# 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): May 26, 2026**

# Kailera Therapeutics, Inc.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-43233** | **99-3088927** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |
| **180 Third Avenue, 4th Floor Waltham, Massachusetts** | | **02451** |
| **(Address of Principal Executive Offices)** | | **(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: 781 317-0290**

**(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 $0.00001 per share | KLRA | Nasdaq Global Select Market |

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 2.02 Results of Operations and Financial Condition.**

On May 26, 2026, Kailera Therapeutics, Inc. (the "Company") issued a press release reporting its financial results for the quarter ended March 31, 2026. A copy of the Company's press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| **Exhibit Number** | **Description** |
|---|---|
| 99.1 | Earnings Press Release dated May 26, 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.

Kailera Therapeutics, Inc.

Date: May 26, 2026

By: /s/ Douglas Pagán

Douglas Pagán
Chief Financial Officer

**Exhibit 99.1**

**Kailera Reports First Quarter 2026 Financial Results and Provides Clinical Data Updates**

- *Important progress across four clinical-stage programs demonstrating depth and breadth of obesity pipeline*
- *Initiated five late-stage global clinical trials in obesity, including the ribupatide injection KaiNETIC Phase 3 program*
- *Reported positive topline clinical data from three trials conducted by our partner Hengrui in China, including new topline data from Phase 3 trial of oral small molecule GLP-1 receptor agonist HRS-7535 (KAI-7535) in type 2 diabetes, and first-in-human topline data from Phase 1 trial for injectable tri-agonist HRS-4729 (KAI-4729)*
- *Cash on hand, including IPO proceeds, is expected to fund operations into mid-2028*

**WALTHAM, Mass. – May 26, 2026** – 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 first quarter ended March 31, 2026, and provided a summary of recent business highlights.

“During the quarter, we continued to build meaningful momentum and made significant progress advancing our clinical portfolio, including initiating several clinical trials and reporting important data readouts that further underscore the breadth, depth, and potential of our pipeline,” said Ron Renaud, President and Chief Executive Officer of Kailera. “Importantly, our ribupatide franchise continues to demonstrate category-leading potential among obesity management medications, highlighted by the initiation of the global KaiNETIC Phase 3 program for ribupatide injection and positive Phase 2 data for ribupatide oral in China. We are also pleased to announce new topline data for HRS-7535 (KAI-7535) and HRS-4729 (KAI-4729) that reflect the shared commitment with our partner to advance a diverse portfolio with multiple mechanisms and injectable and oral modalities to help address the diverse and evolving needs of people living with obesity.”

Renaud, continued, “These achievements, combined with our successful IPO, have positioned us with the capital and operational strength to continue advancing multiple programs in parallel. We are focused on maintaining this momentum and executing across our clinical programs as we work to deliver differentiated therapies for the treatment of obesity.”

**First Quarter Business Highlights and Recent Developments**

***Pipeline Highlights***

- **Ribupatide injection (KAI-9531), GLP-1/GIP receptor dual agonist:**
  - **Initiated global Phase 3 KaiNETIC program:** The program encompasses three double-blind, randomized, placebo-controlled Phase 3 trials (KaiNETIC-1, KaiNETIC-2, and KaiNETIC-3) evaluating once-weekly ribupatide injection doses of up to 10 mg over 76 weeks in adults living with obesity or overweight. Data is anticipated in 2028.
  - **Initiated U.S. Phase 2b high dose obesity clinical trial to evaluate the potential to achieve even greater weight loss with higher doses of ribupatide injection:** The randomized, double-blind, placebo-controlled trial is expected to enroll approximately 250 participants with a BMI of 35 or greater and no type 2 diabetes (T2D). Participants will receive either placebo or doses up to 20 mg of ribupatide injection administered over a period of 48 weeks. Data is anticipated in 2027.

- **Announced data presentation at the 86th Scientific Sessions of the American Diabetes Association (ADA 2026):** Poster presentation will cover Kailera's Phase 1 single ascending dose bridging study of ribupatide injection in participants of non-Asian and Asian descent, which supported the initiation of the ongoing global Phase 3 KaiNETIC clinical program.

