Kairos Pharma, Ltd. (KAPA)
Rating: Buy

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2024 Results; Oncology Pipeline Poised for Multiple Readouts; Initial Phase 2 ENV-105 mCRPC Data Expected 1H25

Stock Data	4/15/2025
Price	$0.98
Exchange	NASDAQ
Price Target	$12.00
52-Week High	$4.00
52-Week Low	$0.85
Enterprise Value (M)	$12
Market Cap (M)	$13
Shares Outstanding (M)	13.7
3 Month Avg Volume	432,096
Short Interest (M)	0.02
Balance Sheet Metrics	
Cash (M)	$1.3
Total Debt (M)	$0.1
Total Cash/Share	$0.09

EPS ($) Diluted			
Full Year - Dec	2024A	2025E	2026E
1Q	--	(0.05)	--
2Q	--	(0.06)	--
3Q	(0.10)	(0.07)	--
4Q	(0.08)	(0.09)	--
FY	(0.23)	(0.29)	(0.27)

Revenue ($M)			
Full Year - Dec	2024A	2025E	2026E
1Q	--	0.0	--
2Q	--	0.0	--
3Q	0.0	0.0	--
4Q	0.0	0.0	--
FY	0.0	0.0	0.0

Public statements available from 3Q24

Financial and corporate update. Kairos announced 4Q24 and 2024 financial results, posting EPS of ($0.23) compared to our estimate of ($0.13), and consensus of ($0.10). The company ended the quarter with $1.3 million in cash. The company continues to advance ts 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 data in mCRPC in 1H25 and initial Phase 1 NSCLC by YE25), and several preclinical candidates nearing IND-stage, we foresee significant newsflow for the remainder of 2025. 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 *Attacking Cancer Rx Resistance and Boosting Immune Function; Initiating at Buy and $12 PT*.

Oncology pipeline could unlock the immune system to overcome cancer resistance in mCRPC and beyond. Kairos is a clinical stage company developing a novel class of drugs targeting cancer drug resistance and checkpoints of immune suppression. Despite the significant advances made with the advent of immunotherapy, low response rates and treatment resistance remain common challenges in the treatment paradigm. To combat this, Kairos has discovered a potential central resistance mechanism utilized in multiple cancer types via the upregulation of CD105 (endoglin). Kairos' lead asset, ENV-105 is currently in clinical development to treat metastatic castration resistant prostate cancer (mCRPC) and non-small cell lung cancer (NSCLC). Endoglin upregulation as a cancer drug resistance mechanism has been implicated across multiple tumor types and a variety of treatment modalities, including hormone and EGFR therapy, as well as in the resistance developed against radiation and chemotherapy, underscoring the potential of ENV-105 in further indications including colon, breast and head and neck cancer tumors. Beyond ENV-105, the company also boasts a robust pipeline of preclinical candidates that specifically target immune checkpoints across a range of solid tumor and autoimmune indications.

Turning back the hands of the cancer drug resistance clock with ENV-105. The goal of the ENV-105 program is reversing cancer drug resistance (i.e. those acquired through hormone therapy, radiation, I.O. etc.) by exploiting synthetic lethality, re-sensitizing patients, and enabling cancer drugs to last longer. A notable feature we highlight, is that ENV-105 adds to the treatment armamentarium by reviving the current SOC treatments (i.e. Xtandi for mCRPC and Tagrisso for EGFR-driven NSCLC) without introducing a brand-new modality per se. As a combination therapy, ENV-105 could be used to improve or extend the efficacy of such blockbuster drugs in their respective indications, providing a unique market opportunity. Here, we see ENV-105 as being leveraged by big pharma to enhance their existing oncology pipelines, providing unique partnering/ collaboration opportunities. Currently, ENV-105 drug seeks to address unmet medical needs in the large markets of prostate and lung cancers. For example, the global prostate cancer therapeutics market size is valued at $12.4 billion and at $4 billion for EGFR mutant NSCLC, representing a significant opportunity for Kairos to strategically position itself.

