Kailera Reports Second Quarter 2026 Financial Results and Provides Business Updates

August 12, 2026

- *IND for ribupatide oral active with U.S. FDA, initiation of global Phase 3 obesity trials planned for the first half of 2027*
- *Ribupatide injection Phase 2b high-dose trial in obesity fully enrolled, data anticipated in mid-2027*
- *Expanded executive team to strengthen technical operations capabilities and corporate affairs leadership*
- *Cash, cash equivalents, and marketable securities expected to support execution of multiple clinical milestones with runway into mid-2028*

WALTHAM, Mass., Aug. 12, 2026 (GLOBE NEWSWIRE) -- Kailera Therapeutics, Inc. (Nasdaq: KLRA) (Kailera), a clinical-stage biotechnology company focused on elevating the next era of obesity care, today reported financial results for the second quarter ended June 30, 2026, and provided a summary of recent business highlights.

Kailera is advancing a diversified GLP-1-based pipeline of clinical-stage therapeutic candidates for the treatment of obesity. The company's approach seeks to improve upon currently available treatments by bringing forward product candidates that have the potential to maximize weight loss, improve tolerability, and address other critical needs in the current therapeutic landscape. The Kailera portfolio includes single-, dual-, and triple-agonist mechanisms and both oral and injectable formulations.

"Our second quarter marked another period of strong execution across the Kailera portfolio. We advanced our global Phase 3 KaiNETIC program for ribupatide injection, completed enrollment in our U.S. Phase 2b high-dose ribupatide injection trial with data expected in mid-2027, and opened our ribupatide oral IND, with initiation of our global Phase 3 obesity program planned for the first half of 2027," said Ron Renaud, President and Chief Executive Officer of Kailera. "With a strong balance sheet and multiple clinical milestones expected over the next 18 months, we believe Kailera is well positioned to deliver differentiated treatment options to people living with obesity."

Second Quarter Business Highlights and Recent Developments

Pipeline Highlights

Ribupatide Injection (KAI-9531), GLP-1/GIP Receptor Dual Agonist

- **Enrollment on track in global Phase 3 KaiNETIC program with data anticipated in 2028:** The program encompasses three global, double-blind, randomized, placebo-controlled Phase 3 trials (KaiNETIC-1, NCT07284875; KaiNETIC-2, NCT07284901; KaiNETIC-3, NCT07284979) enrolling more than 4,700 participants. The program is evaluating once-weekly ribupatide injection doses of up to 10 mg over 76 weeks in adults living with obesity or overweight. Data are anticipated in 2028.
- **Phase 2b high-dose clinical trial in obesity fully enrolled:** The Phase 2b trial (NCT07458269) enrolled 264 participants in the U.S. with a BMI of 35 or greater with no type 2 diabetes (T2D). The trial is evaluating once-weekly ribupatide injection doses of 10 mg, 13 mg, 16 mg, and 20 mg over 48 weeks. Data are anticipated in mid-2027.
- **Phase 1 ribupatide injection site trial data to be presented at the 2026 European Association for the Study of Diabetes Annual Meeting (EASD):** The oral presentation titled *"Effect of Injection Site on the Relative Bioavailability and Safety of Ribupatide, a Novel Dual GLP-1/GIP Receptor Agonist: Phase 1, Randomized, Single-Dose Crossover Study Results,"* will detail Kailera's Phase 1 injection site trial, which supported the ongoing global Phase 3 KaiNETIC clinical program.
- **Phase 1 data presented at the 86th Scientific Sessions of the American Diabetes Association (ADA 2026):** Results from Kailera's Phase 1 single ascending dose trial, the first ribupatide injection clinical data generated outside of China, were presented at ADA 2026. The trial demonstrated similar exposure, tolerability, and weight reduction in participants of Asian and non-Asian descent, which supported the ongoing global Phase 3 KaiNETIC clinical program.
- **Positive topline data from Hengrui-conducted trials in indications beyond obesity further strengthen the growing body of clinical evidence supporting ribupatide:**
  - **Two Phase 3 trials in T2D:** In Hengrui's Phase 3 trial in T2D patients with inadequate glycemic control despite diet and exercise interventions (NCT06650007), once-weekly ribupatide injection (4 mg and 2 mg) vs. placebo showed significant reductions in HbA1c from baseline, with a maximum mean reduction of 2.67%, based on the efficacy estimand[1]. In an additional Phase 3 trial in adults with T2D with inadequate glycemic control after metformin monotherapy or combination therapy with an SGLT2 inhibitor (NCT06649344), the mean HbA1c reductions in the ribupatide injection 4 mg and 2 mg groups reached 2.78% and 2.34%, respectively, compared to 2.29% in the semaglutide injection 1 mg group, with the primary endpoint achieving non-inferiority in both dose groups at Week 36, based on the efficacy estimand[2]. In addition, ribupatide injection 4 mg demonstrated statistically significant superior HbA1c reduction compared to semaglutide 1 mg. In both trials, safety and tolerability data were consistent

