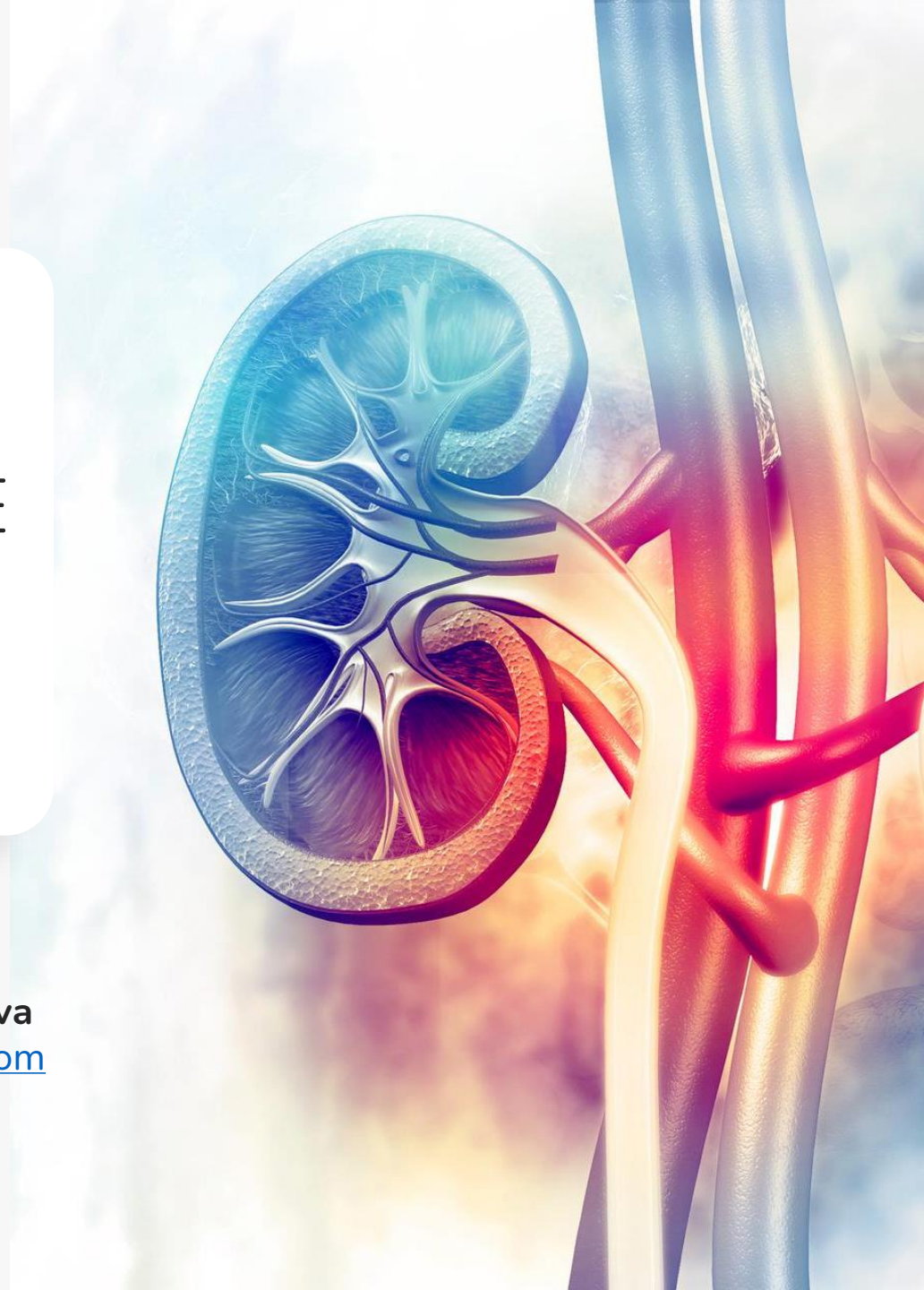
M2RLAB

A FIRST IN CLASS PATENTED PLATFORM TO TREAT MULTIPLE SERIOUS INFLAMMATORY DISEASES



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Comunidad de Madrid
Dirección General de Investigación e Innovación Tecnológica
VICEPRESIDENCIA, CONSEJERÍA DE EDUCACIÓN Y UNIVERSIDADES

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Who we are – M2RLAB

An R&D focused biopharmaceutical company that has developed a **patented cell therapy manufacturing platform** **to favor a decrease in inflammation, necrosis and fibrosis that follow many different inflammatory diseases**, while activating simultaneously mechanisms **regenerating damaged tissue** at the site of the injury.

