Kairos Pharma, Ltd. (KAPA)
Rating: Buy

Joseph Pantginis, Ph.D.
646-975-6968
jpantginis@hcwresearch.com

Sara Nik, Ph.D.
212-916-3970
snik@hcwresearch.com

Matthew Keller, Ph.D.
212-856-5745
mkeller@hcwresearch.com

Lander Egaña Gorroño, Ph.D.
212-916-3977
legana@hcwresearch.com

Joshua Korsen, Ph.D.
212-715-2886
jkorsen@hcwresearch.com

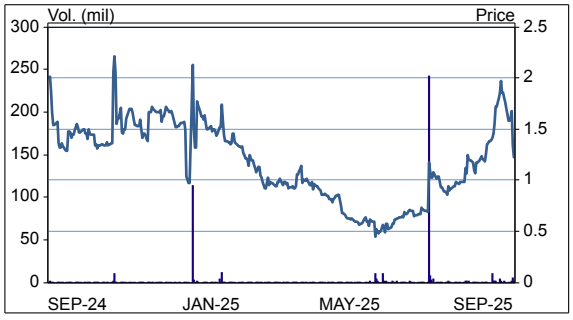
Positive Interim Phase 2 Data For ENV-105 in mCRPC Builds Compelling Profile and Extended PFS Benefit

Stock Data	9/19/2025
Price	$1.22
Exchange	NASDAQ
Price Target	$12.00
52-Week High	$3.25
52-Week Low	$0.40
Enterprise Value (M)	$22
Market Cap (M)	$25
Shares Outstanding (M)	20.7
3 Month Avg Volume	5,137,117
Short Interest (M)	0.50
Balance Sheet Metrics	
Cash (M)	$3.0
Total Debt (M)	$0.1
Total Cash/Share	$0.15

EPS ($) Diluted			
Full Year - Dec	2024A	2025E	2026E
1Q	--	(0.08)A	--
2Q	--	(0.08)A	--
3Q	(0.10)	(0.10)	--
4Q	(0.08)	(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

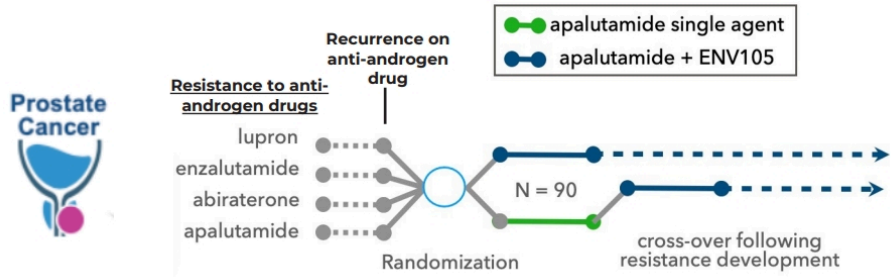


Positive early efficacy update from Phase 2 study of ENV-105 in mCRPC; PFS exceeding benchmarks. Kairos announced a positive interim safety and effciacy update from the ongoing randomized Phase 2 study of its lead asset, ENV-105 (a first-in-class anti-CD105 antibody), in combination with apalutamide for patients with metastatic castration-resistant prostate cancer (mCRPC), who have failed at least one prior line of androgen receptor (AR) hormone therapy. This predetermined interim analysis builds upon and evaluates the same 10 patients from the safety-arm of the trial, which recently reported a positive profile with no DLTs or unexpected AEs. Among eight evaluable patients, median progression-free survival (mPFS) exceeded 13 months, well above the benchmarks from prior SoC therapies, and five patients remain on treatment without progression. Per management, the benchmark for response was if PFS in the combination arm can go beyond 4 months, as a mPFS of 3.7-months and 5.6 months was previously observed in landmark studies for standard 2L or 3L hormone therapies (*NEJM, 2019; Lancet, 2024)*. In the latter study, an arm of Pluvicto (a targeted radio-ligand therapy) saw a mPFS of 11.6 months. Further, in this ongoing study, the combination of ENV-105/apalutamide treatment led to a reduction in PSA from baseline at the 16-week evaluation mark, a further sign of clinical activity. While these are still early days and the patient sample size presented is small, we are encouraged by this early PFS and safety benefit, particularly in the context of past landmark studies.

