

October 20, 2025

Kairos Pharma Highlights Interim Phase 2 Data for ENV-105 in Advanced Prostate Cancer

Kairos Pharma presented positive interim efficacy results from its Phase 2 trial of ENV-105 in metastatic castration-resistant prostate cancer at the ESMO meeting. ENV-105, a CD105 antagonist, combined with apalutamide demonstrated a clinical benefit in 86% of patients, with durable progression-free survival and PSA reductions in the majority of evaluable participants. These findings support the potential of ENV-105 to restore hormonal sensitivity in patients who have progressed on standard therapies.

The interim analysis showed that all responders remained progression-free for at least four months, with half maintaining disease control beyond one year. Seven of nine evaluable patients achieved PSA declines from baseline, reinforcing the biological activity of ENV-105. Median progression-free survival of 13.7 months with the ENV-105 plus apalutamide regimen suggests an advantage in disease management compared with chemotherapy or radioligand therapy, while maintaining a favorable safety profile. The study, led by Cedars-Sinai Cancer Institute with participation from City of Hope and Huntsman Cancer Institute, is enrolling up to 100 patients and remains ongoing.

The market opportunity is significant, with over 3M men globally affected by hormone-resistant prostate cancer and limited durable treatment options. ENV-105's ability to extend disease control without adding toxicity could position it as a compelling alternative or complement to existing regimens.

Catalysts Ahead: Kairos is expected to complete enrollment of the Phase 2 trial in the coming year, with updated efficacy and safety data likely in 2026. Presentation at ESMO raises visibility and may prompt partnering interest or strategic collaborations as the company advances ENV-105 toward later-stage development.

Valuation: We model multiple indications. We apply a Probability of Success factor of just 20% for the Prostate Cancer indication and 10% for NSCLC. In addition to the POS factor, we apply a 30% discount rate (r) to our models. We assume additional capital will be raised in our final share count. We then use these projections to our Free Cash Flow to the firm, or FCFF discounted EPS or dEPS, and sum-of-the-parts or SOP models, which are equal-weighted, averaged, and rounded to the nearest whole number to derive our 12-month price target of \$9.00.

Risk Factors: These include Clinical/Regulatory Risk, Partnership and Financial Risk, Commercial Risk, Legal and Intellectual Property Risk, and Market Share Risk.

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MARKET DATA

Rating	Buy
Price Target	\$9.00
Price	\$1.16
Average Daily Volume (000)	249
52-Week Range (\$)	\$0.85–\$4.00
Market Cap (M)	\$24
Enterprise Value (M)	\$17
Dividend Yield	0.0%
Cash (M)	\$1
Qrtly Burn Rate (M)	\$1

ESTIMATES

	2024A	2025E	2026E
Revenue (M)	\$0.0	\$0.0	\$0.0
Total Expenses (M)	\$2	\$3	\$12
GAAP EPS	\$(0.23)	\$(0.19)	\$(0.40)

One Year Performance Chart



Please see analyst certification and important disclosures on page 3 of this report.

Kairos Pharma																
Revenues	2023A	2024A	1Q25E	2Q25E	3Q25E	4Q25E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
U.S. Prostate Cancer								-	-	-	-	248,516	304,213	362,049	422,087	484,392
Europe Prostate Cancer								-	-	-	-	-	199,851	407,736	499,118	551,579
U.S. Lung Cancer - EGFR Driven								-	-	-	-	3,703	9,445	19,269	27,518	36,092
EU Lung Cancer - EGFR Driven								-	-	-	-	-	17,315	35,326	43,243	51,464
U.S. Head & Neck Cancer								-	-	-	-	-	-	11,156	22,760	46,434
EU Head & Neck Cancer								-	-	-	-	-	-	-	249,339	51,374
Other Platform								-	-	-	-	-	-	-	-	-
Total Product Revenues		-	-	-	-	-	-	-	-	-	-	252,219	530,823	835,535	1,264,065	1,221,336
Royalty Revenue																
Total Revenues (\$000)	-	-	-	-	-	-	-	-	-	-	-	252,219	530,823	835,535	1,264,065	1,221,336
Expenses																
COGS		-						-	-	-	-	45,399	79,624	83,554	126,407	122,134
% COGS	-		-	-	-	-	-					18%	15%	10%	10%	10%
Research and Development	82	414	480	460	500	560	2,000	10,000	15,000	20,000	20,000	21,000	21,420	21,848	22,285	22,731
General and Administrative	1,632	1,929	240	230	250	280	1,000	2,000	5,000	8,000	12,000	20,000	20,400	25,000	25,500	26,010
Operating expenses	1,714	2,343	720	690	750	840	3,000	12,000	20,000	28,000	32,000	86,399	121,444	130,402	174,192	170,875
Oper. Inc. (Loss)	(1,714)	(2,343)	(720)	(690)	(750)	(840)	(3,000)	(12,000)	(20,000)	(28,000)	(32,000)	165,820	409,380	705,133	1,089,873	1,050,461
Interest Income																
Warrants																
Financial Income, Net																
Financial Expenses, Net	(98)	(260)														
Pretax Income	(1,812)	(2,603)	(720)	(690)	(750)	(840)	(3,000)	(12,000)	(20,000)	(28,000)	(32,000)	165,820	409,380	705,133	1,089,873	1,050,461
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income Tax Benefit (Provision)	-	-	-	-	-	-	-	-	-	-	-	24,873	102,345	267,951	414,152	399,175
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	15%	25%	38%	38%	38%
GAAP Net Income (loss)	(1,812)	(2,603)	(720)	(690)	(750)	(840)	(3,000)	(12,000)	(20,000)	(28,000)	(32,000)	140,947	307,035	437,183	675,721	651,286
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0.56	0.58	0.52	0.53	0.53
GAAP-EPS	(0.17)	(0.23)	(0.05)	(0.05)	(0.05)	(0.03)	(0.19)	(0.40)	(0.49)	(0.42)	(0.38)	1.62	3.39	4.64	6.89	6.38
Non GAAP EPS (dil)	(0.17)	(0.23)	(0.05)	(0.05)	(0.05)	(0.03)	(0.19)	(0.40)	(0.49)	(0.42)	(0.38)	1.62	3.39	4.64	6.89	6.38
Wgtd Avg Shrs (Bas)	10,382	11,356	13,514	13,649	13,662	23,676	16,125	23,735	34,060	46,074	50,225	50,427	50,629	50,831	51,035	51,240
Wgtd Avg Shrs (Dil)	10,382	11,356	13,635	13,771	13,909	29,048	17,591	29,782	41,142	71,146	83,669	87,066	90,601	94,280	98,108	102,092

Source: EF Hutton & Company reports

Important Disclosures

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Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent

Kairos Pharma Ltd. Rating History as of 10/17/2025