Our vision: Solving the underlying cause of inflammatory and fibrotic diseases with **no current curing alternatives** for patients across the world in an affordable and timely manner

To meet our vision, we are transitioning to clinical stage with an **approved Phase I/II Clinical trial for AKI**. Our line of research includes two additional inflammatory diseases. More indications to be explored.

Acute Kidney Injury (AKI)

13.3M new patients diagnosed annually, many progressing to CKD resulting in dialysis and poor QoL leading to high mortality rates.

Global burden of AKI-related mortality > breast cancer, heart failure or diabetes

Acute Respiratory Distress Syndrome (ARDS)

Affects **10.4%** of total ICU admissions.

30-46% mortality rate (ARDS). 16-61.5% mortality rate in COVID-19 ARDS

Systemic Lupus Nephritis (SLN)

1.4M patients suffer SLN every year.

Mortality rate for SLN after 5yr is **8%** but increases to 18% at 10yr and 32% at 20yr.

Our team

Management and Clinical Development

Joaquín Juan Sanda
President

- Physiotherapist specialized in top level athletes
- KOL in Sports Medicine and Rehabilitation

Pablo García de la Riva
Chief Executive Officer

- Entrepreneur and executive in health industry
- +25 years of experience in investment banking and management

Dr. Xavier Ginesta
Project and IP Director

- PhD in Chemistry.
- 6 years as Knowledge Transfer Manager at CSIC

Luis Calatrava Calleja
BD & Mrkt Access Director

- MSc. in Health Economics
- 15 years bringing innovative therapies to market
- Global roles at industry players: Jansen, Kite Pharma, Vertex

Advisory Board: Clinical Translation, Regulatory and Production

Prof. Simon Taylor-Robinson
Science and Clinical Leadership

- Professor of Translational Medicine at Imperial College London
- Hepatologist and specialist in liver inflammation and transplant.
- Clinical Dean for the Faculty of Medicine at Imperial College London from 2010-2016

Santiago Lamas, MD, PhD
Science and Clinical Leadership

- Group Director in National Centers of Excellence in Research (CSIC and CNIC)
- Post doc Harvard Medical School

Esteban Poch, MD, PhD
Clinical Leadership

- Chief of the Nephrology Department at the Hospital Clínic Barcelona
- Scientific production IF higher than 680 in 114 articles

Rossana García, BA, MSc
Regulatory & Cell Production

- CEO GradoCell, Regulatory Affairs Consultancy
- Stem Cell Banking expert
- Previously Director of Cell Production in TigeNix (Takeda)

Science and Technology

Dra. Georgina Hotter
Chief Scientific Officer

- Principal Research at IIBB-CSIC
- Expert in tissue regeneration, cell therapy and hypoxia based therapies

Dra. Anna Sola
Scientific Advisor

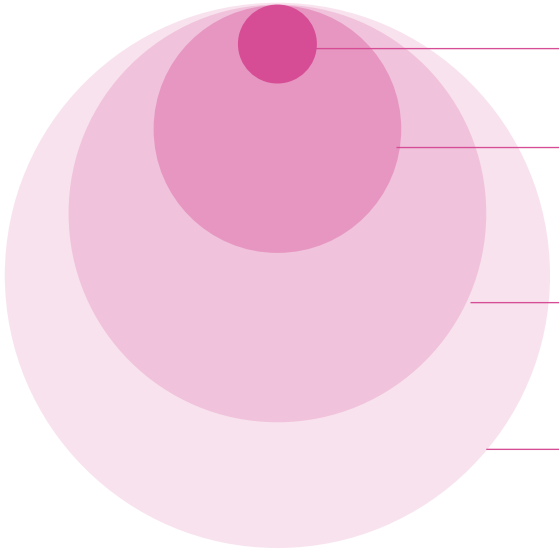
- Research Fellow at IDIBELL
- Recognised scientist with over 20 years of professional experience in life sciences

