August 27, 2024

Breaking the Cycle — Initiating Coverage of Enlivex With a Buy Rating and $13.00 Target

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MARKET DATA

Rating	Buy
Price Target	$13.00
Price	$1.23
Average Daily Volume (000)	57
52-Week Range ($)	$1.15–$4.59
Market Cap (M)	$26
Enterprise Value (M)	$3
Dividend Yield	0.0%
Cash (M)	$23
Qrtly Burn Rate (M)	$(4)

ESTIMATES

	2024E	2025E	2026E
Revenue (M)	$0.0	$0.0	$0.0
Total Expenses (M)	$(15)	$(14)	$(27)
GAAP EPS	$(0.65)	$(0.58)	$(0.59)

One Year Performance Chart

Source: FactSet, 26 August 2024

Enlivex Therapeutics is a cell therapy company **"Breaking the Cycle,"** interrupting the immune response with off-the-shelf macrophage cell therapy. The company's lead product, Allocetra, is in development to treat osteoarthritis, initially focused on the knee and hand (thumb) as well as sepsis. The current clinical data sets show a signal in these indications. We are initiating coverage with a Buy rating and a $13.00 price target.

Enlivex Therapeutics' Focus is on the Role of Macrophages in the Body's Inflammatory-Autoimmune Response. Enlivex has an off-the-shelf, allogeneic (like a pill in a bottle, only cells) ready product that reprograms macrophages to turn them off (back in a quiescent state). The initial indications are sepsis and osteoarthritis-OA of the knee and hand (thumb). A Phase II sepsis trial and treatment of arthritic knees demonstrated promising signals.

Moderate Knee Osteoarthritis: This program involves a Phase II clinical trial to evaluate the safety and efficacy of Allocetra administered through local knee injections. The trial is a double-blind, randomized, multi-center study designed to compare the effects of Allocetra to a placebo in patients with moderate symptomatic knee osteoarthritis. The goal is to assess whether Allocetra can effectively reduce pain and improve joint function in these patients.

End-Stage Knee Osteoarthritis: This is an investigator-initiated study where Allocetra is being tested in patients with end-stage knee osteoarthritis, which is more advanced and often requires significant medical intervention. This trial aims to determine the safety and efficacy of Allocetra when administered directly into the knee joint.

Sepsis Program: This is centered around the development of Allocetra, which works by reprogramming macrophages—key immune cells—back to their normal, homeostatic state. This helps rebalance the immune system and prevent the excessive inflammatory responses and immune suppression that characterize sepsis. An n=160 Phase II trial reported compelling results, particularly in one subset of sepsis patients, those whose origin was a urinary tract infection. If the one-year follow-up data continues to be good, the goal is to partner the indication.

Valuation: We project our model out to 2034. In our product model, we apply a 30% success probability to our projected revenues, in addition to our 30% risk rate applied in our Free Cash Flow to the Firm (FCFF), discounted EPS (dEPS), and Sum-of-the-Parts (SOP) models. We use a fully diluted out-year share count, assuming multiple raises. The result is equal-weighted, averaged, and rounded to the nearest whole number to derive our 12-month projected price target of $13.00

Risks to our thesis include: 1. Regulatory Approvals, 2. Capital Requirements, 3. Adoption Rates, 4. Intellectual Capital, and 5. Dilution.

Please see analyst certification and important disclosures on page 22 of this report.

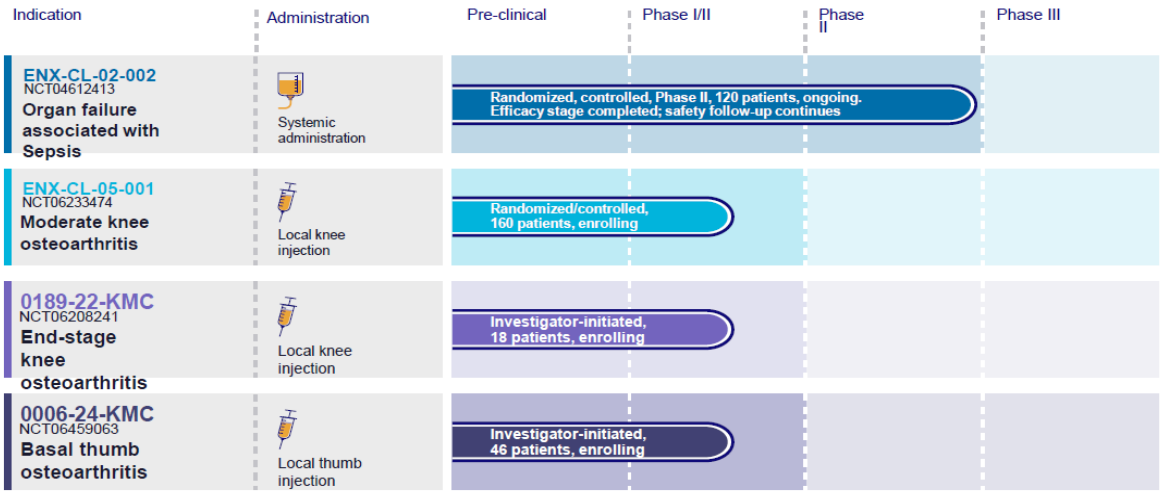
Company Overview
Enlivex Therapeutics is a clinical-stage macrophage reprogramming immunotherapy company developing Allocetra, a universal, off-the-shelf cell therapy designed to reprogram macrophages into their homeostatic state. Resetting non-homeostatic macrophages into their homeostatic state is critical for the immune system to rebalance and resolve debilitating and life-threatening conditions. Non-homeostatic macrophages contribute significantly to the severity of diseases. By restoring macrophage homeostasis, Allocetra can provide a novel immunotherapeutic mechanism for debilitating and life-threatening clinical indications defined as "unmet medical needs" as a stand-alone therapy or combined with leading therapeutic agents. Macrophages are tissue-resident or infiltrating immune cells critical for innate immunity, normal tissue development, and repair of damaged tissue. Macrophages' function results from their original designation, local micro-environment, and the type of metabolites, substances, or pathogens they are exposed to. Reprogrammed out of their homeostatic state, macrophages contribute to the pathophysiology of multiple inflammatory diseases, including sepsis, osteoarthritis, and other inflammatory disorders.

The company focuses on two clinical program verticals, representing inflammatory/autoimmune indications: osteoarthritis and sepsis. Additionally, the company is seeking external collaborations or out-licensing opportunities to develop Allocetra as a next-generation solid cancer immunotherapy.

Strategic Reprioritization Plan. In September 2023, management announced a strategic reprioritization plan to increase the focus on inflammatory and autoimmune indications. As part of the strategic reprioritization plan, in addition to the ongoing Phase II trial of Allocetra in patients with sepsis, Enlivex initiated a clinical program in osteoarthritis, a degenerative disease with low-grade inflammation and an indication with a substantial unmet medical need that potentially represents a multi-billion commercial market.

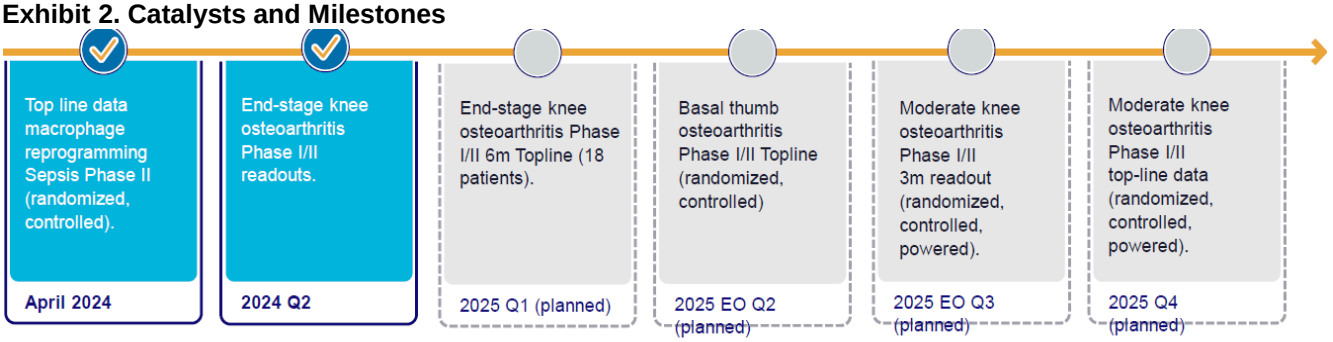
Financials: Enlivex reported $23M in cash and equivalents on the balance sheet as of the first quarter. The company has a modest burn rate; we estimate it will be approximately $3.6M per quarter this year. We expect clinical costs to rise, increasing the burn rate. Our model assumes capital raises.

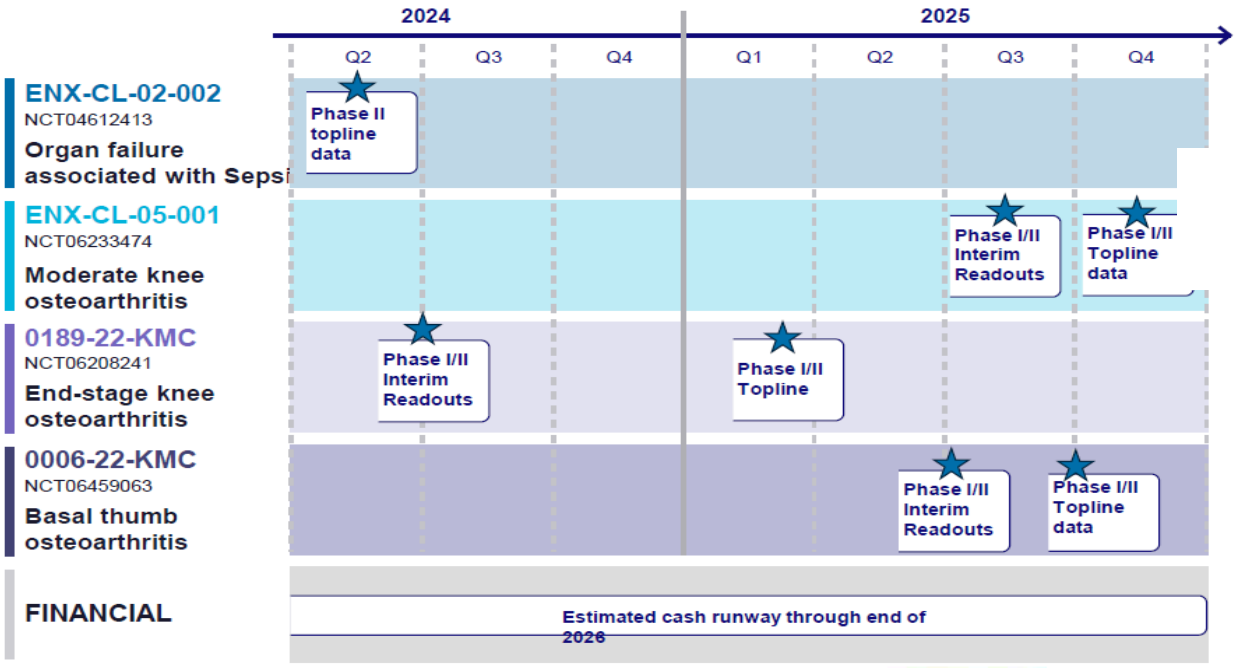
Exhibit 1. Early-Stage Pipeline – Sepsis PII Results Suggest Activity



