Kezar Life Sciences Reports First Quarter 2025 Financial Results and Provides Business Update

May 13, 2025

- *Reported positive topline data from PORTOLA Phase 2a clinical trial evaluating zetomipzomib in patients with autoimmune hepatitis (AIH)*
- *Cash, cash equivalents and marketable securities totaled $114.4 million as of March 31, 2025*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 13, 2025-- Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company developing novel small molecule therapeutics to treat unmet needs in immune-mediated diseases, today reported financial results for the first quarter ended March 31, 2025, and provided a business update.

"We shared exciting results this quarter from the PORTOLA trial, the first successful randomized study in treatment-refractory AIH," said Chris Kirk, CEO and co-founder of Kezar. "There has been almost no change over the last three decades in the treatment of this serious chronic disease, and patients and physicians are in need of new and effective therapies. We are encouraged by the promising safety and efficacy data in this difficult-to-treat patient population, in particular the durable and steroid-sparing remissions observed in patients treated with zetomipzomib. We continue to respond to the FDA Division of Hepatology and Nutrition on the partial clinical hold and are working toward achieving alignment on an appropriate trial design to demonstrate the clinical benefit of zetomipzomib in AIH."

Zetomipzomib: Selective Immunoproteasome Inhibitor

PORTOLA – Phase 2a clinical trial of zetomipzomib in patients with AIH (ClinicalTrials.gov: NCT05569759)

- In March, Kezar reported topline results from the PORTOLA Phase 2a clinical trial evaluating zetomipzomib in patients with autoimmune hepatitis. In relapsed AIH patients who entered screening on steroid-based therapy, 36% (5 of 14) of zetomipzomib-treated patients achieved a complete biochemical response (CR) and clinically significant steroid taper to 5 mg/day or less, compared to 0 of 7 of placebo patients. In the intention-to-treat (ITT) population, 31% (5 of 16) of zetomipzomib patients achieved a CR and steroid taper (5 mg/day or less), compared to 1 of 8 placebo patients. The median duration of response in zetomipzomib patients achieving a CR was 27.6 weeks (including the ongoing open-label extension at the time of the data cutoff), and no disease flares were reported in any zetomipzomib-treated patient achieving CR during study. A favorable safety profile was observed during the 6-month blinded treatment period.
- Kezar is responding to the information request from the FDA Division of Hepatology and Nutrition to resolve the partial clinical hold on the PORTOLA Phase 2a clinical trial.

PALIZADE – Phase 2b clinical trial of zetomipzomib in patients with active lupus nephritis (LN) (ClinicalTrials.gov: NCT05781750)

- In February, Kezar presented an update from the PALIZADE Phase 2b clinical trial evaluating zetomipzomib in patients with active LN. At the time of study termination, no patients had completed the full 52 weeks of treatment. Of the 12 patients receiving 60 mg of zetomipzomib who reached week 25, 42% achieved a urine protein-to-creatinine ratio (UPCR) of 0.5 or less, and the median UPCR was reduced by 79% from baseline. Marked improvements in serologic markers were observed in patients who received a 60 mg dose of zetomipzomib.
- In October 2024, Kezar made the strategic decision following a clinical hold by the FDA to terminate PALIZADE and focus the clinical development of zetomipzomib in AIH.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled $114.4 million as of March 31, 2025, compared to $132.2 million as of December 31, 2024. The decrease was primarily attributable to cash used in operations.
- **Research and development (R&D) expenses** for the first quarter of 2025 decreased by $5.0 million to $12.2 million, compared to $17.2 million in the first quarter of 2024. This decrease was primarily due to the decreased clinical activities resulting from the Company's strategic decision to terminate the PALIZADE trial in October 2024, a decrease in manufacturing expense related to the timing of drug manufacturing runs and a decrease in facility related expenses.
- **General and administrative (G&A) expenses** for the first quarter of 2025 decreased by $1.1 million to $5.4 million compared to $6.5 million in the first quarter of 2024. The decrease was primarily due to a decrease in legal and professional service expenses and non-cash stock-based compensation.
- **Net loss** for the first quarter of 2025 was $16.6 million, or $2.27 per basic and diluted common share, compared to a net loss of $21.7 million, or $2.98 per basic and diluted common share, for the first quarter of 2024.
- **Total shares of common stock outstanding** were 7.3 million shares as of March 31, 2025.