Intellectual Property

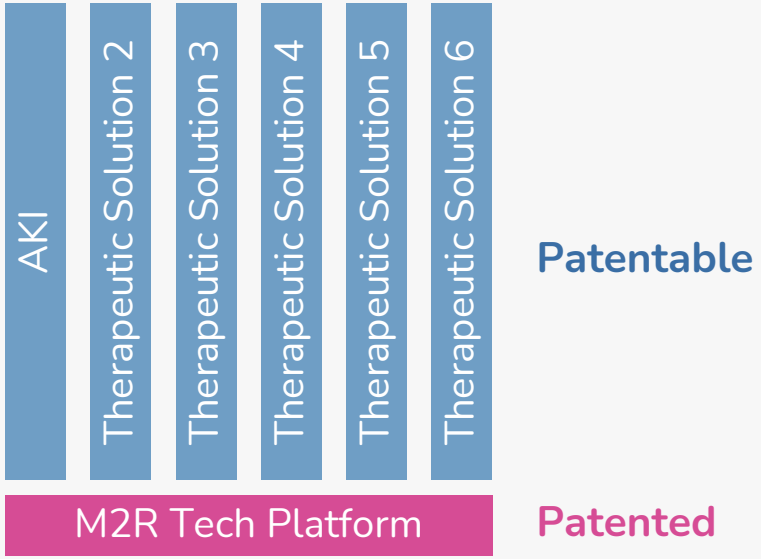
Our M2R® Tech Platform is protected by an approved patent*

Our Tech Platform is, in itself, a key differentiator at the forefront of innovation. It is protected by patents, as well as by industrial trade secrets and proprietary know/how.

We are in the process of presenting a new product patent on its cells with the objective of making the platform a highly versatile and scalable asset.



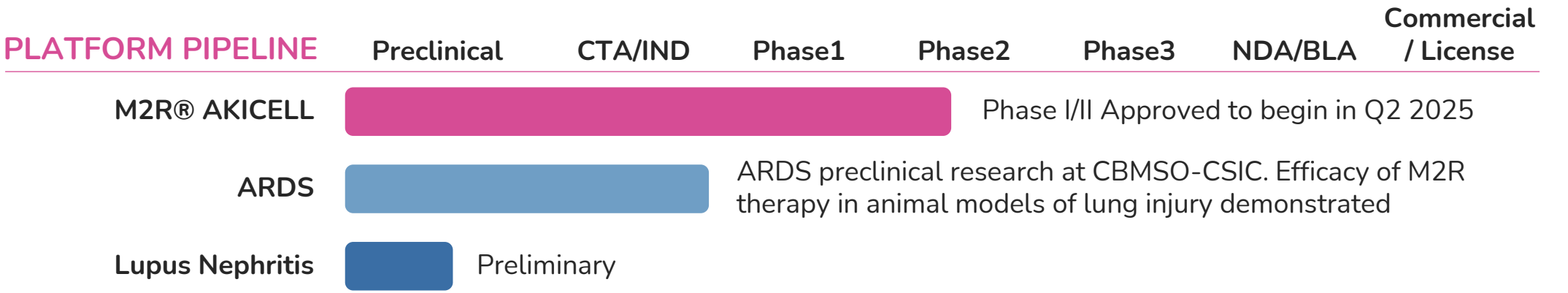
- European Patent EP3299453. Other patents in progress
- Valorization Protocols of M2 to be used as drugs, vehicles or tools for research
- Technical modifications of the methods and M2 aimed at treating different pathologies
- New methods to increase feasibility and efficacy in the M2R Tech Platform-based therapies



