



# Investor Presentation

Bringing organ-restoring solutions to  
critically ill patients

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November 2024

Seastarmedical.com  
Nasdaq: ICU

# Forward-looking statements

This presentation contains certain forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, SeaStar Medical’s expectations with respect to the timing of regulatory approval of its products, the expected timing on enrollment, generation of study results, submission of PMA and other corporate milestones, the ability of SCD to treat patients with AKI, and the potential benefits of SCD to treat other diseases. Words such as “believe,” “project,” “expect,” “anticipate,” “estimate,” “intend,” “strategy,” “future,” “opportunity,” “plan,” “may,” “should,” “will,” “would,” “will be,” “will continue,” “will likely result,” and similar expressions are intended to identify such forward-looking statements. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside SeaStar Medical’s control and are difficult to predict. Factors that may cause actual future events to differ materially from the expected results include, but are not limited to: (i) the risk that SeaStar may not be able to obtain regulatory approval of its SCD product candidates; (ii) the risk that SeaStar may not be able to raise sufficient capital to fund its operations, including clinical trials; (iii) the risk that SeaStar Medical and its current and future collaborators are unable to successfully develop and commercialize its products or services, or experience significant delays in doing so, including failure to achieve approval of its products by applicable federal and state regulators, (iv) the risk that SeaStar Medical may never achieve or sustain profitability; (v) the risk that SeaStar Medical may not be able to access funding under existing agreements; (vi) the risk that third-parties suppliers and manufacturers are not able to fully and timely meet their obligations, (vii) the risk of product liability or regulatory lawsuits or proceedings relating to SeaStar Medical’s products and services, (viii) the risk that SeaStar Medical is unable to secure or protect its intellectual property, and (ix) other risks and uncertainties indicated from time to time in SeaStar Medical’s Annual Report on Form 10-K, including those under the “Risk Factors” section therein and in SeaStar Medical’s other filings with the SEC. The foregoing list of factors is not exhaustive. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and SeaStar Medical assume no obligation and do not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise.



# SEASTAR MEDICAL

Commercial-stage company with patented, clinically validated, organ-agnostic therapeutic device targeting life-threatening hyperinflammation

The Selective Cytopheretic Device (SCD) extracorporeal platform stops the cytokine storm and safely restores organ function

*Changing the standard of care, one patient at a time*

# Investment highlights

## BEST-IN-CLASS TECHNOLOGY

- Patented, proprietary SCD platform addresses life-threatening unmet medical needs
- Clinically proven to reduce mortality and decrease dialysis dependency in acute kidney injury
- Potential to dramatically reduce economic burden of disease
- Proven delivery system
- Shelf-life stability at room temperature

## MULTIBILLION-DOLLAR MARKET

- Platform technology potential application in multiple high-value acute and chronic indications
- Technology requires minimal, if any, modifications for new indications
- Same SCD, Same Mechanism of Action, with access to a multitude of indications

## COMMERCIALIZING FIRST INDICATION

- 1<sup>st</sup> FDA approval for pediatric acute kidney injury with sepsis
- Product shipped in July 2024
- QUELIMMUNE™ (SCD-PED) commercial strategy to target leading children's hospitals
- Approval validates platform and derisks future FDA approvals

## PIVOTAL TRIAL PROGRESS

- Enrolling patients in pivotal adult trial, NEUTRALIZE-AKI
- Adult acute kidney injury population 50x larger than pediatric
- CMS coverage for a portion of trial costs

