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 12, 2019

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)**	**(I.R.S. 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 (see General Instruction A.2. below):

☐ 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**	**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 12, 2019, Kezar Life Sciences, Inc. (the "Company") issued a press release announcing updated data with KZR-616 presented at the American College of Rheumatology 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.

Exhibit No.	Description
99.1	Press release of the Company, dated November 12, 2019.

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.

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

Dated: November 12, 2019

Exhibit 99.1

Kezar Announces Promising New Data with KZR-616 at the American College of Rheumatology Annual Meeting

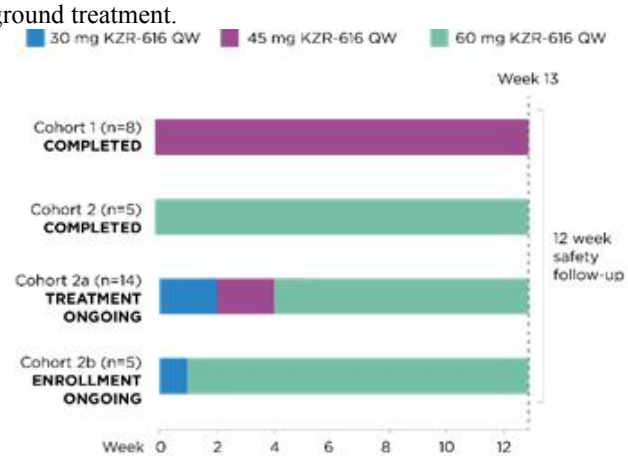
- *Step-up dose titration lowered GI side effects while maintaining clinical activity*
- *Majority of patients completing 13 weeks of treatment demonstrated significant improvement on at least 2 measures of disease activity*
- *Conference Call and Webcast today at 8:30am EST*

SOUTH SAN FRANCISCO, Calif., November 12, 2019 -- Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company discovering and developing novel small molecule therapeutics to treat unmet needs in autoimmune disease and cancer, today announced positive updated results from the Phase 1b (Ph1b) portion of the MISSON study evaluating the safety and tolerability of KZR-616 in patients with systemic lupus erythematosus (SLE). The results are being presented during the American College of Rheumatology (ACR/ARP) Annual Meeting in Atlanta, GA.

"We are thrilled to share these additional promising data with KZR-616, our novel immunoproteasome inhibitor, at the American College of Rheumatology annual meeting," said Christopher Kirk, PhD, Kezar's President and Chief Scientific Officer. "The ongoing Phase 1b portion of MISSION accomplished our primary goal of identifying active and well-tolerated doses that meet target levels of immunoproteasome inhibition and support the further advancement of KZR-616 in autoimmune diseases of high unmet need. We believe the safety and tolerability profile exhibited in patients with SLE will extend into the five indications currently enrolling in our Phase 2 programs."

The primary objective of the Ph1b portion of MISSION is to assess safety and tolerability. Secondary objectives include evaluating pharmacokinetics (PK), pharmacodynamics (PD), and selecting dose levels for the Phase 2 trials. Several exploratory efficacy measures are also being assessed: Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K), Cutaneous Lupus Erythematosus Severity Index-Activity (CLASI-A), Tender and Swollen Joint Counts (TJC/SJC), and Physician Global Assessment (PhGA)/Patient Global Assessment (PtGA)/Patient Assessment of Pain (PtP).

As of the September 20, 2019 data cutoff, the Ph1b portion of MISSION enrolled 32 SLE patients across four separate cohorts (detailed below). All patients received stable background treatment.



Updated data suggest KZR-616 continues to show a differentiated safety profile from non-specific proteasome inhibitors and, importantly, that a dose of 60 mg is well-tolerated when administered via step-up dosing. Additionally, KZR-616 appears to exhibit broad immunomodulatory activity and has the potential for limited immunosuppressive side effects.

The updated results are detailed below:

- Step-up dosing exhibits improved tolerability
  - Nausea and vomiting were reported in <20% of patients following step-up dosing vs. 100% of patients receiving an initial dose of 60 mg
  - Discontinuation rates declined substantially, from 38% to 20%, for patients receiving step-up dosing
- Patients receiving KZR-616 largely avoided toxicities associated with approved non-specific proteasome inhibitors
  - No cases of peripheral neuropathy
  - No prolonged constitutional adverse events, such as fatigue and myalgia
  - No laboratory abnormalities lasted longer than seven days, and only one hematologic event was noted during the period (neutropenia)
- The incidence of serious (≥ Grade 3) and overall infections was low (4% and 22%, respectively)
- One additional SAE (systemic inflammatory response) was reported during the study period; the patient resumed dosing and completed treatment
- Consistent PK and PD was seen across all dose levels, with target levels of immunoproteasome inhibition achieved at each dose level
- Broad and consistent improvements were seen across multiple measures and assessments of disease activity. Of 16 patients completing 13 weeks of treatment (Cohorts 1, 2, and 2a):
  - SLEDAI-2K: 75% had a decrease ≥2 points
  - CLASI-A: 67% with CLASI-A ≥4 at BL had a decrease ≥4 points
  - TJC/SJC: 56% had ≥50% improvement on either TJC or SJC
  - PhGA/PtGA/PtP: 50%, 75%, and 69% had a ≥10-point reduction, respectively