*EP3299453 - CELL THERAPY WITH POLARIZED MACROPHAGES FOR TISSUE REGENERATION

Platform in a Box to Treat Multiple Indications

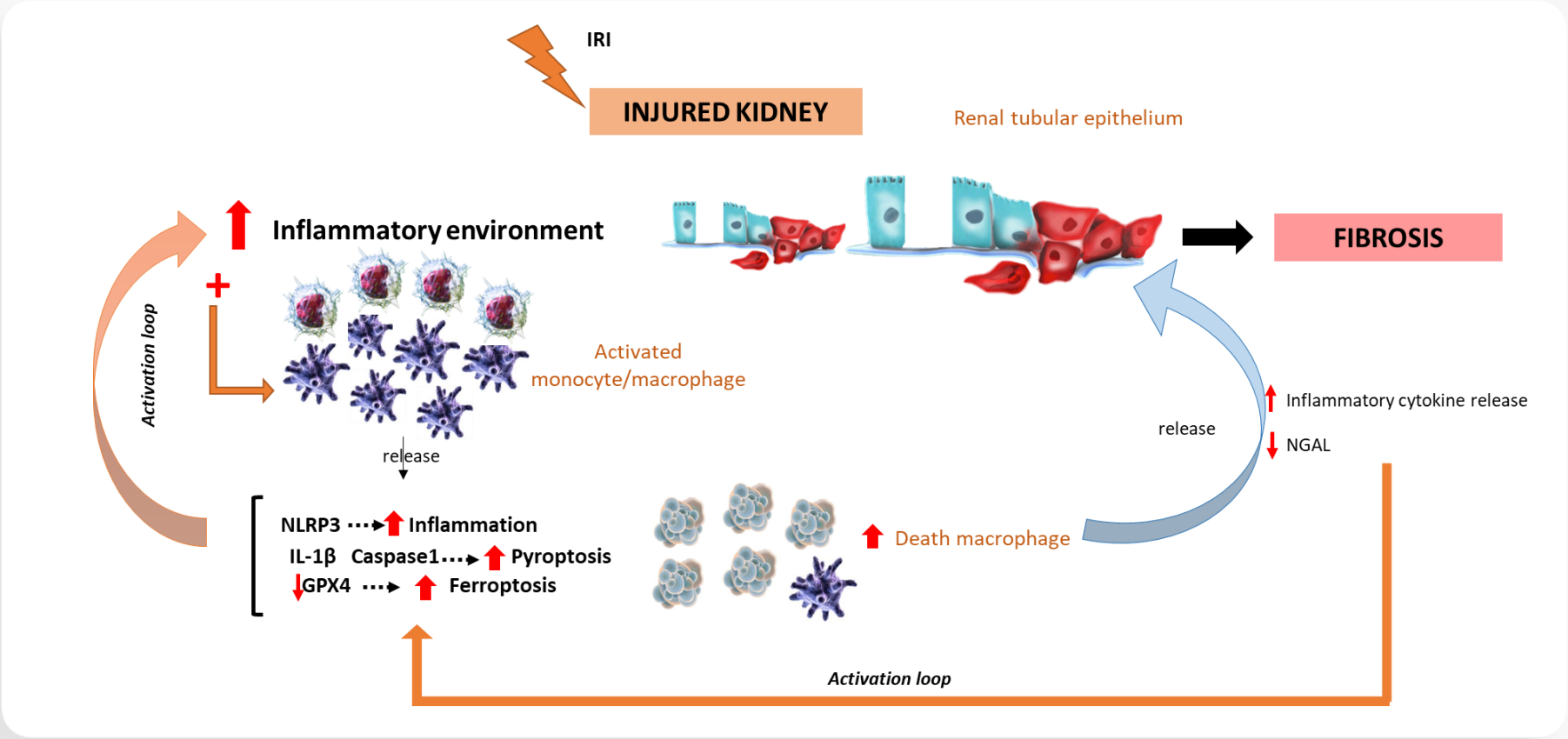
Currently **investigating** the use of our patented M2R® Platform in **three therapeutic areas**.



In the annexes we include preclinical data from our work in ARDS and Lupus Nephritis to provide an initial view to our work in extending to other indications.

We are in addition, analyzing PoC programs for NASH and Longevity. **Exploring additional lines of investigation to leverage our multi-indication patented platform** (subject to resources at hand). Candidates include digestive or haematological/transplant related inflammatory diseases.

