MAXIM GROUP

Equity Research
Company Update

**Biotechnology**

| | |
|---|---|
| **KAPA –** NYSE American | September 18, 2025 |
| **Intraday Price 9/18/25** | **$1.40** |
| Rating: | Buy |
| 12-Month Target Price: | $4.00 |
| 52-Week Range: | $0.40 - $3.25 |
| Market Cap (M): | $29.0 |
| Shares O/S (M): | 20.7 |
| Float: | 42.3% |
| Avg. Daily Volume (000): | 5,048.3 |
| Debt (M): | $0.1 |
| Dividend: | $0.00 |
| Dividend Yield: | 0.0% |
| Risk Profile: | Speculative |
| Fiscal Year End: | December |

**Total Expenses ('000)**

| | 2025E | 2026E | 2027E |
|---|---|---|---|
| 1Q | 1,226A | 1,661 | 2,374 |
| 2Q | 1,456A | 1,733 | 2,477 |
| 3Q | 946 | 1,877 | 2,684 |
| 4Q | 982 | 1,949 | 2,787 |
| CY | 3,693 | 7,220 | 10,323 |


**EVENT INFORMATION**

**KOL webinar to discuss interim data**

Date: 9/18/25

Time: 5pm ET (LINK)


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# Kairos Pharma, Ltd.

**Buy**

## Small N Value but Compelling Data for ENV-105 in Prostate Cancer; KOL Webcast 5pm ET Today


### Summary

- This morning, Kairos announced positive interim efficacy data from the ongoing P2 trial evaluating ENV-105 + Erleada in 2L metastatic castration-resistant prostate cancer (mCRPC) patients. While positive across several key points, KAPA shares are down ~16% on the news, which we believe stems from the recent run-up in ahead of the data.
- The key here is the setting in 2L prior to Pluvicto and chemotherapy and aiming to extend and/or re-sensitize patients to available anti-androgens like Xtandi (enzalutamide) or Zytiga (abiraterone), through blockade of CD105 with the ENV-105 antibody.
- In the 8 patients that were evaluable, median progression-free survival (PFS) now extends beyond 13 months, with 5 patients remaining on treatment without progression, and 7 patients showing PSA declines compared to PFS of 3.7 months and 5.6 months demonstrated in two seminal studies published in 2019 and 2024, respectively. The rising PFS likely points to advances in patient care and management. The latter study also included Pluvicto at 11.6 month PFS.
- Although it is a small value for ENV-105, the combination is outperforming. Additionally, 5 people are on trial, meaning that >13 months PFS is likely to go longer. This is the goal: to extend the time on anti-androgens. The data thus far are compelling; let's see what the KOLs have to say at 5pm ET today.


### Details

**Phase 2 study design.** This ongoing open-label P2 multicenter trial is being conducted at Cedars-Sinai, University of Utah, City of Hope, and Huntsman Cancer Institute. The trial aims to enroll N=100 patients, evaluating the combination of androgen signaling inhibitor (ARSi) Erleada (apalutamide) alone or in combination with ENV-105 for the treatment of castrate-resistant prostate cancer (CRPC) in patients who have failed first-line ARSi therapy. Patients on single-agent Erleda will be allowed crossover to combination therapy upon recurrence. The trial's primary endpoint is progression-free survival (PFS) as measured by 9 prostate-specific antigen (PSA) and radiographic response. The secondary endpoint is a companion biomarker evaluation.

**Positive P2 interim efficacy data.** This morning (9/18), Kairos announced positive interim efficacy data from the ongoing P2 (N=100) trial evaluating ENV-105 + Erleada in 2L metastatic castration-resistant prostate cancer (mCRPC). Of the n=10 enrolled patients, two withdrew for unrelated reasons. Among the remaining eight, five continue on treatment, indicating that median PFS now exceeds 13 months. This result also significantly surpasses the trial's power threshold of a 45% PFS improvement (3.7 to 6.7 months).