with other GLP-1-based treatments, with most treatment-emergent adverse events (TEAEs) being mild to moderate and gastrointestinal-related. Hengrui plans to present additional data from these trials at upcoming medical congresses.

- **Phase 2 trial in obesity with polyendocrine metabolic ovarian syndrome (PMOS):** In Hengrui's Phase 2 trial in adults with obesity and PMOS (NCT06595797), once-weekly ribupatide injection (4 mg, 2 mg, or 1 mg) vs. placebo demonstrated a mean weight loss of up to 21.2% based on the efficacy estimand[3] with no plateau at Week 32. Additionally, the mean change from baseline in the number of menstrual cycles reported by participants taking ribupatide injection 4 mg increased by 0.9 cycles during the final 12 weeks of treatment. Safety and tolerability data were consistent with other GLP-1-based treatments, with most TEAEs being mild and gastrointestinal-related. Hengrui plans to present additional data from this trial at EASD 2026.

Ribupatide Oral (KAI-9531-T), GLP-1/GIP Receptor Dual Agonist

- **Investigational New Drug (IND) application active with U.S. FDA:** With an active IND, Kailera remains on track to initiate planned global Phase 3 trials in obesity in the first half of 2027.
- **Hengrui's Phase 2 obesity trial presented at the 86th Scientific Sessions of the American Diabetes Association (ADA 2026):** In Hengrui's Phase 2 trial in adults with obesity, participants taking ribupatide oral (25 mg and 50 mg) achieved a mean weight loss of up to 12.1%, based on the efficacy estimand[3], with no observed plateau at Week 26. Additionally, up to 38.6% of participants taking ribupatide oral achieved at least 15% weight loss. Incidence of gastrointestinal adverse events was low, with vomiting reported in 11.4% and 7.5% of participants taking 25 mg and 50 mg ribupatide oral, respectively.

KAI-7535, Oral Small Molecule GLP-1 Receptor Agonist

- **Phase 2 trial in obesity ongoing to further optimize KAI-7535's clinical profile:** Kailera's global Phase 2 trial is a multicenter, randomized, double-blind, placebo-controlled clinical trial conducted by Kailera in the U.S. and Australia. This trial is designed to further optimize KAI-7535's clinical profile for the treatment of obesity by evaluating a wide range of doses, starting at a lower dose of 15 mg, and following a more gradual, stepwise titration schedule designed to improve tolerability and determine the optimal balance between weight loss and tolerability. The trial is expected to enroll approximately 320 adult participants with a BMI of 30 or greater, or a BMI of 27 or greater with at least one co-morbidity, which may include T2D. The primary endpoint is percent change in body weight from baseline at Week 44. The trial initiated in April 2026, with data expected in 2027.
- **Positive topline data from two Hengrui Pharma Phase 3 trials in obesity/overweight and T2D:** In Hengrui's Phase 3 trial in adults with obesity (HARBOR-1, NCT06904105), participants taking HRS-7535 180 mg achieved a mean weight loss of up to 11.1% from baseline at Week 50, based on an ad hoc analysis under the efficacy estimand[3]. In Hengrui's Phase 3 trial in adults with T2D (OUTSTAND-2, NCT06589765), HRS-7535 lowered HbA1c by an average of 1.50% to 1.68% across all dose groups (30 mg, 60 mg, 90 mg), based on the efficacy estimand[2]. In both trials, most TEAEs were mild to moderate and gastrointestinal-related. No liver safety signal was observed in either trial, consistent with prior HRS-7535 clinical trials. Hengrui plans to present further data from OUTSTAND-2 at EASD 2026, and additional data from HARBOR-1 at an upcoming medical congress.