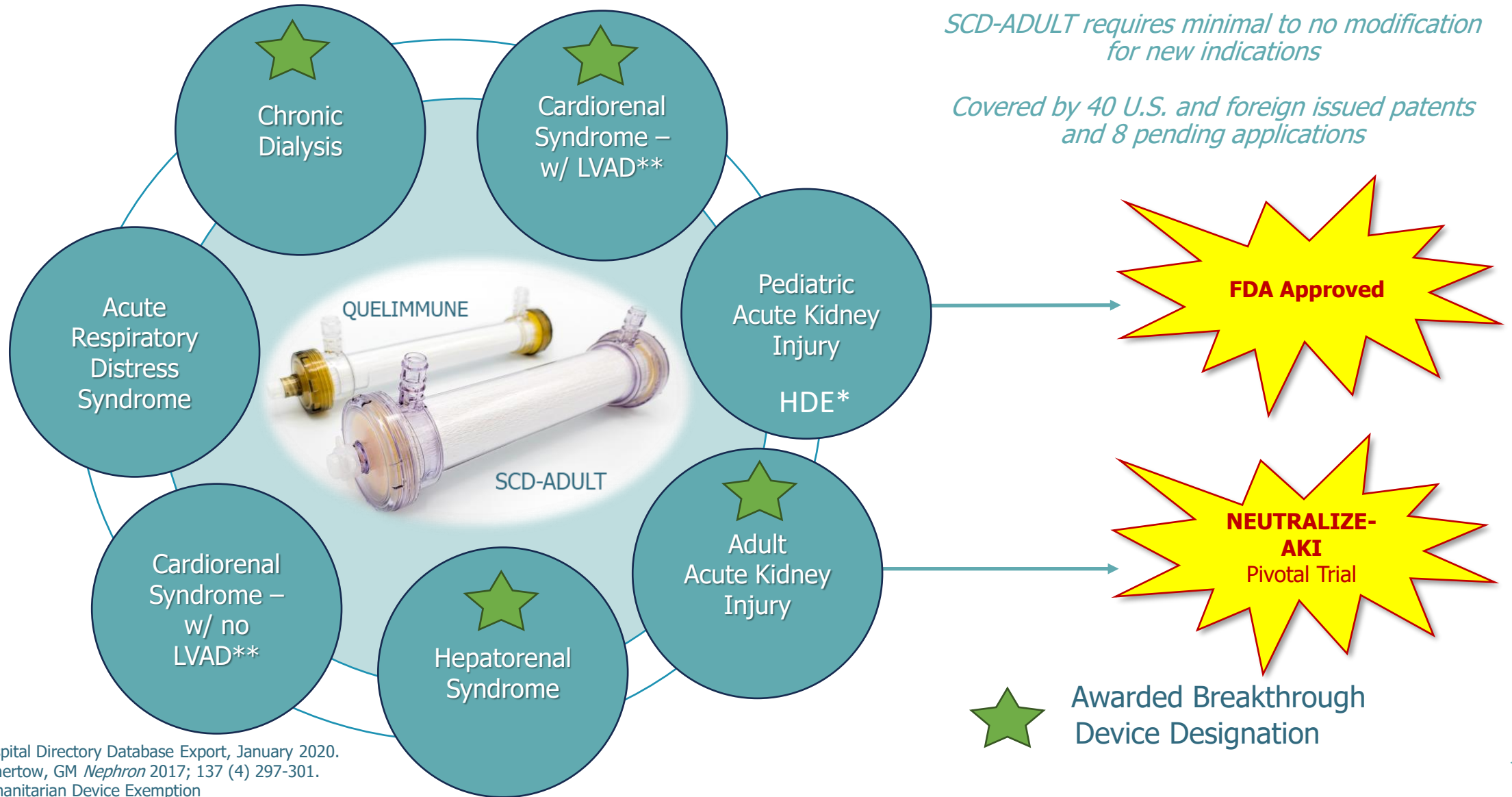
## EXPERIENCED EXECUTIVE TEAM

- Seasoned, dynamic leadership with over 150 years of industry experience\* and clear focus on advancing strategy
- Wealth of executive, operational, financial, clinical and regulatory expertise



\*Based on the 6 members of the leadership team

# Diverse application in multiple blockbuster potential, inflammation-driven diseases where vascular access is in place



*SCD-ADULT requires minimal to no modification for new indications*

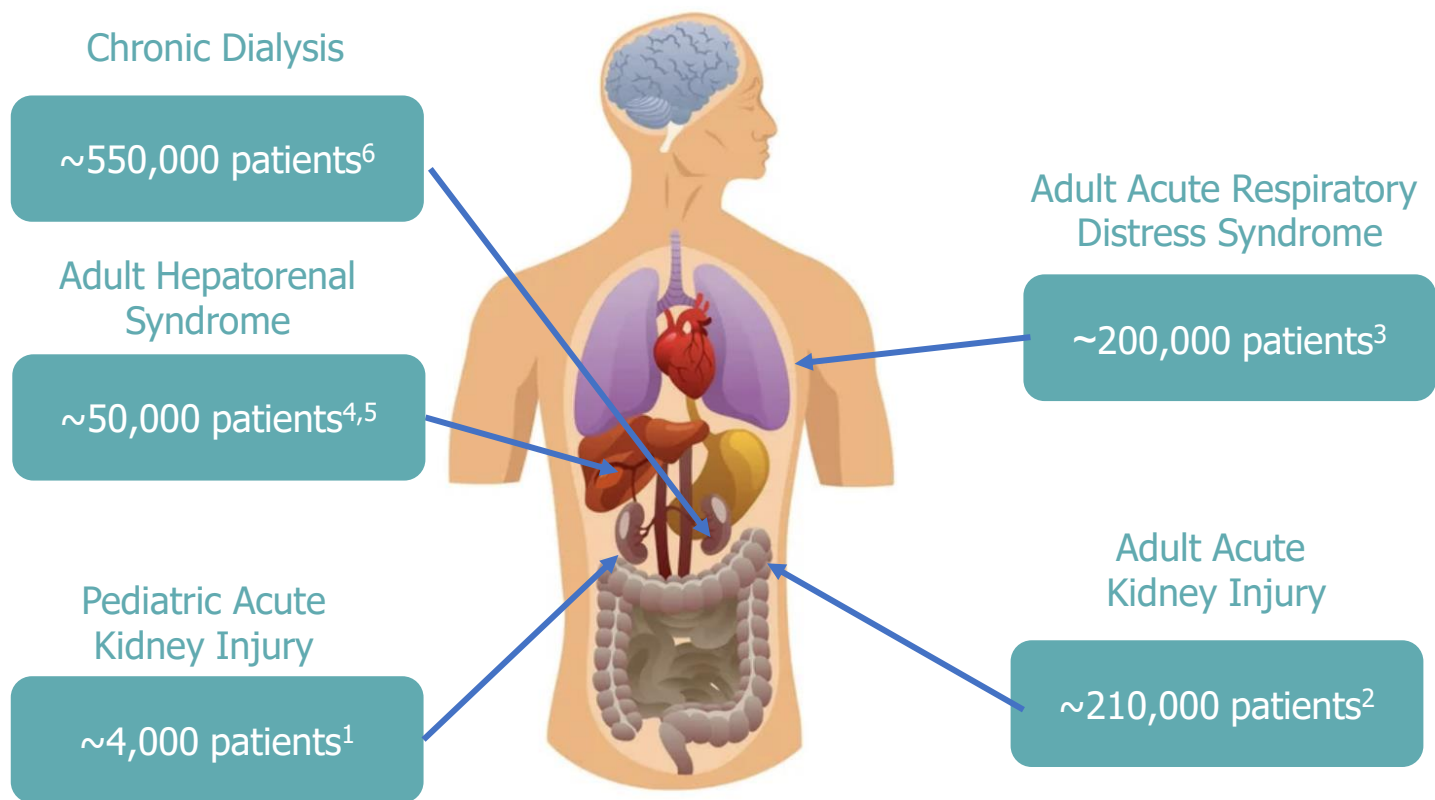
*Covered by 40 U.S. and foreign issued patents and 8 pending applications*

1. America Hospital Directory Database Export, January 2020.
2. Silver SA, Chertow, GM *Nephron* 2017; 137 (4) 297-301.
3. \*HDE – Humanitarian Device Exemption
4. \*\*LVAD – Left Ventricular Assist Device



# Blockbuster potential in near-term indications

*Captive inpatient settings with vascular access intact  
Annual U.S. patient population*



Base Revenue Opportunity

TAM ~1,000,000 patients



Average cost of therapy per patient  
≈ \$10,000-30,000 (3-7 days of treatment)



