UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (date of earliest event reported): July 15, 2026

Kairos Pharma, Ltd.
(Exact name of registrant as specified in its charter)

Delaware	001-42275	46-2993314
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2355 Westwood Blvd, #139
Los Angeles, CA 90064
(Address of Principal Executive Offices) (Zip Code)

(310) 948-2356
(Registrant's Telephone Number, Including Area Code)

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	KAPA	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On July 15, 2026, Kairos Pharma, Ltd. (the "Company") issued a press release reporting interim safety data from the Company's ongoing Phase 1 clinical trial evaluating ENV-105 (Carotuximab), in combination with osimertinib, in patients with advanced EGFR-mutated non-small cell lung cancer. A copy of the press release is furnished herewith as Exhibit 99.1.

The information in this Current Report on Form 8-K, including Exhibit 99.1 furnished herewith, is being furnished and shall not be deemed "filed" for any purpose of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of such Section. The information in this Current Report on Form 8-K shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statement and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated July 15, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KAIROS PHARMA, LTD.

Dated: July 15, 2026

By: */s/ John S. Yu*
Name: John S. Yu
Title: Chief Executive Officer

Exhibit 99.1

Kairos Pharma Reports Breakthrough Interim Safety Data in Phase 1 Trial of ENV-105

in EGFR-Mutated Lung Cancer Patients — Targeting a $10 Billion Drug Resistance Market

Zero Grade 3+ Toxicities associated with ENV-105 in 13 Patients; ENV-105 (Carotuximab) Demonstrates Clean Safety Profile in Combination with Osimertinib (AstraZeneca's Tagrisso®) — Advancing Kairos's Mission to Resensitize the Largest Unmet Need Population in Lung Cancer

LOS ANGELES — July 15, 2026 — Kairos Pharma, Ltd. (NYSE American: KAPA), a clinical-stage biopharmaceutical company addressing drug resistance in cancer, today announced compelling interim safety data from its ongoing Phase 1 clinical trial evaluating ENV-105 (carotuximab) in combination with osimertinib (AstraZeneca's Tagrisso®) in patients with advanced EGFR-mutated non-small cell lung cancer (NSCLC). The data represent a pivotal milestone in Kairos Pharma's lead program: resensitizing patients who have acquired resistance to osimertinib, the global standard-of-care for EGFR-mutated NSCLC. With no serious adverse events (Grade 3 or higher) observed across 13 treated patients to date from ENV-105 treatment, the safety profile supports continued progression toward an early efficacy readout.

Non-small cell lung cancer is the dominant form of lung cancer, accounting for approximately 85% of all lung cancer diagnoses globally. Within NSCLC, EGFR-mutated patients represent the most commercially important and genetically actionable subpopulation. The EGFR-NSCLC market alone is valued at approximately $10 billion across leading current markets, growing at a CAGR of 10.5%, projected to be over $13 billion by 2030.[1-3] Osimertinib (Tagrisso®) is the gold-standard, first-line therapy for this patient population with about $6 billion in sales annually.[4,5] Despite osimertinib's initial efficacy, resistance to the drug is inevitable. Once a patient progresses on osimertinib, therapeutic options are limited with a significant clinical setback with inferior survival outcomes. Currently, there is no FDA-approved agent specifically designed to reverse or overcome osimertinib resistance and restore drug sensitivity.

Kairos Pharma's scientific thesis is grounded in a precision oncology insight of restoring sensitivity to standard of care cancer therapies. CD105 (endoglin) is pathologically elevated in patients who develop osimertinib resistance, and its overexpression drives one of the core resistance signaling pathways.[6, 7] ENV-105 (carotuximab) is a first-in-class CD105 antibody that blocks the signaling of this overexpressed protein, mechanistically dismantling the resistance phenotype and creating the biological conditions for osimertinib sensitivity. This strategy support extending progression-free survival, preserving quality of life, and fundamentally increasing the clinical utility of the world's most prescribed EGFR-targeted therapy. If successful, ENV-105 would not compete with osimertinib — it would extend its commercial life across the entire EGFR-mutated patient population.