Source: Enlivex

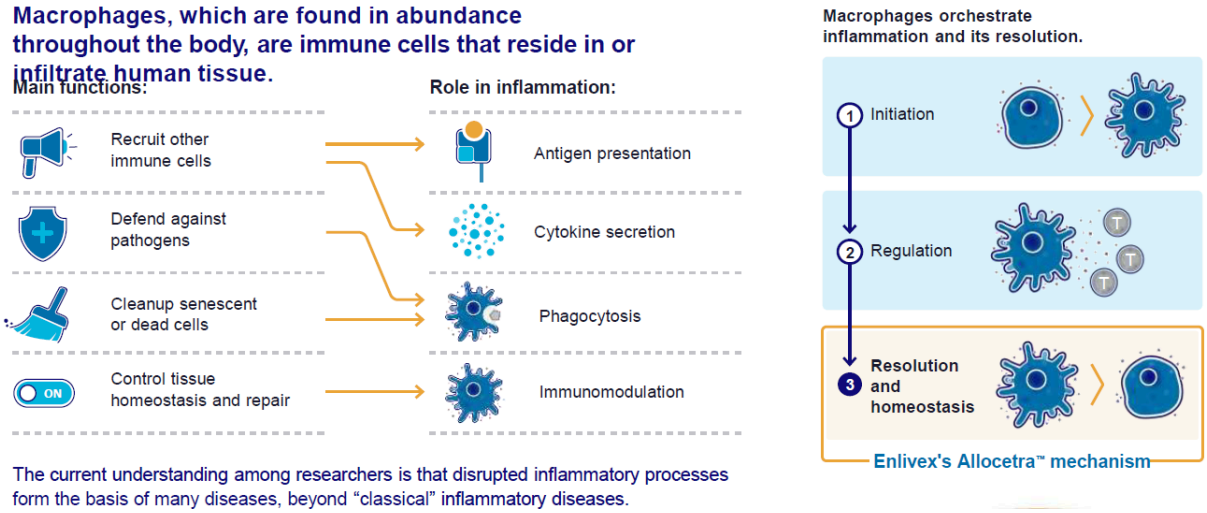
Exhibit 2. Catalysts and Milestones





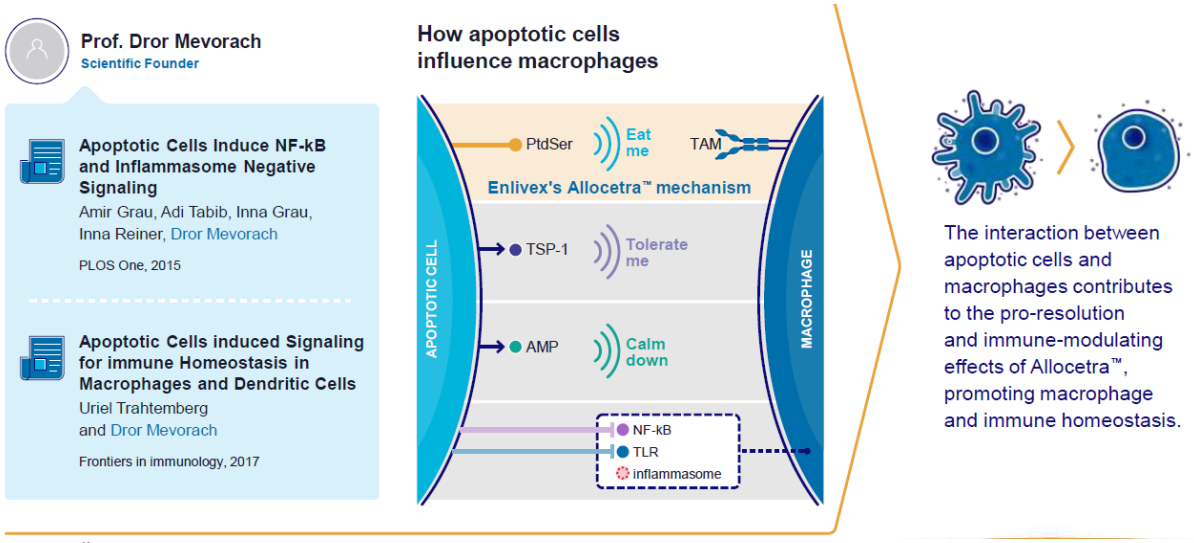
Source: Enlivex

Exhibit 3. The company believes that negatively reprogrammed macrophages may be key contributors to disease severity across the Indications, and effective reprogramming of these negative-reprogrammed macrophages into their respective homeostatic states may facilitate disease resolution for the Indications, some of which are considered unmet medical needs.



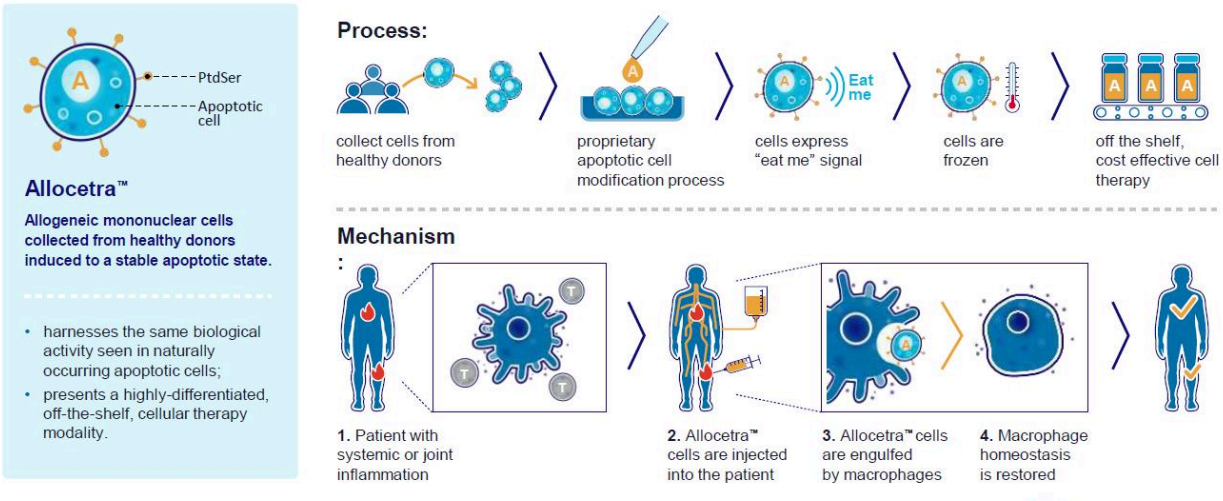
Source: Enlivex

Exhibit 4. Macrophages Can Help Restore Immune Homeostasis. Allocetra represents a paradigm shift in macrophage reprogramming. It moves from targeting a specific subset of macrophages or a specific pathway affecting macrophage activity to a fundamental view of macrophage homeostasis. Restoring macrophage homeostasis may induce the immune system to rebalance itself to normal levels of operation, thereby promoting disease resolution.



Source: Enlivex

Exhibit 5. Allocetra—How Do You Make It and Use It? In late 2002, management completed the construction of a facility in Yavne, Israel, to manufacture Allocetra. As part of the company's strategic reprioritization plan, it was decided to sell the leased manufacturing facility and the equipment installed and then lease it back to the company. The plan was executed on March 31, 2024, with BioHarvest Ltd., an Israeli company, for an aggregate purchase price payable of approximately $3.5 million. We believe the company will be able to produce products at scale, at Biotech, with margins of 80%.



Source: Enlivex

Sepsis Results Announced (April 2024): According to the study protocol, the safety and efficacy topline analysis includes sequential organ failure assessment (SOFA) scores and mortality for 28 days post-treatment.

- Stand-alone analysis of the Allocetra-treated patients, of which 78% had septic shock, and 65% had invasive ventilation at screening, demonstrated substantial reductions in SOFA scores and a 65% reduction in overall mortality rate compared to expected mortality. By day 28, the analysis showed 90% reductions in SOFA scores for sepsis patients whose infection source was a urinary tract, 68% for patients whose infection source was community-acquired pneumonia, and 36% for patients whose infection source was an internal abdominal infection.
- Relative analysis demonstrates a potential indication of the effect of Allocetra as compared with a placebo in a high-risk, severe sepsis patient population (organ failure scores >=7) originating from urinary tract infections (High-Risk UTI). Enlivex intends to consider a potential follow-on, randomized, controlled study of solely the High-Risk UTI sepsis population. Up to 31% of sepsis cases start as urinary tract infections, representing up to 9.8 million cases in the United States and Europe, leading to as many as 1.6 million deaths, and represents a substantial potential market opportunity for Allocetra.
- The study was designed for patients to be randomized with equal SOFA scores across treatment and placebo groups. The randomization resulted in the Allocetra-treated cohorts having a 20% higher frequency of septic shock and 35% higher frequency of invasive ventilation prior to treatment compared with the control group. Both patient attributes are associated with a significantly higher degree of difficulty in treatment and higher mortality rates. These imbalances made it challenging to deduce the relative effect in other patient subgroups.

Exhibit 6. Does it Work? An Early Phase I/II Proof of Concept Study Showed a Signal. Although the N=10 study was small, the fact that all ten treated patients had complete recovery by day 28 suggests a strong signal.