Conservative market penetration  
~10%



**Annual Potential US Revenue ~\$2B**

1. America Hospital Directory Database Export, January 2020.
2. Silver SA, Chertow, GM *Nephron* 2017; 137 (4) 297-301.
3. American College of Physicians, ACP Hospitalist, Coding information from July 2019.
4. Sepanlou, et al. *Lancet Gastroenterology & Hepatology*, 2020 Mar;5(3):245-266.
5. Orman, et al *JAMA Netw Open*. 2019 Oct 2;2(10):e1913673.
6. <https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>



# FDA-approved for pediatric acute kidney injury and pivotal adult acute kidney injury trial underway



*QUELIMMUNE is approved under a Humanitarian Device Exemption for the treatment of children with sepsis or septic condition\**

Indication	
Pediatric acute kidney injury	FDA approval February 2024 – Commercial launch July 2024
Adult acute kidney injury	Pivotal trial underway

Pediatric acute kidney injury approval sets a strong precedent for approvals in additional indications

\*QUELIMMUNE is approved by the FDA as a Humanitarian Use Device (HUD) to treat pediatric patients with acute kidney injury and sepsis or septic condition weighing 10 kilograms and requiring kidney replacement therapy



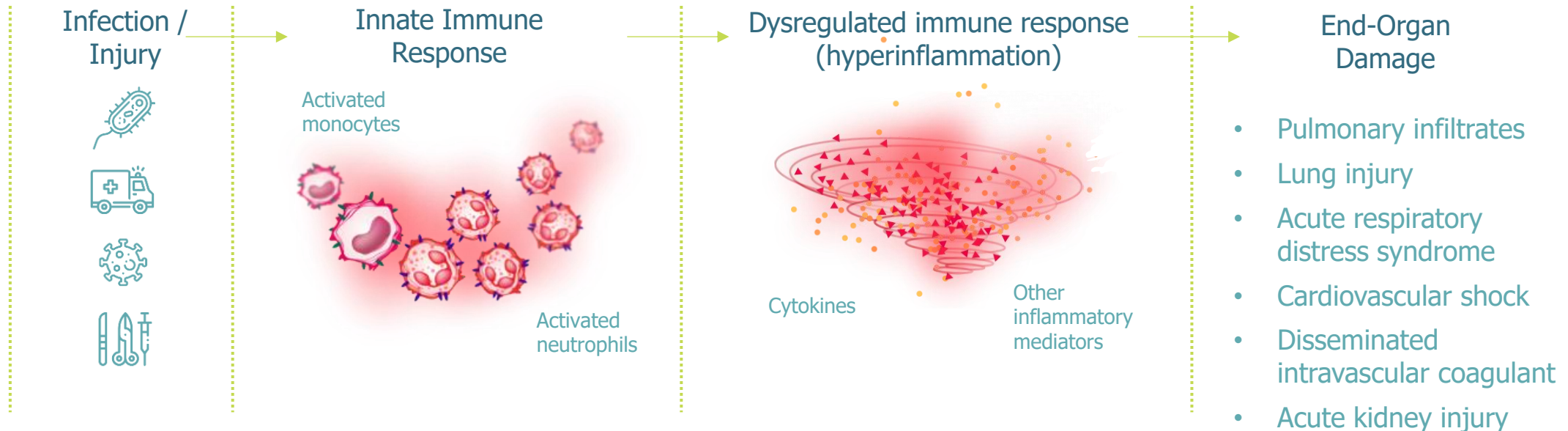
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# SCD TECHNOLOGY PLATFORM

A healthcare professional, likely a nurse or technician, is shown in profile, wearing a light blue scrub top and a yellow surgical mask. She is looking intently at a computer monitor. The background is a clinical setting with various medical equipment, including a patient bed, IV stands, and monitors. The overall tone is professional and focused.