AKI: An unsolved inflammatory disease



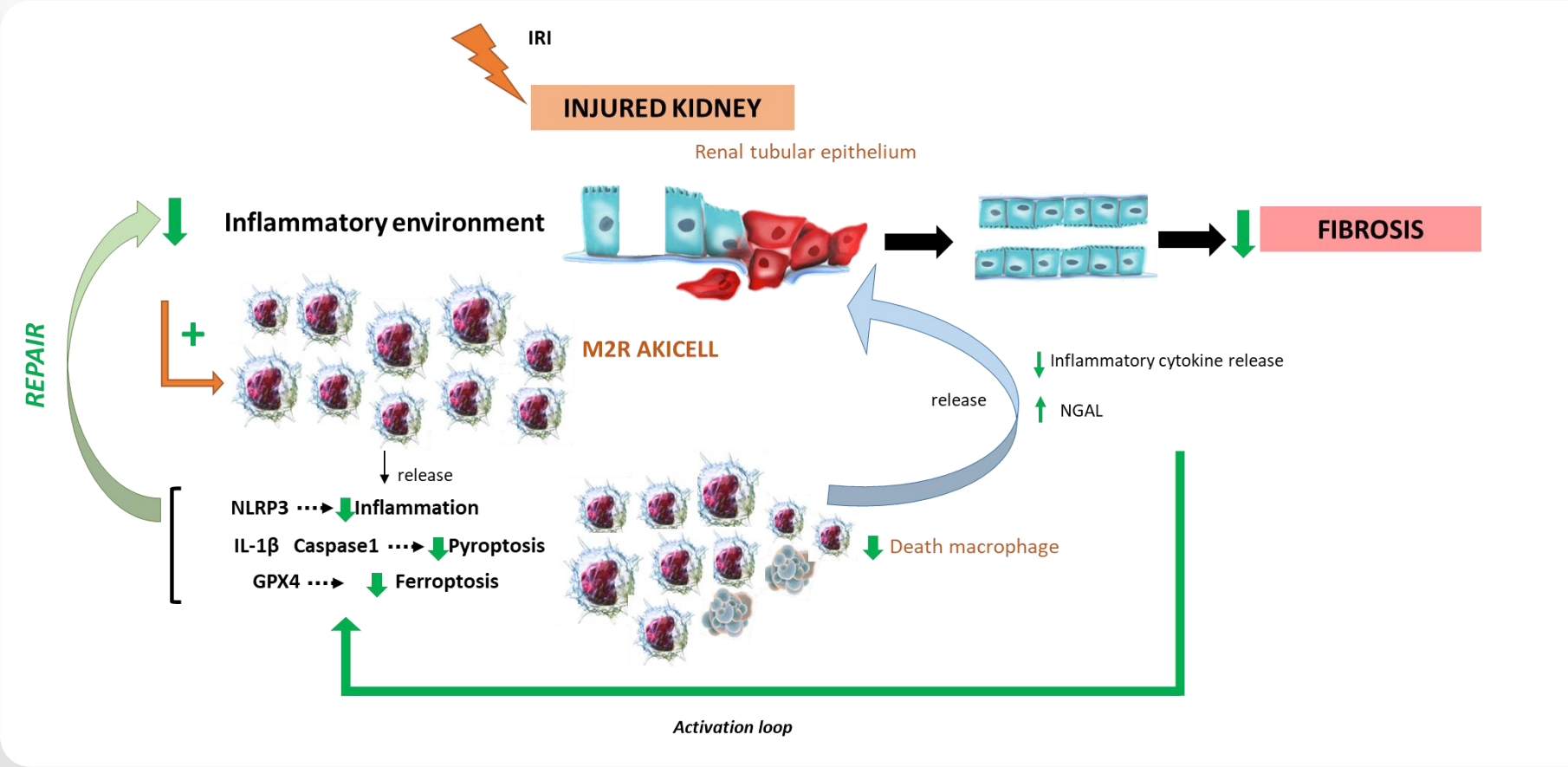
During AKI there is an inflammatory environment that activates macrophages to cause damage. As they release inflammatory mediators and have more pyroptosis and ferroptosis they die in large numbers.

When they die, they release more inflammatory mediators and less NGAL, causing a cascade of activation creating even more cell deaths and increasing inflammation, overall amplifying the response with more damage.

Our Solution: M2R® AKICELL Monocytes*

M2R AKICELL provides monocytes with a specific phenotype that transforms into Macs that release fewer inflammatory mediators and have less pyroptosis and ferroptosis.

With a prolonged life, they release more NGAL, which in turn amplifies the anti-inflammatory response and cleanses the epithelium and inducing less fibrosis creation.



Compared to current therapeutical options, M2R AKICELL **promotes tissue repair** and **regeneration**, and **reduces the fibrosis** associated to uncontrolled inflammatory process.

