apersys
Advanced Perfusion Systems

Ex-vivo
Multi-day
Functional organs

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TODAY
NO ORGAN CAN SURVIVE*
EX-VIVO >24h

*with full functionality

Apersys – Unique Entry Point

Enabling Ex-Vivo, Multi-Day, Functional Organs

1. Liver Transplants

Multi-day…

- Liver viability assessment
- Reconditioning & Recovery
- De-Fatting
- Therapy (gene therapy, immunomodulation, metabolism, …)

2. Other Organs

Multi-day…

- Heart
- Kidney
- Uterus

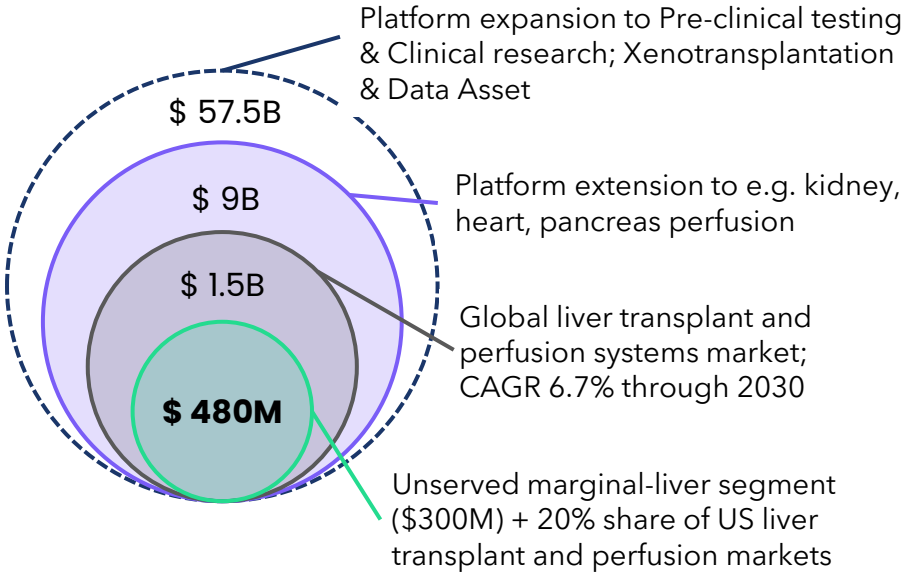
3. Organ Farms

Multi-day…

- Ex-vivo, physiologically viable organs on Apersys NMP perfusion platform
- Enabling large scale organ testing (vs 3D organoids)
- Next-gen CDMO R&D