# Hyperinflammatory response can lead to multi-organ damage and death

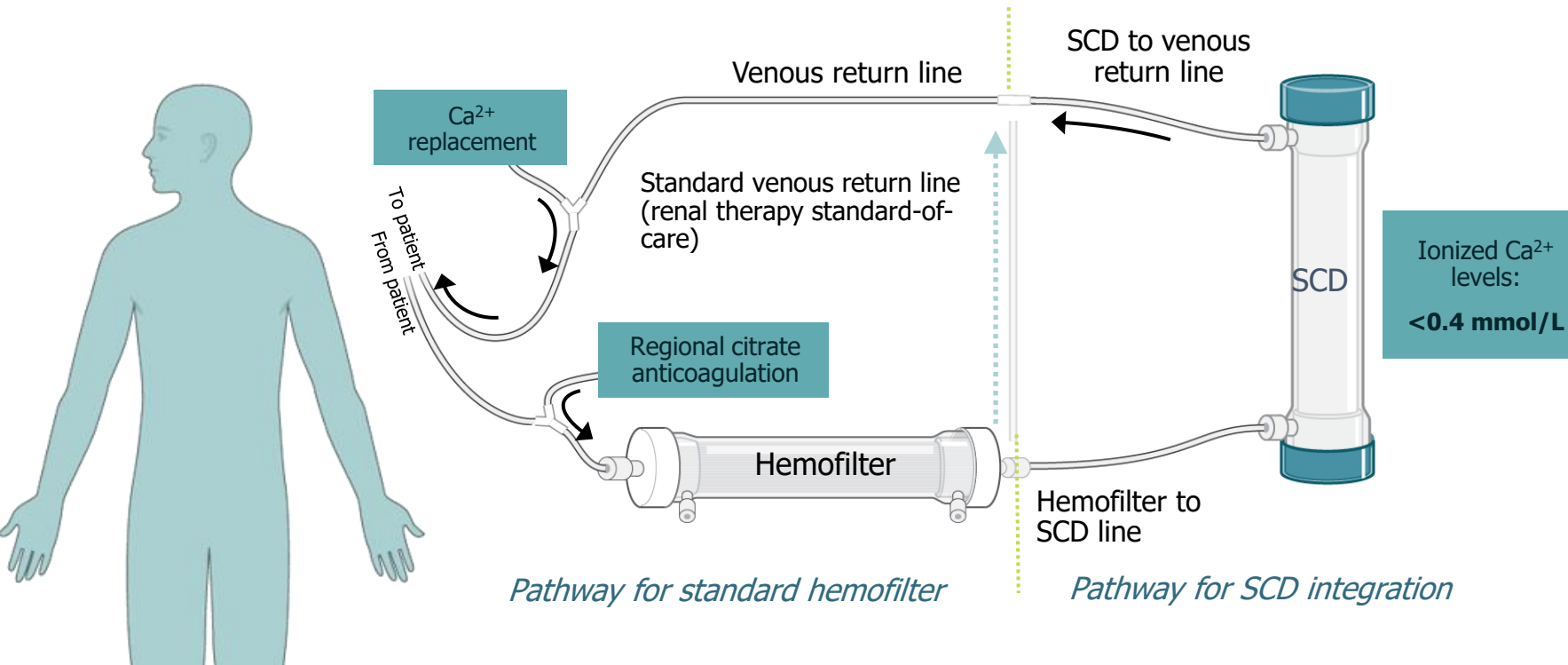


Patient Outcome:

Permanent Organ Damage or Death



# Unique mechanism of action restores reparative physiology

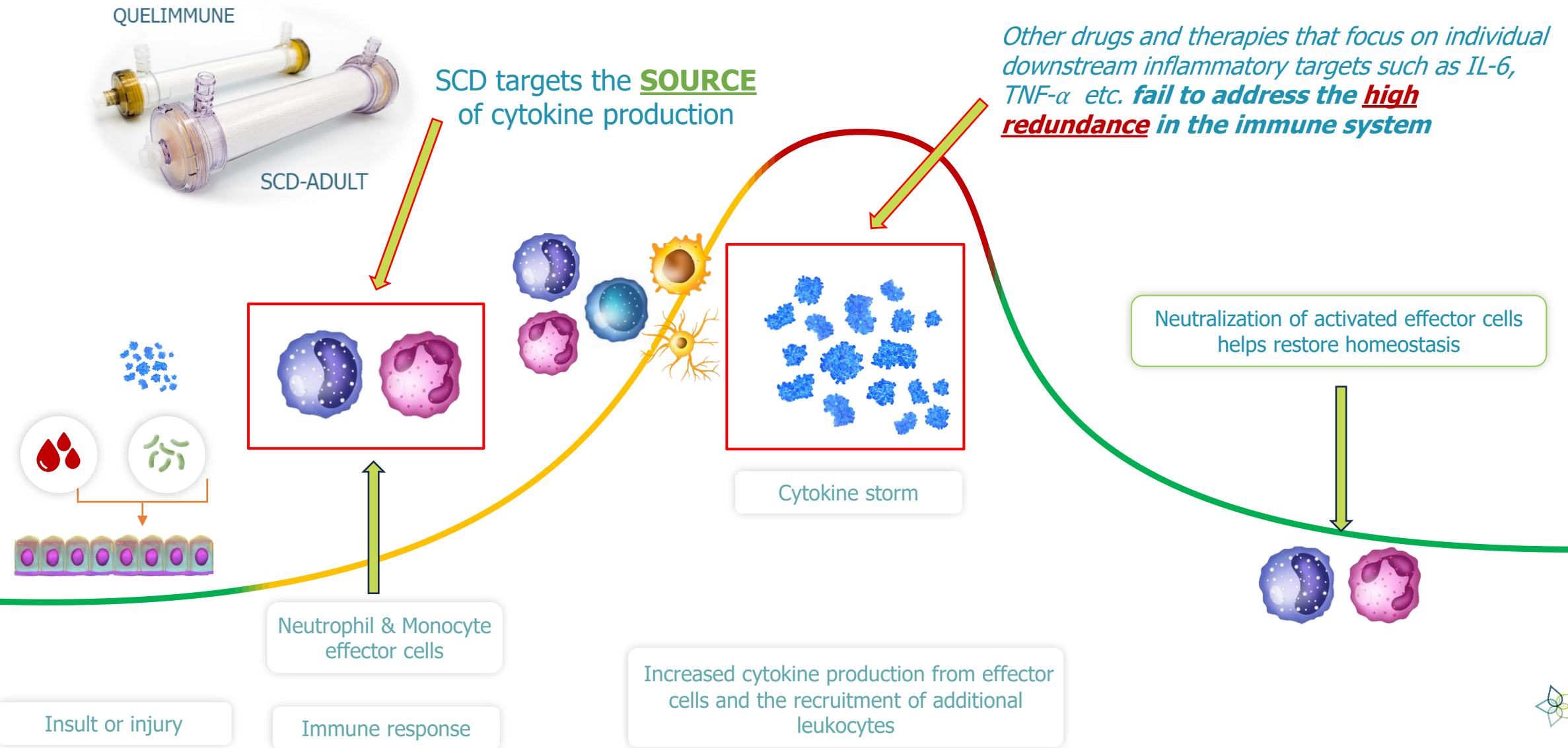


- LOWER ionized calcium in circuit with citrate
- +
- Selectively TARGET highly activated neutrophils & monocytes
- +
- DEACTIVATE through neutrophil apoptosis and monocyte shift to repair phenotype
- =
- HOMEOSTASIS-RESTORING THERAPY**

*SCD conveniently connects with existing continuous kidney renal therapy that's widely available in U.S. ICUs today*



# SCD targets *upstream source* of effector cells and *neutralizes effector cells* that release cytokines



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# SCD CLINICAL EVIDENCE



# Pediatric patients with acute kidney injury are vulnerable to cytokine storms

*Despite ICU's standard care in managing electrolytes, fluids and toxins, the condition of pediatric patients with acute kidney injury often worsens due to untreated hyperinflammation*

**27%**

**ICU**

Overall incidence of acute kidney injury in the pediatric ICU setting<sup>1</sup>

**2x**

**LONGER**

Patients with acute kidney injury stay in the ICU twice as long - 8 days vs 4 days<sup>2</sup>

**50%**

**MORTALITY**

For children with acute kidney injury and multi-organ dysfunction requiring continuous kidney replacement therapy<sup>3-5</sup>

**≥30%**

**CHRONIC DISEASE**

Incidence of chronic kidney disease for pediatric patients with acute kidney injury<sup>6</sup>

1. Kaddourah A, et al. NEJM. 2017; 376:11-20.
2. De Zan F, et al. Blood Purif. 2020;49:1-7.
3. Symons JM, et. al. Clin J. Am Soc Nephrol 2007
4. Modem V, et al. Crit Care Med 2013.
5. Goldstein, SL, et al. Kidney Int 2005; 67; 653-658.
6. Menon S, et. al Ped Nephrol 2023 (38) Suppl 1:S41.



