KaloCyte

KaloCyte is developing ErythroMer™: Field-Deployable Artificial Red Blood Cells (RBC)
A shelf-stable Oxygen Carrier *for when blood is not available*

KaloCyte is a **pre-clinical biotech** company developing **ErythroMer** as an **O_2 carrier for use when blood is not available**

Currently at **TRL 4-5** - Held Pre-IND meeting with CBER and plan to file IND in early 2026

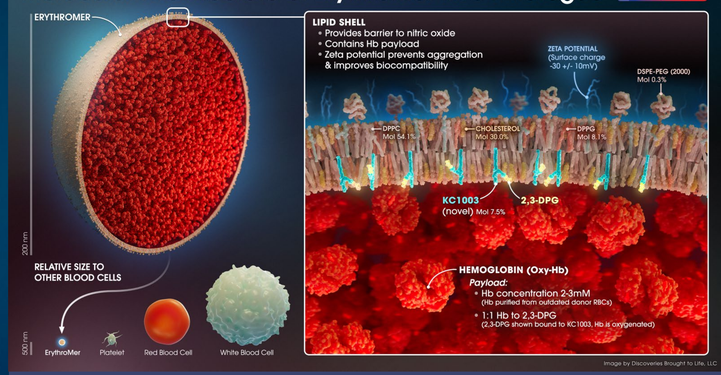
>$5M investor funding and **$17M** grant funding to date, including a subcontract on the $46M **DARPA FSHARP** program (UMB prime)

Transfusion Therapy Where Blood is Not Available

Blood loss after injury is responsible for over 25,000 lost lives each year in the US alone, and every minute of delay in replacing lost blood increases mortality by 5%. ErythroMer will be supplied as a freeze-dried powder, shelf-stable without refrigeration, and packaged as a unit equivalent to one unit of RBCs– "just add water" for rapid use at the point of care or en route.

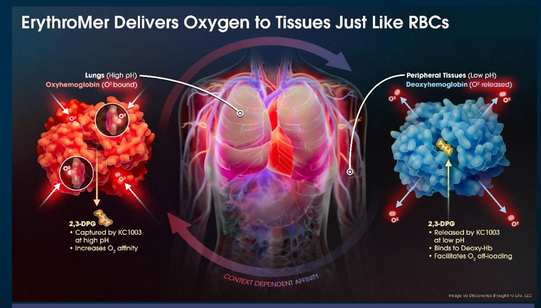
DESIGN STRATEGY

Molecular Architecture of ErythroMer RBC Analogue



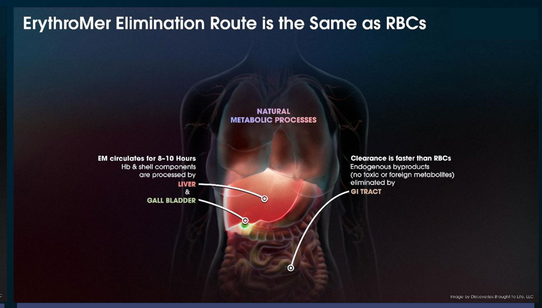
ErythroMer encases purified human hemoglobin (Hb) in a soft lipid nanoparticle "shell" designed to mimic native RBCs, and is a "universal option" for all blood types. The lipid shell provides a barrier to nitric oxide, contains the Hb payload, and has a surface charge (zeta potential) that prevents aggregation and improves biocompatibility.

ErythroMer Delivers Oxygen to Tissues Just Like RBCs



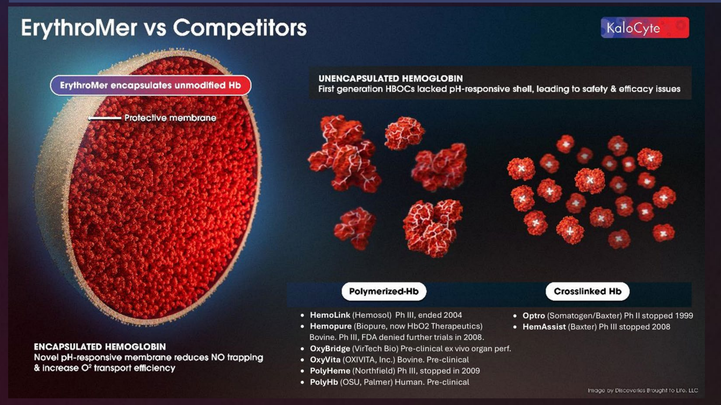
ErythroMer is specifically designed to 1) mimic natural RBC physiology and 2) address the flaws of prior Hemoglobin Based Oxygen Carriers (HBOCs). Its small size and bioinspired design make it a highly efficient oxygen carrier to pick up oxygen in the lungs and deliver it to hypoxic tissues throughout the body.