Bench to bedside in a one-stop shop; strategic relationship with leading academic hospital and extensive IP portfolio fortifies pipeline development. Kairos is helmed by pioneers in the field of cancer therapeutics, including CEO Dr. Jonathan Yu, a leading oncologist/surgeon at Cedars-Sinai Medical Center in Los Angeles specializing in glioblastoma treatment and CSO Dr. Neil Bhowmick who has discovered many of the scientific advancements utilized in the Kairos pipeline, which we detail in this report. The science underlying the intellectual property was also developed at Cedars-Sinai Medical Center. Kairos licensed patents from Cedars-Sinai Medical Center and Tracon Pharmaceuticals (TCON; Not Rated), from which it acquired ENV-105 (previously TRC105). Here we note that as part of its licensing agreement with Tracon, ENV-105 comes partially de-risked to Kairos as it was previously studied in a small Phase 2 proof-of-concept study. Both ongoing clincial studies of ENV-105 are also being run at Cedars-Sinai, with additional centers being actively brought online. Kairos has an extensive IP portfolio of seven drug candidates, valid until 2040, which offers diversification and mitigates the overall exposure to many of the inherent risks of drug development.

Kairos' companion biomarker is an underappreciated strategy that could be a key to success. Another aspect of Kairos' development strategy worth highlighting with investors, in our opinion, is the inclusion of biomarker analysis in the ongoing ENV-105 clinical studies. A three-gene panel was identified to serve as a companion biomarker for patient selection, by distinguishing potential drug responsive and non-responsive patients, prior to therapy, based on the biomarker gene expression levels. Currently under co-development with the Kairos subsidiary, Enviro (acquired in 2021), we see the companion biomarker test as a significant value-add to the ENV-105 program as a means to further ensure successful clinical development and outcomes through to the NDA and FDA approval process. The biomarker test development is further supported by a $3.2 million NIH grant to Kairos CSO, Dr. Bhowmick, which will be used and verified in the ongoing multi-center randomized Phase 2 trial of ENV-105 in mCRPC as well as the randomized Phase 1 study in NSCLC. This diagnostic will seek FDA approval as a critical tool for the identification of suitable patients with mCRPC or EGFR-mutated NSCLC, guiding inclusion for treatment in Phase 3 clinical trials and strengthening an overall regulatory package as trials progress.

Diversified pipeline with transformative potential in oncology and autoimmune indications; KROS-101 set to enter clinic in 2026. While the two ENV-105 clinical program are the primary drivers of our Kairos investment thesis, the company is concurrently progressing several preclinical assets including, KROS-101 (a GITR agonist) and KROS-102 (a GITR antagonist). KROS-101 is being developed as a systemic immune modulator to address immunosuppressive activity of solid cancers. When thinking of how KROS-101 could be added to the current cancer treatment landscape, there could be a viable opportunity in combination with checkpoint inhibitors. Namely, by increasing T cell numbers and function KROS0101 may complement checkpoint inhibitors like pembrolizumab (Merck; MRK; not rated) and nivolumab (Bristol-Myers Squibb; BMY; not rated). Acting in an opposing fashion to KROS-101, KROS-102 is a GITR ligand antagonist designed to increase the inhibitory regulatory T cell functions while hampering T effector cell (killer T cells) numbers and function, which could reduce the overactive immune response observed in autoimmune diseases. By using the same mechanism of controlling T cell growth as KROS-101, but in the opposite direction, KROS-102 reduces T cell numbers and activity to potentially become a new class of agents for autoimmune diseases and transplant rejection. Given the market opportunity and large indications that KROS-102 could target, we envision a partnership with Big Pharma as a potential path forward. Currently in DMPK studies, the company first expects to advance KROS-101 to the clinic in early 2026 as part of a Phase 1 monotherapy study. Although we do not currently include these assets in our NPV, we maintain they represent significant clinical and commercial potential that should be on investors' radar.