# QUELIMMUNE clinical data in pediatric acute kidney injury



**77%** survival<sup>1</sup>  
*At Day 60*

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**NO** dialysis dependency<sup>2</sup>  
*At Day 60 (Post-ICU Discharge)*

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**NO** device-related immunosuppression, serious adverse events or infections



Pooled data from two clinical trials n=22

1. Goldstein SL, et al. *Kidney Medicine*. 2024; 6(4):100792.  
2. Goldstein SL, et al. *Kidney Int Rep*. 2020; 6(3):775-84.



# Adult acute kidney injury study outcomes consistent with pediatric studies

## Pediatric Data

Study / Parameter	SCD-PED-01 (≥ 15kg) (N=16)	SCD-PED-02 (10-20 kg) (N=6)	Combined PED-01 / PED-02 (N=22)
Survival Day 60	12 (75%)	5 (83%)	17 (77%) <sup>1</sup>
Dialysis Dependence Day 60*	0%	0%	0%
Normal Kidney Function Day 60*			87.5%
* - of survivors (Day 60 Post-ICU Discharge)			

## Adult Data

Study / Parameter <i>Patients treated with SCD</i>	US Adult ARF Pilot – 002 (N=35)	US Adult ARF – 003 (N=19)	Historical Control
Survival Day 60	69% <sup>2</sup>	84% <sup>3*</sup>	50% <sup>4</sup>
Dialysis Dependence Day 60	0%	0%	25% <sup>4,5</sup>

1. Goldstein SL, et al. *Kidney Medicine*. 2024; 6(4):100792
2. Tumlin JA, et al. *Semin in Dialysis*. 2013;26(5):616-23.
3. Tumlin JA, et al. *PLoS ONE*. 2015; 10(8):e0132482. \*Treated per protocol (iCa in therapeutic range using citrate)
4. Uchino S, et al. *JAMA*. 2005.
5. Bagshaw SM, et al. *Crit Care*. 2005.

# SCD has been utilized in multiple blockbuster potential indications in critically ill patients with high mortality rates



Examples of Mortality – Underlying Conditions

Condition	In Hospital Mortality
Cardiorenal Syndrome w/ Acute Kidney Injury	~40% <sup>3</sup>
Hepatorenal Syndrome w/ Acute Kidney Injury	~30% <sup>1</sup>
Streptococcal Toxic Shock Syndrome	~40% <sup>2</sup>

1. World J Gastroenterol. 2021 Jul 14; 27(26): 3984–4003.  
 2. Clin Infect Dis 2016 Aug 15;63(4):478-86.  
 3. Int. J Cardiol 2017 Mat1:230:255-261.

## Patients with Acute Kidney Injury on Continuous Kidney Replacement Therapy

### Comorbidities Include (but not limited to):

- BMI over 40 (morbidly obese)
- COVID-19
- All in ICU

### Insults Include (but not limited to):

- Surgery
- Trauma
- Bacterial & Viral Infections

### Underlying Etiologies Treated:

- Cardiorenal Syndrome
- Hemophagocytic Lymphohistiocytosis
- Hepatorenal Syndrome
- Shiga-toxin E. Coli Hemolytic Uremic Syndrome
- Streptococcal Toxic Shock Syndrome





## SCD has demonstrated a safe profile across six adult and pediatric acute kidney injury trials

>150 critically ill ICU patients

>800 devices used & ~20,000 hours of exposure

>50% of these patients were septic

No device-related infections, serious adverse events, immunosuppression or immuno-depletion



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# COMMERCIAL & REGULATORY STRATEGIES





## QUELimmune provides value to a hospital's bottom line

Critically ill patients with characteristics similar to those in SCD studies - continuous kidney replacement therapy with sepsis, high use of mechanical ventilation and/or vasopressors:<sup>1</sup>

- Mean total length of stay is >30 days
- Mean total hospitalization cost is >\$450,000 per patient
- Projected > \$30,000 lower cost per hospitalization @ 6 days of SCD-PED therapy<sup>3</sup>

\*Inflation-adjusted to 2024

SAVE registry to confirm hospital length of stay and readmission rates of acute kidney injury, which could support substantial cost savings to hospitals

### Mortality rate % with multi-organ failure<sup>2</sup>

1 organ	2 organs	3 organs	4 organs
11%	24%	60%	62%

Total SCD Cost  
for a full course (3-7 days)

**~\$10,000 - 30,000**

Disposable model  
changed every 24 hours

1. Kids' Inpatient Database 2019.
2. F. A. Moore, et al., "Postinjury Multiple Organ Failure: A Bimodal Phenomenon," Journal of Trauma, Vol. 40, No. 4, 1996, pp. 501-502.
3. Cost Impact of an Immunomodulatory Selective Cytopheretic Device (SCD-PED) in Acute Kidney Injury Due to Sepsis (AKI-S), Kleinman et al. ASN 2024



# Commercial strategy for pediatric acute kidney injury targeting top 50 leading children’s hospitals



Initial Launch: Top 5 U.S. Pediatric Children's Hospitals. **First product shipped in July 2024**

220 U.S. children’s hospitals<sup>1</sup>

- Treat ~4,000 pediatric acute kidney injury patients
- ~7,200 ICU beds



Top 50 U.S. children’s hospitals

- Treat ~50% of pediatric acute kidney injury patients<sup>2,3</sup>
- ~4,000 ICU beds<sup>2,3</sup>



