Kairos Pharma, Ltd. (KAPA) Rating: Buy Joseph Pantginis, Ph.D. 646-975-6968

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## 2Q25 Results; ENV-105 Phase 2 Study Continues to Advance; Interim Efficacy Data Expected 3Q25

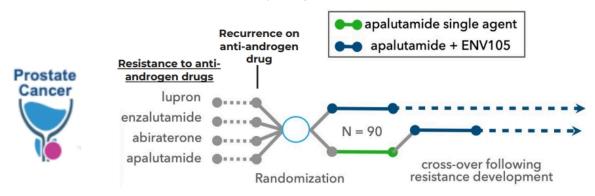
Stock Data			8/12/2025					
Price			\$1.12					
Exchange			NASDAQ					
Price Target			\$12.00					
52-Week High			\$4.00					
52-Week Low			\$0.40					
Enterprise Valu	ie (M)		\$20					
Market Cap (M	)		\$23					
Shares Outstar	nding (M)		20.5					
3 Month Avg Vo	olume		5,062,449					
Short Interest (	M)		0.87					
Balance Sheet Metrics								
Cash (M)			\$3.0					
Total Debt (M)			\$0.1					
Total Cash/Sha	ire		\$0.15					
EPS (\$) Diluted			Ì					
Full Year - Dec	2024A	2025E	2026E					
1Q		A(80.0)						
2Q		A(80.0)						
3Q	(0.10)	(0.10)						
4Q	(80.0)	(0.12)						
FY	(0.23)	(0.29)	(0.33)					
Revenue (\$M)								
Full Year - Dec	2024A	2025E	2026E					
1Q		0.0A						
2Q		0.0A						
3Q	0.0	0.0						
4Q	0.0	0.0						
FY	0.0	0.0	0.0					
Public statements available from 3Q24								

Price 3 Vol. (mil) 300 250 2.5 2 200 150 1.5 100 50 0.5 SEP-24 APR-25 AUG-25 JAN-25

**Financial and corporate update.** Yesterday after the close, Kairos announced 2Q25 financial results, posting EPS of (\$0.08), compared to our estimate of (\$0.06), and consensus of (\$0.05). The company ended the quarter with \$3.0 million in cash, which managements expects to be sufficient to fund operations into 2H26. The company continues to advance its lead asset, ENV-105 (an anti-CD105 antibody) in Phase 1 and Phase 2 clinical trials for mCRPC and NSCLC, respectively. With two clinical catalysts poised for readouts 2025 (interim Phase 2 efficacy data expected in mCRPC in 3Q25 and initial Phase 1 NSCLC data by YE25), and several preclinical candidates nearing IND-stage, we foresee significant news flow for the remainder of 2025 and into 2026. We currently emphasize the imminent Phase 2 interim readout for ENV-105 in mCRPC, as we believe this will represent a significant de-risking event for investors. For further details on the Kairos pipeline, refer to our recent initiation report.

Positive safety update from Phase 2 study of ENV-105 in mCRPC; efficacy update next in 3Q25. Recently, Kairos announced a positive interim safety update from the ongoing randomized Phase 2 study of its lead asset, ENV-105 (a first-in-class anti-CD105 antibody), in patients with metastatic castration resistant prostate cancer (mCRPC). Specifically, ENV-105 was well tolerated when combined with SoC hormone therapy, apalutamide (Erleada) (JNJ; not rated), from the first ten enrolled patients, the pre-specified number required for a safety readout. To date, there have been no dose-limiting toxicities (DLTs) or unexpected adverse events (AEs) reported. In addition, the treatmentrelated side effects were manageable with standard supportive care. Notably, no Grade 3 or 4 toxicities were observed. We remind investors, the Phase 2 study is currently enrolling patients at Cedar-Sinai Medical Center, City of Hope Cancer Center, and Hunstman Cancer Institute. The study is designed to evaluate the safety, tolerability, and early signs of efficacy of ENV-105 in men whose disease has progressed following apalutamide treatment. The study is targeting enrollment of 100 patients in total, to be randomized and given apalutamide as single agent or in combination with ENV-105 for 2 months (the single agent arm can crossover following resistance development). The primary endpoint of the study is progression free survival (PFS), and the secondary endpoint is companion biomarker confirmation. Per management, the benchmark for response is if PFS in the combination arm can go beyond 4 months (as 2L or 3L mCRPC typically become resistant ~2months) in 50% of patients. At 4 months, it is expected that patients on apalutamide would demonstrate tumor progression. Interim efficacy data from the trial are expected to be reported in 3Q25. Following this forthcoming data update, the company intends to meet with regulatory agencies to discuss a path forward to pivotal studies, including a potential Phase 3 study design. Today's safety update continues to bolster our confidence in the program and supports the continued advancement of ENV-105 in this patient population with a high unmet need.

