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): March 14, 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 2.02 Results of Operations and Financial Condition.

On March 14, 2024, Kezar Life Sciences, Inc. (the "Company") issued a press release announcing its financial results for the fiscal year and quarter ended December 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 March 14, 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 thereunto duly authorized.

KEZAR LIFE SCIENCES, INC.

Dated: March 14, 2024

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

Kezar Life Sciences Reports Fourth Quarter and Year End 2023 Financial Results and Provides Business Update

- *PALIZADE Phase 2b clinical trial of zetomipzomib in patients with active lupus nephritis actively enrolling; reiterating guidance of topline data in mid-2026*
- *PORTOLA Phase 2a clinical trial of zetomipzomib in patients with autoimmune hepatitis actively enrolling; reiterating guidance of topline data in mid-2025*
- *KZR-261 dose escalation study currently enrolling ninth cohort; data update by year-end*
- *Cash, cash equivalents and marketable securities totaled $201.4 million as of December 31, 2023*

SOUTH SAN FRANCISCO, Calif.—March 14, 2024 — Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company developing breakthrough treatments for immune-mediated and oncologic disorders, today reported financial results for the fourth quarter and year ended December 31, 2023 and provided a business update.

"The efforts over the past year by the team at Kezar have put us in a strong position as we advance our promising, first-in-class immunology and oncology programs," said Chris Kirk, Kezar's Co-founder and Chief Executive Officer. "We remain focused with the zetomipzomib program on bringing this important new agent to patients with autoimmune hepatitis and lupus nephritis, both severe and poorly treated autoimmune disorders. Our PORTOLA and PALIZADE trials remain on track for readouts in 2025 and 2026, which we expect to demonstrate the potential of zetomipzomib as a promising new agent for the treatment of a wide range of autoimmune disorders. Additionally, we are eager to share data from the KZR-261 program in solid tumors in the fourth quarter of 2024, which will include dose escalation and initial dose expansion safety, PK/PD, and exploratory efficacy analyses. With our strong team and solid balance sheet, we are well positioned to deliver meaningful results across our programs, for the patients and our shareholders."

Zetomipzomib: Selective Immunoproteasome Inhibitor

Clinical Development:

PALIZADE – Phase 2b clinical trial of zetomipzomib in patients with active 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. 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.

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 60 mg 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.

Collaboration with Everest Medicines:

In September 2023, Kezar entered into a collaboration and license agreement with Everest Medicines to develop and commercialize zetomipzomib in Greater China, South Korea and Southeast Asia. Everest Medicines is joining Kezar on the PALIZADE clinical trial and will contribute their local regulatory and clinical trial expertise to enroll patients in these geographies. In February 2024, the Centre for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) approved the investigational new drug (IND) application for the initiation of PALIZADE in China. In addition to PALIZADE, Kezar and Everest Medicines have the opportunity to collaborate on future clinical trials and indications for the continued development of zetomipzomib.

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 tumor-specific solid tumors. 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.

- The KZR-261 trial is currently enrolling Cohort 9 (80 mg/m^2). Previously, Cohort 1 (1.8 mg/m^2) through Cohort 8 (60 mg/m^2) enrolled a total of 35 patients and completed rapid dose escalation without significant safety concerns.

- To date, KZR-261 has shown dose-proportional exposure and no signs of accumulation or altered pharmacokinetics with repeated dosing.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled $201.4 million as of December 31, 2023, compared to $276.6 million as of December 31, 2022. The decrease was primarily attributable to cash used in operations to advance clinical-stage programs and preclinical research and development.

- **Revenue** for the year of 2023 was $7.0 million resulting from the upfront payment under the collaboration and license agreement with Everest Medicines.

- **Research and development (R&D) expenses** for the fourth quarter of 2023 increased by $7.7 million to $22.6 million, compared to $14.9 million in the fourth quarter of 2022. Full year R&D expenses increased by $34.7 million to $85.7 million in 2023, compared to $51.0 million in 2022. This increase was primarily due to clinical trial costs related to the PALIZADE and PORTOLA trials, a milestone payment made to Onyx Therapeutics, and an increase in non-cash stock-based compensation and facility-related expenses.