~20% of top 50 U.S. children’s hospitals have experience with QUELIMMUNE

SeaStar Medical is now shipping directly to hospitals

1. <https://www.childrenshospitals.org>.
2. America Hospital Directory Database Export January 2020
3. <https://www.beckershospitalreview.com/lists-and-statistics/30-largest-childrens-hospitals-in-the-united-states.html>





# Clinical and Economic Burden of Pediatric AKI

## The Problem

Pediatric AKI is often the product of a hyperinflammatory response (cytokine storm) to sepsis or a septic like condition. Typical profiles of this population:

- **High Mortality – ≥50%**
- Multi-organ Failure
- Long term Dialysis - ≈10 to 30%

## The Cost

Complex and fragile patients require massive use of healthcare resources such as:

- Mechanical ventilation
- CRRT / CKRT
- 36-day average length of hospital stay

**Total average hospitalization cost ≈\$450,000**

## The Solution

**QUELIMMUNE** Selective Cytopheretic Device (SCD-PED) for the treatment of pediatric AKI due to Sepsis or a septic-like condition:

- **Projected reduction per hospitalization >\$30,000**
- 77% survival @ day 60
- 0% dialysis dependence @ day 60



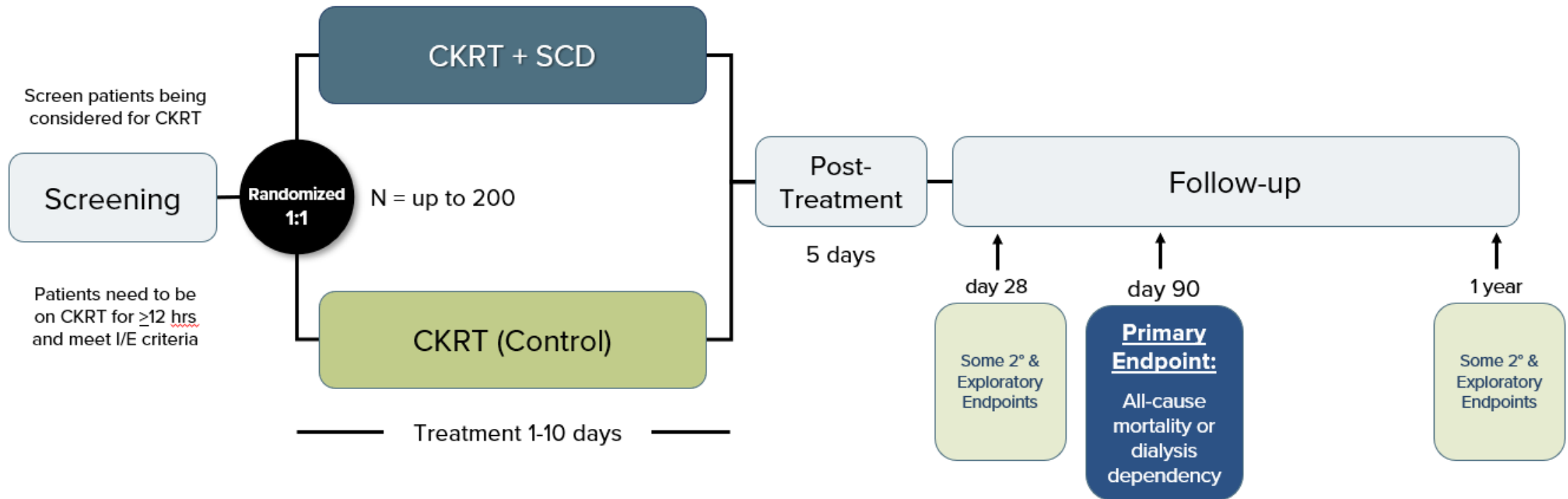
**Cost Neutrality: 8 to 10 QUELIMMUNE Device Days at \$3,750/Day  
6 to 8 QUELIMMUNE Device Days at \$5,000/Day**

Cost Impact of an Immunomodulatory Selective Cytopheretic Device in Pediatrics (SCD-PED) in Acute Kidney Injury Due to Sepsis (S-AKI)  
Nathan L Kleinman, Jennifer Kammerer, Alec Kleinman, Kevin K. Chung, Sai Prasad N. Iyer, Charuhas, V. Thakar, Kleinman Analytic Solutions, LLC, Paso Robles, CA, SeaStar Medical, Denver, CO, Queens University Belfast, Belfast, United Kingdom

# Adult acute kidney injury pivotal trial design



**Study Objective** Assess the safety & efficacy of SCD in acute kidney injury patients requiring continuous kidney replacement therapy (CKRT)



**Patient Population**

- Adults aged 18-80 in ICU with acute kidney injury  $\geq$  stage 2 requiring CKRT (CKRT  $\geq 12$  h  $\leq 48$  h)
- One additional life-threatening organ dysfunction
- Commitment to maintain current level of care for  $\geq 96$  h
- C-reactive Protein > 3.5 mg/dL



## NEUTRALIZE-AKI pivotal trial gaining momentum



- 60 of up to 200 subjects enrolled (>20% to date)
- 12 of up to 30 medical sites activated
- Mix of academic, military and community hospitals
- Interim data review of first 100 subjects at 90-days post-treatment
- Final analysis following last 90-day endpoint
- Publish results in peer-reviewed medical journal
- Present results at scientific conferences
- Commercial launch expected in 2026