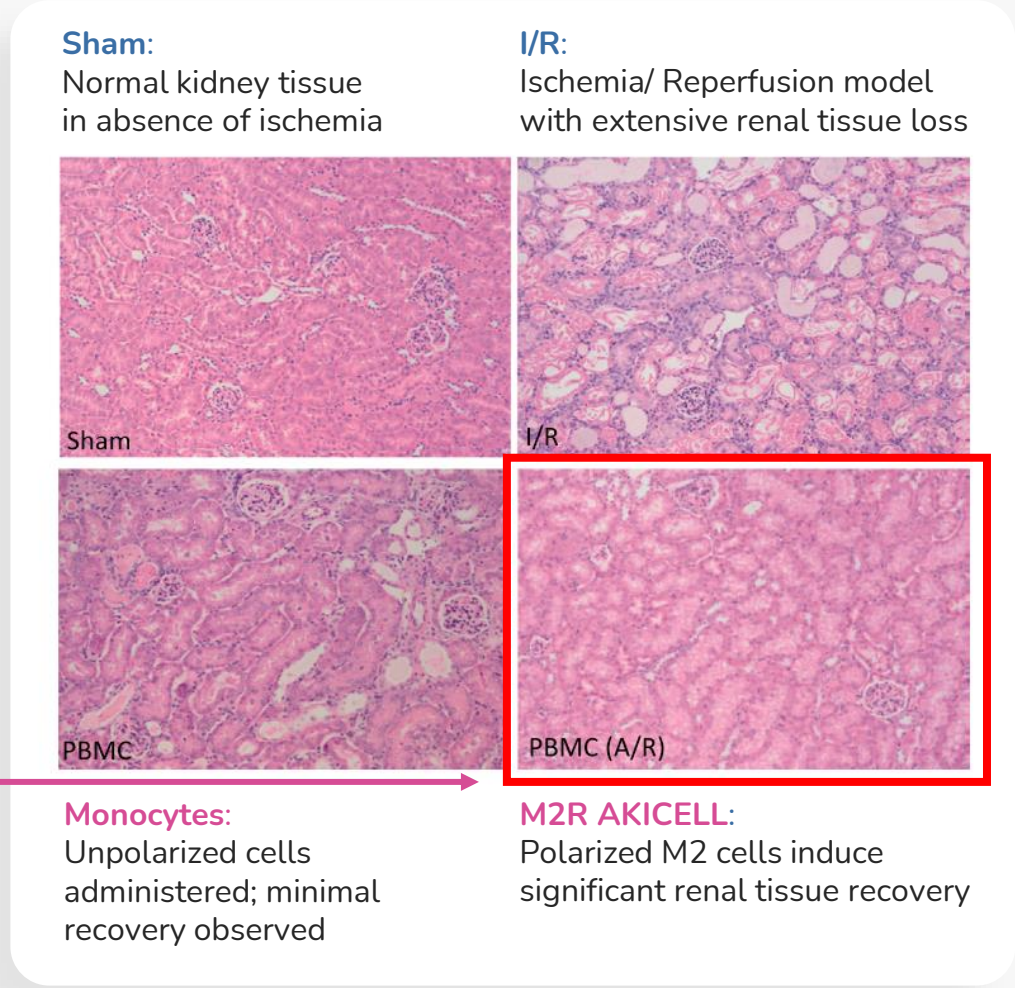
*The principles of how our technology works should be the same for other inflammatory based diseases

Monocytes Polarized to M2R are Effective in AKI Models

Monocytes Polarized to M2 are Effective in AKI Model, reducing inflammatory and fibrotic markers while maintaining cell endurance through the increase of antiferroptopic markers and decrease in pyroptosis.

Restoration of Kidney Function Observed together with formation of new working tissue. See annex 1 with summary key quantitative preclinical data.

In addition, Qualitative data clearly shows that **M2R AKICELL delivers recovery of renal tissue** post ischemia after the administration



Jativa, S., et al. Biomed Pharmacotherapy 153:113415, 2022, doi.org/10.1016/j.biopha.2022.113415

WHAT EXACTLY IS M2R® AKICELL?

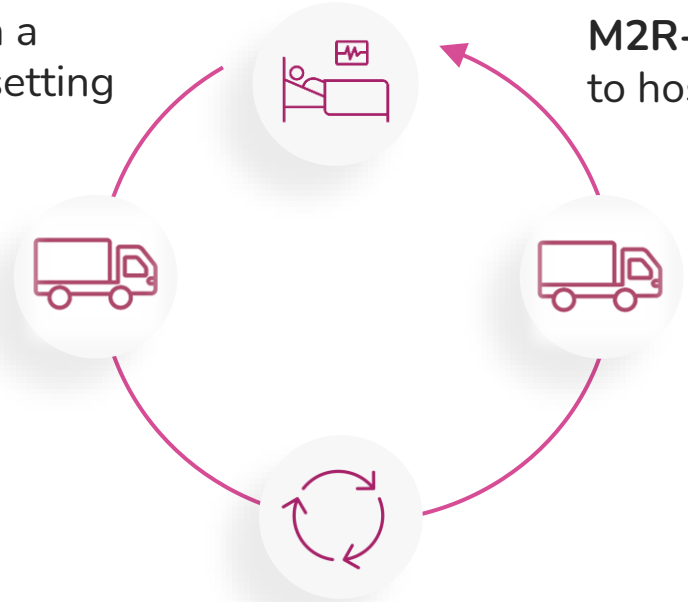
“On demand” autologous cell therapy to treat CS-AKI: ≤ 48 hours from receipt to delivery

Our innovation significantly **reduces manufacturing and logistics problems** of most autologous cell therapies

while **providing our product at a fraction of the cost**

PBMCs obtained in a standard hospital setting

M2R-AKICELL delivered to hospital within 48 hrs



Autologous monocytes harvested from pro-inflammatory (M1) to anti-inflammatory (M2) phenotype via **M2RLAB patented process ***.
They are produced at a **centralized GMP manufacturing facility**.

