UZH IncubatorLab

EU-Innovation Network conference
“Strengthening life-sciences innovation across Europe”
21 November 2023, Dublin

Presented by: Dr. Deana Mohr, CEO Muvon Therapeutics

General introduction

Location

- Hosted by **the Institute for Regenerative Medicine · IREM** at the **University of Zurich (UZH), Switzerland.**
- Access to a vibrant entrepreneurial community hosting 50+ life science entities, from start-ups to global companies.

Foundation

- Created in **April 2019**
- Supported by **Werner Siemens Stiftung (WSS)**, a philanthropic organization dedicated to advancing research and entrepreneurial activities, especially in the MedTech sector.

Aim

- Promote and support projects led by **UZH MedTech and BioTech Entrepreneur Fellows** for a duration of **18-months.**

Environment provided

The UZH IncubatorLab is supporting with the translation of UZH research into marketable business ideas through:

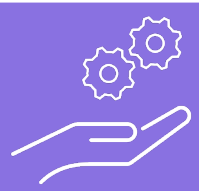
Lab space

Cutting-edge facilities
(advanced lab infrastructure with tools for DNA / RNA analyses, 3D printing, high-resolution microscopy, mass spectrometry; flow cytometry, etc.)

Community

Access to vibrant community and comprehensive networking
(peer-to-peer learning, collaboration opportunities, direct interactions with key industry stakeholders, mentoring by international community of entrepreneurs)

Expert advice



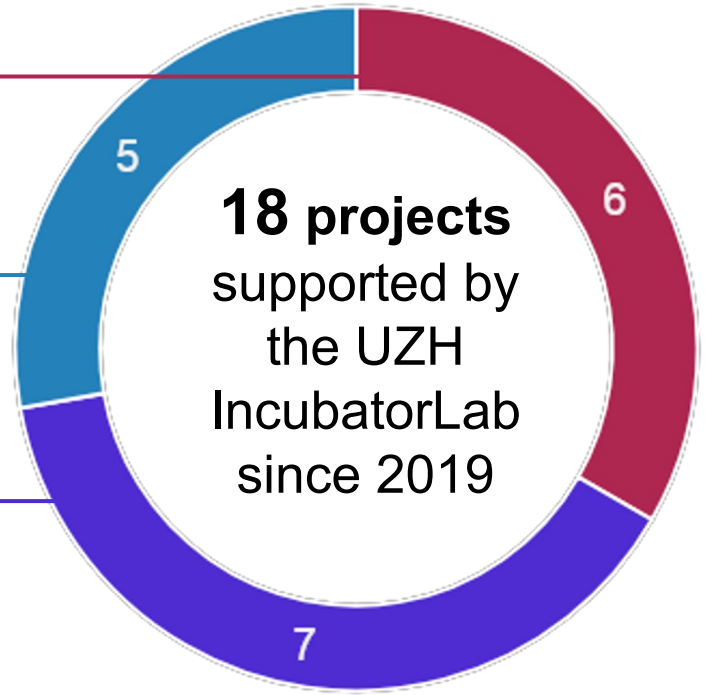
Additional support tailored to user needs
(e.g., regulatory and business training, marketing and scientific visuals, patenting advice, prototype development etc.)

Overview of incubated projects

Medicinal Products & Therapeutic Solutions

Advanced Medical Devices & Platforms

Diagnostic & Biomarker Technologies



A total of **8 incorporated** start-ups

eracal therapeutics
MUVON THERAPEUTICS *
reconnect LABS *
InCephalo therapeutics
KOVE
MGME Neurotech
ON TRACK diagnostics
Clémedi

* Clinical-stage companies

Overview of the incubated projects

Medicinal Products & Therapeutic Solutions

- eracal therapeutics
- InCephalo therapeutics
- MUVON THERAPEUTICS
- LUMAROS ®
- reconnect LABS
- Trojan Therapeutics

MedTech

Diagnostic & Biomarker Technologies

- ON TRACK diagnostics
- Clemedi
- EVIVE
- NEUROPAT
- glimpse HEALTH
- PRIMA Genetics