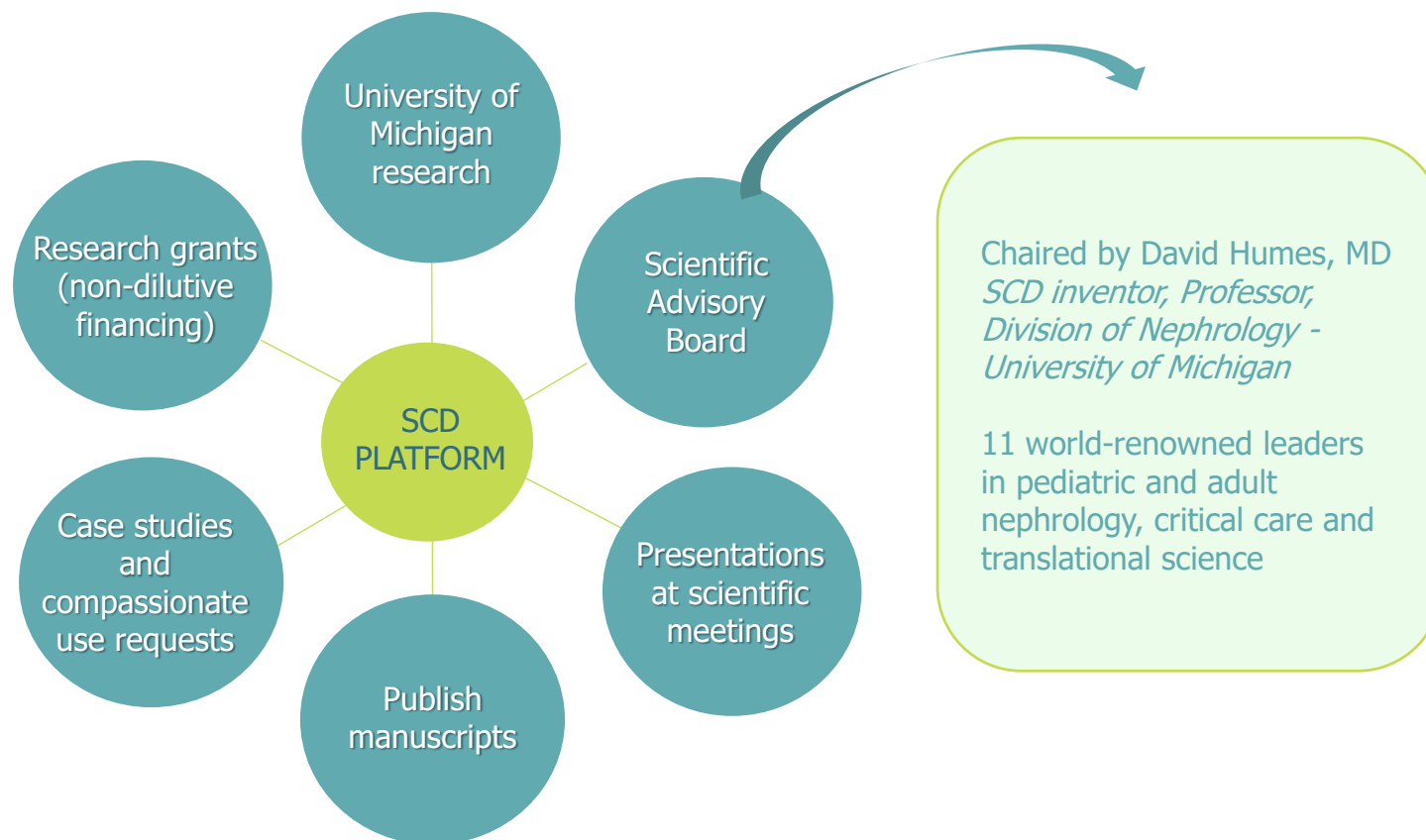
*CMS reimbursement for Medicare patients*

- *Reduces trial costs*
- *Increase site activations and accelerate subject enrollment*

# SCD Platform - Approach to clinical development:

*Scientifically Driven, Cost-Effective, Medical-Community Focused*






## Engage and Drive the Science





# Strategy is to expand indications with platform technology

## Indication Evaluation Process

-  Evaluate inflammation-based conditions or diseases driven by activated neutrophils / monocytes
-  High Burden of disease and unmet medical need in an operable patient setting
-  Clear commercial opportunity based on population size and or lack of approved therapies
-  Clear clinical value proposition that delivers clinical outcomes to the patient and economic value to the customer
-  Clear reimbursement pathway that provides pricing power and flexibility

## Results – Where we are Investing Resources

- Adult Acute Kidney Injury – **Awarded Breakthrough Status**
- Cardiorenal Syndrome w/ LVAD – **Awarded Breakthrough Status**
- Hepatorenal Syndrome – **Awarded Breakthrough Status**
- Chronic Dialysis – **Awarded Breakthrough Status**

# Seasoned, dynamic leadership



**ERIC SCHLORFF**

CEO + Board Member



**DAVID GREEN**

Chief Financial Officer



**KEVIN CHUNG, MD**

Chief Medical Officer



**SAI IYER, PHD**

SVP, Medical Affairs  
and Clinical  
Development



**TOM MULLEN**

SVP, Manufacturing  
and Product  
Development



**TIM VARACEK**

SVP, Commercial  
Business Operations



# Capital Structure

As of November 1, 2024

Ticker Symbol	ICU
Price	\$3.03
Shares Outstanding	4,409,140
Market Capitalization	\$13,359,694
Warrants Outstanding	2,359,829
Weighted Average Exercise Price for Warrants	\$92.88
Interest-bearing Debt	Zero

