

# Nasdaq: ENLV



### **Market Data**

Enlivex Therapeutics Ltd. Nasdaq: ENLV						
Fiscal Year	Dec. 31					
Price	\$3.32					
52-wk Range	\$1.20-\$4.03					
Market Cap	\$64.2M					
Shares Out.	18.6M					
Float	15.0M					
Avg. Vol (90-day)	90,920					
Insider Ownership	19%					
Cash (mrq)	\$30.5M					
Price & share data as of February 16, 2024						
enlivex.com						

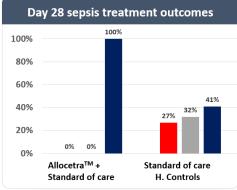
# Reprogramming imbalanced macrophage populations can lead to disease resolution



# **Company Overview**

Enlivex is a clinical stage macrophage reprogramming immunotherapy company developing Allocetra<sup>™</sup>, a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state. A primary immune cell. Diseases such as sepsis, osteoarthritis and many others reprogram macrophages out of their homeostatic state. These non-homeostatic macrophages contribute significantly to the severity of the respective diseases. By restoring macrophage homeostasis, Allocetra<sup>™</sup> has the potential to provide a novel immunotherapeutic mechanism of action and resolution for conditions which are life-threatening and debilitating "unmet medical needs".





# **Investment Highlights**

### Macrophage reprogramming targeting unmet medical need indications

- Off-the-shelf, universal cell therapy for resetting macrophages back to their "resolution settings" and away from "disease settings"
- A type of immune cell, macrophages act as the body's first line of defense, engulfing and destroying pathogens and debris
- Resetting non-homeostatic macrophages into their homeostatic state is critical for immune system rebalancing and resolution of life-threatening conditions

### Advanced clinical-stage pipeline addressing multi-billion-dollar markets

- Phase IIb macrophage reprogramming for sepsis
  - o Data readout anticipated by end of Q1 2024; \$33B global market opportunity
- Phase I/II in osteoarthritis (OA)
  - Top-line data for end-stage knee osteoarthritis expected in Q2 2024; \$2B global market opportunity
  - Top-line data readout from moderate knee osteoarthritis expected in Q2 2025;
     \$7B global market opportunity
  - Favorable pharmacoeconomic model for local OA injection, translates into a highly competitive product pricing for this unmet medical need indication

### Short regulatory approval pathway

 Specialized regulation in Europe potentially enabling post-Phase II marketing approval in sepsis

### Strong leadership

- Previously founded and managed PROLOR Biotech; a \$560M exit event; signed partnership with Pfizer, including \$295 million down payment; and drug (NGenla) approved in 43 countries (incl. US); leading product in \$4 billion market
- Vice Chairman Roger Pomerantz: former Head of Business Development at Merck and former Venture Parter at Flagship Pioneering

### Cash balance supporting multiple clinical milestones within 18-24 months

• \$30.5 million cash (as of Sept. 30, 2023) provides runway through year end 2025

Buy recommendation from H.C. WAINWRIGHT & CO with \$12 per share price target



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## **Pipeline**

Indication	Global Market Size	Pre-Clinical	Phase <u>lb</u>	Phase IIb	Potential support for EU Conditional Marketing Approval Submission	Post EU Marketing US Phase 3
Organ failure associated with Sepsis	\$33B		Completed	Randomized, controlled Phase II ongoing	Top-line data for Phase II Q2-24	
Moderate knee osteoarthritis	\$7B			Randomized, controlled Phase I/II expected Q1 2024	Top-line data for Phase I/II Q3-25	
End-stage knee osteoarthritis	\$2B		Phase I/II Ongoing		Top-line data for Phase I/II Q3-24	

# **Value Proposition**

Enlivex presents a compelling investment opportunity in the biopharmaceutical sector with its innovative approach to treating life-threatening and debilitating conditions through macrophage reprogramming. The company's leading product, Allocetra™, is a groundbreaking, off-the-shelf cost-effective cell therapy platform designed to reset the body's immune cells (macrophages) to their optimal functioning state. This technology addresses a critical need for rebalancing the immune system, offering potential treatments for a range of inflammatory and autoimmune diseases with high unmet medical needs. With macrophages playing a vital role as the body's first line of defense, Enlivex's focus on converting these cells from a "disease setting" back to their "resolution settings" opens the door to addressing complex conditions like sepsis and osteoarthritis, tapping into multi-billion-dollar markets.

The Company is at an advanced clinical stage, with Phase IIb trials for sepsis showing promise for a \$33 billion market opportunity and Phase I/II trials in osteoarthritis aiming at a combined market opportunity of \$9 billion. Additionally, the prospect of a short regulatory approval pathway in Europe for its sepsis treatment enhances the value proposition for investors. Enlivex's strong leadership team, proven by their successful \$560 million exit event with PROLOR Biotech and a significant partnership with Pfizer, underscores the company's potential for high returns. With a robust cash balance and plain vanilla capital structure ensuring operational runway through the end of 2025 and a buy recommendation with a \$12 per share price target, Enlivex stands out as a promising investment for investors seeking to capitalize on the next wave of innovations in immunotherapy and cell reprogramming technologies.

Allocetra<sup>TM</sup>
macrophage
reprogramming
leads to
improved
outcomes for
sepsis patients
Statistically significant
improvement in
hospitalization and
SOFA vs. matched
controls