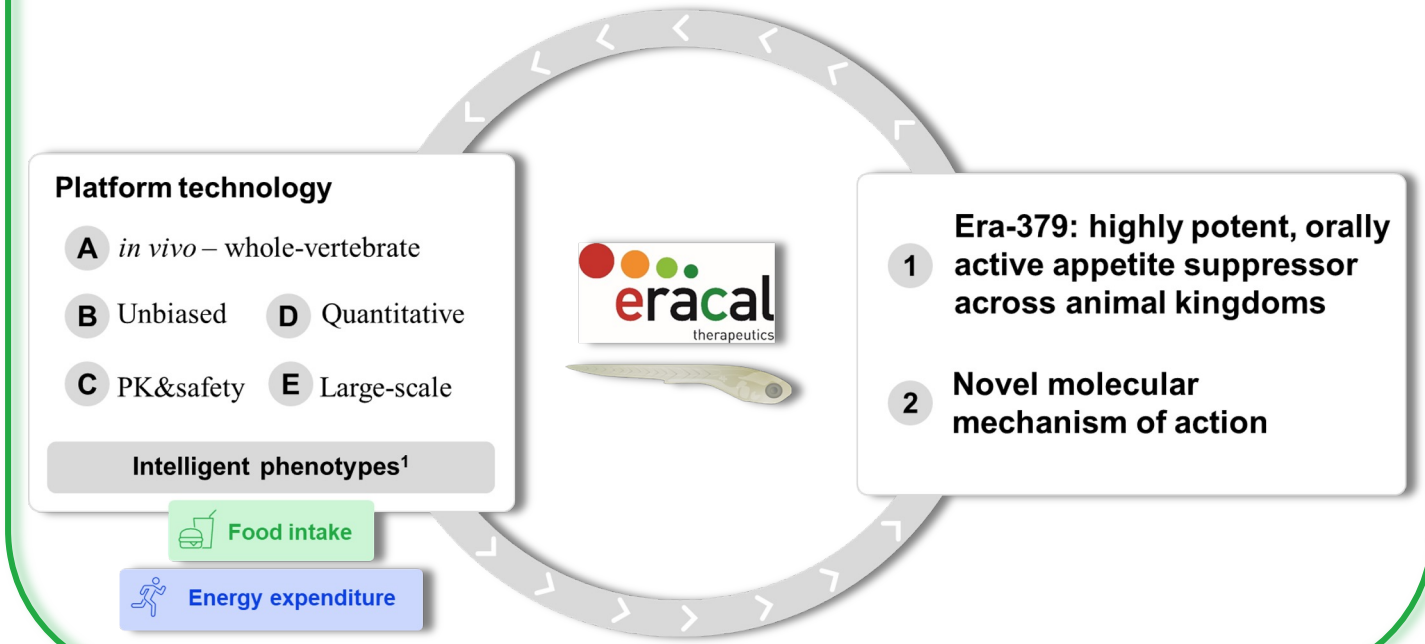
Advanced Medical Devices & Platforms

- KOVE
- Gluckl Newborn Glycemia Under Control
- PIONEER
- condenZero
- MGME Neurotech