Based on these results, the Phase 2 portion of MISSION will evaluate doses of 30, 45 and 60mg in patients with lupus nephritis (LN). Additionally, 30 and 45 mg doses are being evaluated in Phase 2 studies in patients with dermatomyositis/polymyositis (PRESIDIO) and autoimmune hemolytic anemia/immune thrombocytopenia (MARINA).

“I’m enthusiastic about this novel mechanism that has the potential to transcend traditional plasma-cell depleting therapies and inhibit multiple sites of inflammation. Severe autoimmune diseases, such as lupus and lupus nephritis can be life threatening, and effective treatment options are profoundly needed,” said Richard Furie, MD, Chief, Division of Rheumatology, Northwell Health in New York. “While early, the data seen with KZR-616 are encouraging—patients are improving, step-up dosing mitigates early gastrointestinal side effects, and the lack of prolonged hematologic or significant constitutional adverse events suggests a differentiated safety profile from dual proteasome inhibitors.”

In addition to the Ph1b update from MISSION, Kezar presented three other posters on KZR-616 at the conference. First, biomarker analyses of patients treated with KZR-616 demonstrated a reduction in inflammatory gene signatures and an increase in genes involved in red blood cell production. Second, positive results were presented from a Phase 1 trial in healthy volunteers evaluating a simplified lyophilized formulation of KZR-616. Finally, preclinical data in a mouse model of LN showed decreased

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expression of several inflammatory and kidney tissue damage gene signatures and a similarity of the anti-inflammatory effects of KZR-616 in the mouse model and in treated patients.

Conference Call and Webcast Information

To access the live conference call via phone, dial 877-407-9711 (U.S. toll-free) or 412-902-1014 (toll). The conference ID number for the live call is 13696599. Additionally, a live webcast of the call will be available under the Events section of the Kezar's Investor Relations (IR) site at http://investors.kezarlifesciences.com/events. A slide presentation will accompany the call and can be accessed via the weblink. An archived replay of the call will be available on the company's IR site for 90 days following the live call.

About KZR-616

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. Phase 1b clinical trial results in patients with systemic lupus erythematosus provide early evidence that KZR-616 potentially avoids adverse effects caused by currently marketed non-selective proteasome inhibitors, which we believe prevent them from being utilized as a chronic treatment in autoimmune disorders. Phase 2 trials have commenced for the treatment of lupus nephritis (MISSION), dermatomyositis and polymyositis (PRESIDIO), and autoimmune hemolytic anemia and immune thrombocytopenia (MARINA).

About the MISSION Study

The MISSION study (NCT03393013) is a Phase 1b/2 multi-center study in which patients receive weekly subcutaneous injections of KZR-616 for 13 weeks. The study consists of two parts. The Phase 1b portion is an open-label multiple dose escalation study to evaluate the safety and tolerability of KZR-616 in patients with SLE with and without nephritis. The Phase 2 portion is a randomized, placebo-controlled, double-blind study to evaluate the safety and efficacy of 30, 45 and 60 mg of KZR-616 in patients with active proliferative LN.

About Kezar Life Sciences

Based in South San Francisco, Kezar Life Sciences is a clinical-stage biotechnology company committed to revolutionizing treatments for patients with autoimmune diseases and cancer. Kezar is translating its innovative research on the immunoproteasome and protein secretion pathways to advance novel therapeutic approaches. KZR-616, a first-in-class selective immunoproteasome inhibitor, is being evaluated in severe autoimmune diseases, including systemic lupus erythematosus (SLE), lupus nephritis (LN), dermatomyositis (DM), polymyositis (PM), autoimmune hemolytic anemia (AIHA) and immune thrombocytopenia (ITP). Additionally, Kezar has nominated KZR-261 as its first clinical candidate for the treatment of cancer from its protein secretion program and is undergoing IND-enabling studies for the program. 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 likelihood that data will support future development, the association of data with treatment outcomes, the design, progress, timing, scope and results of clinical trials, the anticipated timing of disclosure of results of clinical trials 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 preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, 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.

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