- **General and administrative (G&A) expenses** for the fourth quarter of 2023 increased by $0.6 million to $5.8 million compared to $5.2 million in the fourth quarter of 2022. Full year G&A expenses increased by $6.4 million to $26.5 million in 2023, compared to $20.1 million in 2022. The increase was primarily due to an increase in legal and professional service expense in connection with the collaboration and license agreement with Everest Medicines and an increase in non-cash stock-based compensation, personnel and facility-related expenses.

- **Restructuring and impairment charges** for the fourth quarter of 2023 were $6.2 million. The charges comprised primarily of one-time employee termination benefits and long-lived assets impairment costs related to the right-of-use asset and certain property and equipment no longer utilized.

- **Net loss** for the fourth quarter of 2023 was $32.3 million, or $0.44 per basic and diluted common share, compared to a net loss of $18.2 million, or $0.25 per basic and diluted common share, for the fourth quarter of 2022. Net loss for 2023 was $101.9 million, or $1.40 per basic and diluted common share, compared to a net loss of $68.2 million, or $1.01 per basic and diluted common share, in 2022.

- **Total shares of common stock outstanding** were 72.8 million shares as of December 31, 2023. Additionally, there were options to purchase 13.1 million shares of common stock at a weighted-average exercise price of $2.60 per share and 0.2 million restricted stock units outstanding as of December 31, 2023.

About Kezar Life Sciences

Kezar Life Sciences is a clinical-stage biopharmaceutical company developing novel treatments for immune-mediated and oncologic disorders. Zetomipzomib, a selective immunoproteasome inhibitor, is currently being evaluated in a Phase 2b clinical trial for lupus nephritis and a Phase 2a clinical trial for autoimmune hepatitis. This product candidate also has the potential to address multiple chronic immune-mediated diseases. Kezar's oncology product candidate, KZR-261, targeting the Sec61 translocon and protein secretion pathway, is being evaluated in an open-label dose-escalation Phase 1 clinical trial to assess safety, tolerability and preliminary tumor activity in solid tumors. 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 company’s position to deliver meaningful results across its programs, for patients and shareholders, the design, initiation, progress, timing, scope and results of clinical trials, the expected timing of reporting topline data from our clinical trials, collaboration on clinical trials and development of zetomipzomib in additional indications, the enrollment 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 clinical trial site activation or enrollment rates that are lower than expected, unexpected safety or efficacy data observed during clinical studies, difficulties enrolling and conducting our clinical trials, disputes or failure to perform under the collaboration and license agreement, 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)

	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 201,372	$ 276,561
Total assets	221,235	299,568
Total current liabilities	17,744	10,997
Total noncurrent liabilities	15,921	18,699
Total stockholders' equity	187,570	269,872

Summary of Operations Data

(In thousands except share and per share data)

	Three Months Ended December 31		Year Ended December 31	
	2023	2022	2023	2022
Collaboration revenue	$ —	$ —	$ 7,000	$ —
Operating expenses:				
Research and development	22,643	14,859	85,697	51,009
General and administrative	5,759	5,175	26,540	20,153

Restructuring and impairment charges	6,187	—	6,187	—
Total operating expenses	34,589	20,034	118,424	71,162
Loss from operations	(34,589)	(20,034)	(111,424)	(71,162)
Interest income	2,728	2,202	11,104	4,108
Interest expense	(399)	(349)	(1,550)	(1,185)
Net loss	$ (32,260)	$ (18,181)	$ (101,870)	$ (68,239)
Net loss per common share, basic and diluted	$ (0.44)	$ (0.25)	$ (1.40)	$ (1.01)
Weighted-average shares used to compute net loss per common share, basic and diluted	72,736,956	72,231,697	72,553,645	67,368,935

Investor and Media Contact:
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