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 11, 2023

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 2.02 Results of Operations and Financial Condition.

On May 11, 2023, Kezar Life Sciences, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended March 31, 2023. 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 May 11, 2023
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 thereunto duly authorized.

KEZAR LIFE SCIENCES, INC.

Dated: May 11, 2023

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

Kezar Life Sciences Reports First Quarter 2023 Financial Results and Provides Business Update

- *PALIZADE Phase 2b clinical trial evaluating zetomipzomib in lupus nephritis on track to initiate in first half of 2023*
- *KZR-261 dose escalation study continues to progress; the dose expansion study expected to initiate in second half of 2023*
- *Cash, cash equivalents and marketable securities totaled $257.7 million as of March 31, 2023*

SOUTH SAN FRANCISCO, Calif.—May 11, 2023 — Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company discovering and developing breakthrough treatments for immune mediated and oncologic disorders, today reported financial results for the first quarter ended March 31, 2023 and provided a business update.

“This quarter, Kezar continued to make meaningful progress on its clinical strategy. We remain focused on actively exploring zetomipzomib’s promise in lupus nephritis and autoimmune hepatitis, in addition to advancing our protein secretion inhibitor pipeline, showcasing our ability to discover and develop first in class small molecule therapeutics against novel targets,” said John Fowler, Kezar’s Co-Founder and Chief Executive Officer. “To that end, we recently presented the trial design for PALIZADE, our Phase 2b clinical trial of zetomipzomib in lupus nephritis, and provided an encouraging early update from our Phase 1 oncology study of KZR-261, our Sec61 translocon inhibitor. We look forward to continued strong execution in our programs and are excited to share results from our KZR-261 dose escalation trial in the second half of this year.”

Zetomipzomib: Selective Immunoproteasome Inhibitor

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

- PALIZADE is a global, placebo-controlled, randomized, double-blind Phase 2b clinical trial evaluating the efficacy and safety of two dose-levels of zetomipzomib in patients with active LN. Target enrollment will be 279 patients, randomly assigned (1:1:1) to receive 30 mg of zetomipzomib, 60 mg of zetomipzomib or placebo subcutaneously once weekly for 52 weeks, in addition to standard background therapy. Background therapy can, but will not be mandated to, include standard induction therapy. Over the initial 16 weeks, there will be a mandatory corticosteroid taper to 5 mg per day or less. End-of-treatment assessments will occur at Week 53, and the end-of-study assessments will occur at Week 57. The primary efficacy endpoint is the proportion of patients who achieve a complete renal response (CRR) at Week 37, including a urine protein-to-creatine ratio (UPCR) of 0.5 or less without receiving rescue or prohibited medications. PALIZADE is on track to initiate in the first half of 2023.

PORTOLA – Phase 2a clinical trial of zetomipzomib in patients with autoimmune hepatitis (AIH) who have not benefited from standard-of-care treatment (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. Target enrollment will be 24 patients, randomized (2:1) to receive 60mg of zetomipzomib or placebo in addition to background corticosteroid therapy for 24 weeks, with a protocol-mandated steroid taper by Week 14. The primary efficacy endpoint will measure the proportion of patients who achieve a complete response measured as normalization of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels with a successful corticosteroid taper by Week 24.

MISSION – Completed open-label Phase 2 clinical trial of zetomipzomib in patients with active LN (ClinicalTrials.gov: NCT03393013)

- An abstract featuring post-hoc analysis across LN biopsy classes from the open-label Phase 2 MISSION clinical trial was presented at the National Kidney Foundation (NKF) Spring Clinical Meeting 2023, which took place April 11-15, 2023 in Austin, Texas.

- An abstract featuring complete MISSION Phase 1b/2 results, along with a post hoc subgroup analysis in the Phase 2 Hispanic/Latino population, was presented at the Pan American League of Associations for Rheumatology (PANLAR) 2023 Congress, which took place April 26-29, 2023 in Rio de Janeiro, Brazil.

- An abstract featuring complete MISSION Phase 1b/2 results has been selected for oral presentation at the upcoming LUPUS & KCR 2023 meeting, taking place May 17-20, 2023 in Seoul, Korea.

- Three abstracts featuring complete MISSION Phase 2 results, MISSION Phase 2 uCD163 data, and the unmet need of European patients with LN have been selected for poster presentations at the upcoming European Alliance of Associations for Rheumatology (EULAR) 2023 Congress, taking place May 31 – June 3, 2023 in Milan, Italy.