About PORTOLA

PORTOLA is a placebo-controlled, randomized, double-blind Phase 2a clinical trial evaluating the efficacy and safety of zetomipzomib in patients with AIH that are insufficiently responding to standard of care or have relapsed from a previous CR. The trial enrolled 24 patients, randomized (2:1) to receive 60 mg of zetomipzomib or placebo in addition to background therapy for 24 weeks, with a protocol-suggested steroid taper. All patients were required to receive a starting daily steroid dose of 20-40 mg/day of prednisone (or budesonide equivalent) and physicians were encouraged to taper daily steroid usage to 5 mg/day consistent with AIH treatment guidelines established by the American Association for the Study of Liver Diseases (AASLD). The primary efficacy endpoint of PORTOLA, which was not powered for efficacy, evaluated the proportion of patients who achieved a CR by Week 24, measured as normalization of alanine aminotransferase (ALT), aspartate aminotransferase (AST) and Immunoglobulin G (IgG) values (if elevated at baseline), with steroid dose levels not higher than baseline. A key secondary endpoint was the proportion of patients who achieved a CR by Week 24 with a steroid dose of 5 mg/day or less.

About Kezar Life Sciences

Kezar Life Sciences is a clinical-stage biopharmaceutical company developing novel small molecule therapeutics to treat unmet needs in immune-mediated diseases. Zetomipzomib, a selective immunoproteasome inhibitor, is currently being evaluated for autoimmune hepatitis. This product candidate also has the potential to address multiple chronic immune-mediated diseases. For more information, visit www.kezarlifesciences.com, and follow us on LinkedIn, Facebook, Twitter and Instagram.

Cautionary Note on Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "can," "should," "expect," "believe," "potential," "anticipate" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Kezar's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties that could cause Kezar's clinical development programs, future results or performance to differ materially from those expressed or implied by the forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the design, initiation, progress, timing, scope and results of clinical trials, the enrollment and expected timing of reporting topline data from our clinical trials, preliminary nature of topline data from our clinical trials, the likelihood that data will support future development and therapeutic potential, the association of data with treatment outcomes, expectations regarding the removal of the partial clinical hold on the PORTOLA trial and the initiation of a registrational trial of zetomipzomib in AIH, and the likelihood of obtaining regulatory approval of Kezar's product candidates. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during clinical studies, difficulties enrolling and conducting our clinical trials, changes in expected or existing competition, changes in the regulatory environment, the uncertainties and timing of the regulatory approval process, and unexpected litigation or other disputes. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Kezar's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" contained therein. Except as required by law, Kezar assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

KEZAR LIFE SCIENCES, INC.

Selected Balance Sheets Data

(In thousands)

	March 31, 2025	December 31, 2024
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 114,361	$ 132,245
Total assets	125,260	144,682
Total current liabilities	16,963	20,329
Total noncurrent liabilities	5,228	7,437
Total stockholders' equity	103,069	116,916

Summary of Operations Data

(In thousands except share and per share data)

	Three Months Ended March 31	
	2025	2024
	(unaudited)	
Operating expenses:		
Research and development	$ 12,180	$ 17,172
General and administrative	5,449	6,539
Total operating expenses	17,629	23,711
Loss from operations	(17,629)	(23,711)
Interest income	1,420	2,453
Interest expense	(347)	(400)
Net loss	$ (16,556)	$ (21,658)
Net loss per common share, basic and diluted	$ (2.27)	$ (2.98)
Weighted-average shares used to compute net loss per common share, basic and diluted	7,305,658	7,279,991

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