

**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 12, 2022

Kezar Life Sciences, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38542
(Commission File Number)

47-3366145
(IRS Employer
Identification No.)

4000 Shoreline Court, Suite 300
South San Francisco, California
(Address of Principal Executive Offices)

94080
(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 12, 2022, Kezar Life Sciences, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended March 31, 2022. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of the Company, dated May 12, 2022
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 12, 2022

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

Kezar Life Sciences Reports First Quarter 2022 Financial Results and Provides Business Update

Topline data from MISSION Phase 2 trial of zetomipzomib for the treatment of lupus nephritis expected in June 2022, consistent with previous guidance

KZR-261 continues to enroll patients with solid tumors in Phase 1 dose-escalation trial

Company to host virtual Investor and Analyst Day in June 2022

Cash, cash equivalents and marketable securities totaled \$242.6 million as of March 31, 2022

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE) – May 12, 2022 – 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, 2022 and provided a business update.

“I want to thank my colleagues at Kezar for their excellent execution across both of our novel programs so far this year,” said John Fowler, Kezar’s Co-founder and CEO. “We are excited to present the topline results from our Phase 2 MISSION trial in lupus nephritis this June and remain committed to exploring zetomipzomib’s potential in inflammatory diseases with high unmet need. Our strengthened balance sheet is key in supporting both of our programs, including our Phase 1 trial of KZR-261 in solid tumors.”

Zetomipzomib: Selective Immunoproteasome Inhibitor

MISSION – Phase 2 clinical trial of zetomipzomib (KZR-616) in patients with lupus nephritis (LN) (NCT03393013)

In November 2021, Kezar reported interim data from the MISSION Phase 2 open-label trial in patients with active, proliferative LN. The interim data showed that, of the five patients who completed the full 24 weeks of weekly treatment with zetomipzomib 60mg doses, two achieved partial renal responses (PRRs) and two achieved complete renal responses (CRRs). The primary efficacy endpoint for the trial is the number of patients achieving a renal response measured by a 50% or greater reduction in UPCr at the end of treatment compared to baseline.

- o Kezar reiterates prior guidance and expects to report Phase 2 topline data in June 2022

An abstract featuring zetomipzomib has been selected for poster presentation as part of the EULAR Science Exhibit session at the upcoming Annual European Congress of Rheumatology (EULAR), taking place June 1-4, 2022, in Copenhagen, Denmark. The virtual presentation will be available beginning Wednesday, June 1, 2022, at 2:00 am Eastern Time through July 31, 2022.

- o *POS0715: Treatment of SLE Patients with Zetomipzomib (KZR-616), a Selective Inhibitor of the Immunoproteasome, Results in Circulating Gene Expression, Protein Level, and Immune Cell Phenotypic Changes with Potential Correlations to Clinical Response*, presented by Andrea Fan, PhD, Vice President, Head of Biology and Translational Research, Kezar Life Sciences
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PRESIDIO – Phase 2 clinical trial of zetomipzomib (KZR-616) in patients with active dermatomyositis (DM) or polymyositis (PM) (NCT04033926)

On May 3, 2022, Kezar reported topline data from the *PRESIDIO* Phase 2 clinical trial of zetomipzomib in patients with DM (n=13) and PM (n=12). 20 of the 25 patients enrolled in the study completed end-of-treatment (Week 32). Topline results from *PRESIDIO* showed that most DM and PM patients saw clinically meaningful improvements in total improvement score (TIS), but zetomipzomib demonstrated no significant differentiation from placebo. The overall safety and tolerability of zetomipzomib was favorable and consistent with previous results.

KZR-616-003E (NCT04628936) is an open-label extension (OLE) study available to patients who completed 32 weeks in the *PRESIDIO* trial. Following completion of *PRESIDIO*, 18 out of 20 patients enrolled in the OLE. For the first time, patients have the option to self-administer zetomipzomib in the OLE. As of the release date, active participation in the OLE ranged from 2 to 77 weeks, and six patients had discontinued for reasons unrelated to zetomipzomib. No additional safety or tolerability issues have been observed, and mean TIS scores have improved over scores observed at the 32-week conclusion of *PRESIDIO*.

KZR-261: Protein Secretion Inhibitor

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

KZR-261 is a novel, broad-spectrum agent that acts through direct interaction and inhibition of the Sec61 translocon. In preclinical studies, KZR-261 has been shown to induce a direct anti-tumor effect as well as modulate the tumor microenvironment, including enhancing anti-tumor immune responses.

The Phase 1 clinical trial of KZR-261 is being conducted in two parts: dose escalation and dose expansion in subjects with selected tumor types. The trial is designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, as well as to explore the preliminary anti-tumor activity of KZR-261 in patients with locally advanced or metastatic disease.