KOLs underscore mCRPC unmet need and potential role of ENV-105 in treatment landscape. The company held a call with KOLs to discuss these early findings, and the key takeaway was the promise of ENV-105 to re-sensitize patients to AR inhibitor therapy and prolong its treatment benefit, while not compromising patient QoL. We remind investors, with a high prevalence and aging population, mCRPC remains the second leading cause of cancer death among men. Despite advances, patients commonly develop resistance to standard hormone therapy treatments, and limited options remain for patients that do not pose an increased toxicity profile. Beyond switching hormone therapies, chemotherapy is an option for patients, which negatively impacts QoL after typically years on hormone therapy in the 1L setting. Newer options, such as Pluvicto, can also present with harsh side effects including bone marrow and renal toxicity. In this context, KOLs highlighted patient preference for a therapy with a manageable, reversible side effect profile. Enter ENV-105, which aims to prolong hormone therapy benefit and has demonstrated a favorable safety profile based on prior studies and the initial safety run-in for the current Phase 2 study, with epistaxis and headaches being the most frequently reported AEs. Further patient enrollment will be crucial to see how this AE profile scales with time and increased subjects. We also note that while apalutimide was the combination hormone therapy for the current study, ENV-105 has broad applicability for use in combination with AR inhibitors, providing a potential class effect of resensitizaiton.

What's next? 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 company intends to meet with regulatory agencies to discuss a path forward to pivotal studies, including a potential Phase 3 study design. The recent safety and early efficacny 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.

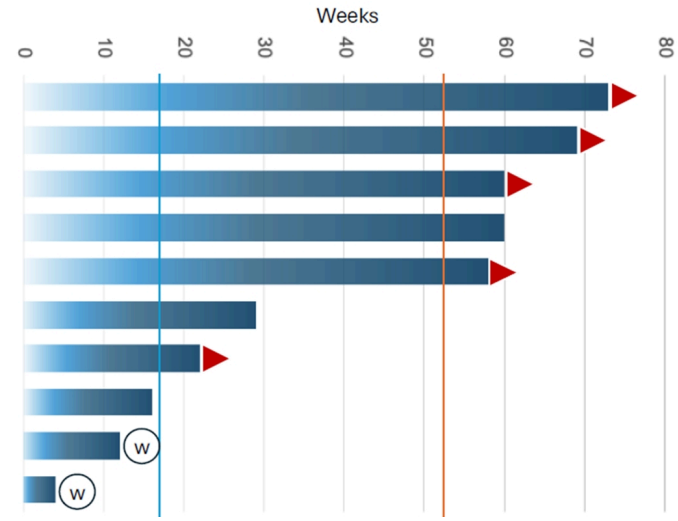
ENV-105 in mCRPC: Randomized Phase 2 Study Design



Source: Company materials

The swimmers plot below highlights the impact of ENV-105/apalutamide treatment on mPFS. The red triangle denote patient that are still on study. Two patients withdrew for reasons unrelated to the trial.

ENV-105/ Apalutamide Treatment: mPFS



Source: Company materials

Baseline Patient Characteristics

Patient ID	Age at enrollment	Pre-treatment PSA	Previous therapies	RECIST/PWCG @ week 16
001	68	7.59	Abiraterone	Stable disease
002	76	278.55	Enzalutamide, Lu-PSMA	Not assessable (unrelated stroke)
003	73	32.35	Enzalutamide	Stable disease
004	82	59.03	Enzalutamide, Abiraterone	Stable disease
005	60	4.49	Apalutamide	Stable disease
006	68	278.43	Abiraterone, Enzalutamide	Stable disease
007	79	5.63	Enzalutamide	Stable disease
008	71	3.37	Abiraterone	Stable disease
009	69	20.59	Abiraterone	clinical PD at 3 months
010	85	0.82	Enzalutamide, Darolutamide, Lu-PSMA	Stable disease