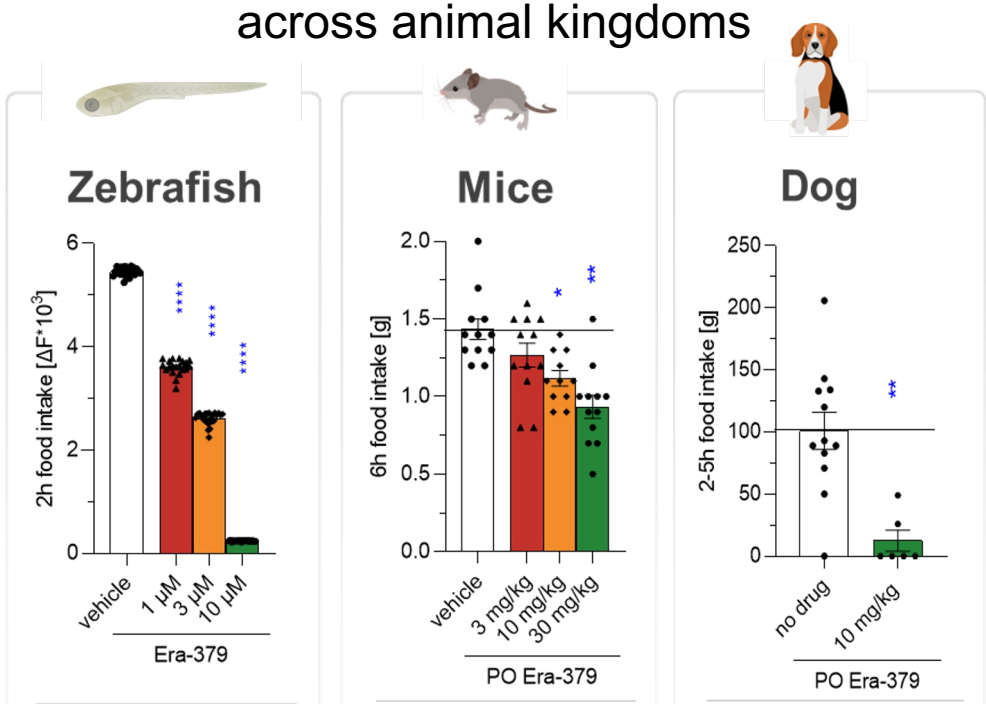
EraCal Therapeutics: Fighting Obesity

Joined UZH IncubatorLab in September 2018

Platform: Harnessing the power of zebrafish for drug discovery of intelligent phenotypes, e.g. food intake



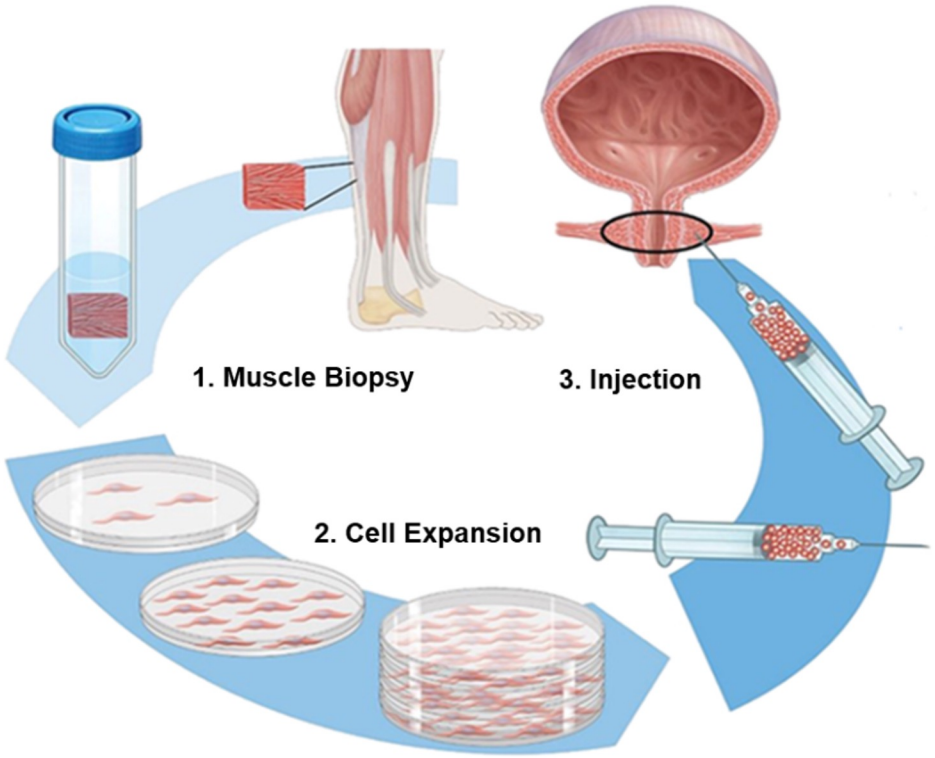
Era-379: orally active appetite suppressor across animal kingdoms