ENV-105 in mCRPC: Randomized Phase 2 Study Design



Source: Company materials

DoD funds support advancement of ENV-105 in EGFR-driven NSCLC. Recently, Kairos announced that its academic partner, Cedars-Slnai Medical Center, has received a U.S Department of Defense (DoD) grant to support the advancement of its lead asset, ENV-105 for the treatment of EGFR-driven NSCLC. Specifically, the company has secured \$876,000 of non-dilutive financing from the DoD to support research in Kairos CSO Dr. Neil Bhowmick's laboratory to identify biomarkers of patients with NSCLC who have developed resistance to Osimertinib (SoC in treatment of EGFR-mutated NSCLC). This strategy will provide a means to identify patients who are most likely to benefit from ENV-105 treatment. The DoD grant underscores the validity of the underlying ENV-105 mechanism and its potential in the ongoing Phase 1 clinical study, particularly in today's challenging market environment. The company expects these additional funds to lead to more effective monitoring and early detection of drug resistance development, opening the window for more timely intervention with ENV-105, and potentially provide better patient outcomes and survival metrics. We believe this award is a sign of external validation to advance ENV-105's clinical development, and look forward to the initial Phase 1 study updates, expected by YE25. For further details on the Kairos pipeline, refer to our recent initiation report Attacking Cancer Rx Resistance and Boosting Immune Function; Initiating at Buy and \$12 PT.

**Valuation and Risks.** We reiterate our Buy rating and \$12 price target. Our valuation is based on our clinical net present value (NPV) model, which allows us to flex multiple assumptions affecting a drug's profile. We consider two key factors when considering our valuation of Kairos using our NPV approach:

- We only value ENV-105 for mCRPC for the U.S. market (20% PoS 100% contribution), which has the potential to be a blockbuster indication for Kairos. We feel we are being conservative in our market model approach of ENV-105 by only attaining ~20% market penetration and ~\$700 million peak sales, while still representing an unmet medical need.
- We purposely omit the rest of Kairos' pipeline, including ENV-105 for NSCLC, which is already in the clinic. This represents
  a not only an additional layer of conservatism, but provides significant upside potential over the long-term by having multiple
  opportunities increasing the changes of potential success, in our belief.

Factors that could impede reaching our price target include failed or inconclusive clinical trials, the inability of the company to secure adequate funding to progress its drug through the development pathway or the occurrence of dilutive capital raises.

(\$ in millions except per s	share data)	١
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Profit & Loss	2022A	2023A	2024A	2025E	2026E	2027E	2028E
Licensing and R&D revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Milestone revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Product and Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CoGS	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross Profit	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross margin	0%	0%	0%	0%	0%	0%	0%
G&A	0.5	1.6	1.9	4.5	5.6	10.7	17.1
R&D	0.1	0.1	0.4	3.0	4.7	10.5	19.9
Other op ex	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBIT	(0.6)	(1.7)	(2.3)	(7.5)	(10.3)	(21.2)	(37.0)
EBIT margin	nm	nm	nm	nm	nm	nm	nm
Depreciation	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Amortization Intangibles	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA	(0.6)	(1.7)	(2.3)	(7.5)	(10.3)	(21.2)	(37.0)
EBITDA margin	nm	nm	nm	nm	nm	nm	nm
Non operating expenses	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Interest Income/Other	0.0	0.0	0.0	0.1	0.1	0.3	0.3
Interest expense	0.5	0.1	0.3	0.0	0.0	0.0	0.0
EBT	(1.1)	(1.8)	(2.6)	(7.4)	(10.2)	(20.8)	(36.7)
EBT margin	nm	nm	nm	nm	nm	nm	nm
Provision for taxes	0.0	0.0	0.0	0.0	0.0	0.0	(9.2)
Net Income	(1.1)	(1.8)	(2.6)	(7.4)	(10.2)	(20.8)	(36.7)
Participation of preferred stock	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income to common	(1.1)	(1.8)	(2.6)	(7.4)	(10.2)	(20.8)	(27.5)
net margin	nm	nm	nm	nm	nm	nm	nm
Number of shares - basic	10.2	10.4	11.4	25.4	30.4	39.2	45.0
Number of shares - diluted	10.2	10.4	11.4	25.4	30.4	39.2	45.0
EPS - basic	(0.1)	(0.17)	(0.23)	(0.29)	(0.33)	(0.53)	(0.61)
EPS - diluted	(0.1)	(0.17)	(0.23)	(0.29)	(0.33)	(0.53)	(0.61)
Source: SEC filings and H.C. Wainwright estimates							