KAI-4729, Injectable GLP-1/GIP/glucagon Receptor Tri-Agonist

- **On track to begin global clinical development:** Kailera remains on track to begin a Phase 1 trial in 2026 with data anticipated in 2027.
- **Additional data to be presented by Hengrui at EASD and AASLD:** Building on Hengrui's previously reported topline data demonstrating HRS-4729 (12 mg) achieved a mean weight loss of up to 16.0% from baseline at Week 12, compared to 5.4% with placebo, Hengrui will present additional HRS-4729 Phase 1 clinical trial data at EASD 2026 and AASLD 2026.

Corporate Highlights

- **Expanded leadership team to support the next phase of growth:**
  - **Appointed Nur Nicholson as Chief Technology Officer:** Nur brings nearly three decades of experience leading global technical operations, manufacturing, quality, supply chain and other organizations across the pharmaceutical and biotechnology industries. She previously served as Chief Technical Operations Officer at Apellis Pharmaceuticals, where she built and led the company's technical operations organization through its transition from clinical-stage biotech to commercial-scale enterprise.
  - **Appointed Kathleen Tregoning as Chief Corporate Affairs Officer:** Kathleen brings more than two decades of experience leading global corporate affairs organizations and guiding innovative biopharmaceutical companies through complex policy, regulatory, reputational, and stakeholder environments. She previously served as Chief Corporate Affairs Officer and Head of Commercial Strategy at Cerevel Therapeutics, where she helped lead the neuroscience company through a period of significant growth prior to its acquisition by AbbVie in 2024.
- **Added to the Russell 2000® Index:** Effective on June 29, Kailera was added to the Russell 2000® Index as part of the

first 2026 Russell indexes reconstitution. The June reconstitution of the Russell US indexes captures up to the 4,000 largest US stocks as of April 30, ranking them by total market capitalization. FTSE Russell determines membership for its Russell indexes primarily by objective, market-capitalization rankings and style attributes.

Anticipated Key Milestones

- **Ribupatide injection:** U.S. Phase 2b high dose obesity data anticipated in mid-2027; global Phase 3 obesity data anticipated in 2028
- **Ribupatide oral:** Global Phase 3 obesity trial initiations anticipated in the first half of 2027
- **KAI-7535:** Global Phase 2 obesity data anticipated in 2027
- **KAI-4729:** Phase 1 trial initiation anticipated by end of year 2026; data anticipated in 2027

Second Quarter 2026 Financial Results

As of June 30, 2026, Kailera had cash, cash equivalents and marketable securities of $1,171.8 million, which is expected to fund operations into mid-2028.

R&D expenses were $101.1 million for the quarter ended June 30, 2026, compared to $19.5 million for the same period in 2025. The increase of $81.5 million was primarily driven by the increase in product candidate development and the related nonclinical, clinical, and contract manufacturing costs associated with the Company's portfolio, as well as the increase in personnel-related costs to support its ongoing R&D activities.

General and administrative expenses were $20.3 million for the quarter ended June 30, 2026, compared to $11.1 million for the same period in 2025. The increase of $9.2 million was primarily driven by personnel-related costs and professional service costs as the Company continues to expand its operations.

Net loss was $111.3 million for the quarter ended June 30, 2026, compared to a net loss of $28.9 million for the same period in 2025.

Upcoming Events

Kailera expects to participate in the following upcoming investor conferences and medical congresses:

- Bernstein's 3 rd Annual Healthcare Forum – September 23-24, 2026
- 2026 European Association for the Study of Diabetes (EASD) Annual Meeting – September 28-October 2, 2026

About Kailera Therapeutics

Kailera Therapeutics (Kailera) is a clinical-stage biotechnology company focused on elevating the next era of obesity care by progressing a diversified pipeline to provide options for people living with obesity no matter where they are in their treatment journey. With an obesity-first focus, Kailera is advancing four clinical-stage product candidates leveraging multiple GLP-1-based mechanisms of action and routes of administration specifically designed to address critical needs in the current therapeutic landscape with a lead product candidate, ribupatide injection (also known as KAI-9531), that has the potential for the greatest weight loss. Ribupatide injection is in global Phase 3 trials as a once-weekly injectable GLP-1/GIP receptor dual agonist. Kailera is expanding the ribupatide franchise by developing a once-daily oral formulation with the goal of providing an oral option with the potential for compelling weight loss and highly differentiated tolerability. Additionally, Kailera is advancing the development of KAI-7535, a once-daily oral small molecule GLP-1 receptor agonist, and KAI-4729, a once-weekly injectable GLP-1/GIP/glucagon receptor tri-agonist. Kailera's vision is to deliver category-leading obesity management medications that give people the power to restore their health and transform their lives. Kailera is based in Waltham, MA. For more information, visit www.kailera.com and follow us on LinkedIn and X.