ErythroMer Elimination Route is the Same as RBCs



Current preclinical studies project EM will be effective for at least 8–10 hours between doses and cleared just like native cells, with all natural byproducts. Lipid shell components are processed by the liver, presumably converted by phospholipases into endogenous phospholipids, and eliminated by the GI tract with Hb.

ErythroMer vs Competitors



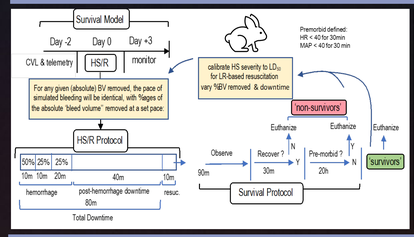
In terms of competition, the standard of care is blood – a type-specific and perishable liquid that requires refrigeration, cold-chain, and use within about a month, so there have been many attempts to develop a substitute with more ideal features that improve upon these limitations. Attempts to date have failed due safety (vasoactivity caused by nitric oxide (NO) trapping) and efficacy issues that ended FDA trials.

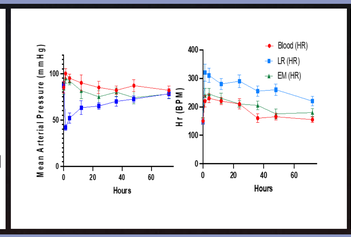
ErythroMer was specifically designed to fix these issues, and we have a growing set of data to support its future use in humans. In studies to date, we are demonstrating preclinical safety and efficacy in vivo, ex vivo, and in vitro.

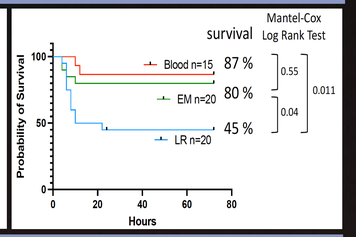
EFFICACY

In Vivo Efficacy - Acute Hemorrhagic Shock

(50% BV removal - NZW rabbit) PFC model & Initial Survival Outcomes



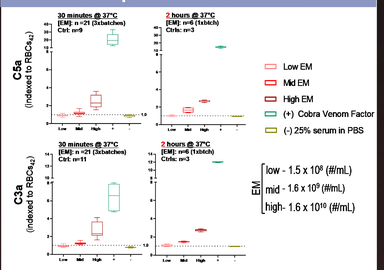




ErythroMer-based resuscitation is superior to crystalloids (LR) and noninferior to blood

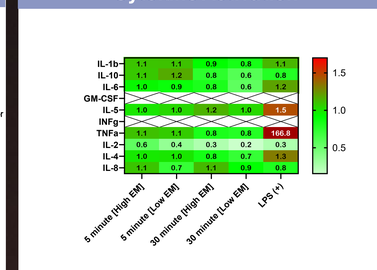
BIOCOMPATIBILITY & METABOLISM

Complement Activation



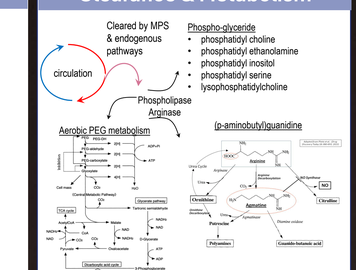
Minimal complement activation at anticipated EM blood concentrations, equivalent to that of stored RBCs.

Cytokine Activation



Minimal cytokine activation by EM at low and high doses, at both 5 –min and 30-min incubation periods

Clearance & Metabolism



All metabolic end-products are endogenous biomolecules

LYOPHILIZATION & STABILITY

Lyophilized for extended shelf-life at ambient temperature

- Designed for field use: rapid reconstitution with IV saline in minutes
- Lyophilization process and cryoprotectants maintain the physiochemical properties and product attributes (effective oxygen transport, no disruption of normal vascular tone, retention of Hb payload, preservation of Hb oxidative state with minimal metHb formation)

Dry Stability Findings

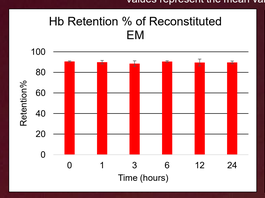
- ✓ High Hb Payload Retention (>90%)
- ✓ Rapid Reconstitution time (3-5 min at RT)
- ✓ Low metHb % (<5% at 28 days)
- ✓ Vial headspace O2 and moisture levels below limit of detectability