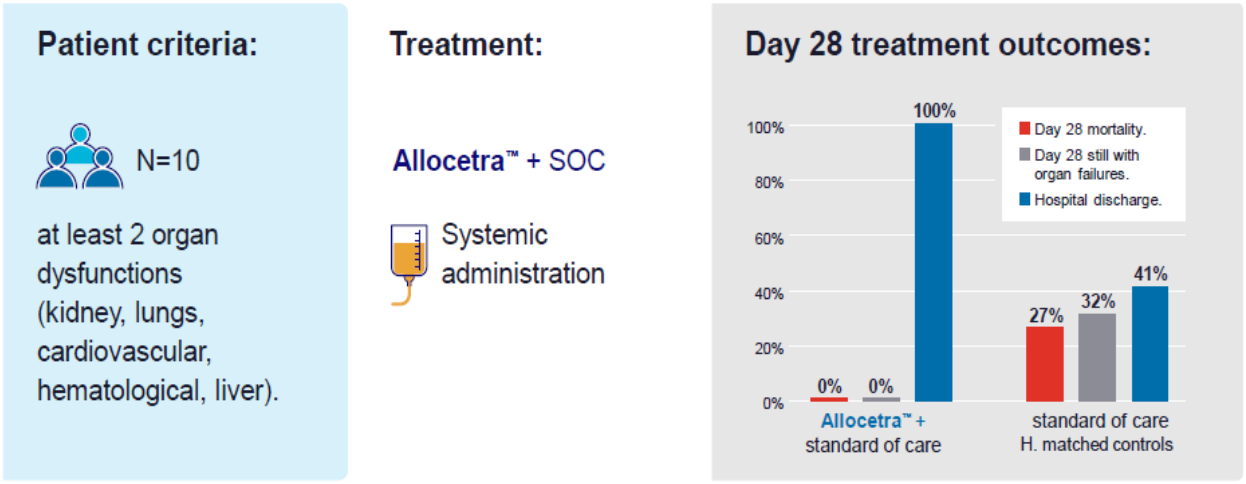
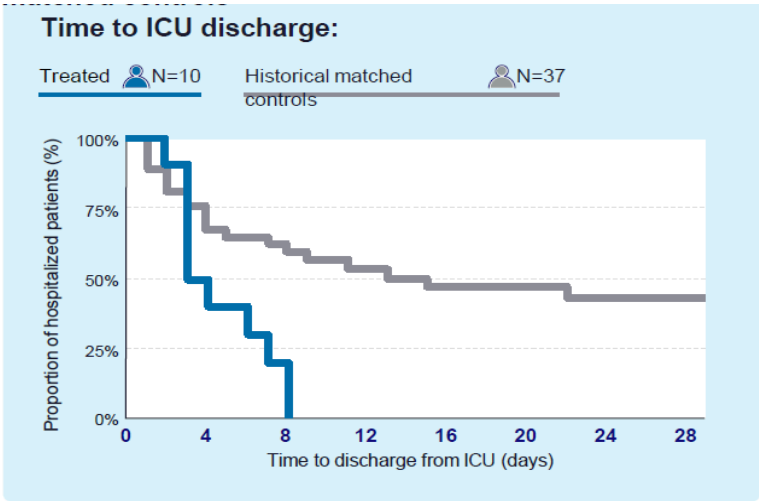
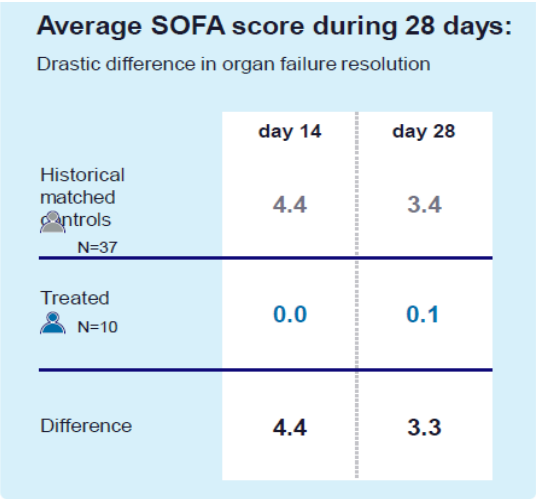


Exhibit 7. The small study showed a statistically significant improvement in duration of hospitalization and SOFA score vs. matched controls





Source: Enlivex

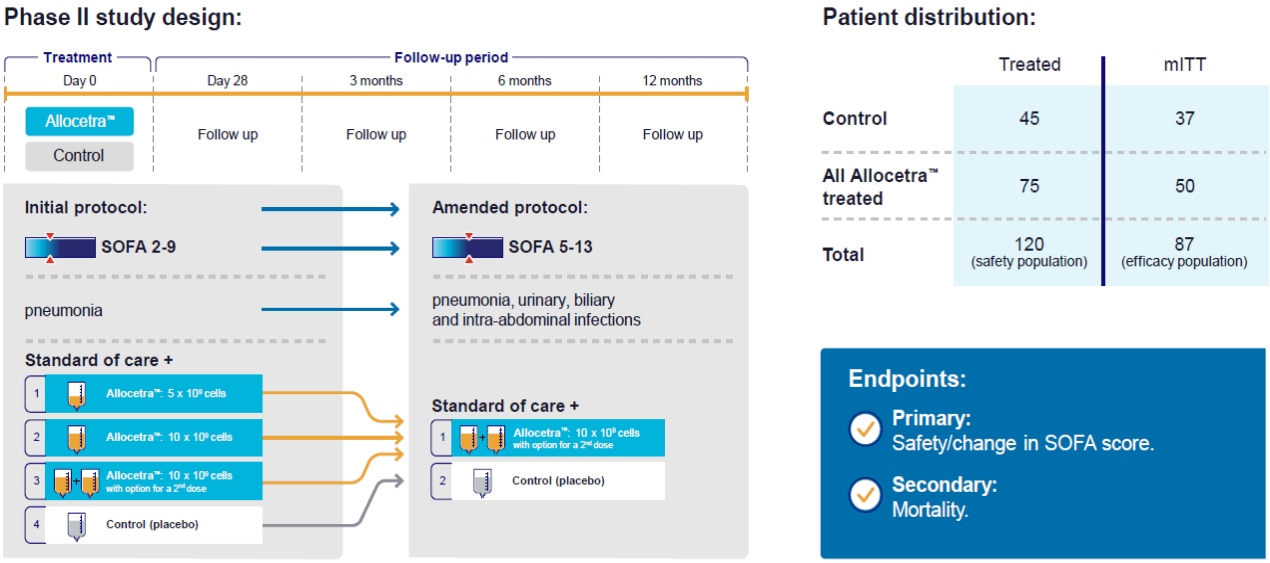
Exhibit 8. Historical Data versus Control. The table below summarizes sepsis 28-day mortality from recent trials in the 23-30% range.

REVIVAL[1] Phase III (AM-PHARMA) Pickkers et al, 2024	ASTONISH[2] Phase IIb (INOTREM) Francois et al, 2023	Analysis of 2 randomized controlled trials[3] (VARIOUS ACADEMIA) Karakike et al, 2019
Patient population:	Patient population:	Patient population:
N=649	N=355	N=448
SOFA: ~9	SOFA: ~10	SOFA: 6-8
Acute kidney injury **100%**	Septic shock **100%**	Septic shock: **20% - 43%**
28-day mortality **28%**	28-day mortality **25-32%**	28-day mortality **23-30%**

28-days mortality range 23-30%

1 - Pickkers, P., Angus, D.C., Bass, K. et al. Intensive Care Med 50, 68–78 (2024). https://pubmed.ncbi.nlm.nih.gov/38172296/
2 - François B. et al. ASTONISH investigators. Lancet Respir Med. 2023 Oct;11(10):894-904. https://pubmed.ncbi.nlm.nih.gov/37269870/
3 - Karakike et al. The early change of SOFA score as a prognostic marker of 28-day sepsis mortality: analysis through a derivation and a validation cohort. Critical Care (2019) 23:387.
Source: Enlivex

Exhibit 9. The Phase II Study Design: Randomized and Controlled.



Patient distribution:

	Treated	mITT
Control	45	37
All Allocetra™ treated	75	50
Total	120 (safety population)	87 (efficacy population)

Endpoints:
- **Primary:** Safety/change in SOFA score.
- **Secondary:** Mortality.

Source: Enlivex

Phase II Sepsis Trial Study. The study was initiated (2021) as a placebo-controlled, randomized, dose-finding, multi-center, Phase II trial evaluating liquid Allocetra in patients with pneumonia-associated sepsis. In 2022, the company amended the protocol to treat newly recruited patients with the frozen formulation Allocetra. It expanded the study population to include patients whose septic condition stemmed from biliary, urinary tract, or peritoneal infections. An additional amendment to the study protocol was filed in the second quarter of 2023 to include an increase in the patients' sequential organ failure assessment or SOFA score range, effectively allowing the recruitment of patients with higher levels of sepsis severity and a change to two cohorts (treatment and placebo) instead of the four-cohort structure previously contemplated. The first patient was dosed under the amended protocol during the second quarter of 2023, and in December 2023, enrollment of all n=120 patients was completed.

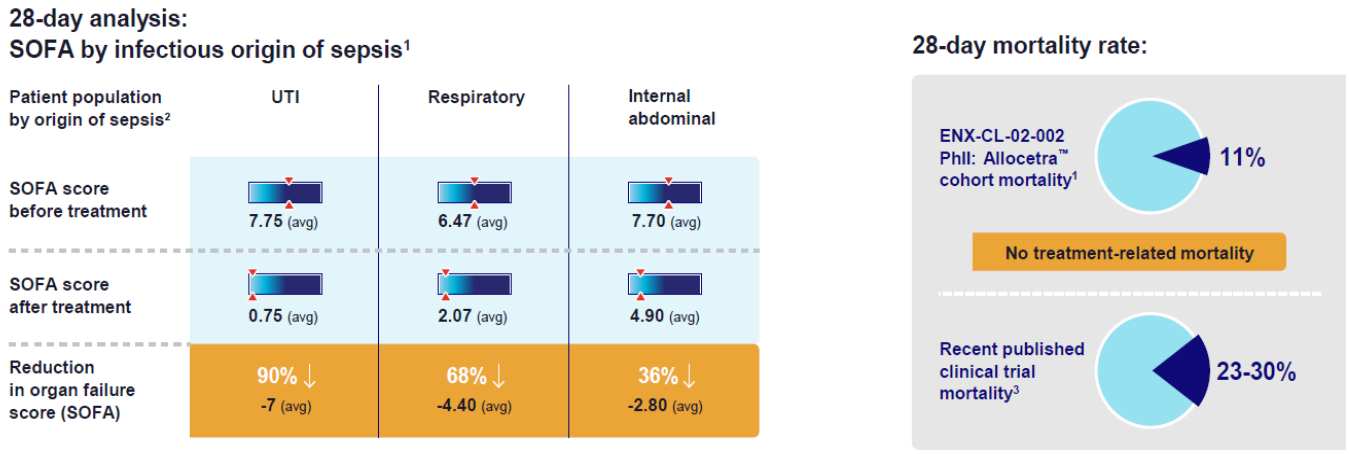
Exhibit 10. ENX-CL-02-002 Sepsis Phase II Randomized & Controlled Study. The ALLOCETRA Group Presented a Higher Mortality Risk. Compared with the control cohort, Allocetra-treated cohorts presented a 20% higher frequency of septic shock and 35% higher frequency of invasive ventilation. These attributes are associated with higher mortality rates.