Special Note Regarding Kailera Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding the profile of product candidates, the potential of Kailera's portfolio, the timing, design and outcome of research and development activities, including with respect to the timing of initiation and completion of clinical trials and the design and goals of clinical trials, market opportunities for product candidates, the competitive landscape, timing and format of sharing of full clinical trial data, future results of operations and financial position, sufficiency of cash position to fund operations, and participation in upcoming events. Forward-looking statements can be identified by terms such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "suggest," "plan," "goal," "vision," "potential," "predict," "project," "should," "target," "will," "would," or similar expressions and the negatives of those terms. Kailera cannot assure you that the forward-looking statements in this press release will prove to be accurate. Information in this press release may also include statements relating to past performance, which should not be regarded as a reliable indicator of future performance. Forward-looking statements are based on current expectations and assumptions together with projections of the future which are inherently uncertain, and involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied. These risks and uncertainties include, among others, uncertainties inherent in clinical development, regulatory review, manufacturing, competition, market

opportunities, reliance on third parties, estimates of capital requirements, needs for additional financing, and other important factors, including those discussed under the caption “Risk Factors” in Kailera’s filings with the Securities and Exchange Commission. These statements speak only as of the date of this press release, and Kailera undertakes no obligation to update or revise any forward-looking statements. Kailera may not actually achieve the plans, intentions, or expectations disclosed in its forward-looking statements, and you should not place undue reliance on these forward-looking statements.

[1] *Based on the efficacy estimand, which was pre-specified as the supplementary estimand: treatment effect assuming participants adhered to protocol treatment and excludes data collected after premature treatment discontinuations or use of other glucose-lowering medications from the analysis.*

[2] *Based on the efficacy estimand, which was pre-specified as the primary estimand: treatment effect assuming participants adhered to protocol treatment and excludes data collected after premature treatment discontinuations or use of other glucose-lowering medications from the analysis.*

[3] *Based on the efficacy estimand, which was pre-specified as the supplementary estimand: treatment effect assuming participants adhered to protocol treatment and excludes data collected after premature treatment discontinuations or use of other medications with a substantial effect on body weight from the analysis.*

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KAILERA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)
(UNAUDITED)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 130,301	$ 160,267
Marketable securities	786,440	385,789
Prepaid expenses and other current assets	12,426	11,481
Total current assets	929,167	557,537
Property and equipment, net	1,753	1,955
Restricted cash	761	761
Long-term marketable securities	255,076	106,672
Non-current clinical deposits	14,671	12,185
Operating lease right-of-use assets	9,898	10,463
Other non-current assets	90	2,721
Total assets	$ 1,211,416	$ 692,294
Liabilities, convertible preferred stock and stockholders’ equity (deficit)		
Current liabilities:		
Accounts payable	$ 19,202	$ 7,529
Accrued expenses and other current liabilities	63,399	37,836
Operating lease liabilities, current	1,050	1,040
Total current liabilities	83,651	46,405
Operating lease liabilities, non-current	9,166	9,713
Other non-current liabilities	135	270
Total liabilities	92,952	56,388
Commitments and contingencies		
Convertible preferred stock:		
Series A convertible preferred stock	—	390,306
Series B convertible preferred stock	—	602,058
Stockholders’ equity (deficit):		
Preferred stock	—	—
Common stock	—	—

Additional paid-in capital	1,679,098	11,981
Accumulated other comprehensive (loss) income	(1,794)	229
Accumulated deficit	(558,840)	(368,668)
Total stockholders' equity (deficit)	1,118,464	(356,458)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 1,211,416	$ 692,294

KAILERA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS)
(UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses				
Research and development	$ 101,061	$ 19,522	$ 171,934	$ 29,651
General and administrative	20,312	11,129	34,099	21,457
Total operating expenses	121,373	30,651	206,033	51,108
Loss from operations	(121,373)	(30,651)	(206,033)	(51,108)
Other income				
Interest income	9,994	2,126	15,710	3,801
Other income (expense), net	72	(422)	151	377
Total other income	10,066	1,704	15,861	4,178
Net loss	$ (111,307)	$ (28,947)	$ (190,172)	$ (46,930)