Additionally, 7 patients experienced a PSA decline, reinforcing biological activity. This compares quite favorably to standard of care (SOC) in mCRPC. In the CARD trial, the median PFS was 3.7 months with 2L/3L anti-androgen drugs, such as Xtandi (enzalutamide) or Zytiga (abiraterone). In the same study, chemotherapy with Jevtana (cabazitaxel) extended PFS to 8.0 months but came with significantly greater toxicity.

There was another study published in 2024 in the LANCET which demonstrated PFS of 5.6 months, pointing to, in our view, advancements in patient management since the prior study was conducted (2019). The LANCET study included a Pluvicto-treated group with PFS of 11.6 months. The ENV-105 study has 5 patients from the update still in the trial, and thus it's expected that the 13+ months PFS could get extended. The trial is still enrolling, with a target of 100 patients.

In our view, despite the small sample size, the data suggest that blocking CD105 may allow patients to respond to anti-androgen therapy again, with five of eight patients remaining progression-free, an early yet highly encouraging signal of clinical benefit. Combined, these results point to ENV-105 as a differentiated 2L option in mCRPC following 1L anti-androgen failure, with potential to re-sensitize tumors

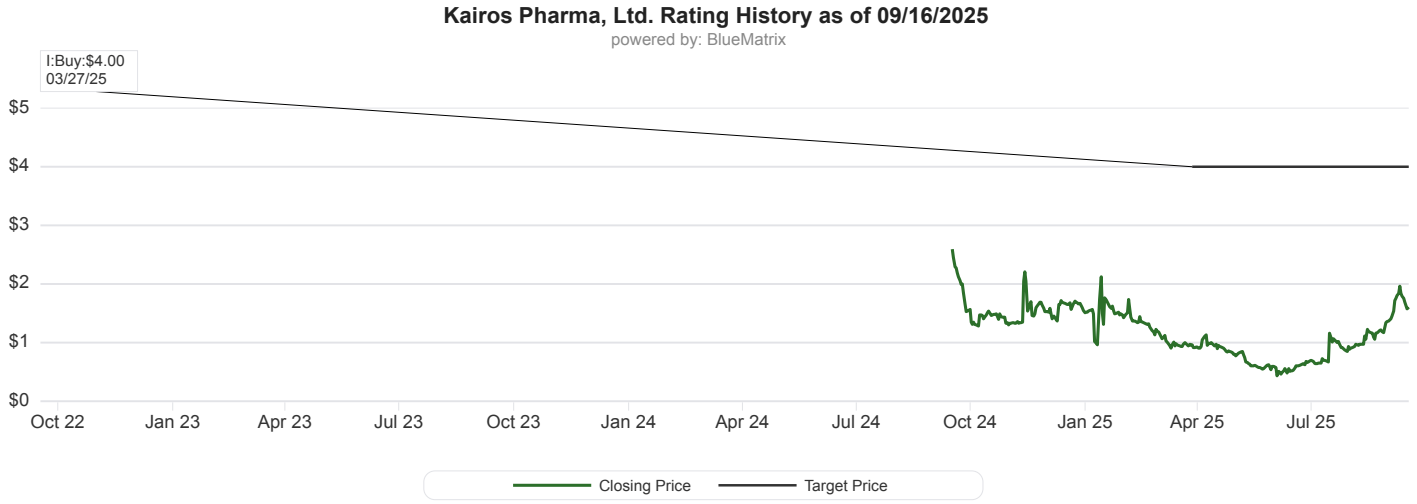
to SOC agents such as Xtandi ($2B in 2024), Zytiga, and Erleada, representing a significant potential opportunity.

**ENV-105 – targeting cancer drug resistance.** ENV-105 is a novel neutralizing antibody designed to overcome cancer drug resistance by targeting CD105 (Endoglin), a transmembrane protein critically involved in tumor angiogenesis. Expressed predominantly on proliferating endothelial cells within the tumor microenvironment, CD105 has emerged as a key resistance node. Notably, CD105 expression is upregulated in response to SOC therapies, including anti-androgen agents in metastatic castration-resistant prostate cancer (mCRPC) and anti-EGFR therapies in EGFR-mutant non-small cell lung cancer (NSCLC). ENV-105 acts by blocking CD105-driven signaling, with the potential to re-sensitize resistant tumor cells to SOC regimens.