Demographics and baseline characteristics:

mITT population[1]	Control N=37	Allocetra™ N=40
Age	64.2 (30-89)	65.1 (30-89)
BMI	27.2 (17-38)	26.3 (17-39)
Screening SOFA	8.1 (5-12)	8 (5-13)
APACHE II[2]	21.1 (6-44)	20.5 (6-47)
Septic shock	24 (65%)	31 (78%) ↑+20%
Invasive ventilation	16 (43%)	23 (58%) ↑+35%
Pneumonia	14 (38%)	16 (40%)
Urinary (UTI)	9 (24%)	9 (22.5%)
Intra-abdominal	5 (14%)	10 (25%)
Skin and soft tissue infections	4 (11%)	3 (7.5%)
Acute cholangitis	5 (13%)	2 (5%)

Source: Enlivex

Exhibit 11. Phase II Results. The ALLOCETRA Cohort Stand-Alone Analysis Shows a Substantial Reduction in Organ Failure Scores.

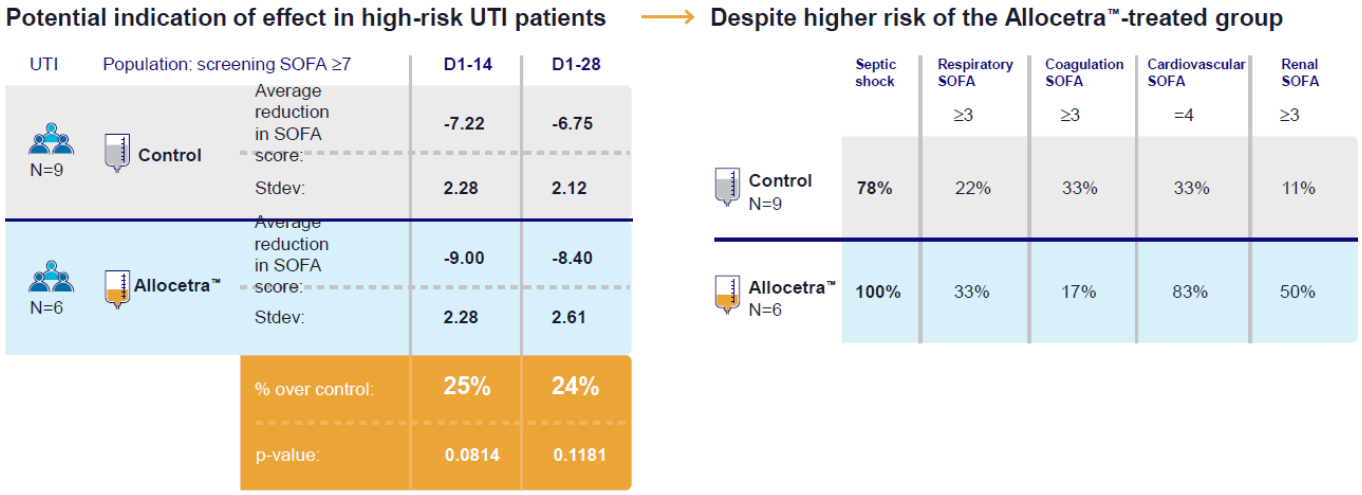


1 - Analysis of modified intent-to-treat (mITT) placebo population for all patients who were randomized, had a screening total SOFA score ≥ 5 points
above pre-admission total SOFA score, had at least one post-baseline total SOFA score, and was determined as eligible by an Adjudication Committee.
2 - The number of patients in cholangitis and skin/soft tissue groups was too small for analysis.
3 - Compared with recently completed sizable clinical trials – Revival Phase III (2024), Astonish Phase IIb (2023), Karakike (2019) – in which mortality rates were 23% - 30%.
Source: Enlivex

Did Allocetra Work in High-Risk UTI-Sepsis? The data showed substantial SOFA score reductions and a low mortality rate in the Allocetra-treated patients across all origins of sepsis in the study, an indication of effect compared with placebo for the high-risk patients whose sepsis originated from urinary tract infections, and the favorable safety profile of Allocetra.

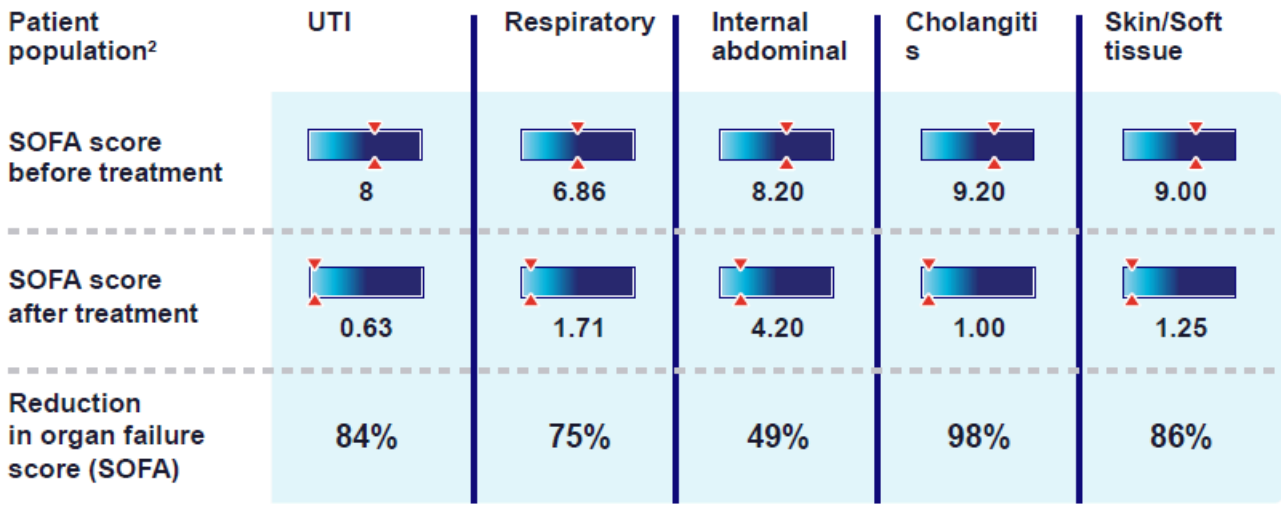
The company intends to consider a follow-on, randomized, controlled study of a solely High-Risk UTI sepsis population. Up to 31% of sepsis cases start as UTIs, representing a substantial potential market opportunity for Allocetra. The randomization resulted in the Allocetra-treated cohorts having a 20% higher frequency of septic shock and a 35% higher frequency of invasive ventilation prior to treatment than the placebo group. Both patient attributes are associated with a significantly higher degree of difficulty of treatment and higher mortality rates and potentially resulted in patients with more severe sepsis in the Allocetra-treated cohorts.

Exhibit 12. Phase II Results. The UTI High-Risk Patients Showed a Clear Signal. The sub-group alone represents a substantial piece of the Sepsis market.



1 - Management of Urosepsis in 2018, Bonkat et. Al. , European Urology Focus Volume 5, Issue 1, (2019).
Source: Enlivex

Exhibit 13. Control Cohort Stand-Alone Analysis, Day 28: Organ Failure Score (SOFA) by Infectious Origin (sepsis). The relatively small control cohort exhibited uncharacteristically high organ recovery rates and low mortality, which are not aligned with recent clinical trial data[1]. This unusual result, taken together with the higher-risk patient population in the Allocetra cohort, makes it challenging to interpret the results in the non-high-risk UTI population.



1 - Compared with recently-completed sizable clinical trials – Revival Phase III (2024), Astonish Phase IIb (2023), Karakike (2019) – in which mortality rates were in the range of 23%–30%.
2 - Analysis of modified intent-to-treat (mITT) placebo population for all patients who were randomized, had a screening total SOFA score >= 5 points above pre-admission total SOFA score, had at least one post-baseline total SOFA score and determined as eligible by an Adjudication Committee.
Source: Enlivex

Phase II Study Conclusions (*from Enlivex*):

- *The efficacy (mITT) population presented a 20% higher frequency of septic shock in Allocetra-treated patients compared to placebo and a 35% higher frequency of invasive ventilation –key determinants of disease severity, potentially indicating risk imbalance between the groups.*
- *Stand-alone analysis of the Allocetra-treated patients demonstrated a substantial reduction in organ failure scores (SOFA) and low mortality rate compared to expected mortality[1]. The analysis showed reductions, by day 28, in organ failure scores (SOFA) of 90% for sepsis patients whose infection source was urinary tract (UTI), 68% for patients whose infection source was community-acquired pneumonia, and 36% for patients whose infection source was internal abdominal.*
- *A potential indication of relative efficacy is demonstrated in a population of high-risk UTI patients.*
- *Up to 31 percent of sepsis cases start as UTIs, representing up to 9.8 million cases annually in the U.S. and Europe, leading to as many as 1.6 million deaths[2]This is a substantial target market for the potential commercialization of Allocetra in sepsis, and the company intends to consider, upon reviewing the totality of the data, a potential follow-on, randomized, controlled study of a solely high-risk UTI sepsis population.*
- *The difference in the risk profile of the Allocetra group challenges the interpretation of efficacy in other populations.*
- *Safety: No serious adverse events were reported related to the study treatment, and overall, fewer events were considered related to Allocetra compared to placebo (9.3% vs 15.6%). All deaths were determined to be unrelated to treatment, as further confirmed by the independent DSMB. No safety signals were detected*.

