Enlivex Therapeutics Ltd. (ENLV)
Rating: Buy

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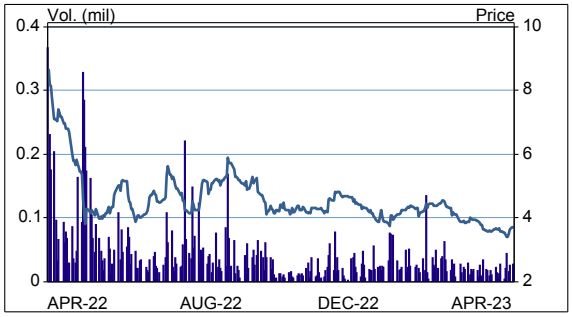
Clinical Progress Continues; 2022 Financial Results; Reiterate Buy

Stock Data	04/04/2023
Price	$2.51
Exchange	NASDAQ
Price Target	$15.00
52-Week High	$8.64
52-Week Low	$2.51
Enterprise Value (M)	$(4)
Market Cap (M)	$46
Public Market Float (M)	14.3
Shares Outstanding (M)	18.4
3 Month Avg Volume	25,086
Short Interest (M)	0.16
Balance Sheet Metrics	
Cash (M)	$50.2
Total Debt (M)	$0.0
Total Cash/Share	$2.73
Book Value/Share	$3.44

EPS ($) Diluted			
Full Year - Dec	2022E	2023E	2024E
1Q	(0.45)A	(0.40)	(0.38)
2Q	(0.54)A	(0.46)	(0.34)
3Q	(0.31)A	(0.41)	(0.33)
4Q	(0.39)A	(0.48)	(0.33)
FY	(1.69)A	(1.75)	(1.37)



Multiple clinical trials advancing toward value inflection points. In a press release yesterday, Enlivex reported its 2022 financial results and provided a corporate update. The company is working on an amendment to the protocol of its Phase 2 trial evaluating Allocetra™ in patients with sepsis. The amendment will include an increase in the patients' SOFA score inclusion range, effectively allowing recruitment of patients with higher levels of sepsis severity, along with a change to two cohorts (treatment and placebo) in lieu of the current four-cohort structure. The company expects to submit the proposed protocol amendments to regulators in the coming weeks (i.e., early in the current quarter) and does not expect a material delay for top-line data readouts, slated for release in 1Q24. In order to maximize the potential to observe potential therapeutic effect in the Phase 2 sepsis trial, Enlivex has decided to alter its original staged plan for an interim analysis and move to a single analysis that will be conducted with top-line data readouts in 1Q24 (possibly late 2023). Recruitment remains on track in a Phase 1/2 trial of Allocetra plus chemotherapy in patients with peritoneal metastases arising from solid cancers, with top-line data release slated for 2Q24. In addition, clearance was recently received to continue a second Phase 1/2 trial evaluating Allocetra as monotherapy and combined with anti-PD1 checkpoint inhibitors in patients with advanced-stage solid tumors. The company expects to complete enrollment in the intravenous-infusion monotherapy and low-dose combination cohorts by the end of 2Q23. In our view, a series of data readouts could occur in the late 2023 — 1H24 time frame, possibly driving considerable upside to the current valuation if results prove positive. We reiterate our Buy rating and 12-month price target of $15 per share.

Financial results reported—by the numbers. Enlivex ended 2022 with $50.2M in cash and short-term deposits. We expect these resources to be sufficient to fund operations well into 2H24. The company recorded a 2022 net loss of $1.69 per share, roughly in-line with our forecast of a full-year 2022 net loss of $1.68 per share. Our 2023 net loss per share estimate has widened somewhat to $1.75 per share vs. the prior forecast of a net loss of $1.55 per share, while we have instituted a 2024 estimate forecasting a net loss of $1.37 per share. We expect R&D to continue increasing as Enlivex advances multiple proof-of-concept clinical trials with Allocetra.

High-visibility collaboration arrangement established. Earlier this week, Enlivex announced a clinical collaboration agreement with BeiGene (BGNE; not rated), one of China's leading biopharmaceutical companies and a recognized leader in the development of oncology-focused therapies. Enlivex intends to study Allocetra in combination with tislelizumab, an anti-PD-1 immune checkpoint inhibitor, for the treatment of patients with advanced-stage solid tumors as part of an ongoing Phase 1/2 clinical trial. The evaluation of the safety and efficacy of the combination of Allocetra with tislelizumab is the focal point of the collaboration arrangement with BeiGene.

Positive results for the combination of Allocetra and tislelizumab could position Allocetra for broader usage with an array of marketed checkpoint inhibitor drugs. Under the terms of the agreement with BeiGene, Enlivex has agreed to amend its ongoing Phase 1/2 trial in patients with advanced-stage solid tumors to include the evaluation of Allocetra in combination with tislelizumab. This Phase 1/2 trial is a multi-center, open-label, dose escalation trial that is designed to enroll up to 48 patients with advanced solid tumors across two trial stages. Stage 1 of the trial shall examine escalating doses of Allocetra monotherapy administered intravenously (IV) or intraperitoneally (IP) once a week for three consecutive weeks. Stage 2 shall evaluate escalating doses of Allocetra administered IV or IP and combined with anti-PD1 therapy. BeiGene is to provide the clinical supply of tislelizumab for the trial. We note that positive results would confirm the preclinical evidence supporting the utility of combining Allocetra with a checkpoint inhibitor and could suggest potential for usage of Allocetra in combination with an entire class of checkpoint inhibitor drugs, including widely-used agents such as Keytruda (pembrolizumab) from Merck & Co. (MRK; not rated) and Opdivo (nivolumab) from Bristol-Myers Squibb (BMY; not rated). Investors should be aware that multiple recently-reported large trials—e.g., KEYNOTE-641 (metastatic castration-resistant prostate cancer, or mCRPC), KEYNOTE-789 (non-squamous, metastatic non-small cell lung cancer) and KEYNOTE-921 (metastatic castration-resistant prostate cancer) with pembrolizumab—have failed to show meaningful benefit and thus demonstrated the limitations of checkpoint inhibitor therapy in various advanced solid tumor settings, underscoring the need for combination regimens that potentiate the impact of these widely-deployed agents.

