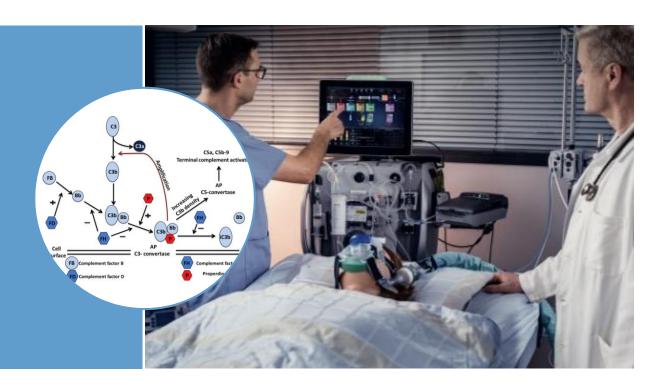


## Complement Activation – a Major Clinical Challenge



Over 100M treatments in the US alone are at risk of complications from harmful complement induced immune responses





Up to 20%<sup>(1)</sup> of all ICU patients need Extracorporeal Treatment (ExT) (e.g., dialysis, ECMO, cardiac bypass)



The human organism reacts to foreign bodies by triggering a complement induced immune response



This natural reaction leads to inflammation, clotting and fibrosis at a time when patients are at their weakest



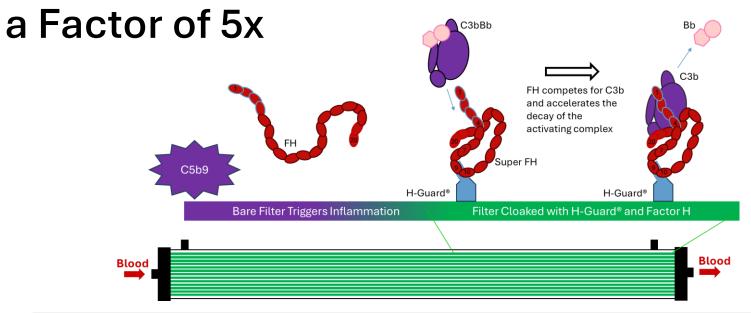
Complement activation negatively impacts patient outcomes, particularly in Acute Kidney Injury (AKI) cases



In up to 60% of patients complement activation exacerbates conditions, contributing to higher mortality rates.



We Can Reduce Complement Activation by



## H-Guard®'s patented mechanism acts as a biological "invisibility cloak"

01

H-Guard® uses the patient's own Factor H ("FH"), a key down-regulator of complement, to create a protective layer on the treatment surfaces

02

Immobilised Factor
H coats the
immunogenic
surface of the device

03

H-Guard® binds
Factor H, causing a
change in FH's shape
and transforming it
into the 5x more
active Super FH

04

By deactivating the complement complex, H-Guard® makes the foreign surface of the device invisible to the immune system

## Simple Use with Maximum Efficacy

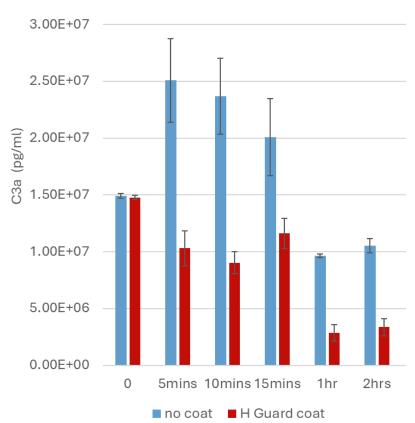
- No change in the existing clinical workflow needed
- Device agnostic
- Unlike personalized treatments, H-Guard® is an off-the-shelf solution, suitable for all patients without modification
- Applicable to various treatments beyond AKI, such as hemodialysis and cardiac bypass, Invizius' technology has the potential to impact a \$100 billion market



# Successful Ph2a Safety Trial indicated a Reduction in Inflammatory Markers

Statistically significant results demonstrate H-Guard®'s potential to prevent AKI progression to chronic conditions.





01

Significant reduction of key inflammatory mediators

C3a, C5a, C5b9 and MPO

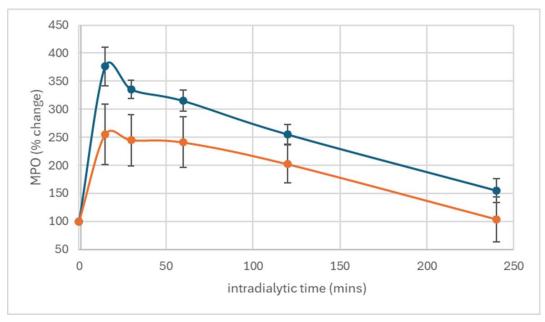
02

43% reduction in inflammatory markers in Ex Vivo CRRT.