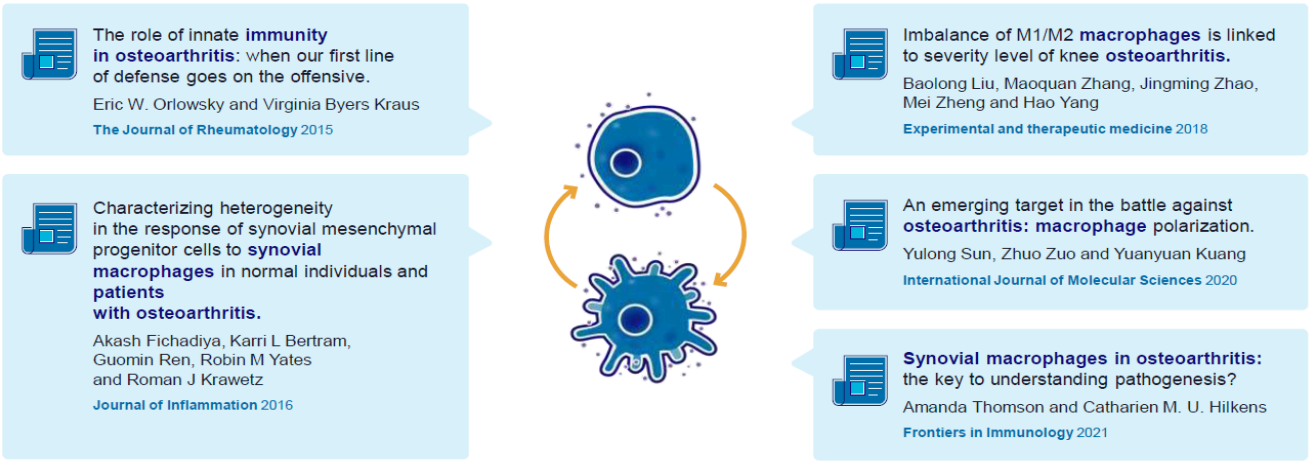
What's Next? We assume the company will scrutinize the one-year data. Suppose the curves continue to show separation between active and control. In that case, we expect the company to partner the product with a deep-pocketed pharma company with the financial depth, clinical expertise, and machinery to run a large sepsis trial.

[1] Compared with recently-completed sizable clinical trials – Revival Phase III (2024), Astonish Phase IIb (2023),Karakike (2019) – in which mortality rates were in the range of 23%–30%.
[2] Management of Urosepsis in 2018, Bonkat et. Al. , European Urology Focus Volume 5, Issue 1,2019

Knee Osteoarthritis: First End-Stage Patient Dosed and Initiation of Randomized Controlled Phase I/II Study Clinical Trials. In 3Q-2023, Enlivex dosed the first patient with a direct injection of Allocetra to the knee in a Phase I/II investigator-initiated clinical trial evaluating the safety and efficacy of Allocetra in end-stage knee osteoarthritis patients indicated for knee replacement surgery.

In January 2024, the company sponsored a multi-country, double-blind, randomized, placebo-controlled Phase I/II trial to evaluate the efficacy, safety, and tolerability of Allocetra following injections into the target knee joint of up to n=160 moderately to severely symptomatic osteoarthritis patients.

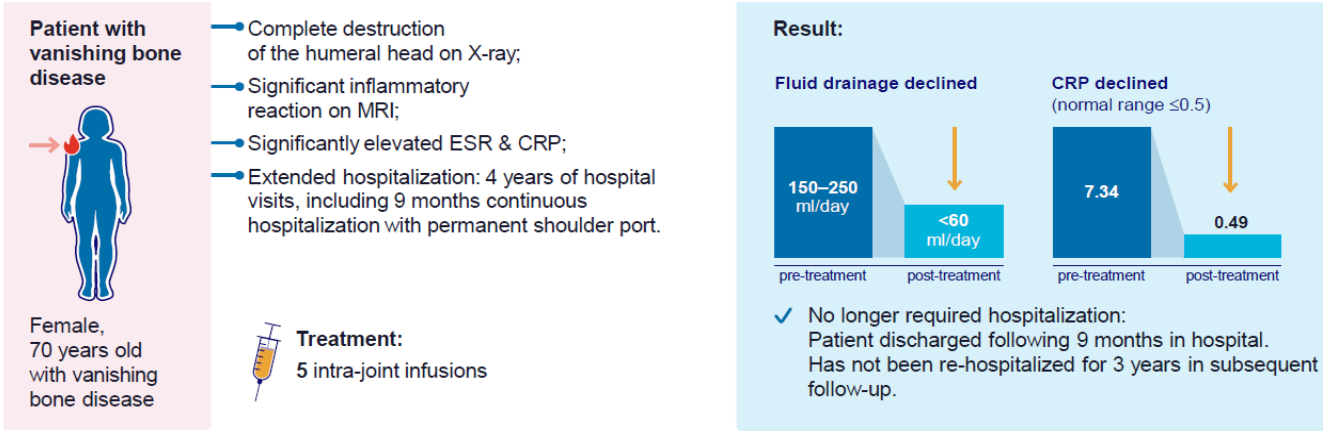
Exhibit 14. Is There a Scientific Basis for Macrophages as a Therapy to Treat Osteoarthritis —Yes



Source: Enlivex

The initiation of the clinical program in osteoarthritis follows preclinical evidence of the potential applicability of Allocetra's mechanism of action to resolve chronic low-grade inflammation of joints afflicted with osteoarthritis, as well as a substantial recovery in a case of a 70-year-old patient who suffered for many years from vanishing bone disease (Gorham-Stout syndrome). Despite exhaustive therapeutic attempts, the patient's disease remained refractory to treatment, requiring extended hospitalization for nine months prior to compassionate treatment with Allocetra to the shoulder joint. Following five intra-articular Allocetra injections, substantial improvement was documented in multiple clinical parameters, and the patient was successfully discharged from the hospital. At a two-year follow-up, the improvement in the afflicted shoulder was maintained, and no subsequent hospital readmissions were required.

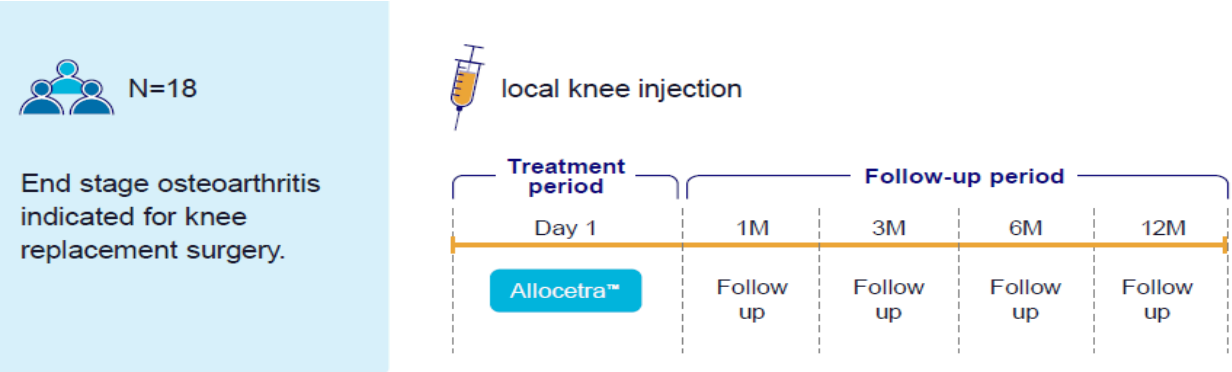
Exhibit 15.ALLOCETRA Compassionate Case Study Results



Source: Enlivex

This Phase I/II multi-center trial is composed of two stages. The first stage is a safety run-in, open-label dose escalation phase to characterize the safety and tolerability of Allocetra injections to the target knee in order to identify the dose and injection regimen for the second, randomized stage. The second stage is a double-blind, randomized, placebo-controlled stage, which follows the completion of the safety run-in stage and confirmation by the safety and tolerability independent Data and Safety Monitoring Board. In addition to evaluating the safety, the blinded randomized stage is statistically powered to assess the efficacy of Allocetra injections into the knee. The primary measurements will evaluate joint pain and joint function compared to placebo at three months, six months, and 12 months. The goal is topline data by 3Q-2025.

Exhibit 16. 0189-22-KMC – End-Stage Knee Osteoarthritis Trial Design

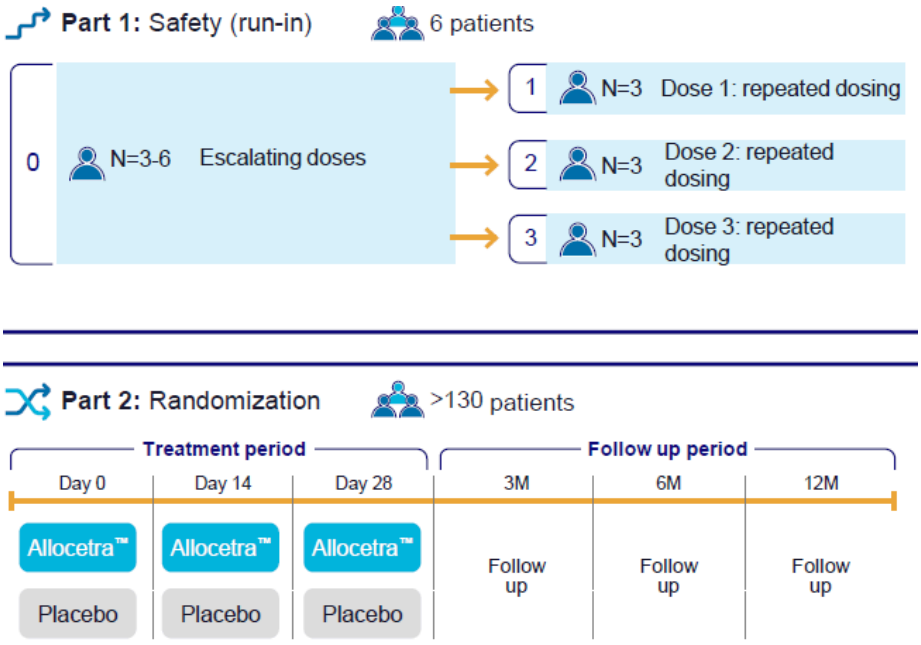


Source: Enlivex

Exhibit 17. Will the Data Be Positive? Three-month interim data from nine patients showed a significant reduction in pain and a favorable safety profile. Pain reduction: Patients reported an average pain reduction of 64% from baseline. Complete Pain Resolution: 33%of patients reported complete pain relief, from an average pain level of 9 to a pain level of 0; the pain scale used in the study ranged from 0 (no pain) to 10 (maximum pain). Avoidance of Surgery: 89%of patients did not proceed with knee replacement surgery at three months post-injection. Safety: No severe adverse events related to Allocetra were reported.