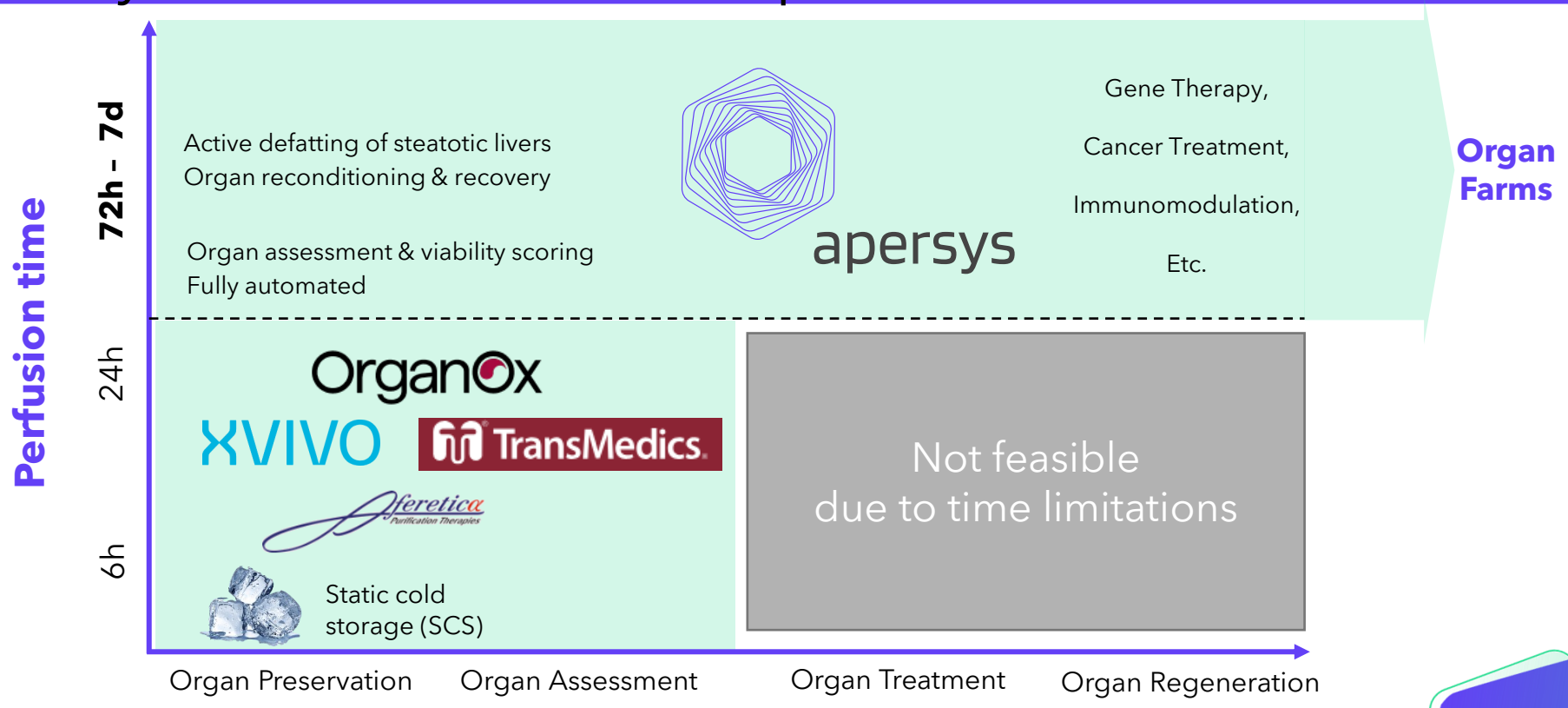
NOT POSSIBLE TODAY

Today: **LT alone** is a **significant and growing market**



TransMedics (NASDAQ: TMDX) - 2025 $4.3B market cap · $240M revenue · 17× multiple
OrganOx – acquired by Terumo for $1.5B · $70M revenue · >20× multiple
Paragonix - acquired by Getinge for $477M · $40M revenue · 12× multiple

Our approach ***transforms*** organ ***business*** beyond current 24h transplantation limit



A growing, **unresolved** medical emergency

1 in 3

liver patients die waiting for a transplant

~40%

of donated livers discarded due to quality or time limits

+8.5%

more patients added to waiting lists in 2023 YoY[1]

- Organ shortage has grown unabated since monitoring began in 1988 - a >5% annual increase.
- 40% discard rate driven by aging donors, fatty liver disease, and ischemia-reperfusion injury.
- Aging donor pool & rising fatty-liver prevalence leading to Extended Criteria Donor (ECD) expansion.
- A new driver is oncological liver transplantation.
- DCD surge: 49% of U.S. deceased donors are now DCD (2025), up from 45% in 2024 and growing.
- Clinicians forced to operate on weekends with sub-optimal organs, raising patient risk and surgical stress.
- Existing devices (TransMedics, OrganOx) max out at 24 hours - too short for organ repair or treatment, unfavorable economics and/or poor usability.