# 2024 financial highlights

## Commercial Activity

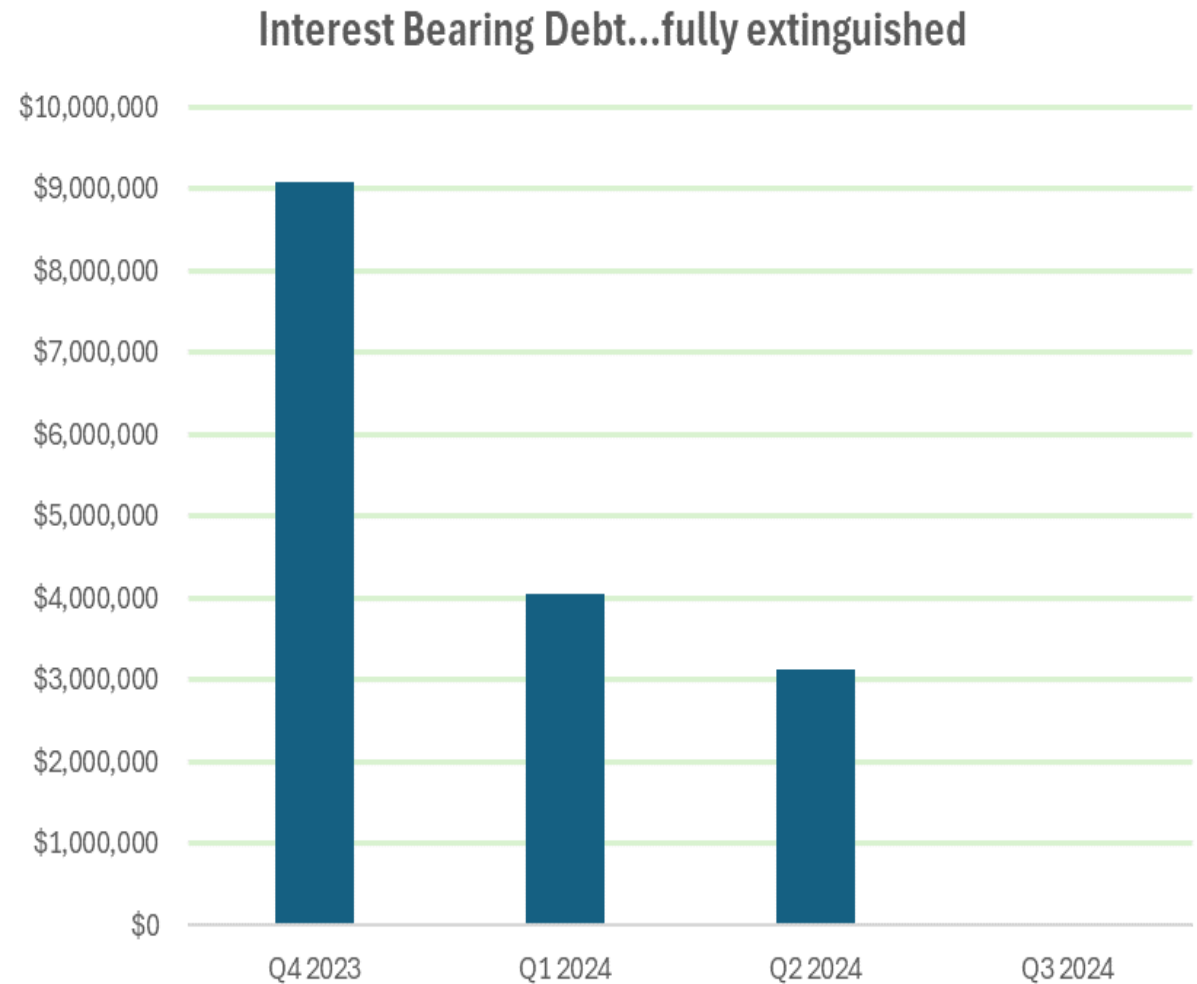
- Initial sales for QUELIMMUNE in Q3
- Assumed all responsibility for direct sales, marketing and distribution of QUELIMMUNE™ in Q4
- Total of 3 hospital customers added

## Improved Capital Structure

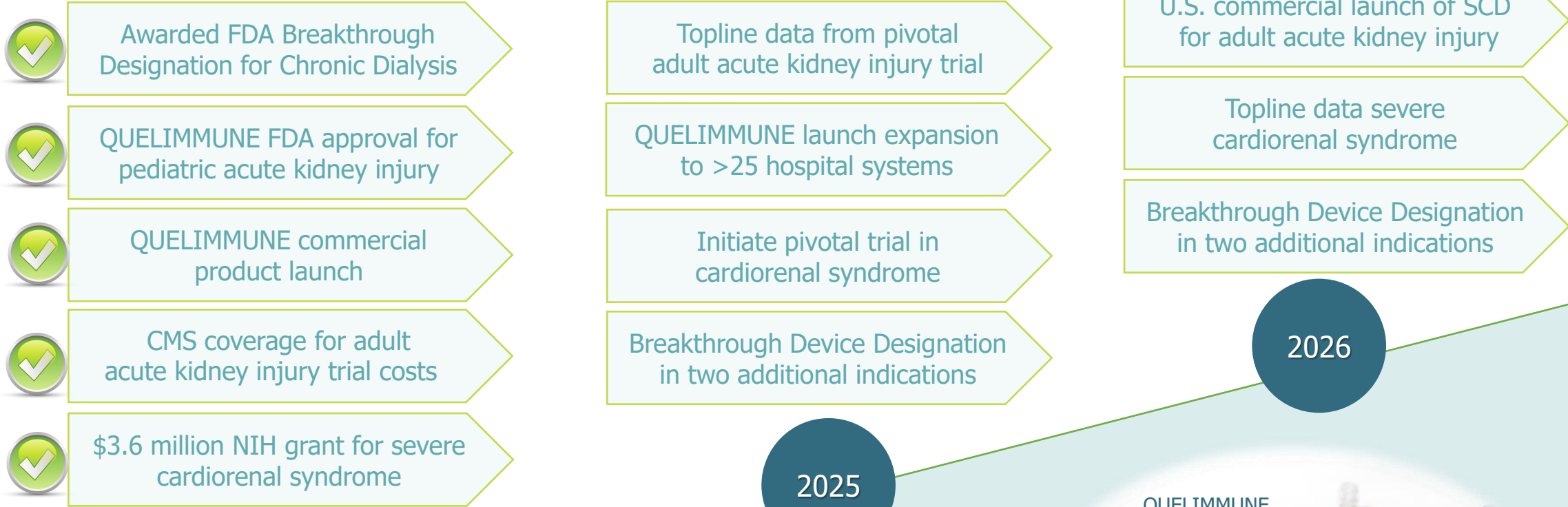
- Extinguished all outstanding debt
- Raised \$20 million new equity

## Cash used in operations (9 mos. 2024)

- \$11.3 million while funding pivotal clinical trial



# Catalysts to drive value creation



# Investment highlights

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**Investor Contact:**  
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**Jody Cain**  
**Jcain@allianceadvisors.com**  
**310-691-7107**



\*Based on the 6 members of the leadership team