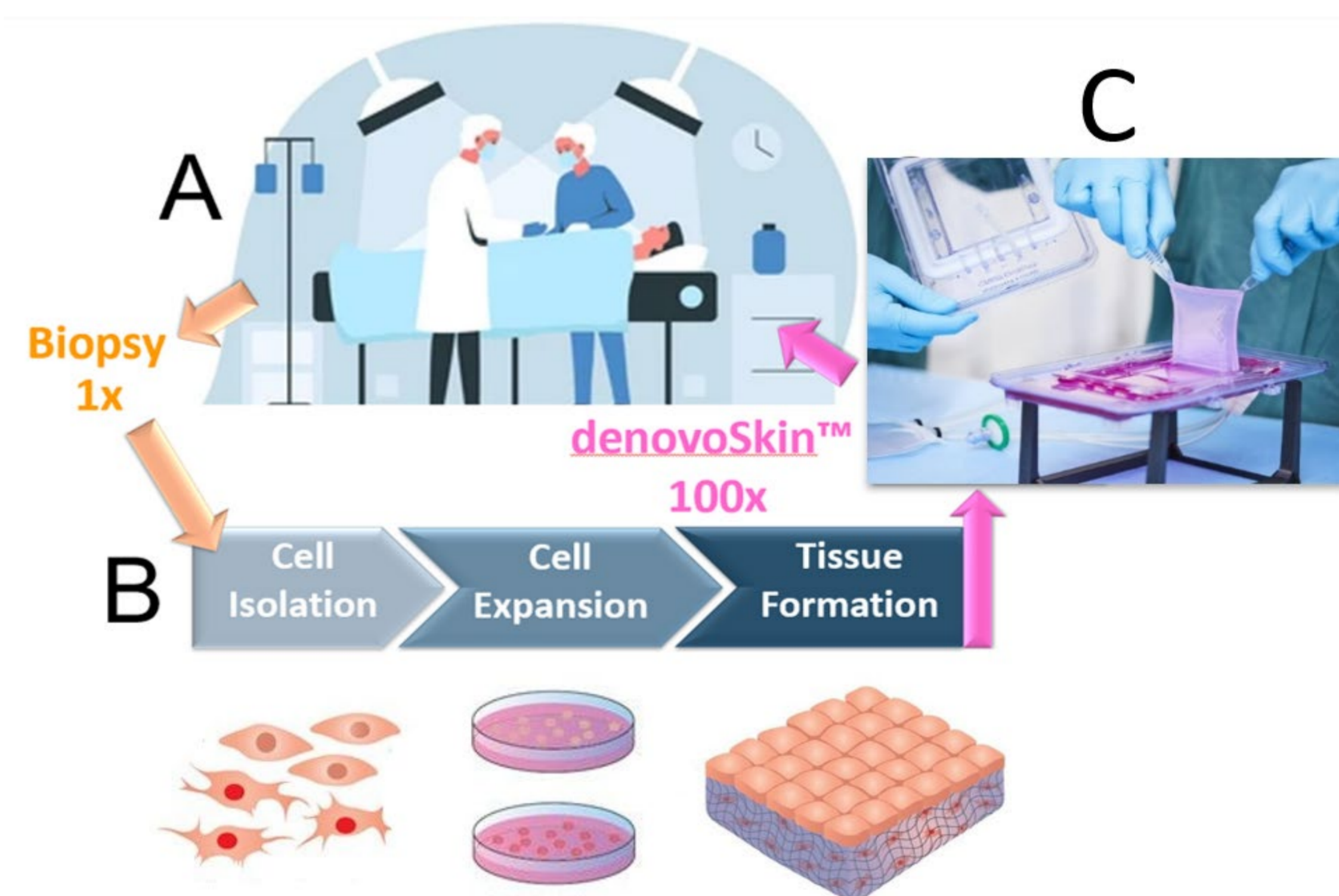
### CURRENT PIPELINE

**denovoSkin™** - developed by CUTISS - is bio-engineered on demand. Same as one's skin, it is composed of an epidermis (top, protective layer=life) and a dermis (the structural, below layer=quality of life). Key differences from the standard of care (SoC) - autografting (thin skin sheets harvested from patient's own healthy sites and applied on the wounds):

	SoC	denovoSkin™
Thickness ideal for deep wounds	No	Yes
Expansion factor of patient's skin sample	<9x	>100x
Scarring	Significant	Minimal

**VITICELL®** – acquired under a global, exclusive commercialization license from IBSA Pharma – has been CE-marked for the cell therapy-based treatment of vitiligo and dyspigmented burn scars at point of care. We are also working on other in-house-developed medical devices.

### OUR PERSONALIZED SKIN GRAFTING



Together, denovoSkin™ (de-pigmented skin graft) and VITICELL® (pigmentation device) offer a unique complete personalized solution.

