

**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 03, 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 8.01 Other Events.

On November 3, 2022, the Company issued a press release reporting its presentation of the complete results from its MISSION Phase 2 clinical trial evaluating zetomipzomib in patients with lupus nephritis at the American Society of Nephrology's Kidney Week 2022 Annual Meeting. A copy of the press release is filed 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.

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Press Release, dated November 3, 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.

Date: November 3, 2022

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

Kezar Life Sciences Presents Positive Complete Results from the MISSION Phase 2 Trial Evaluating Zetomipzomib in Lupus Nephritis at ASN's Kidney Week 2022 Annual Meeting

- *Zetomipzomib added to stable background therapy reduced proteinuria by 50% or greater (ORR) in 11 of 17 patients (64.7%) reaching end of treatment at Week 25. This benefit occurred with a 53% mean reduction of background corticosteroid use.*
- *ORRs increased to 94.1% at Week 29 and 88.2% at Week 37 during the safety follow-up period with stable background therapy.*
- *Complete renal responses, including a urine protein to creatinine ratio (UPCR) of 0.5 or less (CRR), were achieved in 6 of 17 patients (35.3%) at end of treatment and increased to 7 of 17 patients (41.2%) during the safety follow-up period at Weeks 29 and 37.*
- *Reduction in proteinuria was consistently observed with reduction in extra-renal manifestations of SLE and improvements in key biomarkers.*
- *Zetomipzomib continues to demonstrate a favorable safety and tolerability profile, with no evidence of immunosuppression and no new safety signals during the follow up period.*

SOUTH SAN FRANCISCO, Calif. -- November 3, 2022 -- Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company discovering and developing breakthrough treatments for immune-mediated and oncologic disorders, today announced that it presented the complete data set from the MISSION Phase 2 clinical trial evaluating zetomipzomib, a novel, first-in-class, selective immunoproteasome inhibitor, in active lupus nephritis (LN) at the American Society of Nephrology's (ASN) Kidney Week 2022 Annual Meeting in Orlando, FL.

"MISSION Phase 2 accomplished the goal of demonstrating that zetomipzomib, a first-in-class inhibitor of the immunoproteasome, has potent anti-inflammatory effects which result in clinically meaningful reductions in proteinuria in patients who do not respond fully to standard-of-care therapies. The anti-inflammatory effect is sustained following discontinuation of zetomipzomib, consistent with earlier data, and occurs without evidence of immunosuppression. Based on these exciting results, we believe zetomipzomib has the potential to be a long-term, steroid-sparing, broad immunomodulating treatment for patients with lupus nephritis," said Noreen R. Henig, M.D., Kezar's Chief Medical Officer. "We are moving quickly to launch a multi-country randomized placebo-controlled study to evaluate zetomipzomib in patients with LN, as well as exploring the potential of the novel mechanism of action in diseases such as autoimmune hepatitis and systemic lupus erythematosus."

The MISSION Phase 2 clinical trial was an open-label study designed to demonstrate the responder rate of zetomipzomib in patients with active LN. During the 24-week treatment period, patients received 60 mg of zetomipzomib subcutaneously once weekly (first dose of 30 mg) in addition to stable background therapy. End-of-treatment (EOT) assessments occurred at Week 25, with completion of the study at Week 37 (EOS). Patients in the MISSION Phase 2 clinical trial received zetomipzomib without induction therapy, which represents a significant difference from other recently published clinical trials in LN. The primary efficacy endpoint for this trial was the proportion of patients achieving an overall renal response (ORR), measured as a 50% or greater reduction in urine protein to creatinine ratio (UPCR) at

EOT. A key secondary efficacy endpoint was the number of patients with a complete renal response (CRR), measured as an absolute reduction in proteinuria values to a UPCR of 0.5 or less, with preserved renal function (eGFR), and corticosteroid use of 10 mg or less prednisone/prednisone equivalent and no use of prohibited medication. Exploratory endpoints included measures of systemic lupus erythematosus (SLE) disease activity, including Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K), Physician Global Assessment and Patient Global Assessment scores.