Suggesting reduced 28Day mortality, reduced Renal Tubule Injury, and faster recovery times.

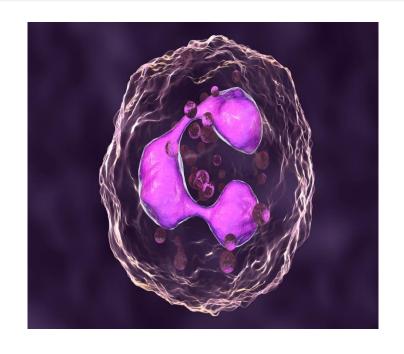


## Ph2a – Consistent Reduction in Neutrophil Activation (MPO)



Without H-Guard: higher MPO (more inflammation)

With H-Guard: lower MPO (less inflammation)



H-Guard consistently lowers MPO (Neutrophil Activation) at 15mins with a p= 0.00834

"Myeloperoxidase enzyme (MPO), a well-recognised proinflammatory biomarker released during oxidative stress, is strongly linked with cardiovascular disease, and may provide a pathogenic link between Inflammation and CV disease, both commonly observed in haemodialysis patients."

Prof. Sandip Mitra (Manchester Royal Infirmary)

"Thank you for this very interesting finding. It corroborates the fact that MPO and C activation are linked, also a good point is that H-Guard as a mitigating effect. In this perspective, that reinforces the potential of H-Guard for improving AKI3D outcomes."

Prof. Bernard Canaud (former Chief Medical Officer Fresenius Medical Care)



## First Indication: Acute Kidney Injury (AKI) – a \$3.5 billion Opportunity

AKI<sup>(1)</sup> related mortality exceeds that from Heart Failure, Breast Cancer or Diabetes

#### Significant unmet medical need

**Up to 60%** ICU patients develop AKI

> 25% of those will need dialysis and are at the greatest risk of death

#### **Intended Impact of H-Guard**



Downregulate local and systemic immune (and inflammatory response caused by CRRT)



H-Guard should enable faster and better recovery reducing CRRT treatment related inflammation of Kidnevs



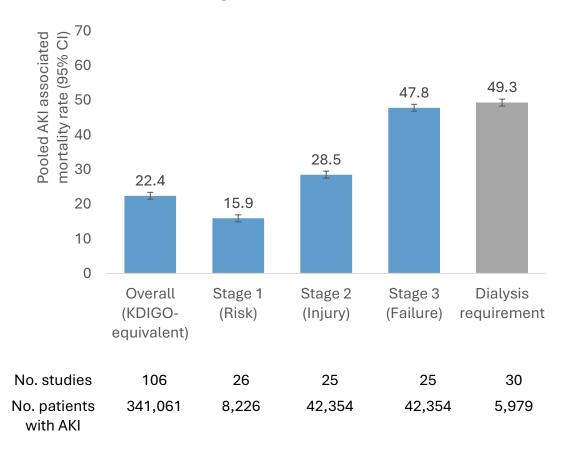
Protect Kidney Tubular cells from Complement and Neutrophil mediated damage



Expected release from ICU up to 3 days earlier (25% fewer ICU days). Lower 28 Day Mortality, Protects against need for long term dialysis.

(1) AKI is defined as an abrupt decrease in kidney function which frequently occurs in the ICU and during CRRT

## Patients with severe AKI requiring dialysis ("AKI-D") are at the greatest risk of death





# We Have a Solid Business Opportunity in the ICU



The total US/Europe ICU AKI market opportunity is 3 million units/year assuming 3 vials per ICU stay



**Up to 3 ICU Day Reduction with H-Guard®** 



28 Day Mortality Reduction (25%+)



Prevention of CKD and Long Term RRT (25% +)