[1]Latest available public data

Solution – Apersys **Artificial Organ Home**

- **Biomimicry – creating a physiological environment** for the organ outside the human body
- **Automation & Usability-first architecture** - robust Proprietary Controls; 2 successful Human Factors studies
- **10 yrs** of looped engineering & research ETH/UZH
- **8 patent families** covering: Perfusion loop, Viability assessment, Defatting, technical features, and several further applications
- **CHF11M** non-dilutive funding invested by Wyss Translational Center

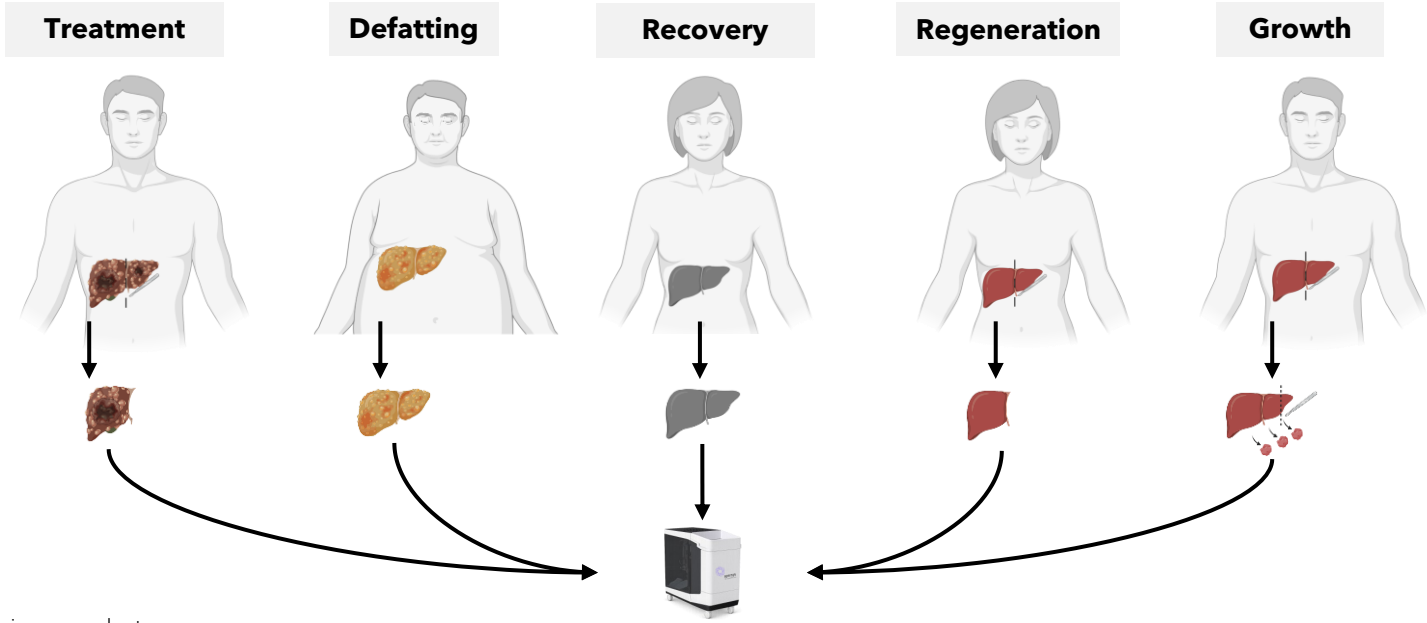
Artificial Organ Home

multi-day

Expanding the transplant window for multiple use cases

An enabling **platform**

The ability to preserve livers/organs ex-vivo long-term can support healthcare in full transition to elective procedures and enable new possibilities for **research and clinical applications**.