Summary of Results from the Completed MISSION Trial

In the MISSION Phase 2 clinical trial, 17 of 21 enrolled patients reached end-of-treatment at Week 25 and end-of-study at Week 37. Zetomipzomib treatment demonstrated clinically meaningful renal responses with additional ORRs and CRRs observed during the safety follow-up period.

- **Overall Renal Responses:**
 - o At EOT, 11 of 17 patients (64.7%) achieved an ORR measured as a 50% or greater reduction in UPCR compared to baseline, the primary endpoint of the clinical trial.
 - o During the safety follow-up period, clinical responses deepened, and ORRs increased to 16 of 17 patients (94.1%) at Week 29 and 15 of 17 patients (88.2%) at EOS.
 - o 12 of 17 patients (70.6%) also reached UPCR of 0.7 or less at EOS.
 - **Complete Renal Responses:**
 - o At EOT, 6 of 17 patients (35.3%) achieved a CRR, including a UPCR of 0.5 or less, stable eGFR, daily prednisone/prednisone equivalent dose of 10 mg or less, and no use of prohibited medication.
 - o During the safety follow-up period, an additional patient achieved a CRR, with the total CRRs increasing to 7 of 17 patients (41.2%) at Week 29 and EOS, demonstrating a deepening renal response throughout the 37-week trial.
 - Urinary CD163, a biomarker that suggests active inflammation in the kidney, showed a strong correlation to UPCR across all timepoints in the study. These data indicate that patients had active inflammation at baseline despite standard-of-care therapy and that the addition of zetomipzomib has the potential to resolve inflammation.
 - By Week 13, 14 of 17 patients (82.4%) achieved a daily corticosteroid dose of 10 mg or less, despite no protocol-mandated steroid taper. Doses of background immunosuppressive agents remained stable throughout the study, including during the 12-week safety follow-up.
 - Mean eGFR (estimated glomerular filtration rate) remained stable from baseline to EOS.
 - Key measurements of SLE disease activity were reduced and key biomarkers of SLE improved. There was no evidence of early rebound of inflammation following discontinuation of zetomipzomib.
 - o SLEDAI-2K scores reduced from a mean of 11.3 at baseline to 6.5 at EOT and 5.8 at EOS.
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- o Physician Global Assessment scores reduced from a mean of 57.2 at baseline to 23.9 at EOT and 16.2 at EOS.
- o Patient Global Assessment scores reduced from a mean of 23.6 at baseline to 10.7 at EOT and 6.6 at EOS.
- o Of the 12 patients with abnormal levels of double-stranded DNA antibody levels (anti-dsDNA) at baseline, 10 patients showed improved or normalized levels of anti-dsDNA at EOT, which improvement was maintained in 9 patients at EOS.

Safety

Zetomipzomib continued to be well-tolerated over the course of the 37-week study, demonstrating a favorable safety and tolerability profile. Overall, adverse events were generally mild-to-moderate (Grade 1 or 2) and were consistent with what was previously reported with topline data. Early terminations occurred in 4 out of 21 patients. No opportunistic or Grade 3 infections were reported in the trial.

Poster Presentation Details:

Abstract Title: Zetomipzomib (KZR-616), A First-in-Class Selective Immunoproteasome Inhibitor for the Treatment of Lupus Nephritis: Preliminary Results from the Phase 2 MISSION Study

Session: Glomerular Diseases: Clinical, Outcomes, Trials - I [PO1303-1]

Date/Time: November 3, 2022 from 10:00 AM - 12:00 PM ET

Presenter: Dr. Samir V. Parikh, MD, Associate Professor of Medicine, Division of Nephrology, The Ohio State University Wexner Medical Center

The MISSION poster presentation is currently available in the “Scientific Publications” section of Kezar Life Science’s website at www.kezarlifesciences.com.

About Zetomipzomib

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 and Phase 2 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 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 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," "should," "expect," "believe", "potential," "plan" 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, the anticipated clinical and regulatory development and future clinical trials involving zetomipzomib, the likelihood that data will support future development and therapeutic potential and the association of data with treatment outcomes. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during clinical studies, changes in expected or existing competition, 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.

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