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	1.8	2.2	4.3	6.8
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)**	**(4.8)**	**(6.9)**	**(14.7)**	**(26.7)**
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)**	**(4.8)**	**(6.9)**	**(14.7)**	**(26.7)**
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)**	**(4.7)**	**(6.8)**	**(14.4)**	**(26.4)**
EBT margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*
Provision for taxes	0.0	0.0	0.0	0.0	0.0	0.0	(6.6)
Net Income	**(1.1)**	**(1.8)**	**(2.6)**	**(4.7)**	**(6.8)**	**(14.4)**	**(26.4)**
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)**	**(4.7)**	**(6.8)**	**(14.4)**	**(19.8)**
net margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*
Number of shares - basic	10.2	10.4	11.4	16.2	25.4	39.2	45.0
Number of shares - diluted	10.2	10.4	11.4	16.2	25.4	39.2	45.0
EPS - basic	**(0.1)**	**(0.17)**	**(0.23)**	**(0.29)**	**(0.27)**	**(0.37)**	**(0.44)**
EPS - diluted	**(0.1)**	**(0.17)**	**(0.23)**	**(0.29)**	**(0.27)**	**(0.37)**	**(0.44)**

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

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Quarterly P&L

	Q3'24A	Q4'24E	FY'24E	Q1'25E	Q2'25E	H1'25E	Q3'25E	9M'25E	Q4'25A	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	0.39	0.41	0.80	0.43	1.23	0.56	1.8
R&D	0.01	0.10	0.4	0.40	0.65	1.05	0.80	1.85	1.15	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)**	**(0.8)**	**(1.1)**	**(1.9)**	**(1.2)**	**(3.1)**	**(1.7)**	**(4.8)**
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	0.03	0.03	0.05	0.03	0.08	0.03	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)**	**(0.8)**	**(1.0)**	**(1.8)**	**(1.2)**	**(3.0)**	**(1.7)**	**(4.7)**
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)**	**(0.8)**	**(1.0)**	**(1.8)**	**(1.2)**	**(3.0)**	**(1.7)**	**(4.7)**
net margin			*nm*							*nm*
NoSH	10.91	13.83	11.36	16.69	17.90	17.30	18.20	17.60	18.74	16.18
NoSH	10.91	13.83	11.36	16.69	17.90	17.30	18.20	17.60	18.74	16.18
EPS - basic	**(0.10)**	**(0.08)**	**(0.23)**	**(0.05)**	**(0.06)**	**(0.10)**	**(0.07)**	**(0.17)**	**(0.09)**	**(0.29)**
EPS - diluted	**(0.10)**	**(0.08)**	**(0.23)**	**(0.05)**	**(0.06)**	**(0.10)**	**(0.07)**	**(0.17)**	**(0.09)**	**(0.29)**

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

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****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.

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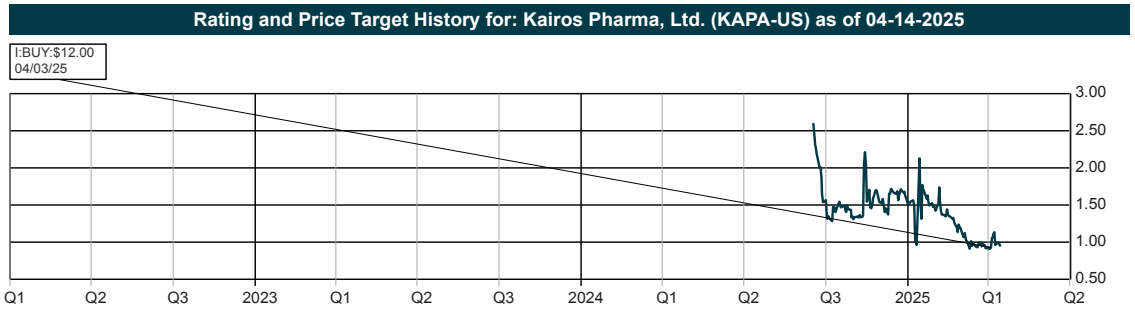

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Distribution of Ratings Table as of April 15, 2025

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	572	86.40%	128	22.38%
Neutral	85	12.84%	12	14.12%
Sell	0	0.00%	0	0.00%
Under Review	5	0.76%	2	40.00%

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