**Valuation.** We model commercialization of ENV-105 in mCRPC in 2030 and EFGR-mutated NSCLC in 2031 in the US. An 80% revenue risk adjustment is factored in based on stage of development and clinical trial risk. A 30% discount rate is then applied to our free cash flow, discounted EPS, and sum-of-the-parts models, which are equally weighted to derive a 12-month price target of $4.00.

***Company description:*** *Kairos Pharma is a clinical-stage biopharmaceutical company focused on overcoming drug resistance and immune suppression in cancer patients. Its lead candidate, ENV-105, targets CD105 to reverse resistance and enhance the efficacy of standard therapies across multiple cancer types.*

## DISCLOSURES




| Maxim Group LLC Ratings Distribution | | | As of: 09/17/25 |
|---|---|---|---|
| | | % of Coverage Universe with Rating | % of Rating for which Firm Provided Banking Services in the Last 12 months |
| **Buy** | Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months. | **85%** | **48%** |
| **Hold** | Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither outperform nor underperform its relevant index over the next 12 months. | **15%** | **53%** |
| **Sell** | Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months. | **0%** | **0%** |
| | **See valuation section for company specific relevant indices* | | |

I, **Jason McCarthy, Ph.D.**, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

I, **Chad Yahn**, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

**Maxim Group makes a market in Kairos Pharma, Ltd.**

**Maxim Group received compensation for investment banking services from Kairos Pharma, Ltd. in the past 12 months.**

**Maxim Group expects to receive or intends to seek compensation for investment banking services from Kairos Pharma, Ltd. in the next 3 months.**

**KAPA:** For Kairos Pharma, Ltd., we use the BTK (Biotechnology Index) as the relevant index.

**Valuation Methods**
**KAPA:** We model commercialization of ENV-105 in metastatic castration-resistant prostate cancer (mCRPC) and EFGR-mutated non-small cell lung cancer (NSCLC). We apply a revenue risk adjustment based primarily on the stage of development and clinical trial

risk. A discount rate is then applied to the free cash flow, discounted EPS, and sum-of-the-parts models, which are equally weighted to derive a 12-month price target.

**Price Target and Investment Risks**
**KAPA:** Aside from general market and other economic risks, risks particular to our price target and rating for Kairos Pharma, Ltd. include: (1) the regulatory and clinical risk associated with product development; (2) the rate and degree of progress of product development; (3) the rate of regulatory approval and timelines to potential commercialization of products; (4) the level of success achieved in clinical trials; (5) the requirements for marketing authorization from regulatory bodies in the United States and other countries; (6) the liquidity and market volatility of the company's equity securities; (7) regulatory and manufacturing requirements and uncertainties; (8) product and technology developments by competitors, potentially with more resources and commercial infrastructure; (9) inability, of product(s), if approved, to gain adequate market share and maintain adequate revenue growth; (10) the ability of the company to maintain its exchange listing; (11) the ability to access capital to fund operations, if the company cannot secure sufficient capital, the company could cease operations; (12) Kairos is a controlled company, with insiders controlling over 50% of the voting rights; (13) recent changes to NYSE Section 802.01C limit listed issuers' ability to use multiple reverse stock splits to remedy listing requirements, thereby putting the stock at a higher risk of being delisted in the future.

## RISK RATINGS

Risk ratings take into account both fundamental criteria and price volatility.

**Speculative** – Fundamental Criteria: This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. Price Volatility: Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

**High** – Fundamental Criteria: This is a risk rating assigned to companies having below-average revenue and earnings visibility, negative cash flow, and low market cap or public float. Accordingly, fundamental risk is expected to be above the industry. Price Volatility: The price volatility of companies falling within this category is expected to be above the industry. High-risk stocks may not be suitable for a significant class of individual investors.

**Medium** – Fundamental Criteria: This is a risk rating assigned to companies that may have average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to approximate the industry average.

**Low** – Fundamental Criteria: This is a risk rating assigned to companies that may have above-average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to be below the industry.

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**ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST**

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