MUVON Therapeutics: REGAIN CONTROL

Joined UZH IncubatorLab in September 2019

REGENERATING THE URINARY SPHINCTER USING THE PATIENTS' OWN CELLS



UNIQUE ADVANTAGES OF OUR TISSUE ENGINEERING APPROACH

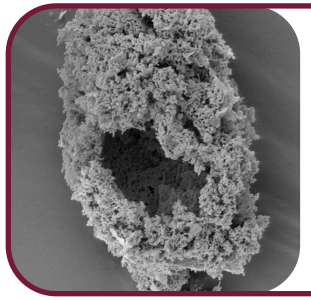
- ✓ **No genetic modifications**
- ✓ **No synthetic material**
- ✓ **Minimally-invasive**
- ✓ **Low risk**[1]
- ✓ **Potential cure**
- ✓ **No hindrance to child-birth**
- ✓ **Early Clinical PoC**[2]

[1] *Demonstrated with 0 Serious Adverse Events in Phase I Trial (9 Patients Treated) See Appendix*

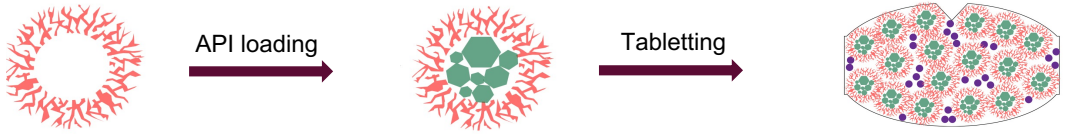
[2] *Early efficacy measurements from Phase I Trial*

Reconnect Labs – Regenerative Therapeutics For Mental Health

Joined UZH IncubatorLab in October 2019



Leveraging cutting-edge oro-mucosal microcarrier technology



Asset	MoA	Indication	Clinical stage
REO1 ***N,N-DMT + Harmine***	• 5-HT_{2a} agonist • Psychedelic Psychoplastogen	Substance Abuse Disorder	**Phase 1b – completed** ✓ Phase 2a in Q3 2023
REO2 ***5-MeO-DMT***	• 5-HT_{1a} agonist • Non-Psychedelic Psychoplastogen	Generalized Anxiety Disorder	**Phase 1b – completed** ✓ Phase 2a in Q2 2023
REO3 ***Dexmedetomidine***	• Alpha2 NA agonist • Regenerative sleep induction	PTSD-related Insomnia	**Phase 1b – completed** ✓ Phase 2a in Q2 2023

- ✓ Addressing psychiatric indications with high unmet need
- ✓ Rapid-acting interventions
- ✓ Novel indications due to reformulation
- ✓ Exceptional pharmacokinetic profiles
- ✓ Established TOX and safety
- ✓ Promising efficacy from Ph1b trials
- ✓ Novel MoAs with plastogenic, restorative and disease modifying potential

Scientific and regulatory challenges encountered

Research and Development

- RnD data translation into GLP documents
- Novel mechanisms of action: lack of guidance on pharmacodynamic profiling to define adequate therapeutic index
- FDA has released the draft Guidance for effectiveness evidence for well-controlled clinical trial and confirmatory evidence: EMA harmonization?

Regulatory and Compliance

- No aligned regulatory requirements/ product classifications by EMA and FDA: challenging parallel compliance for a small start-up
- Long-term changes in obesity clinical trial design. Will comparators become necessary with the recent successful drugs on the market
- Any plans to harmonize the regulatory requirements and terminology used by the regulatory Agencies for ATMP/regenerative therapies?

Market Access and Adoption

- Missalignment between regulatory endpoints and requirements by HTA
- How will payers react to novel anti-obesity drugs with comparable efficacy to the standard-of-care with improved safety?
- Any plans for the evolution/revisions of HTA requirements to consider the different nature of ATMPs vs. the existing and more traditional pharmaco-/bio-logical treatments?