Valuation and risks. We value Enlivex using a discounted cash flow (DCF)-based methodology. This employs a 12% discount rate, 1% terminal growth rate and 25% effective tax rate. Conservatively, we do not model Allocetra sales in cancer indications beyond non-small cell lung cancer (NSCLC), although we believe that the platform could have applicability across multiple solid tumor types, including peritoneal cancer, ovarian cancer and mesothelioma. We derive a total firm value of $320M, or a price objective of $15 per share assuming 21.3M total shares outstanding as of end-2023. Risks include, but are not limited to: (1) adverse results from clinical studies; (2) inability to identify partners to advance applications in oncology indications; (3) failure to file for approval of Allocetra in a timely manner; (4) inability to secure approval of Allocetra; (5) lower than anticipated market penetration; and (6) potential long-term dilution risk.

Table 1: Enlivex Therapeutics Ltd. (ENLV)—Historical Income Statements, Financial Projections

FY end December 31
$ in thousands, except per share data

	2022A					2023E					
	1QA	2QA	3QA	4QA	2022A	1QE	2QE	3QE	4QE	2023E	2024E
Revenue											
Product revenue	-	-	-	-	-	-	-	-	-	-	-
Service revenue	-	-	-	-	-	-	-	-	-	-	-
Research and other	-	-	-	-	-	-	-	-	-	-	-
Total revenue	-	-	-	-	-	-	-	-	-	-	-
Expenses											
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-
Research & development	4'682	4'110	4'201	5'700	18'693	5'300	5'400	5'500	5'800	22'000	24'000
Selling and marketing	-	-	-	-	-	-	-	-	-	-	-
General and administrative	1'722	1'761	1'476	2'145	7'104	2'000	2'000	2'000	2'000	8'000	8'800
Total expenses	6'404	5'871	5'677	7'845	25'797	7'300	7'400	7'500	7'800	30'000	32'800
Gain (loss) from operations	(6'404)	(5'871)	(5'677)	(7'845)	(25'797)	(7'300)	(7'400)	(7'500)	(7'800)	(30'000)	(32'800)
Other income/expense											
Financial income	-	-	-	-	-	-	-	-	-	-	-
Financial expenses	-	-	-	-	-	(5)	(1'000)	(6)	(1'000)	(2'011)	-
Other income/expense	(1'821)	(4'042)	(56)	656	(5'263)	-	-	-	-	-	-
Total investment income and other	(1'821)	(4'042)	(56)	656	(5'263)	(5)	(1'000)	(6)	(1'000)	(2'011)	-
Loss before provision for income taxes	(8'225)	(9'913)	(5'733)	(7'189)	(31'060)	(7'305)	(8'400)	(7'506)	(8'800)	(32'011)	(32'800)
Deferred income tax benefit	-	-	-	-	-	-	-	-	-	-	-
Net loss/income	(8'225)	(9'913)	(5'733)	(7'189)	(31'060)	(7'305)	(8'400)	(7'506)	(8'800)	(32'011)	(32'800)
Net loss per share (basic)	(0.45)	(0.54)	(0.31)	(0.39)	(1.69)	(0.40)	(0.46)	(0.41)	(0.48)	(1.75)	(1.37)
Net loss per share (diluted)	(0.45)	(0.54)	(0.31)	(0.39)	(1.69)	(0.40)	(0.46)	(0.41)	(0.48)	(1.75)	(1.37)
Weighted average number of shares outstanding (basic)	18'370	18'375	18'392	18'443	18'395	18'325	18'253	18'303	18'353	18'308	23'916
Weighted average number of shares outstanding (diluted)	18'370	18'375	18'392	18'443	18'395	18'325	18'253	18'303	18'353	18'308	23'916

Source: Company reports and H.C. Wainwright & Co. estimates.

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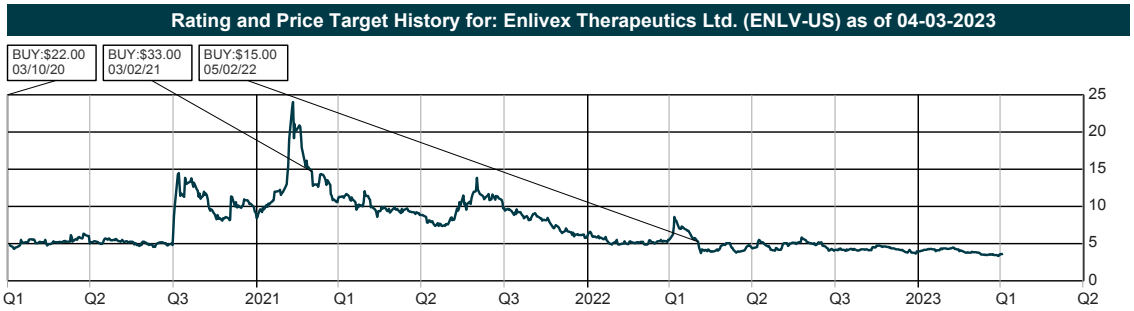

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Distribution of Ratings Table as of April 3, 2023				
			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	557	87.85%	131	23.52%
Neutral	63	9.94%	11	17.46%
Sell	0	0.00%	0	0.00%
Under Review	14	2.21%	3	21.43%

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