### THE MARKET AND OUR BUSINESS PLAN

In early July 2023, Coloplast announced the acquisition of our peer Kerecis in a USD 1.3bn deal, a significant validation of the tissue engineered skin substitutes for burns and tissue regeneration. The global bio-engineered skin graft market is expected to grow at CAGR of 11% due to increased skin injuries caused by diseases and incidents (also global warming-related), and higher number of aesthetic procedures. The global vitiligo market is expected to grow at CAGR of 4.3%, ~2% of world population is affected (cell therapy 10% share). With 2.6M total addressable patients p.a. (burns, reconstructive, vitiligo), CUTISS' sales are expected to reach CHF 2Bn within 10 years, with stabilized margins. denovoSkin™ has no direct competitor on its target market segments several products in the space (e.g. dermal templates like Integra® artificial skin) can be used in combination with denovoSkin™.

## INTELLECTUAL PROPERTY

**2x** Patents exclusively licenced from UZH, Granted EU, US and others

- Method and device (2013)
- Tissue graft (2014)

**6x** Patents owned by CUTISS, in national phase

- Automation family (2019/2020)

Trade secret of production process.

## EXCELLENT CLINICAL DOSSIER

**denovoSkin™**: Safety (Phase 1) trial completed with 5-year follow-up on burns and reconstructive patients. Efficacy (Phase 2) endpoint reached in adolescent & adult burns (Q1 2023). Confirmatory (Phase 3) trials are in planning. Efficacy trial in reconstructive is close to recruitment completion. Six burn compassionate patients treated; reports are published in peer-reviewed journals.

**VITICELL®**: Clinical validation completed.

## CLEAR GO-TO-MARKET STRATEGY

**denovoSkin™**: produced in-house (first manually, then automatically), in CUTISS' regional hubs. We first target the highly accessible, orphan burn market with direct sales, an attractive pricing strategy and very favorable reimbursement terms. Reconstructive and aesthetic surgery markets will follow.

**VITICELL®**: sold directly in CH; via distributors in other target regions.

## HIGHLY EXPERIENCED TEAM

Outstanding expertise at executive and advisory level. Extensive international experience and network in skin engineering and skin therapy, from bench-2-bed-2-market, manufacturing, engineering. Experience in leading SME and large enterprises like MODEX (CH), L'OREAL (FR, China), HEALTHPOINT (US), SMITH&NEPHEW (US), A-STAR (Singapore), ORGANOGENESIS (US) etc.

### Key members

**Daniela Marino**, Dr. CEO and Co-Founder, Board of Directors

**Vincent Ronfard**, Dr. Chief Innovation Officer

**Kathi L. Mujynya**, MBA COO

**Anke Gerding**, CFO

**Luc Teot**, Dr. med. Medical officer

**Thierry Passeron**, Dr. med. Medical advisor

**Clemens Schiestl**, Dr. med Medical advisor and co-founder

**Ralf Rosenow**, Legal Counsel and BoD Secretary

### Board of Directors

**Martin Meuli**, Dr. med. Chairman and Co-Founder

**Ernst Reichmann**, Dr. Co-Founder

**Giammaria Giuliani**, Investor, Royalty Pharma, HBM

**Gerard Ber**, Independent board member (Ex COO of AAA)

## SUSTAINABILITY AND IMPACT

- CUTISS contributes to ensuring healthy lives and promotes well-being for all, at all ages. It also supports social (re)integration of patients with severe skin defects.
- With our scale up plans we strongly commit to reducing inequality within and among countries.
- Via continuous progress we commit to ensuring a sustainable manufacturing process.

## PIONEERING AUTOMATION PLATFORM

CUTISS has developed three automated modules to manufacture large quantities of denovoSkin™ via 1. cell isolation, 2. cell expansion, 3. tissue formation in a fully closed system, disposal based. Developed with leading Swiss and international partners, those modules are fully active in the laboratory and are now entering the industrialization phase, towards clinical use readiness.

## BEST IN CLASS INDUSTRY PARTNERS



## CURRENT CAP TABLE

Experienced investors, family offices, HNWI, foundations, banks, such as: Giammaria Giuliani of Giuliani Pharma, Wyss Foundation, ZKB, Yellowstone Holding, UZH LF fund, Liechtensteiner foundation, Innosuisse, EU commission. Largest shareholder: 10%. Team/founders/UZH: 47%

## SERIES C ROUND - PAVING THE WAY TO MARKET

To date, > CHF 67M was raised (dilutive and non). Post positive efficacy results in burns, a Series C for CHF 40-60M is now open (minimum ticket size CHF 250k). The round is co-led by the family office of Giammaria Giuliani (existing investor) and a US family (new). A liquidity event is planned in the next 2-3 years.

The Round C proceeds will be used to:

- complete the clinical validation of denovoSkin™;
- finalize the Market Authorization (incl. fast track) dossiers for Swissmedic, EMA and FDA;
- bring the automated tissue engineering modules to clinical readiness and expand manufacturing capacity;
- commercially launch VITICELL®;
- grow the management, team and board expertise in commercial, medical and financial.

CUTISS

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