Kailera Reports Third Quarter 2026 Financial Results and Provides Business Updates

November 4, 2026

- *Ribupatide oral global Phase 3 program expected to begin in 1H 2027 following completion of End-of-Phase 2 meeting with FDA*
- *Ribupatide injection Phase 2b trial and KaiNETIC global Phase 3 program fully enrolled; data expected mid-2027 and mid-2028, respectively*
- *Safiglipron (KAI-7535) global Phase 2 trial fully enrolled; data now anticipated mid-2027*
- *KAI-4729 IND now active with U.S. FDA; on track to initiate Phase 1 single-dose injection site/ethnic bridging trial by the end of 2026*
- *Cash continues to support execution of multiple clinical milestones with runway into mid-2028*

WALTHAM, Mass., Nov. 04, 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 third quarter ended September 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 developing products 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.

"Kailera was built to bring new medicines to people living with obesity, and our strong execution this quarter reflects that commitment," said Ron Renaud, President and Chief Executive Officer of Kailera. "All four of our product candidates are on track to deliver important clinical milestones in 2027, including the initiation of our Phase 3 trial for ribupatide oral and the data readout from the ribupatide injection high-dose Phase 2b trial. With the ribupatide franchise's category-leading potential at the core of a diversified portfolio, and a balance sheet that supports multiple value-creating inflection points into mid-2028, I am proud of our team and energized by what we aim to deliver for people living with obesity."

Third Quarter Business Highlights and Recent Developments

Pipeline Highlights

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

- **KaiNETIC Global Phase 3 program in obesity fully enrolled with data anticipated mid-2028:** The program encompasses three global, double-blind, randomized, placebo-controlled Phase 3 trials (KaiNETIC-1, NCT07284875; KaiNETIC-2, NCT07284901; KaiNETIC-3, NCT07284979) enrolling approximately 5,000 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 mid-2028.

- **Phase 2b high dose clinical trial in obesity fully enrolled with data anticipated mid-2027:** The double-blind, randomized, placebo-controlled Phase 2b trial (NCT07458269) enrolled approximately 260 participants in the U.S. with a BMI of 35 or greater without 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.

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

- **Completed End-of-Phase 2 meeting with U.S. FDA:** Following the End-of-Phase 2 meeting, Kailera expects to initiate a global Phase 3 program in obesity in the first half of 2027. The Phase 3 program will include two trials evaluating once-daily ribupatide oral doses up to 25 mg over 60 weeks in adults living with obesity or overweight with comorbidities, with and without T2D.

Safiglipron (KAI-7535), Oral Small Molecule GLP-1 Receptor Agonist

- **Global Phase 2 trial in obesity fully enrolled with data now anticipated in mid-2027:** The double-blind, randomized, placebo-controlled Phase 2 trial (NCT07497880) enrolled approximately 300 adult participants in the U.S. and Australia

with a BMI of 30 or greater or a BMI of 27 or greater with at least one co-morbidity, which may include T2D. This trial is designed to further optimize safiglipron's clinical profile for the treatment of obesity by evaluating a wide range of doses over 44 weeks, with a starting dose of 15 mg, and following a gradual, stepwise titration schedule designed to improve tolerability and determine the optimal balance between weight loss and tolerability. Data are anticipated in mid-2027.

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

- **Investigational New Drug (IND) application active with U.S. FDA:** With an active IND, Kailera is on track to initiate its Phase 1 single-dose injection site/ethnic bridging trial by the end of 2026, with data anticipated in 2027.

Anticipated Key Milestones

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

Third Quarter 2026 Financial Results

As of September 30, 2026, Kailera had cash, cash equivalents and marketable securities of $1,037.6 million, which is expected to fund operations into mid-2028.

R&D expenses were $84.7 million for the quarter ended September 30, 2026, compared to $27.0 million for the same period in 2025. The increase of $57.7 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 $21.7 million for the quarter ended September 30, 2026, compared to $13.1 million for the same period in 2025. The increase of $8.6 million was primarily driven by personnel-related costs and professional service costs as the Company continues to expand its operations.

Net loss was $95.7 million for the quarter ended September 30, 2026, compared to a net loss of $39.6 million for the same period in 2025.

Upcoming Events

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

- Stifel 2026 Healthcare Conference – November 10-12, 2026
- ObesityWeek 2026 – November 14-17, 2026
- Jefferies Global Healthcare Conference in London – November 16-19, 2026
- 9th Annual Evercore Healthcare Conference – November 30-December 2, 2026
- 45th Annual J.P. Morgan Healthcare Conference – January 11-14, 2027

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 safiglipron (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.

Contact Information
Maura Gavaghan
Vice President, Investor Relations
maura.gavaghan@kailera.com

Anna Robinson
Vice President, Communications
anna.robinson@kailera.com

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

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 106,537	$ 160,267
Marketable securities	794,917	385,789
Prepaid expenses and other current assets	18,302	11,481
Total current assets	919,756	557,537
Property and equipment, net	1,652	1,955
Restricted cash	761	761
Long-term marketable securities	136,187	106,672
Non-current clinical deposits	14,129	12,185
Operating lease right-of-use assets	9,630	10,463
Other non-current assets	63	2,721
Total assets	$ 1,082,178	$ 692,294
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 9,434	$ 7,529
Accrued expenses and other current liabilities	31,590	37,836
Operating lease liabilities, current	1,092	1,040
Total current liabilities	42,116	46,405
Operating lease liabilities, non-current	8,879	9,713
Other non-current liabilities	67	270
Total liabilities	51,062	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	1,689,358	11,981
Accumulated other comprehensive (loss) income	(3,737)	229
Accumulated deficit	(654,505)	(368,668)
Total stockholders' equity (deficit)	1,031,116	(356,458)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 1,082,178	$ 692,294

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses				
Research and development	$ 84,667	$ 26,994	$ 256,601	$ 56,645
General and administrative	21,669	13,115	55,768	34,572
Total operating expenses	106,336	40,109	312,369	91,217
Loss from operations	(106,336)	(40,109)	(312,369)	(91,217)
Other income				
Interest income	10,611	2,251	26,321	6,052
Other income (expense), net	60	(1,765)	211	(1,388)
Total other income	10,671	486	26,532	4,664
Net loss	$ (95,665)	$ (39,623)	$ (285,837)	$ (86,553)