"Our goal is not simply to complete a Phase 1 trial; it is to deliver a resensitization solution that changes the post-progression treatment paradigm and positions Kairos as the essential complement to the EGFR-targeted therapy market with this clean safety profile now confirmed across 13 patients" said Dr. John Yu, Chief Executive Officer of Kairos Pharma.

The scientific rationale for targeting CD105 is well-established: CD105 is a validated driver of resistance and disease relapse across multiple cancer types, including EGFR-driven NSCLC, and pre-clinical models have already confirmed ENV-105's capacity to sensitize tumors to both radiation and hormone therapy. Critically, ENV-105's clinical validation extends beyond lung cancer with an ongoing Phase 2 trial for castrate-resistant prostate cancer, ENV-105 delivered median progression-free survival exceeding 13 months, a significant improvement over standard of care. We believe that this demonstrated that the CD105 suppression mechanism translates into durable clinical benefit across fundamentally different tumor types and resistance contexts.

"ENV-105 continues to be extremely well tolerated, now across two very different indications," said Dr. Neil Bhowmick, Chief Science Officer of Kairos Pharma. "As we continue to showcase ENV-105's potential for targeting drug resistance, this data is another important milestone in achieving our goal to ultimately provide better patient care over a longer term."

Interim Phase 1 Safety Data: Clinical Highlights

The interim safety analysis of the Phase 1 trial evaluating ENV-105 + osimertinib in EGFR-mutated advanced NSCLC patients demonstrates a clean early safety profile in the 13 patients treated with combination therapy. The trial is intended to assess safety, tolerability, and recommended Phase 2 dose, with adverse events evaluated under Common Terminology Criteria for Adverse Events (CTCAE) 5.0 and dose-limiting toxicities monitored during the initial treatment cycles. All side effects were manageable with standard supportive care.

About Kairos Pharma Ltd.

Based in Los Angeles, California, Kairos Pharma Ltd. (NYSE American: KAPA) is at the forefront of oncology therapeutics, utilizing structural biology to overcome drug resistance and immune suppression in cancer. Kairos Pharma's lead candidate, ENV-105 (carotuximab), is an antibody targeting CD105 — a protein identified as a key driver of resistance and disease relapse in response to standard cancer therapy. ENV-105 aims to reverse drug resistance by targeting CD105 and restore the effectiveness of standard therapies across multiple cancer types. For more information, visit kairospharma.com.

Cautionary Statement Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements are identified by terminology such as "may," "should," "expects," "anticipates," "contemplates," "estimates," "believes," "plans," "projected," "predicts," "potential," or "hopes," or the negative of these or similar terms. Actual results could vary materially from expectations and projections of Kairos Pharma if underlying assumptions prove inaccurate or if known or unknown risks or uncertainties materialize. Risk factors include but are not limited to: success and/or completion of Phase 1 and Phase 2 clinical trials; challenges inherent in product research and development; uncertainty regarding future regulatory approval and commercial success; and other factors described in Kairos Pharma's SEC filings, including its Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. Kairos Pharma is not obligated to update any forward-looking statement except as required by applicable law.

Investor Contact:

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References

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3. Epidermal Growth Factor Receptor (EGFR) Inhibitors Market Forecasts to 2030 – Global Analysis By Type (Monoclonal Antibodies (mAbs), Tyrosine Kinase Inhibitors (TKIs), Combination Therapies and Other Types), Drug Type, Mode of Administration, Distribution. Market Research.com
4. Osimertinib As First-Line Treatment of EGFR Mutation–Positive Advanced Non–Small-Cell Lung Cancer (https://ascopubs.org/doi/10.1200/JCO.2017.74.7576) - PurposeThe AURA study (ClinicalTrials.gov identifier: NCT01802632) included two cohorts of treatment...
5. AstraZeneca results. Continued strong commercial performance and unprecedented pipeline delivery in the year to date. https://data.fca.org.uk/artefacts/NSM/RNS/f0e08565-612c-442e-91ff-2d622ae9a7d9.html?utm_source=chatgpt.com
6. Osimertinib in EGFR-Mutated Lung Cancer: A Review of the Existing and Emerging Clinical Data
7. CD105 blockade restores osimertinib sensitivity in drug-resistant EGFR-mutant non-small cell lung cancer. https://www.sciencedirect.com/science/article/pii/S1368764625000378