A decade of evidence - **including FIH**

120

PIG LIVERS

perfused in pre-clinical studies (2016 – 2019)

60+

HUMAN LIVERS

discarded human livers perfused (since 2017)

3

ORGANS TESTED

POC in porcine **hearts**, **kidneys** and **uterus**

7 days

MAX. PERFUSION

clinical use; **14 days** in research

2021

FIRST-IN-HUMAN

3-day perfusion; compassionate use

FDA Breakthrough Device Designation - April 2023

- Immediate Medicare coverage on FDA approval date via TCET - 4 y of national reimbursement guaranteed
- Rolling review of application sections and priority sprint discussions with FDA
- Fewer than ~200 devices receive this designation per year vs. >18,000 standard 510(k) submissions

FDA BREAKTHROUGH DEVICE DESIGNATION

Patient **saved** using a **discarded organ**

First-in-human liver transplantation following **3 days of machine perfusion**

3 years after

ARTICLES
https://doi.org/10.1038/s41587-022-01354-7
nature biotechnology
Check for updates

Transplantation of a human liver following 3 days of ex situ normothermic preservation

Surgeons save damaged liver — and use it to save cancer patient

THE TIMES

The APERSYS **USP**

	Apersys	**OrganOx Ltd.**	**Transmedics Inc.**	**XVIVO AB**	**Aferetica Srl.**
Perfusion duration	**7d (+)**	12h in US, 24h in EU	24h	24h	24h
Applications	Preservation & Recovery, **Treatment*, Regeneration***	Preservation	Preservation	Preservation	Preservation
Dialysis	✓	✗	✗	✗	~
Integrated blood gas analysis	✓	✓	✗	✗	✗
Autonomous monitoring and control (temp, pressure, flow rate, glucose, etc.)	✓	✗	✗	✗	✗
Automation	✓	~	✗	✓	~
Transportation	✗	✓	✓	✗	✗

*targeted future applications

Traction

EFS site selection

- Mayo Clinics (3 sites)
- Julie Heimbach as PI

Clinical Trial interest

- >7 sites in EU & US interested
- Mayo lead site for pivotal multi-center study

Research Leads

- >7 LOI for research sales
- >18 leads derived from ILTS 2026 (each with a volume of >0.5M CHF)

Research sale 2026

First research unit sold to Paul Brousse, Paris, France.

ILTS 2026

first time attendance with outstanding results (> 500 visits)

Traction

Leo Buehler
Transplant Surgeon, Switzerland

Multi-Day Perfusion will be a catalyst for xenotransplantation.

Pal Dag Line
Transplant Surgeon, Norway

The organ that was declined yesterday can be transplanted tomorrow.

Damiano Patrono
Transplant Surgeon, Italy

The longer we perfuse, the more we can intervene.

The first Multi-Day Perfusion by Apersys is a landmark step in transplantation.

Krzysztof Zieniewicz
Transplant Surgeon, Poland

Mayo Clinic will be happy to lead the early feasibility study of Apersys.

Julie Heimbach
Transplant Surgeon, USA

Multi-Day Perfusion and FMN can revolutionize liver transplantation.

Antonio Pinna
Transplant Surgeon, USA

Business Model – **ARR at scale**

Revenue generation for our customers (LT case)

- **increased (10-20%) number of viable transplants (from discarded organs) = increasing transplant revenue**
- Avoidance of:
  - re-transplantation (5-10%): **250k – 400k** USD
  - EAD/ischemic cholangiopathy **50k – 150k** USD
- Elective vs. urgent surgery: **150 – 400k** USD per transplant
- ERAS (Enhanced Recovery After Surgery): **30 – 80k** USD per transplant

Single-Use Sets (SUS)

~80%

$[redacted] / perfusion

Primary revenue driver. Each device drives 20–70 SUS/year.

Device Sales / Lease

~15%

$[redacted] purchase · $[redacted]/year lease

Leasing lowers upfront barrier for transplant centers and OPOs; builds predictable annuity base.

Software Licensing

~5%

Annual fee per organ module

Modular software enables upsell for research, defatting protocols, and multi-organ control. Data Assets depict another revenue stream.

Go-to-Market Strategy

01

Early Feasibility Study (EFS) (2027)

De-risking

Mayo Clinic as primary investigator. Study framework aligned with FDA - Focus on discarded livers. 10 patients to be treated. Study plan finalized and machines in production.