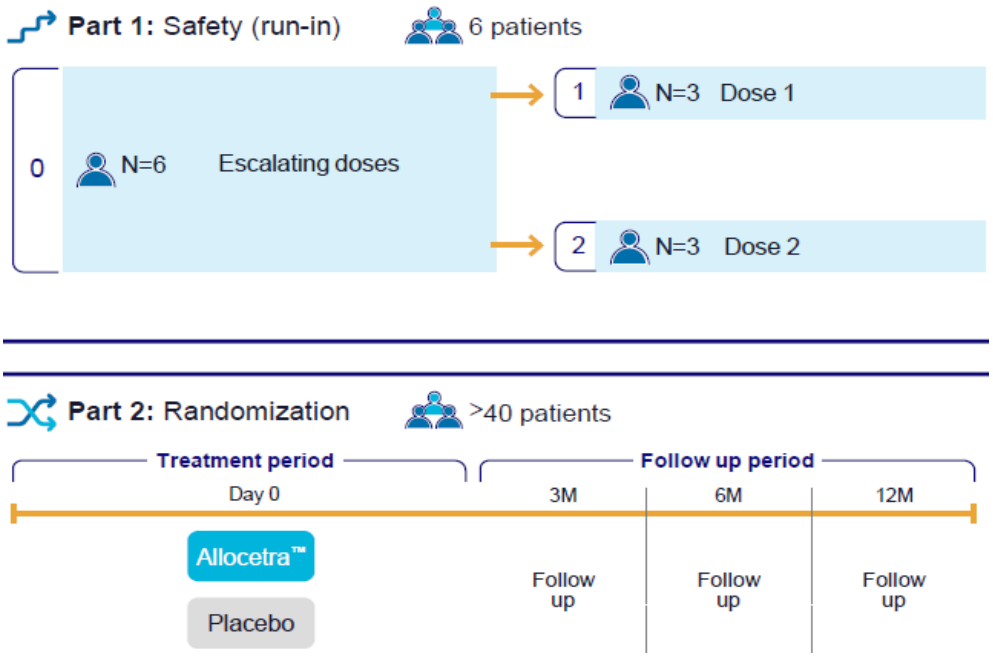
Source: Enlivex

Exhibit 18. Moderate Stage Knee OA Trial. A Phase I/II randomized, double-blind, placebo-controlled study in patients with symptomatic knee OA who have failed to respond to conventional OA therapy (ages 48-80). Patients will receive local knee injections.



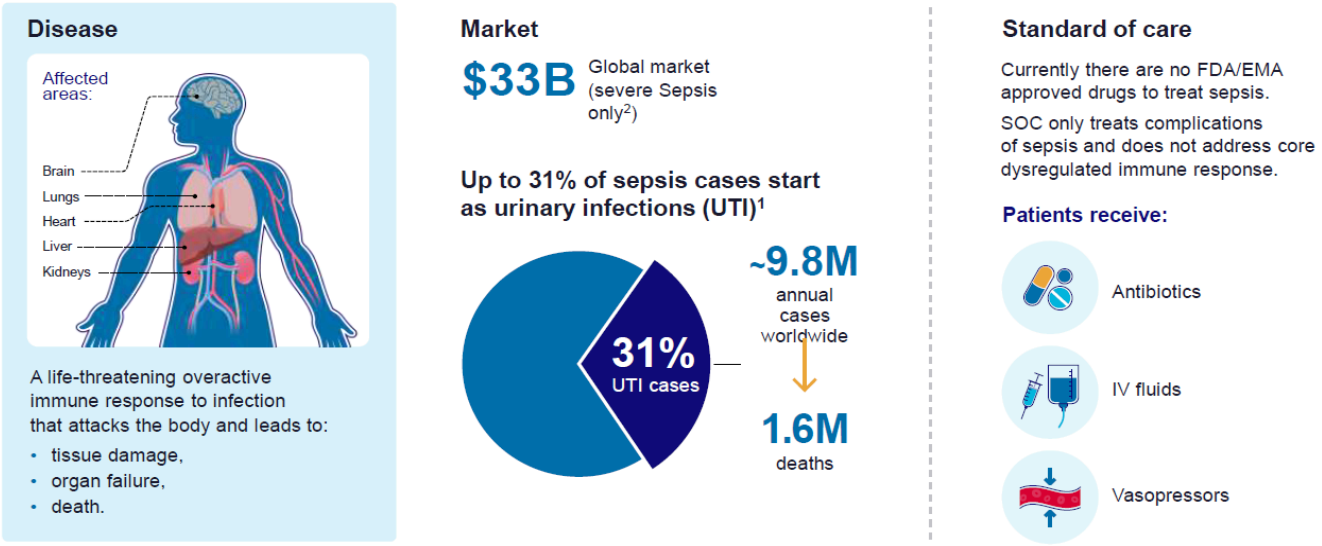
Source: Enlivex

Exhibit 19. Basal Thumb OA Trial Design. An Investigator-initiated Phase I/II randomized, double-blind, placebo-controlled study. Patients with basal thumb joint (first carpometacarpal (CMC) joint) osteoarthritis; Age >40 years; Eaton classification Grade 2 or 3.



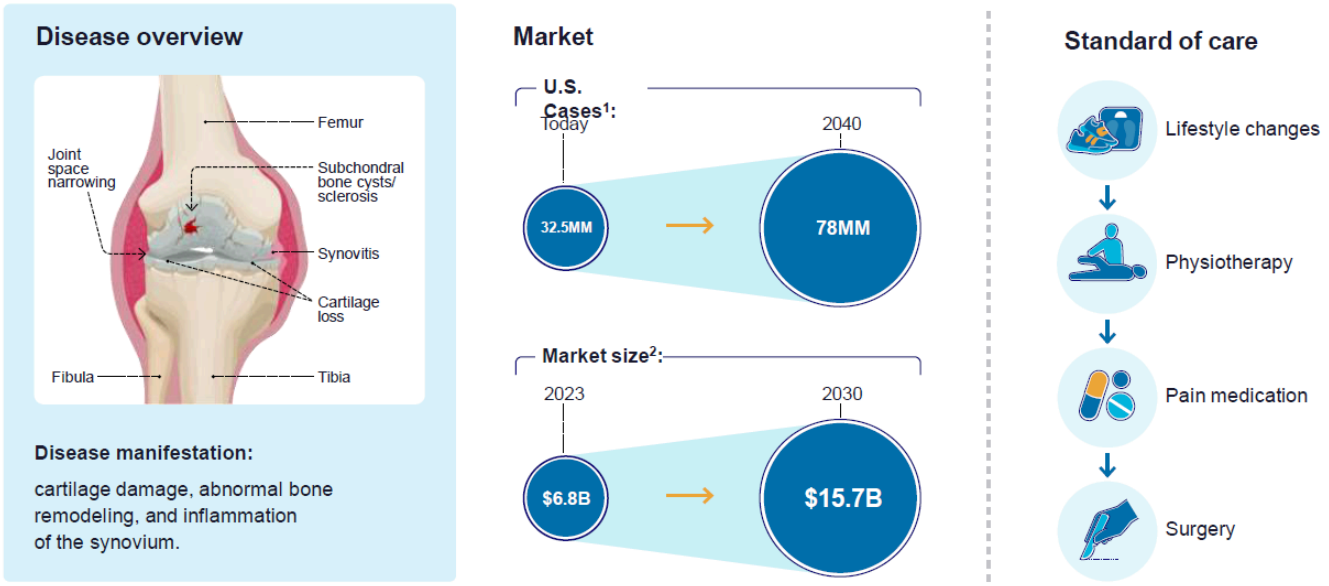
Source: Enlivex

Exhibit 20. The Sepsis Opportunity



1 - Management of Urosepsis in 2018, Bonkat et. Al. , European Urology Focus Volume 5, Issue 1, (2019)
2 - Number of severe cases (www.cdc.gov/sepsis/what-is-sepsis) of 675,000 for US & EU (estimated 25% of the sepsis cases) multiplied by the expected product pricing of $50k = 33B
Source: Enlivex

Exhibit 21. The Knee Opportunity



Source: Enlivex

Modeling Assumptions:

1. We assume the Sepsis is developed with a partner. We also assume the company develops the OA indications (knee and thumb) and licenses them to a partner for commercialization.
2. Our model considers the U.S. Opportunity alone strictly for conservatism.
3. We assume a 30% Probability of Success factor in our Sepsis and Knee models and 10% in the Thumb as we have limited data in that indication. We recognize that success in Knee has wider implications for OA-joint disease.
4. We assume premium pricing for Sepsis at $60,000 as the COGS are typically higher from the higher dose and systemic administration) versus local administration for Knee and Thumb which have a more moderate COGS. We assume an annual cost, which includes multiple treatments/injections of $4,800 for the Knee, $6,000 for the End-Stage Knee, and $3,000 for the Thumb.
5. We assume just a 10% peak share of Sepsis at-risk patients, which could be conservative. For knees, we assume a higher share, 30-33%, as injectable therapy that has the potential to be disease-modifying at a relatively low cost has the potential to be significant. We make similar assumptions for Thumb OA.