* Described in WIPO Application WO2018055153A. Also see Torrico, et al. Biomed and Pharmacot 2024, 178:117186, https://doi.org/10.1016/j.biopha.2024.117186

Recognized value of M2R® PLATFORM - AKICELL

Our patented platform already delivering value … beginning our Clinical Program

First in class clinical trial approved by EMA-AEMPS* in Jan-2025 – Phase I/II Clinical Trial Modified autologous leukocyte cells to treat acute kidney injury (AKI) aftercardiac surgery

Study Design

- 98 adult patients of both sexes, undergoing cardiac surgery with a diagnosis of AKI using the KDIGO criteria
- Phase II clinical trial, randomized 1:1, single-blind, placebo-controlled, with 2 treatment arms.

Primary Objectives

- Evaluation of the efficacy of cell therapy versus placebo by measuring the time of recovery of renal function.
- To evaluate the safety and tolerability of cell therapy versus placebo

Study Design

- First 7 days after administration
- At 30 and 90 days

- Need and duration of renal replacement therapy
- Need and duration of ICU and hospital stay
- Patient Survival

Project 190171232—M2R platform funded by:

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*EU CT - 2023-504610-30-01

Take aways from M2R® PLATFORM - AKICELL

EFFICACY

Double action:
1) **protects** the kidney during the AKI episode
2) **regenerates** tissue in injured kidney's areas

EFFICIENCY

Administration in **just 48 hours** delivered to any hospital
no cell expansion needed

UNIQUE VALUE

Renal function recovered in 7 days with no rejection or contraindications
Reducing hospital stays, chronic care and improving QoL

QUALITY

Company produces M2R AKICELL at **GMP-Accredited Centralized production facility** with capability to distribute/service to large geographic areas

AFFORDABLE COST

€9,000-€15,000 per treatment
One-off treatment

M2R® PLATFORM
simplified approach to CT: offering curative value in underserved TA

Clinical value already recognised by the AEMP/EMA with F I/II Clinical Trial approved

HECON benefits delivering a cost-effective solution to health payors

Business Model and Financial Forecast

First revenue streams of the M2R® Tech Platform: M2R-AKICELL®, as the first therapeutic indication AKI are expected to come from up-front payments for co-development from companies licensing for the indication

The projections below include a second indication that is licensed in 2028

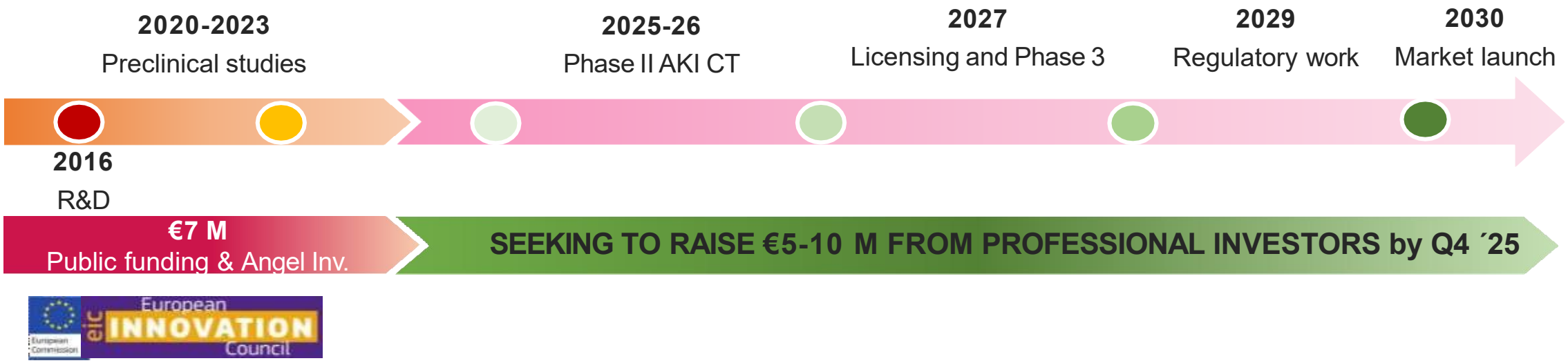
M2RLAB will be profitable in 2028

BP Financial Forecast

(figures in US$)	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
REVENUES	700.000	6.375.000	32.100.000	30.075.000	72.100.000	18.875.000	88.100.000	82.875.000	88.100.000	129.000.000
COSTS	4.700.500	7.686.235	16.595.958	17.059.749	25.902.678	25.467.808	26.850.032	26.869.204	20.044.676	20.888.465
EBITDA	-4.000.500	-1.311.235	15.504.042	13.015.251	46.197.322	-6.592.808	61.249.968	56.005.796	68.055.324	108.111.535
FREE CASH FLOWS	-4.011.500	-1.345.225	10.826.879	7.522.149	31.014.218	-6.592.808	46.317.154	39.944.488	48.251.990	76.304.297