Source: Company materials

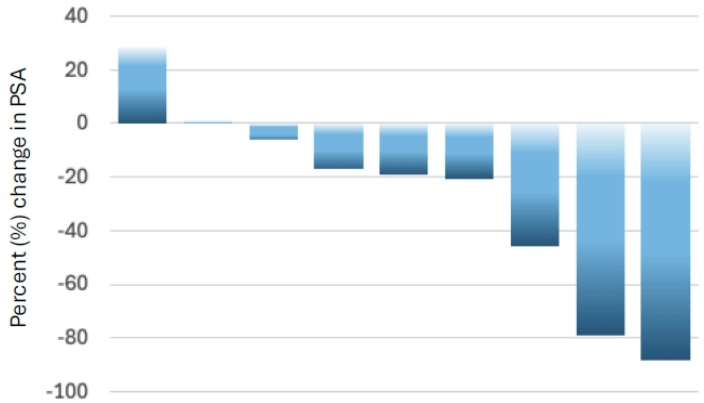
Importantly, as highlighted below, no Grade 4 or 5 AEs were reported.

ENV-105 Presents a Favorable Safety Profile

Event	All grades	Grade 3
Epistaxis	8	1
Headache	8	0
Gum bleeding	5	0
Fatigue	4	0
Nausea	4	0
Pruritis	3	0
Anemia	3	0
Anorexia	3	0
Dehydration	2	0
Dizziness	2	0
Edema	2	0
Rash	2	0

Source: Company materials

Change in PSA From Baseline



Source: Company materials

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 share data)

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.

Joseph Pantginis, Ph.D. jpantginis@hcwco.com

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)**	**(0.08)**	**(0.23)**	**(0.08)**	**(0.08)**	**(0.16)**	**(0.10)**	**(0.26)**	**(0.12)**	**(0.29)**
EPS - diluted	**(0.10)**	**(0.08)**	**(0.23)**	**(0.08)**	**(0.08)**	**(0.16)**	**(0.10)**	**(0.26)**	**(0.12)**	**(0.29)**

Source: SEC filings and H.C. Wainwright estimates.

Joseph Pantginis, Ph.D. jpantginis@hcwco.com

****Public statements available from 3Q24**

IPO September 16, 2024

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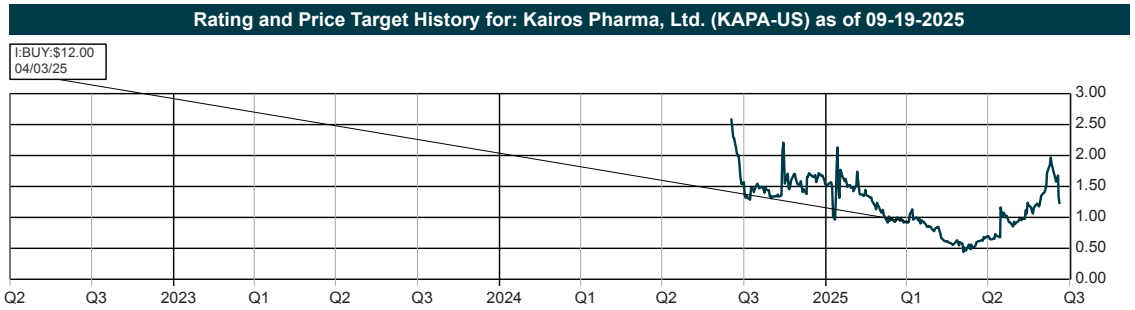
Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

Market Perform (Neutral): The common stock of the company is expected to mimic the performance of a passive index comprised of all the common stock of companies within the same sector.

Market Underperform (Sell): The common stock of the company is expected to underperform 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 September 19, 2025

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	561	83.36%	112	19.96%
Neutral	76	11.29%	12	15.79%
Sell	2	0.30%	0	0.00%
Under Review	34	5.05%	9	26.47%

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