Exhibit 22. U.S. Market Models for Sepsis, Knee, and Thumb Opportunities

ENX-CL-02-002 (Sepsis)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
U.S. Prevalence	1,600,000	1,632,000	1,664,640	1,697,933	1,714,912.13	1,732,061	1,749,382	1,766,876	1,784,544	1,802,390	1,820,414
Growth	2%	2%	2%	1%	1%	1%	1%	1%	1%	1%	1%
Target Population	272,000	261,120	266,342	271,669	274,386	277,130	279,901	282,700	285,527	288,382	291,266
Market Share	0%	0%	0%	0%	0%	2%	5%	7%	8%	9%	10%
Treated Patients	-	-	-	-	-	5,543	13,995	19,789	22,842	25,954	29,127
Cost per year					$60,000	$60,600	$61,206	$61,818	$62,436	$63,061	$63,691
% Price Increase	0%	0%	0%	0%	0%	1%	1%	1%	1%	1%	1%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Total sales ($M)	**$0**	**$0**	**$0**	**$0**	**$0**	**$101**	**$257**	**$367**	**$428**	**$491**	**$557**

ENX-CL-05-001 (Moderate Knee)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
Prevalence	32,000,000	32,640,000.00	33,292,800	33,958,656.00	34,298,243	34,641,225	34,987,637	35,337,514	35,690,889	36,047,798	36,408,276
Growth	2%	2%	2%	1%	1%	1%	1%	1%	1%	1%	1%
Target Population	1,600,000	1,632,000	1,664,640	1,697,933	1,714,912	1,732,061	1,749,382	1,766,876	1,784,544	1,802,390	1,820,414
Market Share	0%	0%	0%	0%	0%	0%	1%	5%	15%	25%	33%
Treated Patients	-	-	-	-	-	-	17,494	88,344	267,682	450,597	600,737
Cost per year					$4,800	$4,848	$4,896	$4,945	$4,995	$5,045	$5,095
% Price Increase					0%	1%	1%	1%	1%	1%	1%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Total sales ($M)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$26**	**$131**	**$401**	**$682**	**$918**

0189-22-KMC (End Stage Knee Osteo)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
Prevalence	32,000,000	32,640,000	33,292,800	33,958,656	34,637,829	35,330,586	36,037,197	36,757,941	37,493,100	38,242,962	39,007,821
Growth	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Target Population - 1%	320,000	326,400	332,928	339,587	346,378	353,306	360,372	367,579	374,931	382,430	390,078
Market Share	0%	0%	0%	0%			1%	4%	12%	20%	30%
Treated Patients	-	-	-	-	-	-	3,604	14,703	44,992	76,486	117,023
Cost per year					$6,000	$6,060	$6,121	$6,182	$6,244	$6,306	$6,369
% Price Increase					0%	1%	1%	1%	1%	1%	1%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Total sales ($M)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$7**	**$27**	**$84**	**$145**	**$224**

Basal Thumb Osteoarthritis	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
Prevalence	10,000,000	10,200,000	10,404,000	10,612,080	10,824,322	11,040,808	11,261,624	11,486,857	11,716,594	11,950,926	12,189,944
Growth	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Target Population 5%	500,000	510,000	520,200	530,604	541,216	552,040	563,081	574,343	585,830	597,546	609,497
Market Share	0%	0%	0%	0%					5%	15%	25%
Treated Patients	-	-	-	-	-	-	-	-	29,291	89,632	152,374
Cost per year					$3,000	$3,000	$3,000	$3,000	$3,000	$3,000	$3,000
% Price Increase	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Probability of Success	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Total sales ($M)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$9**	**$27**	**$46**

Source: EF Hutton Estimates

Valuation: Our valuation is based on our therapeutic models and the assumptions associated with our projected revenues in sepsis, knee, and thumb indications out to 2034. Our model assumes equity capital raises, so our share count is based on a fully diluted 2034 estimate. We apply a 30% Probability Of Success (POS) to most of our therapeutic models. See our modeling assumptions for specific details. On top of the POS factor, we use a 30% risk rate in our free cash flow to the firm (FCFF), discounted EPS (dEPS), and sum-of-the-parts (SOP) models. We equal weight, average these metrics, and then round to the nearest whole number to derive our price target.

Exhibit 23. Free Cash Flow Model

Average	$	13

Price Target	$	19
Year		2024

DCF Valuation Using FCF (mln):

units ('000)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
EBIT	(11,997)	(14,000)	(27,000)	(37,000)	(46,440)	26,573	181,431	369,266	685,602	1,022,584	1,341,179
Tax Rate	0%	0%	0%	0%	0%	10%	10%	30%	35%	36%	38%
EBIT(1-t)	(11,997)	(14,000)	(27,000)	(37,000)	(46,440)	23,916	163,288	258,486	445,641	654,454	831,531
CapEx											
Depreciation											
Change in NWC (ex cash)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
FCF	(11,997)	(14,000)	(27,000)	(37,000)	(46,440)	23,916	163,288	258,486	445,641	654,454	831,531
PV of FCF	(11,997)	(10,769)	(15,976)	(16,841)	(16,260)	6,441	33,829	41,194	54,631	61,715	60,318
Discount Rate	30%										
Long Term Growth Rate	1%										
Terminal Cash Flow	2,896,021										
Terminal Value YE2034	1,013,978										
NPV	1,200,262										
NPV-Debt	-										
Projected Shares out (thousands)	62,524	2034E									
NPV Per Share	$ 19.20										

Source: EF Hutton estimates

Exhibit 24. Discounted EPS Model

Current Year		2024
Year of EPS		2034
Earnings Multiple		10
Discount Factor		30%
Selected Year EPS	$	13.30
NPV	$	9.65

Source: EF Hutton & Company reports

	Discount Rate and Earnings Multiple Varies, Year is Constant 2034 EPS						
Earnings Multiple	9.65	5%	10%	15%	20%	25%	30%
1		$8.16	$5.13	$3.29	$2.15	$1.43	$0.96
5		$40.82	$25.63	$16.43	$10.74	$7.14	$4.82
10		$81.63	$51.27	$32.87	$21.48	$14.28	$9.65
15		$122.45	$76.90	$49.30	$32.21	$21.42	$14.47
20		$163.27	$102.53	$65.74	$42.95	$28.56	$19.29
25		$204.08	$128.17	$82.17	$53.69	$35.69	$24.11
30		$244.90	$153.80	$98.61	$64.43	$42.83	$28.94
35		$285.72	$179.43	$115.04	$75.16	$49.97	$33.76

Exhibit 25. Sum-of-the-Parts Model

Enlivex Sum of the Parts	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MM's	Term Val
ENX-CL-02-002 (Sepsis)	1%	30%	7	30%	$1,855	$6,397
NPV						$3.42
ENX-CL-05-001 (Moderate Knee)	1%	30%	8	30%	$3,061	$10,555
NPV						$4.35
0189-22-KMC (End Stage Knee Osteo	1%	30%	9	30%	$745	$2,570
NPV						$0.81
Basal Thumb Osteoarthritis	1%	30%	10	10%	$457	$1,576
NPV						$0.13
Net Margin						70%
MM Shrs OS (2034E)						63
Total						$8.7

Source: EF Hutton estimates

Intellectual Property

Exhibit 26. What IP Protects Enlivex Portfolio of Products? The company has fourteen issued patents and five pending patent applications in the United States (the slide below is out-of-date), five issued patents and two pending applications in Israel, four issued patents and two pending patent applications in Europe Patent Office (EPO), and two international patent applications filed with the World Intellectual Property Organization under the PCT. Enlivex has sought patent protection for certain methods of producing and using autologous and allogeneic Allocetra. The company intends to seek patent protection for its discovery programs and any other inventions to which it has rights, where available and when appropriate.

The risks to our thesis include: 1. Clinical/Regulatory Risk, 2. partnership and Financial Risk, 3. Commercial Risk, 4. legal and Intellectual Property Risk, and 5. Market Share Risk.

Clinical / Regulatory Risk. Enlivex is dependent on the outcome of its clinical trials. Regulatory risk often goes beyond the trials and includes the elements associated with the approval process, such as properly submitting the required forms and data.

Partnership Risk. Enlivex is a small company that may pursue a partnership deal for U.S. and Rest of the World marketing. There can be no assurance that the company can find an appropriate partner and realize attractive partnership terms.

Financial Risk. Enlivex is a small capital company, which can translate into high volatility and risk for investors. The company has no revenues and is dependent on the clinical progress of its therapeutics.

Financial Risk. Enlivex will likely require additional capital raises before it can be self-sustaining, and there is no guarantee that it will raise the needed capital.

Commercial Risk. Enlivex hopes to compete in the markets in Sepsis and Osteoarthritis. Large “deep pocket” big pharma companies tend to dominate these markets, and there can be no assurance that the company will effectively market its products.

Legal and Intellectual Property. Enlivex may face multiple legal challenges, specifically IP challenges, which could force the company to defend its patents or claim it infringes on others.

Enlivex																
	2023A	1Q24A	2Q24A	3Q24E	4Q24E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
Revenue																
ENX-CL-02-002 (Sepsis)										-	100,764	256,974	366,995	427,854	491,010	556,533
ENX-CL-05-001 (Moderate Knee)										-	-	25,697	131,070	401,113	681,959	918,279
089-22-KMC (End Stage Knee)										-	-	6,617	27,268	84,273	144,697	223,601
0006-24-KMC (Basal Thumb)										-	-	-	-	8,787	26,890	45,712
Total Revenues ($000)	-	-	-	-	-	-	-	-	-	-	100,764	289,289	525,333	922,027	1,344,556	1,744,125
Expenses																
COGS						-				-	25,191	57,858	105,067	184,405	268,911	348,825
% COGS	-						-	-	-		25%	20%	20%	20%	20%	20%
Research and Development	19,012	2,857	2,600	2,600	2,600	10,657	10,000	15,000	22,000	22,440	19,000	15,000	15,300	15,606	15,918	16,236
General and Administrative	6,139	1,093	1,000	1,000	1,000	4,093	9,000	12,000	15,000	24,000	30,000	35,000	35,700	36,414	37,142	37,885
Operating expenses	29,395	3,950	3,600	3,600	3,600	14,750	14,000	27,000	37,000	46,440	74,191	107,858	156,067	236,425	321,972	402,947
Oper. Inc. (Loss)	(29,395)	(3,950)	(3,600)	(3,600)	(3,600)	(14,750)	(14,000)	(27,000)	(37,000)	(46,440)	26,573	181,431	369,266	685,602	1,022,584	1,341,179
Interest Income																
Warrants																
Financial Income, Net																
Financial Expenses, Net	327	11	2,742													
Pretax Income	(29,068)	(3,939)	(858)	(3,600)	(3,600)	(11,997)	(14,000)	(27,000)	(37,000)	(46,440)	26,573	181,431	369,266	685,602	1,022,584	1,341,179
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income Tax Benefit (Provision)					-	-	-	-	-	-	2,657	36,286	110,780	239,961	368,130	509,648
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	10%	20%	30%	35%	36%	38%
GAAP Net Income (loss)	(29,068)	(3,939)	(858)	(3,600)	(3,600)	(11,997)	(14,000)	(27,000)	(37,000)	(46,440)	23,916	145,145	258,486	445,641	654,454	831,531
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0.24	0.50	0.49	0.48	0.49	0.48
GAAP-EPS	(1.56)	(0.21)	(0.08)	(0.21)	(0.15)	(0.65)	(0.58)	(0.59)	(0.78)	(0.94)	0.47	2.72	4.66	7.72	10.89	13.30
Non GAAP EPS (dil)	(1.56)	(0.21)	(0.08)	(0.21)	(0.15)	(0.65)	(0.58)	(0.59)	(0.78)	(0.94)	0.47	2.72	4.66	7.72	10.89	13.30
Wgtd Avg Shrs (Bas)	18,574	18,727	11,307	16,420	19,584	16,510	19,633	34,734	34,874	35,013	35,154	35,294	35,436	35,578	35,720	35,863
Wgtd Avg Shrs (Dil)	18,574	18,727	11,307	17,420	23,594	17,762	24,190	45,474	47,321	49,242	51,242	53,322	55,487	57,740	60,085	62,524