*In these numbers we have not factored early access schemes like the “Compassionate Access Program” run in France

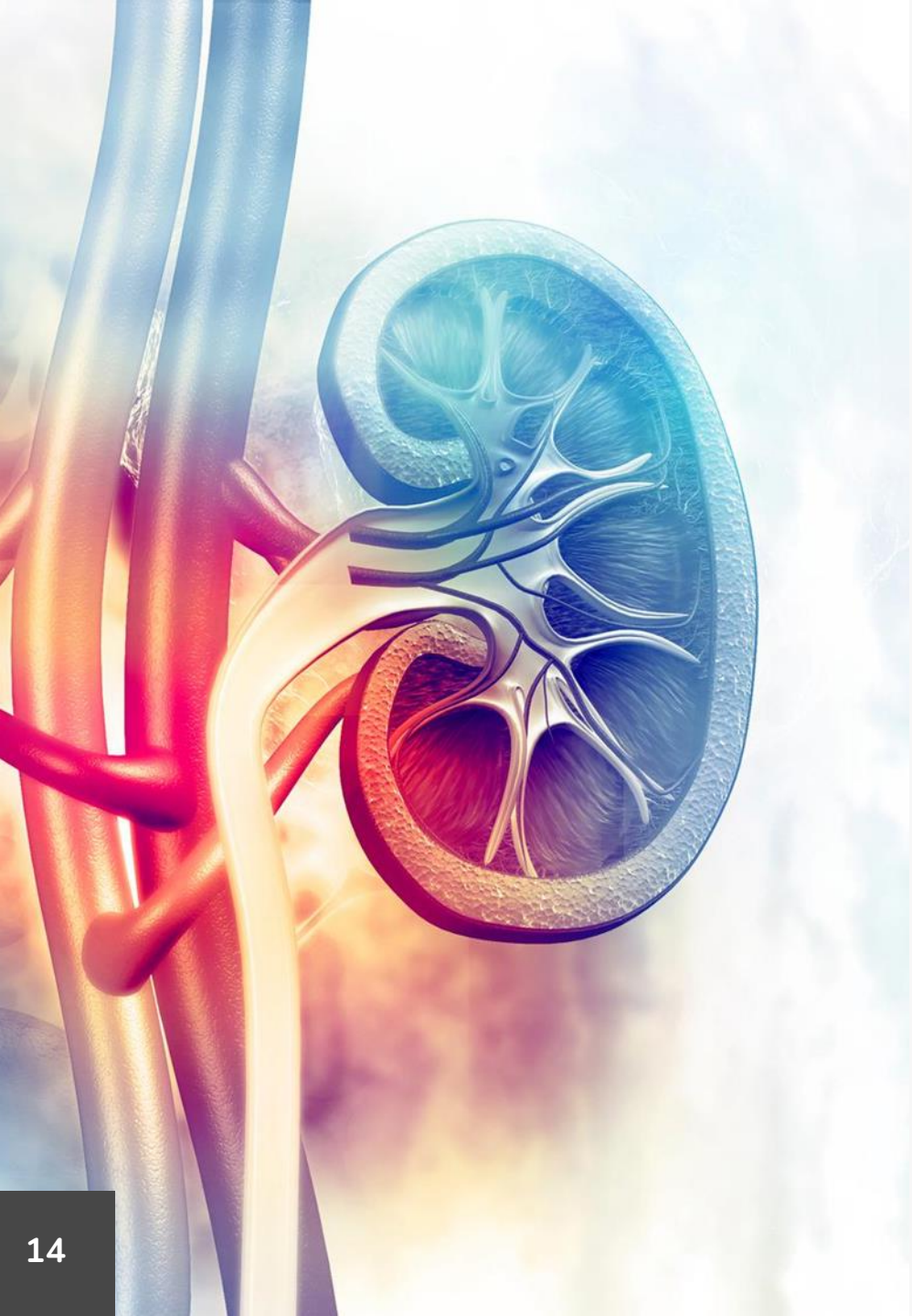
Time Schedule and Funding Requirements



Funds will be used to complete Phase II clinical trial, IND registration with FDA and expand / internationalise our team

First set of 20 patients from CT expected to be available early 2026

Depending on availability of funds raised early access to European and US markets through fast-track and compassionate programs will also be pursued



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