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

August 13, 2025

- *Announced FDA removal of partial clinical hold on PORTOLA Phase 2a trial evaluating zetomipzomib for the treatment of patients with autoimmune hepatitis*
- *Submitted Type C meeting request to the FDA to meet during the fourth quarter of 2025 to discuss the development plan for zetomipzomib in autoimmune hepatitis*
- *PORTOLA Phase 2a data selected for oral presentation at The Liver Meeting® 2025*
- *Cash, cash equivalents and marketable securities totaled $101 million as of June 30, 2025*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 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 second quarter ended June 30, 2025, and provided a business update.

“We are on track with our clinical development and regulatory submission plan for zetomipzomib in autoimmune hepatitis,” said Chris Kirk, PhD, CEO and co-founder of Kezar. “We are committed to working closely with the FDA to align on our next trial design, which we have proposed as a registration-enabling study. The Type C meeting will be an important milestone as we continue to believe that zetomipzomib has the potential to positively transform the lives of patients living with autoimmune hepatitis.”

Zetomipzomib: Selective Immunoproteasome Inhibitor

- In March, Kezar reported topline results from the PORTOLA Phase 2a clinical trial evaluating zetomipzomib in patients with autoimmune hepatitis (AIH). In relapsed or refractory 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 by 6 months, compared to 0 of 7 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.
- In July, Kezar announced that the Division of Hepatology and Nutrition of the U.S. Food and Drug Administration (FDA) removed the partial clinical hold on the completed PORTOLA Phase 2a clinical trial evaluating zetomipzomib, a first-in-class selective immunoproteasome inhibitor, in patients with AIH.
- Kezar submitted a Type C meeting request to the FDA to meet during the fourth quarter of 2025 to discuss the AIH development plan for zetomipzomib.
- Kezar submitted a complete response to the FDA Division of Rheumatology and Transplant Medicine with a request to remove the clinical hold on zetomipzomib in lupus nephritis.

Medical Conferences

- An abstract featuring PORTOLA Phase 2a data has been selected for an oral presentation at The Liver Meeting® 2025, taking place November 7-11, in Washington, DC.
- An abstract featuring PORTOLA biomarker data has been selected for poster presentation at The Liver Meeting® 2025.

Business Updates

- In June, Zung To was promoted to Chief Development Officer. Mr. To joined Kezar in 2023 as Senior Vice President & Head of Clinical Development and brings 35 years of industry experience, with more than 20 years in senior leadership roles in early-and late-stage clinical development. He has been instrumental in leading Kezar’s development strategy and has played a pivotal role in progressing the Company’s clinical trials with speed and precision.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled $100.8 million as of June 30, 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 second quarter of 2025 decreased by $6.7 million to $9.6 million, compared to $16.3 million in the second quarter of 2024. This decrease was primarily due to the decreased clinical activities resulting from the completion and closeout of clinical trials, a decrease in personnel costs including non-cash stock-based compensation and a decrease in facility related expenses.

- **General and administrative (G&A) expenses** for the second quarter of 2025 decreased by $0.6 million to $5.0 million compared to $5.6 million in the second quarter of 2024. The decrease was primarily due to a decrease in non-cash stock-based compensation and personnel-related expenses.
- **Restructuring and impairment charges** for the second quarter of 2025 decreased by $1.5 million, compared to the second quarter of 2024. The decrease was primarily attributed to the impairment charge in 2024 related to the right-of-use asset for the vacated floor in the company's leased office facility.
- **Net loss** for the second quarter of 2025 was $13.7 million, or $1.87 per basic and diluted common share, compared to a net loss of $21.5 million, or $2.96 per basic and diluted common share, for the second quarter of 2024.
- **Total shares of common stock outstanding** were 7.3 million shares as of June 30, 2025.

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, X 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 initiation of a registration-enabling trial of zetomipzomib, the clinical development of and regulatory submission plan for zetomipzomib in AIH, and the likelihood of obtaining regulatory approval of zetomipzomib. 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)

	June 30, 2025	December 31, 2024
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 100,849	$ 132,245
Total assets	109,123	144,682
Total current liabilities	14,365	20,329
Total noncurrent liabilities	2,972	7,437
Total stockholders' equity	91,786	116,916

Summary of Operations Data
(In thousands except share and per share data)

	Three Months Ended June 30		Six Months Ended June 30	
	2025	2024	2025	2024
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	$ 9,583	$ 16,298	$ 21,763	$ 33,470
General and administrative	5,016	5,603	10,465	12,142
Restructuring and impairment charges	-	1,482	-	1,482
Total operating expenses	14,599	23,383	32,228	47,094
Loss from operations	(14,599)	(23,383)	(32,228)	(47,094)
Interest income	1,197	2,237	2,617	4,690
Interest expense	(302)	(401)	(649)	(801)
Net loss	$ (13,704)	$ (21,547)	$ (30,260)	$ (43,205)
Net loss per common share, basic and diluted	$ (1.87)	$ (2.96)	$ (4.14)	$ (5.93)
Weighted-average shares used to compute net loss per common share, basic and diluted	7,311,032	7,284,587	7,308,360	7,282,289

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