At the American Association of Cancer Research (AACR) 2022 Annual Meeting, held in April 2022 in New Orleans, LA, Kezar presented data on its proprietary small molecule inhibitors of the Sec61 translocon, specifically KZR-834, a working analog of KZR-261.

Financial Results

Cash, cash equivalents and marketable securities totaled \$242.6 million as of March 31, 2022, compared to \$208.4 million as of December 31, 2021. The increase was primarily attributable to net proceeds from the issuance of common stock under the “at-the-market” Sales Agreement with Cowen and Company, LLC, net of cash used by the company in operations to advance its clinical stage programs and preclinical research and development.

Research and development expenses for the first quarter of 2022 increased by \$1.7 million to \$11.0 million compared to \$9.3 million in the first quarter of 2021. This increase was primarily related to advancing the KZR-616 clinical program and the KZR-261 Phase 1 clinical trial.

General and administrative expenses for the first quarter of 2022 increased by \$1.1 million to \$4.9 million compared to \$3.8 million in the first quarter of 2021. The increase was primarily due to an increase in personnel expenses, including non-cash stock-based compensation.

Net loss for the first quarter of 2022 was \$16.0 million, or \$0.26 per basic and diluted common share, compared to a net loss of \$13.0 million, or \$0.25 per basic and diluted common share, for the first quarter of 2021.

Total shares of common stock outstanding were 59.6 million shares as of March 31, 2022. Additionally, there were outstanding pre-funded warrants to purchase 3.8 million shares of common stock at an exercise price of \$0.001 per share and outstanding options to purchase 8.9 million shares of common stock at a weighted average exercise price of \$7.94 per share as of March 31, 2022.

About Zetomipzomib (KZR-616)

Zetomipzomib (KZR-616) is a novel, first-in-class, selective immunoproteasome inhibitor with broad therapeutic potential across multiple autoimmune diseases. Preclinical research demonstrates that selective immunoproteasome inhibition results in a broad anti-inflammatory response in animal models of several autoimmune diseases, while avoiding immunosuppression. Data generated from Phase 1 clinical trials provide evidence that zetomipzomib exhibits a favorable safety and tolerability profile for development in severe, chronic autoimmune diseases.

About Lupus Nephritis

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 KZR-261 and the Inhibition of Protein Secretion

KZR-261 is a first-in-class small molecule compound, derived from Kezar's research and discovery platform of protein secretion pathway inhibitors. This broad-spectrum anti-tumor agent directly targets the Sec61 translocon and inhibits multiple cancer drivers both within tumor cells and the tumor microenvironment. A Phase 1 clinical trial is underway for the treatment of solid tumor malignancies.

Kezar's drug discovery platform of protein secretion pathway inhibitors is a novel approach with broad application. The protein secretion pathway is a highly conserved and ubiquitously functioning pathway in all cells in the body and involves a conserved protein complex called the Sec61 translocon, the target of Kezar's compounds. In preclinical models, Kezar's library of protein secretion inhibitors have demonstrated broad activity with far-reaching potential in oncology, immune-oncology, and autoimmunity.

About Kezar Life Sciences

Kezar Life Sciences is a clinical-stage biopharmaceutical company discovering and developing breakthrough 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 being evaluated in 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,” “should,” “expect,” “believe” 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, progress, timing, scope and results of clinical trials, anticipated regulatory development of Kezar's product candidates, the anticipated timing of disclosure of interim and topline data from clinical trials, the anticipated approval of the nonproprietary name of KZR-616, the preliminary nature of interim and topline data, 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 the performance of audit and verification procedures on interim and topline data, delays in cleaning and verifying clinical trial data, unexpected safety or efficacy data observed during clinical studies, clinical trial site data collection and reporting, the impacts of the COVID-19 pandemic and other global events on the company's business and 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, 2022	December 31, 2021
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 242,609	\$ 208,355
Total assets	251,866	217,933
Total current liabilities	6,978	8,212
Total noncurrent liabilities	12,573	12,845
Total stockholders' equity	232,315	196,876

Summary of Operations Data

(Unaudited in thousands except share and per share data)

	Three Months Ended	
	March 31,	
	2022	2021
Operating expenses:		
Research and development	\$10,944	\$9,286
General and administrative	4,934	3,762
Total operating expenses	15,878	13,048
Loss from operations	(15,878)	(13,048)
Interest income	108	54
Interest expense	(254)	—
Net loss	(\$16,024)	(\$12,994)
Net loss per common share, basic and diluted	(\$0.26)	(\$0.25)
Weighted-average shares used to compute net loss per common share, basic and diluted	60,630,389	51,058,039

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