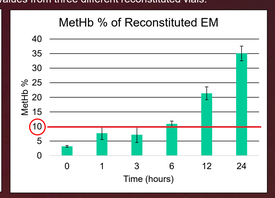
Characterization of Reconstituted "Wet EM"

Time point (hr)	Recon-stitution Time min:sec	pH	Size (nm)	Zeta Potential (mV)	HEMOX at pH 7.4 (p50) Loading	HEMOX at pH 7.4 (p50) Unloading	Total lipid (mg/mL)
0	2:09	6.6	213	-43	22.7	22.0	25.1
1	NA	6.7	218	-45	22.6	21.6	NA
3	NA	6.7	215	-38	21.7	21.3	NA
6	NA	6.6	209	-38	23.1	22.0	NA
12	NA	6.8	214	-46	20.0	19.2	NA
24	NA	6.6	213	-48	21.1	20.2	24.2

*Values represent the mean values from three different reconstituted vials.

From **"Evaluation of the Storage Stability of ErythroMer as a Lyophilized Powder and as a Reconstituted Liquid"** presented at MHSRS 2024



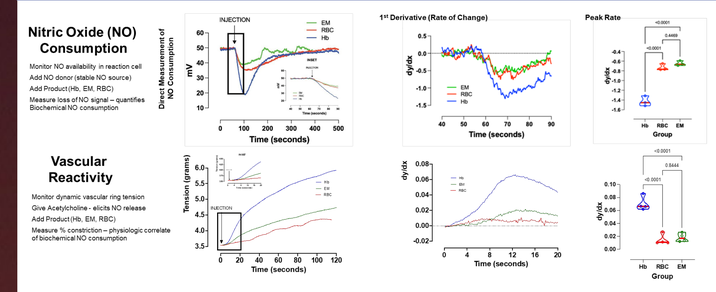


Wet Stability Findings

- ✓ Maintained 90% Hb retention after 24h
- ✓ No significant pH change (6.5-7)
- □ Need to improve p50 (addressed with newer version)
- □ Need to reduce MetHb% to ≤10%

SAFETY

Safety (Vasoactivity)



Disruption of normal vascular tone due to NO trapping is minimal, equivalent to that of stored RBCs

FEDERAL FUNDING

Current DOD Efforts and Accomplishments

DARPA-FSHARP

- ✓ Exceeded Y1 production target by >2x
- ✓ Defined EM human unit size: Hb formulated as **EM is 3.75x more potent**; equipotent EM-Hb dose is 20g/unit, vs 75g/unit for WB or RBC
- Tech-transfer fabrication process to SwRI for scale up
- Optimizing cryoprotectant formulation and lyophilization cycle to meet performance metrics

CDMRP PRMRP TTDA

- **Optimize Lyophilization** and Stability
- **Optimize Reconstitution** with common crystalloid solutions within 2 minutes

$17M Awarded Federal Funding

Source	Awardees (Prime*)	Program Number	Total $ Duration	2020	2021	2022	2023	2024	2025	2026
NIH NHLBI	KaloCyte* UMB	Fast Track STTR 4R42HL135965	$2M 4Y	Pilot-Scale, pre-IND Groundwork						
DOD CDMRP	UMB* KaloCyte, CellPhire	CCCRP PFCRA W81XWH-17-1-0668	$3M 4Y		In-Field Shock Resuscitation					
NIH NHLBI	KaloCyte* UMB	Ph1 SBIR 1R43HL151073	$373K 2Y		Rapid Reconstitution					
DOD CDMRP	Haima*, CWRU, UMB, KaloCyte	CRRP W81XWH-19-S-CRRP	$1.6M 3Y			Whole Blood Surrogate				
University of Maryland	KaloCyte* UMB	MIPS 6729	$200K 2Y			1. Bait/Capture	2. Optimize			
NIH NHLBI	KaloCyte* UMB	SBIR CRP 2SB1 HL135965	$500K 3Y				KC1003 Scale & GMPMfg			
DARPA	UMB* KaloCyte	FSHARP N66001-23-9-4005	$3.6M 4Y					FSHARP	Dried Whole Blood Analog	
NIH NHLBI	KaloCyte* UMB, PSU, LBRI	PhIIB 2R44HL135965 -04A1	$3M 3Y						GLP Toxicology, Safety/Pharmacology	
DOD CDMRP	KaloCyte* UMB, Labyrinth	PRMRP TTDA HT94252410157	$2.5M 2Y						Optimize Lyophilization	

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