- **Ribupatide oral (KAI-9531-T), GLP-1/GIP receptor dual agonist:**
  - **Reported positive topline data from Hengrui's Phase 2 obesity trial:** Participants taking ribupatide oral achieved a mean weight loss of up to 12.1% with no observed plateau at Week 26, and up to 38.6% of participants taking ribupatide oral achieved at least 15% weight loss. Results demonstrated a potentially highly differentiated tolerability profile with low rates of gastrointestinal adverse events observed. The full data will be presented in a poster presentation at ADA 2026.
  - Subject to discussions with the FDA and other regulatory agencies, Kailera plans to initiate Phase 3 global trials as early as the first half of 2027.
- **KAI-7535, oral small molecule GLP-1 receptor agonist:**
  - **Initiated global Phase 2 obesity trial:** The double-blind, randomized, placebo-controlled trial is expected to enroll approximately 320 participants with a BMI of 30+ or a BMI of 27+ with at least one co-morbidity, which may include T2D. Participants will receive either placebo or doses up to 360 mg of KAI-7535 administered over a period of 44 weeks. Data is anticipated in 2027.
  - **Reported positive topline data from OUTSTAND-1, Hengrui's Phase 3 T2D clinical trial (NCT06672172)**: OUTSTAND-1, the first of multiple Phase 3 trials, met the primary endpoint at Week 32, demonstrating significant HbA1c reductions across all three HRS-7535 (KAI-7535) dose levels (30 mg, 60 mg, and 90 mg) compared to placebo. The multi-center, randomized, double-blind, placebo-controlled trial was designed to evaluate the efficacy and safety of HRS-7535 in adult participants with T2D. The trial enrolled 284 participants with T2D with a mean baseline HbA1c of 7.95%, mean baseline body weight of 77.5 kg (171 lbs.) and mean body mass index (BMI) of 27.8 kg/$m^2$and a median T2D duration of 1.60 years at baseline. Prior use of glucose-lowering medication was reported by 33.5% of the participants. The participant population was 33.1% female.
    - Based on the efficacy estimand[1], HbA1c reductions ranged from 1.40% to 1.68%, compared to 0.06% for placebo. Based on the treatment policy estimand[2], HbA1c reductions ranged from 1.38% to 1.63%, compared to 0.18% for placebo. HRS-7535 also demonstrated clinically meaningful benefit across multiple metabolic and organ function measures, including reduction in weight, urinary protein and blood pressure, and improvements in blood lipids.
    - The trial results demonstrated favorable safety and tolerability data consistent with oral GLP-1-based treatments and previously reported HRS-7535 Phase 2 clinical data. Most treatment-emergent adverse events (TEAEs) were mild to moderate and gastrointestinal-related. No Grade 3 hypoglycemic events were reported, and no liver safety signal was observed.
    - Hengrui intends to share the full HRS-7535 Phase 3 T2D clinical trial data at an upcoming scientific conference, and plans to submit an NDA for HRS-7535 for the treatment of T2D in China.
    - Data from Hengrui's ongoing Phase 3 clinical trial in participants living with obesity is anticipated later this year.

- **KAI-4729, injectable GLP-1/GIP/glucagon receptor tri-agonist:**
  - **Reported positive topline data from Hengrui's Phase 1 SAD/MAD trial (NCT06762600):** The randomized, double-blind, placebo-controlled first-in-human trial evaluated the safety, tolerability, pharmacokinetics and pharmacodynamics of HRS-4729 (KAI-4729) injection in healthy participants. The MAD portion of Phase 1 trial of KAI-4729 enrolled 60 participants with a mean baseline body weight of 87.3 kg (192 lbs) and mean baseline body mass index (BMI) of 31.4 $kg/m^2$. Participants received once-weekly doses of 1 mg, 4 mg, 8 mg or 12 mg HRS-4729, 4 mg ribupatide (active control) or placebo for 12 weeks.
    - HRS-4729 demonstrated linear pharmacokinetics, with a half-life of approximately 4 to 5 days, supporting once-weekly dosing.
    - In the MAD portion of the trial at Week 12, participants receiving multiple doses of 12 mg of HRS-4729 achieved a mean weight loss of up to 16.0% from baseline, compared to 5.4% with placebo.
    - HRS-4729 demonstrated favorable safety and tolerability data consistent with GLP-1-based treatments. Most treatment-emergent adverse events (TEAEs) were mild to moderate and gastrointestinal-related.
    - HRS-4729 demonstrated dose-dependent reduction in liver fat content as measured by magnetic resonance imaging proton density fat fraction.
    - Hengrui intends to share the full HRS-4729 Phase 1 clinical trial data at an upcoming scientific conference.
    - Hengrui plans to advance HRS-4729 to Phase 2 clinical trials including for the treatment of obesity and metabolic dysfunction-associated steatohepatitis (MASH) in China, and Kailera plans to initiate a Phase 1 clinical trial outside of China in 2026, with data expected in 2027.

