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): October 04, 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

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 8.01 Other Events.

On October 4, 2024, Kezar Life Sciences, Inc. issued a press release providing an update on its zetomipzomib development program. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated October 4, 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: October 4, 2024

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

Exhibit 99.1

Kezar Life Sciences Announces Clinical Hold of Zetomipzomib IND for Treatment of Lupus Nephritis

SOUTH SAN FRANCISCO, Calif., Oct. 4, 2024 – Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company developing a novel small molecule to treat unmet needs in immune-mediated diseases, today announced that it was informed via teleconference with the U.S. Food and Drug Administration (FDA) that the zetomipzomib Investigational New Drug (IND) application for the treatment of lupus nephritis (LN) has been placed on clinical hold. This action follows Kezar's communication to the FDA that Kezar was voluntarily suspending enrollment and dosing in its Phase 2b PALIZADE clinical trial of zetomipzomib in patients with active LN at the recommendation of the trial's Independent Data Monitoring Committee (IDMC). The IDMC's recommendation followed their review of emerging safety data, including an assessment of four Grade 5 (fatal) serious adverse events (SAEs) that have occurred during the course of the trial in patients enrolled in the Philippines and Argentina. The FDA indicated that they will provide an official clinical hold letter to Kezar within 30 days.

"We are steadfastly committed to patient safety and have directed our efforts to investigating these cases as we look to continue the zetomipzomib development program." said Chris Kirk, PhD, Kezar's Chief Executive Officer. "At this time, our zetomipzomib IND for the treatment of autoimmune hepatitis is unaffected. Our Phase 2a PORTOLA clinical trial of zetomipzomib in patients with autoimmune hepatitis remains active, and we have not observed any Grade 4 or 5 SAEs in the PORTOLA trial to date."

About Lupus Nephritis

LN is one of the most serious complications of systemic lupus erythematosus (SLE). LN is a disease comprising a spectrum of vascular, glomerular and tubulointerstitial lesions and develops in approximately 50% of SLE patients within 10 years of their initial diagnosis. LN is associated with considerable morbidity, including an increased risk of end-stage renal disease requiring dialysis or renal transplantation and an increased risk of death. There are limited approved therapies for the treatment of LN. Management typically consists of induction therapy to achieve remission and long-term maintenance therapy to prevent relapse.

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. 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 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 nature, frequency and severity of adverse events; the design,

progress and outcome of Kezar's clinical trials; the Company's ability to complete its clinical trials on expected timelines, if at all; and the timing and outcome of regulatory submissions and actions by the FDA, EMA or any other regulatory agencies with respect to zetomipzomib or Kezar's clinical trials. Many factors may cause differences between current expectations and actual results, including those factors that 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.

Investor and Media Contact:

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