- Two abstracts featuring post-hoc analysis of MISSION Phase 2 patients with nephrotic range proteinuria and the unmet need of European patients with LN will be presented as focused oral presentations at the 60th European Renal Association (ERA) Congress, taking place June 15-18, 2023 in Milan, Italy.

Protein Secretion Inhibition Platform

KZR 261: Broad-Spectrum Sec61 Translocon Inhibitor

KZR-261-101 – Phase 1 clinical trial of KZR-261 in patients with locally advanced or metastatic solid malignancies (ClinicalTrials.gov: NCT05047536)

- The Phase 1 clinical trial of KZR-261 is being conducted in two parts: dose escalation and dose expansion in four tumor-specific solid tumors and one all-tumor cohort. The study is designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, identify a recommended Phase 2 dose and to explore the preliminary anti-tumor activity of KZR-261 in patients with locally advanced or metastatic disease. Kezar plans to initiate the dose expansion study in the second half of 2023, with topline data expected starting mid-2024.

- The KZR-261 trial is currently enrolling Cohort 6 (27 mg/m2). To date, KZR-261 has shown dose-proportional exposure and no signs of accumulation or altered pharmacokinetics with repeated dosing. There have been no consistent patterns of safety signals. Kezar plans to report safety and dose escalation data from this trial in the second half of 2023.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled $257.7 million as of March 31, 2023, compared to $276.6 million as of December 31, 2022. The decrease was primarily attributable to cash used to advance clinical-stage programs and preclinical research and development.

- **Research and development expenses** for the first quarter of 2023 increased by $7.4 million to $18.3 million compared to $10.9 million in the first quarter of 2022. This increase was primarily due to advancing the zetomipzomib clinical program in multiple indications and the KZR-261 clinical program, and an increase in compensation and related personnel costs, including non-cash stock-based compensation expense, attributable to higher headcount to support the progression of the company's programs and drug discovery.

- **General and administrative (G&A) expenses** for the first quarter of 2023 increased by $1.3 million to $6.2 million compared to $4.9 million in the first quarter of 2022. The increase was primarily due to an increase in legal and professional services and an increase in compensation and related personnel costs, including non-cash stock-based compensation expense as a result of an increase in headcount and salaries.

- **Net loss** for the first quarter of 2023 was $22.2 million, or $0.31 per basic and diluted common share, compared to a net loss of $16.0 million, or $0.26 per basic and diluted common share, for the first quarter of 2022.

- **Total shares of common stock outstanding** were 70.8 million shares as of March 31, 2023. Additionally, there were outstanding pre-funded warrants to purchase 1.6 million shares of common stock at an exercise price of $0.001 per share, 0.5 million outstanding restricted stock units and options to purchase 12.5 million shares of common stock at a weighted-average exercise price of $7.83 per share as of March 31, 2023.

About Kezar Life Sciences

Kezar Life Sciences is a clinical-stage biopharmaceutical company discovering and developing novel treatments for immune-mediated and oncologic disorders. The company is pioneering first-in-class, small-molecule therapies that harness master regulators of cellular function to inhibit multiple drivers of disease via single, powerful targets. Zetomipzomib, its lead development asset, is a selective immunoproteasome inhibitor that has completed a Phase 2 clinical trial in lupus nephritis. This product candidate also has the potential to address multiple chronic immune-mediated diseases. KZR-261 is the first anti-cancer clinical candidate from the company's platform targeting the Sec61 translocon and the protein secretion pathway. An open-label dose-escalation Phase 1 clinical trial of KZR-261 to assess safety, tolerability and preliminary tumor activity in solid tumors is underway. For more information, visit www.kezarlifesciences.com.

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,” “plans,” “believe”, “potential” 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, anticipated therapeutic benefit and regulatory development of Kezar’s product candidates, 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)

	March 31, 2023 (unaudited)	December 31, 2022
Cash, cash equivalents and marketable securities	$ 257,671	$ 276,561
Total assets	284,180	299,568
Total current liabilities	13,644	10,997
Total noncurrent liabilities	18,046	18,699
Total stockholders' equity	252,490	269,872

Summary of Operations Data

(In thousands except share and per share data)

	Three Months Ended March 31	
	2023	2022
	(unaudited)	
Operating expenses:		
Research and development	$ 18,318	$ 10,944
General and administrative	6,206	4,934
Total operating expenses	24,524	15,878
Loss from operations	(24,524)	(15,878)
Interest income	2,695	108
Interest expense	(370)	(254)
Net loss	$ (22,199)	$ (16,024)
Net loss per common share, basic and diluted	$ (0.31)	$ (0.26)
Weighted-average shares used to compute net loss per common share, basic and diluted	72,328,231	60,630,389

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