Source: EF Hutton & Company reports

Enlivex Balance Sheet ($'000)																
Assets	2023A	1Q24A	2Q24E	3Q24E	4Q24E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
Cash and Cash Equivilents	$813	$1,913	($8,280)	($5,905)	($5,771)	($5,771)	($19,675)	($27,536)	($64,348)	($110,589)	($86,464)	$58,902	$317,622	$763,509	$1,418,223	$2,250,028
Short Term Interest bearing deposits	$26,507	$21,523	$21,098	$21,098	$21,098	$21,098	$21,098	$21,098	$21,098	$21,098	$21,098	$21,098	$21,098	$21,098	$21,098	$21,098
Prepaid expenses and receivables	$1,336	$4,711	$4,711	$4,711	$4,711	$4,711	$4,711	$4,711	$4,711	$4,711	$4,711	$4,711	$4,711	$4,711	$4,711	$4,711
Assets classified as held for sale	$5,108	$229	$229	$229	$229	$229	$229	$229	$229	$229	$229	$229	$229	$229	$229	$229
Total Current Assets	$33,764	$28,376	$17,758	$20,133	$20,267	$20,267	$6,363	($1,498)	($38,310)	($84,551)	($60,426)	$84,940	$343,660	$789,547	$1,444,261	$2,276,066
Property & Equipment (net)	$1,539	$1,299	$1,299	$1,299	$1,299	$1,299	$1,299	$1,299	$1,299	$1,299	$1,299	$1,299	$1,299	$1,299	$1,299	$1,299
Other Assets	$1,528	$1,372	$1,372	$1,372	$1,372	$1,372	$1,372	$1,372	$1,372	$1,372	$1,372	$1,372	$1,372	$1,372	$1,372	$1,372
Total Assets	$36,831	$31,047	$20,429	$22,804	$22,938	$22,938	$9,034	$1,173	($35,639)	($81,880)	($57,755)	$87,611	$346,331	$792,218	$1,446,932	$2,278,737
Current Liabilities																
Accounts payable and acurred liabilities	$827	$643	$3,395	$3,395	$3,395	$3,395	$3,395	$3,395	$3,395	$3,395	$3,395	$3,395	$3,395	$3,395	$3,395	$3,395
Accrued Expenses	$4,001	$2,966	$663	$663	$663	$663	$663	$663	$663	$663	$663	$663	$663	$663	$663	$663
Liability classifies as held for sale	$1,233															
Total Current Liabilities	$6,061	$3,609	$4,057	$4,057	$4,057	$4,057	$4,057	$4,057	$4,057	$4,057	$4,057	$4,057	$4,057	$4,057	$4,057	$4,057
Other LT Liabilities	$686	$587	$2,740	$2,740	$2,740	$2,740	$2,740	$2,740	$2,740	$2,740	$2,740	$2,740	$2,740	$2,740	$2,740	$2,740
Total liabilities	$6,747	$4,196	$6,797	$6,797	$6,797	$6,797	$6,797	$6,797	$6,797	$6,797	$6,797	$6,797	$6,797	$6,797	$6,797	$6,797
Stockholders' equity:																
Ordinary Shares	$2,137	$2,160	$1	$1	$1	$1	$1	$1	$1	$1	$1	$1	$1	$1	$1	$1
Addional Paid-In Capital	$138,939	$139,823	$129,621	$135,595	$139,330	$139,330	$139,426	$158,565	$158,753	$158,951	$159,161	$159,382	$159,615	$159,861	$160,121	$160,395
Accumulated Deficit	($112,093)	($116,233)	($117,091)	($120,691)	($124,291)	($124,291)	($138,291)	($165,291)	($202,291)	($248,731)	($224,815)	($79,670)	$178,817	$624,458	$1,278,912	$2,110,443
Fx Reserve	$1,101	$1,101	$1,101	$1,101	$1,101	$1,101	$1,101	$1,101	$1,101	$1,101	$1,101	$1,101	$1,101	$1,101	$1,101	$1,101
Total Equity	$30,084	$26,851	$13,632	$16,007	$16,141	$16,141	$2,237	($5,624)	($42,436)	($88,677)	($64,552)	$80,814	$339,534	$785,421	$1,440,135	$2,271,940
Total Liab & Equity	$36,831	$31,047	$20,429	$22,804	$22,938	$22,938	$9,034	$1,173	($35,638)	($81,880)	($57,755)	$87,611	$346,331	$792,218	$1,446,932	$2,278,737
Shares Iss'd (000)	18,574	18,727	11,307	16,420	19,584	$16,510	$19,633	$34,734	$34,874	$35,013	$35,154	$35,294	$35,436	$35,578	$35,720	$35,863
Shares Out (000)	18,574	18,727	11,307	17,420	23,594	$17,762	$24,190	$45,474	$47,321	$49,242	$51,242	$53,322	$55,487	$57,740	$60,085	$62,524

Source: EF Hutton & Company reports

Enlivex Cash Flow Statement ($000)	2023A	1Q24A	2Q24A	3Q24E	4Q24E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
Cash Flows From Operating Activities:																
Net Loss	**(29,068)**	**(4,140)**	**(6,087)**	**(9,687)**	**(13,287)**	**(13,287)**	**(14,000)**	**(27,000)**	**(37,000)**	**(46,440)**	**23,916**	**145,145**	**258,486**	**445,641**	**654,454**	**831,531**
Depreciation	835	188	188	188	188	188										
Capital Gain on sale of property and equipment	(20)	(76)	(76)	(76)	(76)	(76)										
Loss (income) on marketable securities	(343)	(66)	(66)	(66)	(66)	(66)										
Loss on assets and liabilities	4,244	98	98	98	98	98										
Non cash operating lease expense	696	383	383	383	383	383										
Share-based compensation	1,951	65	65	65	65	65										
Changes in assets and liabilities:																
Prepiad Expense	608	355	355	355	355	355										
Accounts payable	(1,121)	(183)	(183)	(183)	(183)	(183)										
Accrued Exp. & Liabilities	(350)	(1,030)	(1,030)	(1,030)	(1,030)	(1,030)										
Decrease in liabilities as helf for sale securities	(101)	(104)	(104)	(104)	(104)	(104)										
Operating lease laibilities	(854)		0	0	0	0										
Net Cash Used in Operating Activities	**(23,523)**	**(4,510)**	**(6,457)**	**(10,057)**	**(13,657)**	**(13,657)**	**(14,000)**	**(27,000)**	**(37,000)**	**(46,440)**	**23,916**	**145,145**	**258,486**	**445,641**	**654,454**	**831,531**
Cash Flows From Investing Activities:																
Purchase of Property & Equipment	(236)	(43)	(43)	(43)	(43)	(43)										
Proceeds from sale of property & equipment	133	171	171	171	171	171										
Investment in ST interest bearing deposits	(26,166)	53	53	53	53	53										
Release of ST deposits	301	(8,483)	(8,483)	(8,483)	(8,483)	(8,483)										
Purchase of Marketable securities	0	13,400	13,400	13,400	13,400	13,400										
Proceeds from sale of marketable securities	0		0	0	0	0										
Net cash provided by investing activities	**(25,968)**	**5,098**	**5,098**	**5,098**	**5,098**	**5,098**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Cash flows from financing activities:																
Issuance of common shares, net of issue costs	360	524	(8,146)	(2,172)	1,563	1,563	96	19,139	188	199	209	221	233	246	260	274
Warrants			0	0	0	0										
Options																
Net cash provided by financing activities	360	524	(8,146)	(2,172)	1,563	1,563	96	19,139	188	199	209	221	233	246	260	274
Increase (decrease) in Cash and Cash Equivilents	(49,131)	1,112	(9,506)	(7,131)	(6,997)	(6,997)	(13,904)	(7,861)	(36,812)	(46,241)	24,125	145,366	258,720	445,887	654,714	831,805
Cash and Cash Equivilents - Beginning Of Period	50,357	1,226	1,226	1,226	1,226	1,226	(5,771)	(19,675)	(27,536)	(64,348)	(110,589)	(86,464)	58,902	317,622	763,509	1,418,223
Exchange Differences on Cash and Cash Equivilents	0															
Cash and Cash Equivilents - End of Period	1,226	2,338	(8,280)	(5,905)	(5,771)	(5,771)	(19,675)	(27,536)	(64,348)	(110,589)	(86,464)	58,902	317,622	763,509	1,418,223	2,250,028

Source: EF Hutton & Company reports

Important Disclosures

Analyst Certification

I, Jason Kolbert, certify that all of the views expressed in this research report accurately reflect my personal views about the subject security(ies) and subject company(ies). I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed in this research report.

Company-Specific Disclosures

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EF Hutton rating definitions are expressed as the total return relative to the expected performance of S&P 500 over a 12-month period.

BUY (B) - Total return expected to exceed S&P 500 by at least 10%

HOLD (H) - Total return expected to be in-line with S&P 500

SELL (S) - Total return expected to underperform S&P 500 by at least 10%

Distribution of Ratings/IB Services

EF Hutton

			IB Serv./Past 12 Mos.	
Rating	**Count**	**Percent**	**Count**	**Percent**
BUY	**22**	**95.65**	**4**	**18.18**
HOLD	**1**	**4.35**	**0**	**0.00**
SELL	**0**	**0.00**	**0**	**0.00**


Enlivex Rating History as of 08/23/2024
14
12
10
8
6
4
2
0
Oct 21
Jan 22
Apr 22
Jul 22
Oct 22
Jan 23
Apr 23
Jul 23
Oct 23
Jan 24
Apr 24
Jul 24
Price (USD)
Closing Price