Addressable AKI market opportunity is \$ 3.5bn



**Competitive COGS** 

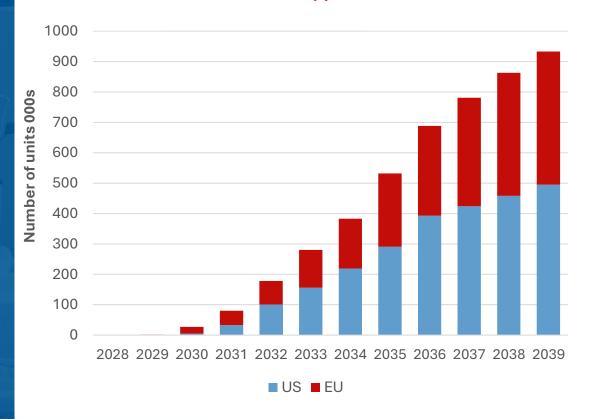


The ICU market is growing at high single digits and does not have the cost constraints of CKD-HD



Conservative Sales of 10% EU market share after 10 years, 10% US Market Share after 7 years and 20% RoW Market Share after 10 years

#### H-Guard® units supplied for treatment





## A Platform Technology

Product (Patented)	Indication Device (d) Therapeutic (t)	Market	R&D	Pre- Clinical	Phase 2a	Phase 2b	Phase 3
H-Guard®	AKI-CRRT (d)	\$2.4 bn					
H-Guard®	STROKE & TBI (t)	\$8.0bn+\$3.4bn					
H-Guard®	CP Bypass (d)	\$16.0bn					
Meso-Guard™	Peritoneal Dial.(t)	\$5.0bn					



Invizius' technology enables numerous product developments based on H-Guard as well as coating Extracorporeal Membranes

Including: Stroke and Traumatic Brain Injury(TBI)using current molecule.



Meso-Guard™ reduces complement activation on the Peritoneal membrane in response to dialysis fluid. Expected to reduce peritonitis and fibrosis in this patient group. Extending therapeutic window by up to 2 years as well as reducing mortality and healthcare provider costs.



Other applications for InVisius patented Complement Modulating Anti-Inflammatory platform technology

Pre-eclampsia, Diabetic Nephropathy, Fibrotic Diseases and Neurological Diseases.



## **Expanding Applications > \$100 billion Opportunity**

Significant revenue potential across multiple disease categories

Disease Category	Est. TAM	Comment
Acute Kidney Injury (AKI)	~ \$2.40 billion	Our immediate target market
Other acute extracorporeal applications (ICU)	~ \$7.00 billion	Hemodialysis, ECMO/CPB
Potential systemic indications	~ \$100.00 billion	E.g. Stroke, Diabetes, IgA Nephropathy, Fibrosis etc.





In addition to Cardiovascular, Stroke and Neurological diseases, indications such as Kidney Fibrosis, Pulmonary Fibrosis, Liver Fibrosis SLE, Preeclampsia etc., all have significant Complement involvement.



Many of these potential applications for Invizius' technology are the largest unmet clinical needs of our time with a total market value of over USD 100 billion.



Fighting inflammation at its source opens up a very large market!



# A Competitive Edge in the Extracorporeal Market

H-Guard® stands out with a unique approach requiring minimal workflow changes and addressing Inflammation right at its source.

CRRT Product	Manufacturer	Treatment price For 3 Days (estimated)	Target
QuellImmune®	SeaStar Inc	£6,000+	Neutrophils (Cells)
Depuro® D2000	Terumo	N/A 4hr life	Cytokines
CytoSorb®	CytoSorbents Inc	£2,760	Cytokines
Oxiris®	Baxter	£1,407	Toxins
Jafron® HA 380	Jafron China	£1,350	Cytokines
H-Guard®	Invizius Ltd	£2,250	Complement



#### Minimized workflow changes:

Unlike competitors who add filters to extracorporeal circuits,
H-Guard® coats existing CRRT filters, therefore facilitating adoption



#### **Acting Root of the problem**

Competitors like CytoSorb® target cytokine reduction, while H-Guard® focuses on complement system inhibition, addressing the root cause of inflammation



#### **Better Efficiency at Lower Costs**

H-Guard® also offers superior cost efficiency with no need to develop new hardware or filters



### **Key Opinion Leaders' Feedback**

AKI- KOLs agree that H-Guard®'s potential benefits include increased rate of renal recovery, shorter ICCU time, fewer new infections, fewer circuit changes, and lower mortality



"Extracorporeal circuits like those used for renal replacement therapy can result in immune activation just as patients are recovering from AKI. Preventing complement activation on the dialysis circuit is a promising approach to reducing inflammation-driven damage and could accelerate recovery. I would encourage clinical studies of H-Guard with AKI patients."