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IPO September 16, 2024

Quarterly P&L										
	Q3'24A	Q4'24E	FY'24E	Q1'25A	Q2'25A	H1'25A	Q3'25E	9M'25E	Q4'25E	FY'25E
Licensing and R&D revenue	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Milestone revenue	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Product and Royalties	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Other revenues	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Revenues	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
CoGS	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Gross Profit	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Gross margin	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
G&A	0.37	0.37	1.9	0.77	0.96	1.73	1.20	2.93	1.57	4.5
R&D	0.01	0.10	0.4	0.49	0.50	0.99	0.80	1.79	1.21	3.0
Other op ex	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
EBITDA	(0.4)	(0.5)	(2.3)	(1.3)	(1.5)	(2.7)	(2.0)	(4.7)	(2.8)	(7.5)
EBITDA margin			nm							nm
Non operating expenses	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Net Interest Income/Other	(0.66)	(0.70)	0.0	0.00	0.03	0.04	0.03	0.06	0.04	0.1
Interest expense	0.00	0.00	0.3	0.00	0.00	0.00	0.00	0.00	0.00	0.0
EBT	(1.0)	(1.2)	(2.6)	(1.3)	(1.4)	(2.7)	(2.0)	(4.7)	(2.7)	(7.4)
EBT margin			nm							nm
Provision for taxes	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Participation of preferred stock			0.0							0.0
Net Income to common	(1.0)	(1.2)	(2.6)	(1.3)	(1.4)	(2.7)	(2.0)	(4.7)	(2.7)	(7.4)
net margin			nm							nm
NoSH	10.91	13.83	11.36	15.88	17.21	16.54	20.74	17.94	23.20	25.40
NoSH	10.91	13.83	11.36	15.88	17.21	16.54	20.74	17.94	23.20	25.40
EPS - basic	(0.10)	(80.0)	(0.23)	(80.0)	(80.0)	(0.16)	(0.10)	(0.26)	(0.12)	(0.29)
EPS - diluted	(0.10)	(0.08)	(0.23)	(80.0)	(80.0)	(0.16)	(0.10)	(0.26)	(0.12)	(0.29)
Courses CEC filings and H.C. Wainwright actimates										

Source: SEC filings and H.C. Wainwright estimates. Joseph Pantginis, Ph.D. jpantginis@hcwco.com

<sup>\*\*</sup>Public statements available from 3Q24

IPO September 16, 2024

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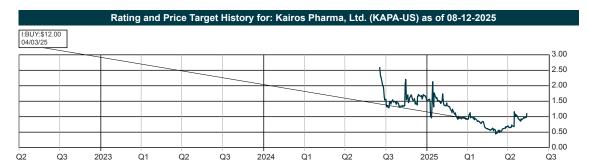
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**Market Outperform (Buy):** The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

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Distribution of Ratings Table as of August 12, 2025							
			IB Se	IB Service/Past 12 Months			
Ratings	Count	Percent	Count	Percent			
Buy	542	80.90%	109	20.11%			
Neutral	77	11.49%	12	15.58%			
Sell	2	0.30%	0	0.00%			
Under Review	49	7.31%	14	28.57%			

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