02

Pivotal Clinical Trial (2029/2030)

FDA

Pivotal multicenter study; Mayo Clinic as primary investigator. Based on EFS outcome. FDA sprint discussions underway. Goal: reduced study size and timeline.

03

US Launch (2031)

Revenue

Target 19 high-volume centers (>100 LT/yr). Initial devices to Mayo, Stanford, Duke, UCSF. Parallel OPO placement (East + West Coast) to maximize organ recovery.

04

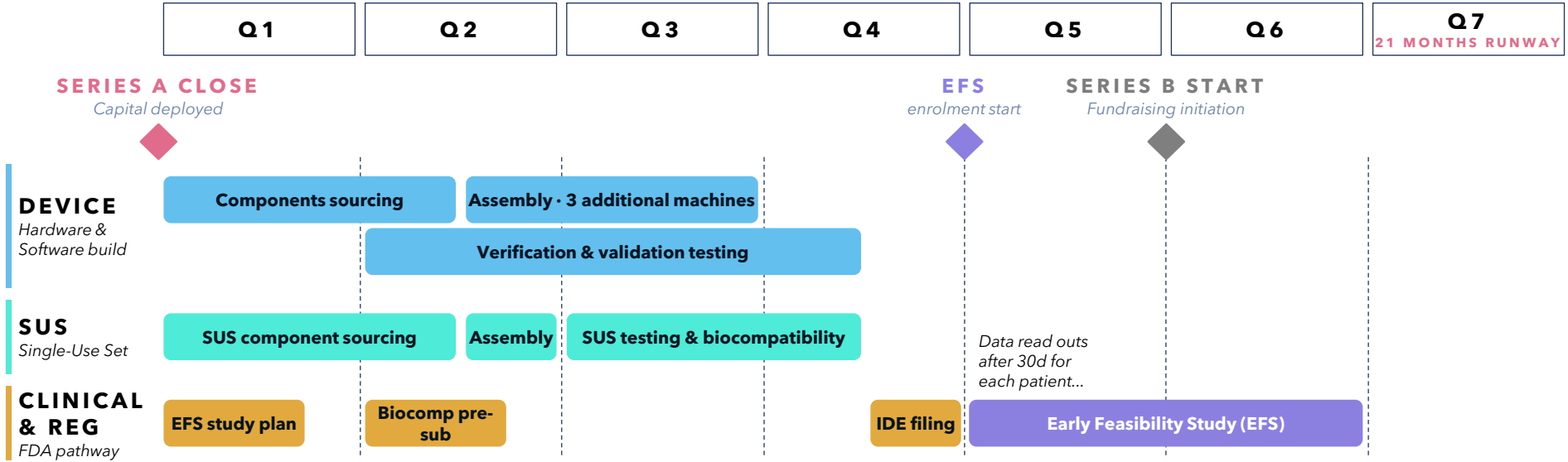
EU & Scale (2031+)

Scale

BSI Group Netherlands B.V. identified for CE marking. Fresenius Medical Care distribution partnership enables EU-wide rollout. Expansion to additional organ types.

Letters of Interest: Pisa University Hospital · Hôpital Paul Brousse · Duke · Ohio State · UMass · Toronto General · Leiden UMC · Cleveland Clinic

Ready to ignite – Discarded Liver EFS



WHAT THIS SERIES A BUYS

3 build-ready machines + SUS line

Locked supply chain and in-house assembly capability – no external dependencies before EFS.

REGULATORY MILESTONE

IDE filed by Q4 · EFS start Q5

Breakthrough Device Designation accelerates review; pre-sub completed in Q2 de-risks IDE.

SERIES B TRIGGER

Clinical evidence

EFS readouts unlock the next valuation step-up - proof of safety on DISCARDED human livers.

CHF 12M Series A (7M+ open)

We have initial commitment of CHF 5M

We have serious interest from China

Clinical evidence 10 patients

Follow-up data >30d

3+ machines built

R&D collaborations

Initial exit window ...