Professor John Kellum, Critical Care Nephrologist, Pittsburgh University Medical Centre, US; CMO, Spectral Medical Inc, Canada



"Patients [on CRRT] could definitely benefit from H-Guard, and I would love to take part in clinical studies. Benefits could come from less clotting activity, lower inflammation, less dialysis-induced kidney injury, and faster recovery from AKI. I hope that you are able to persuade your investors."

**Professor Alex Zarbock**, Intensivist, Münster University, Germany



"Reducing inflammation in AKI patients to avoid subsequent CKD/ESKD is a hot topic among clinicians. Based on your early inman data, H-Guard clearly has potential. The timing is very good"

Professor Patrick Honoré, Intensivist Nephrologist, Brugmann University Hospital, Belgium



## Intellectual Property Position

Intellectual Property Position The Company has patent protection over H-Guard® and the opportunity to expand its patent base.

- **01** PspCN (H-Guard) **WO 2015/055991** (Filed 13/10/14, expires 12/10/34)
- O2 Territorial Austra
  Coverage China

Australia (x3 granted)
Canada (x1 pending)
China (x1 granted,
x1 pending)

Europe (European Patent Office, x1 granted, x1 pending) Japan (x3 granted) USA (x2 granted, x1 pending)

Further Points — Supplementary Patent Certificate (SPC) can extend patent term by up to 5 years in Europe. — Data exclusivity/market protection period of 10 years in Europe from market authorisation that prevents third parties using Invizius clinical data to obtain market authorisation for a generic product.

- A patent application was filed for the specific **H-Guard®** construct in early September 2024 (expected expiry of which would be **September 2044).**
- (04) Meso-Guard™ Patent Position for Peritoneal Dialysis Peritonitis WO 2023/161662 A1
- Meso-Guard™ is Invizius' second renal dialysis product designed to prevent and reduce peritonitis and fibrosis in Peritoneal Dialysis Patients. Invizius has excellent IP protection for using Complement inhibition in this indication.

### A World Class Team with Deep Expertise





Dr. Magnus Nicolson **CEO** 



Dr. Joe Conner Head of Research



CFO (Interim)





**Eric Beard** Chairman



Non-Executive Director

#### **Key Team Members**



Dr. Liz Blackburn **Principal Scientist** 



Dr. Eliza Makou Principal Scientist & Co founder



Dr. Christine Jack Process & Bioassay Senior Scientist



Dr. Rosie Tobin QC Scientist



Dr. Aisya Gany Research Scientist

#### **Scientific Advisors**



Prof. Peter Stenvinkel Karolinska Institute



Prof. Sandip Mitra Manchester Royal Infirmary



Prof. Bernard Canaud Universite de Montpellier

#### Dr. Magnus Nicolson, CEO

with a doctorate in Immunology and an MBA, has led multiple companies, raised funds in both public and private markets, and directed global R&D partnerships & products licensings to multinationals. Two companies he led were acquired by large corporations. His extensive leadership has spanned diverse markets across over 40 countries.

#### Dr. Joe Conner, Hd. of Research

Over 10 years of experience as a CSO in the life sciences, specializing in complement inhibition. His expertise spans molecular virology, immunology, and antibody engineering, with significant research in protein production and purification. He is highly published with an extensive patent portfolio.

#### Hazel Allen, CFO

Chartered Accountant with over 30 years of experience in finance, including 15 years in senior management. She has expertise in finance, strategy, HR, and IT, with a strong track fundraising, record stakeholder management, and improving business profitability across diverse sectors, including private equity and angel investment.

#### **Board Members & Scientific Advisors**

Bring expertise from companies such as Pfizer, Baxter, and Spectral Medical, positioning Invizius for clinical and commercial success.

### Summary



Clinical stage biotech with highly qualified scientists, strong medical advisory board and external partnerships



Developing second generation complement therapies to control the body's innate immune response dysregulated by devices or disease.



Lead product H-Guard® to help recovery from **Acute Kidney Injury &** avoid progression to End **Stage Renal Failure** 



















Raising \$12m Series B to fund Phase 2b trial in CRRT following **AKI-CS** via existing strong syndicate of VCs/CVC and seeking new Investors



**Technology Substantially** de-risked with proven and scalable Manufacturing, clear Regulatory pathway and **Strong IP** position



H-Guard® has successfully completed First-in-Human (Phase2a) with safety and efficacyrelated biomarker data

## Thank you!

Dr Magnus Nicolson

CEO

mnicolson@invizius.com