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): November 12, 2024

Kezar Life Sciences, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38542**	**47-3366145**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
4000 Shoreline Court, Suite 300 South San Francisco, California		**94080**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 650 822-5600

(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, $0.001 par value	KZR	The Nasdaq Stock Market LLC
Preferred Share Purchase Rights	N/A	The Nasdaq Stock Market LLC

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 November 12, 2024, Kezar Life Sciences, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 30, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided under this Item 2.02 in this Form 8-K, including Exhibit 99.1 hereto, 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 into any of the Company's filings 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 No.	Description
99.1	Press release of the Company, dated November 12, 2024
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.

KEZAR LIFE SCIENCES, INC.

Date: November 12, 2024

By: /s/ Marc L. Belsky
Marc L. Belsky
Chief Financial Officer and Secretary

Exhibit 99.1

Kezar Life Sciences Reports Third Quarter 2024 Financial Results and Provides Business Update

- *Topline data from PORTOLA Phase 2a clinical trial evaluating zetomipzomib in patients with autoimmune hepatitis (AIH) expected in first half 2025*

- *Cash, cash equivalents and marketable securities totaled $148 million as of September 30, 2024*

SOUTH SAN FRANCISCO, Calif.—November 12, 2024 — 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 third quarter ended September 30, 2024, and provided a business update.

"The team at Kezar has made great progress towards completing the double-blind portion of the PORTOLA trial as we prepare for a data release in first half of 2025," said Chris Kirk, PhD, Kezar's Chief Executive Officer. "There are currently no approved drugs for the treatment of autoimmune hepatitis, and we are focused on bringing zetomipzomib to patients living with this life-threatening disease. In addition, we are working to understand the safety events that occurred in the PALIZADE trial in lupus nephritis, including deaths that occurred in both the placebo and drug arms, so that we can provide patients and physicians appropriate guidance during our ongoing and future clinical trials."

Zetomipzomib: Selective Immunoproteasome Inhibitor

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

- 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. The study has completed enrollment of 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. The primary efficacy endpoint will measure the proportion of patients who achieve a complete biochemical response 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.

- Kezar plans to report topline data in the first half of 2025. In October, the Independent Data Monitoring Committee (IDMC) recommended that the PORTOLA trial proceed without modification. The IDMC examined safety data from all patients enrolled in the trial, including data from patients who completed the 24-week double-blind treatment period (DBTP) and continued to the open-label extension (OLE) portion of the trial that includes an additional 24 weeks of treatment. To date, no Grade 4 or 5 serious adverse events (SAEs) have been observed in this trial, which is being conducted at clinical trial sites in the United States. This recommendation occurred following the FDA's clinical hold on the PALIZADE trial, as described below.

- Following the recommendation made by the IDMC, the FDA notified Kezar that it is allowing enrolled patients to complete the DBTP of the PORTOLA trial without modification. However, the FDA has placed a partial clinical hold on PORTOLA requiring that the four remaining patients

currently in the DBTP should not continue to the OLE portion of the trial. Patients who are currently participating in the OLE may continue treatment on zetomipzomib, but their prednisone dosage may not be tapered below 5 mg/day, and any patients who tapered below this amount will raise their prednisone back to 5 mg/day.

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

- In October, Kezar made the strategic decision to terminate the PALIZADE Phase 2b clinical trial in patients with active LN and focus clinical development efforts on zetomipzomib in AIH. PALIZADE was placed on full clinical hold following the recommendation of the PALIZADE IDMC after its assessment of four Grade 5 (fatal) SAEs that occurred in patients enrolled in the Philippines and Argentina (including one patient on placebo).

- Kezar is unblinding the trial and will perform a full investigation into all safety events from the study. 84 patients were enrolled in PALIZADE as of termination, and Kezar expects to report available data from PALIZADE at a later date.

MISSION – Kezar will present results from the open-label Phase 1b/2 MISSION trial in patients with systemic lupus erythematosus (SLE) with or without LN showing zetomipzomib demonstrated improvements in SLE/LN disease measures and biomarkers in patients with highly active SLE or nephrotic range proteinuria at the upcoming American College of Rheumatology (ACR) Convergence 2024, which is taking place November 14 – 19, 2024, in Washington, D.C.

Business Updates

In October, Kezar effected a one-for-ten reverse stock split of its outstanding shares of common stock (Reverse Stock Split) to regain compliance with the minimum bid price requirement of $1.00 per share required to maintain continued listing on The Nasdaq Capital Market. The Reverse Stock Split reduced the number of shares of Kezar's outstanding common stock from 72,962,220 shares to 7,296,222 shares, subject to adjustment due to the issuance of full shares in lieu of fractional shares.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled $148.4 million as of September 30, 2024, compared to $201.4 million as of December 31, 2023. The decrease was primarily attributable to cash used in operations to advance clinical-stage programs.

- **Research and development (R&D) expenses** for the third quarter of 2024 decreased by $7.5 million to $16.2 million, compared to $23.7 million in the third quarter of 2023. This decrease was primarily due to the Company's strategic restructuring in October 2023 to prioritize its clinical-stage programs, reducing personnel-related costs and spending in its early-stage research activities. The decrease was partially offset by the increased clinical trial costs related to the PALIZADE and PORTOLA trials.

- **General and administrative (G&A) expenses** for the third quarter of 2024 decreased by $3.1 million to $5.7 million compared to $8.8 million in the third quarter of 2023. The decrease was primarily due to a decrease in legal and professional service expenses and non-cash stock-based compensation.

- **Net loss** for the third quarter of 2024 was $20.3 million, or $2.78 per basic and diluted common share, compared to a net loss of $23.1 million, or $3.18 per basic and diluted common share, for the third quarter of 2023. The weighted-average shares used to compute net loss per basic and diluted common share have been retroactively adjusted to reflect the one-for-ten reverse stock split completed on October 29, 2024.

- **Total shares of common stock outstanding** were 7.3 million shares as of September 30, 2024, after taking into effect the retroactive application of the one-for-ten reverse stock split completed on October 29, 2024.

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 in a Phase 2a clinical trial 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, the likelihood that data will support future development and therapeutic potential, the association of data with treatment outcomes 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)

	September 30, 2024	December 31, 2023
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 148,388	$ 201,372
Total assets	164,086	221,235
Total current liabilities	20,429	17,744
Total noncurrent liabilities	9,608	15,921
Total stockholders' equity	134,049	187,570

Summary of Operations Data

(In thousands except share and per share data)

	Three Months Ended September 30		Nine Months Ended September 30	
	2024	2023	2024	2023
	(unaudited)		(unaudited)	
Collaboration revenue	$ -	$ 7,000	$ -	$ 7,000
Operating expenses:				
Research and development	16,242	23,738	49,712	63,055
General and administrative	5,706	8,789	17,848	20,780
Impairment charge	-	-	1,482	-
Total operating expenses	21,948	32,527	69,042	83,835
Loss from operations	(21,948)	(25,527)	(69,042)	(76,835)
Interest income	2,038	2,820	6,728	8,376
Interest expense	(403)	(396)	(1,204)	(1,151)
Net loss	$ (20,313)	$ (23,103)	$ (63,518)	$ (69,610)
Net loss per common share, basic and diluted	$ (2.78)	$ (3.18)	$ (8.72)	$ (9.60)
Weighted-average shares used to compute net loss per common share, basic and diluted [1]	7,296,222	7,268,165	7,286,967	7,249,188

(1) Shares outstanding have been retroactively adjusted to reflect the one-for-ten reverse stock split that completed on October 29, 2024, subject to adjustment due to the issuance of full shares in lieu of fractional shares.

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