30% **Product Development**
Device build, design transfer, CMO service for SUS

30% **EFS Preparation & Execution**
FDA sprint sessions, CRO selection, protocol finalization

10% **Regulatory & Quality**
QMS build-out, FDA filing fees, EU MDR compliance

15% **Team Expansion**
Engineering, perfusionist, and compliance

15% **Working Capital**
Operations, IP maintenance, partnerships

6 Professionals. **40+ years of MedTech Expertise**

Waldemar Hoffmann, PhD
Co-Founder & CEO

Biomedical engineer; 12+ years medtech R&D across full product value chain; serial connector of clinical and engineering teams

Sven Leppert, MSc
Head Engineering & Co-Founder

Chemical engineer; 8+ years in medtech R&D; Class II & III device development; leads development and design control activities

Hannah Rasel, MD
Clinical Lead

MD, 5+ years of experience in visceral and transplant surgery, experience in organ procurement.

Andrea Venturato, PhD
Head Product Management & Co-Founder

8+ years' experience in medical device, R&D, and project/product management.

Chris Stahle
Commercial Lead

MBA, Commercial strategist with 15+ years of medtech leadership; KOL engagement, and scaling commercial operations

Giorgio Poma
Biomedical Engineer

Biomedical Engineer; 1+ year experience in medical device development for the U.S market

Clinical & Scientific Advisors

Prof. Pierre-Alain Clavien · University Hospital Zurich · Lead surgeon, FIH transplant
Dr. Julie K. Heimbach · **Mayo Clinic** · Anticipated EFS Principal Investigator
Dr. Will Chapman · **WashU** · Clinical Advisor and anticipated pivotal study participant
Prof. Philipp Dutkowski · University Hospital Basel · Viability marker inventor
Prof. Mark W. Tibbitt · ETH Zurich · Co-inventor · Macromolecular Engineering
Prof. em. Philipp R. von Rohr · ETH Zurich · Co-inventor · Process Engineering
Dawn Balazs-Metz, PhD· **RA&QA Advisor** · > 20 y of medical device industry experience

Board of Directors

Line Stigen Raquet – Chairwoman
Dr. Martin Riediker – Board Member
Dr. Waldemar Hoffmann – Board Member & CEO

Why Now ? Why Apersys ?

Technology Readiness
Tested on >60+ human livers and POC in other organs; first-and-only discarded human LT in patient

Apersys way ahead of competition
Competitors are capped at 24h. No product addresses the $300M marginal-organ segment.

Proven exit market
Strategic acquirers active at 10-20x revenue multiples:
Transmedix -> $4.3B market cap ; 17x rev
OrganOx -> Terumo USD 1.5Bn, Oct 2025; >20x rev
Paragonix -> Getinge USD 400M, Sep 2024; 10x rev

Only 2 major players, Market wide open
Transmedics and OrganOx. Serving a different market segment.

Societal tailwinds drive further demand
Obesity, aging donors, government mandates. Fatty-liver volume rising; mandates to increase organ utilization.

Donor shift
DCD organs are strongly increasing requiring tools for reconditioning and optimization. Apersys is uniquely positioned.

Regulatory Fast Track Cleared
FDA Breakthrough Device Designation. Fast-track review and immediate Medicare reimbursement at approval.

High R&D demand
Strong interest in research use of Apersys platform technology

Multi-use platform
Beyond organ transplantation… Huge, untapped upside in drug-testing, gene therapy, organ farms...

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Ex-vivo Multi-day Functional organs

Enabling the impossible...

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Wyss Zurich
Translating
Science into Life

USZ
Universitäts
Spital Zürich

ETH zürich

Spin-off

ETH zürich

Universität
Zürich[UZH]

venturelab

Top100
Swiss Startup Award
Public Voting 2025
Winner
Medtech
Apersys

reddot winner 2025

MC15
MASSCHALLENGE