***Corporate Highlights***

- **Expanded leadership team with key appointments:**
  - Appointed Martin Mackay, Ph.D. and Shelley Liu, Ph.D to Board of Directors. Dr. Mackay brings more than 30 years of biopharmaceutical leadership experience overseeing research and development (R&D) across leading pharmaceutical and biotechnology companies and helping to advance transformative medicines across multiple therapeutic areas and through every stage of development. Dr. Liu, China Head of Corporate Development at Hengrui, brings expertise in evaluating R&D innovation and advising on corporate development strategy across the healthcare industry.
- **Closed $718.8M Initial Public Offering:**
  - Closed initial public offering of 44,921,875 shares of its common stock at the initial public offering price of $16.00 per share. All of the shares of common stock were offered by Kailera and gross proceeds from the offering, before deducting underwriting discounts and commissions and other offering expenses, were $718.8 million. Kailera began trading on the Nasdaq Global Select Market under the ticker symbol "KLRA" on April 17, 2026.

**Anticipated Key Milestones**

- **Ribupatide injection:** U.S. Phase 2b high dose obesity data anticipated in 2027; global Phase 3 obesity data anticipated in 2028
- **Ribupatide oral:** Initiate global Phase 3 obesity trials as early as 1H'2027
- **KAI-7535:** Global Phase 2 obesity data anticipated in 2027
- **KAI-4729:** Initiate Phase 1 trial by end of year 2026; data anticipated in 2027

**First Quarter 2026 Financial Results**

As of March 31, 2026, Kailera had cash, cash equivalents and marketable securities of $581.9 million, which, together with the $718.8 million of gross proceeds raised as part of its initial public offering, is expected to fund operations into mid-2028.

R&D expenses were $70.9 million for the quarter ended March 31, 2026, compared to $10.1 million for the same period in 2025. The increase of $60.7 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 $13.8 million for the quarter ended March 31, 2026, compared to $10.3 million for the same period in 2025. The increase of $3.5 million was primarily driven by personnel-related costs and professional service costs as the Company continues to expand its operations.

Net loss was $78.9 million for the quarter ended March 31, 2026, compared to a net loss of $18.0 million for the same period in 2025.

**Upcoming Events**

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

- Jefferies Global Healthcare Conference – June 4, 2026
- American Diabetes Association Scientific Sessions – June 5-8, 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, 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 on hand to fund operations, and participation in upcoming events or presentations. 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 treatment policy estimand: treatment effect including the impact of premature discontinuations or use of other glucose-lowering medications therapies.*

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

| | March 31, 2026 | December 31, 2025 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 111,826 | $ 160,267 |
| Marketable securities | 407,348 | 385,789 |
| Prepaid expenses and other current assets | 11,141 | 11,481 |
| Total current assets | 530,315 | 557,537 |
| Property and equipment, net | 1,854 | 1,955 |
| Restricted cash | 761 | 761 |
| Long-term marketable securities | 62,747 | 106,672 |
| Non-current clinical deposits | 13,318 | 12,185 |
| Operating lease right-of-use assets | 10,170 | 10,463 |
| Other non-current assets | 5,591 | 2,721 |
| Total assets | $ 624,756 | $ 692,294 |
| **Liabilities, convertible preferred stock and stockholders' deficit** | | |
| Current liabilities: | | |
| Accounts payable | $ 7,095 | $ 7,529 |
| Accrued expenses and other current liabilities | 46,714 | 37,836 |
| Operating lease liabilities, current | 1,027 | 1,040 |
| Total current liabilities | 54,836 | 46,405 |
| Operating lease liabilities, non-current | 9,443 | 9,713 |
| Other non-current liabilities | 201 | 270 |
| Total liabilities | 64,480 | 56,388 |
| Commitments and contingencies | | |
| Convertible preferred stock: | | |
| Series A convertible preferred stock | 390,306 | 390,306 |
| Series B convertible preferred stock | 602,058 | 602,058 |
| Stockholders' deficit: | | |
| Common stock | — | — |
| Additional paid-in capital | 15,977 | 11,981 |
| Accumulated other comprehensive (loss) income | (532) | 229 |
| Accumulated deficit | (447,533) | (368,668) |
| Total stockholders' deficit | (432,088) | (356,458) |
| Total liabilities, convertible preferred stock and stockholders' deficit | $ 624,756 | $ 692,294 |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2026 | 2025 |
| **Operating expenses** | | |
| Research and development | $ 70,873 | $ 10,130 |
| General and administrative | 13,787 | 10,328 |
| Total operating expenses | 84,660 | 20,458 |
| **Loss from operations** | (84,660) | (20,458) |
| **Other income** | | |
| Interest income | 5,716 | 1,675 |
| Other income, net | 79 | 800 |
| Total other income | 5,795 | 2,475 |
| Net loss | $ (78,865) | $ (17,983) |