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): June 13, 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. Results of Operations and Financial Condition.

On June 13, 2019, Kezar Life Sciences, Inc. (the "Company") issued a press release announcing data from its first in patient study of KZR-616 at the European League Against Rheumatism (EULAR) 2019 annual meeting taking place in Madrid, Spain. 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 June 13, 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: June 13, 2019

Exhibit 99.1

Kezar Life Sciences Announces Promising Data from First in Patient Study of KZR-616 at EULAR 2019 Annual Meeting

- *Repeat dosing of KZR-616 demonstrates tolerability and broad and consistent evidence of efficacy across multiple measures of disease activity*
- *Patients receiving KZR-616 have not experienced the hematologic and constitutional toxicities seen with approved nonselective proteasome inhibitors*
- *Phase 2 portion of the MISSION study underway in patients with active lupus nephritis*
- *Conference Call and Webcast at 4:05 pm EDT*

SOUTH SAN FRANCISCO, Calif., June 13, 2019 -- Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company discovering and developing novel small molecule therapeutics to treat unmet needs in autoimmunity and cancer, today announced positive results from the Phase 1b open-label dose escalation portion of the MISSION study evaluating KZR-616 in patients with systemic lupus erythematosus (SLE). The results of the trial are being featured in a poster presentation at the European League Against Rheumatism (EULAR) 2019 annual meeting taking place in Madrid, Spain.

The primary objective of this first-in-patient study is to assess the safety and tolerability of KZR-616. Secondary objectives of the study include evaluating pharmacokinetics (PK) and determining doses for the Phase 2 portion of the study. Pharmacodynamics (PD) and efficacy are also being assessed.

“We are thrilled to share our first in patient data with KZR-616, our novel immunoproteasome inhibitor with the clinical and scientific community at the EULAR 2019 annual meeting,” said Niti Goel, MD, Kezar’s Chief Medical Officer. “We are encouraged by the early safety and efficacy data for KZR-616. Data from the Phase 1b portion of the MISSION study accomplished our primary goal of enabling the identification of active and well-tolerated doses that meet target levels of immunoproteasome inhibition and further supports the development of KZR-616 in lupus nephritis and other autoimmune diseases of high unmet need. To that end, the Phase 2 portion of the MISSION study in patients with lupus nephritis has been initiated, and we look forward to commencing Phase 2 trials with KZR-616 in additional indications later this year.”

As of the data cutoff date of May 6, 2019, the Phase 1b portion enrolled 24 SLE patients with a median SLEDAI score of 10 across three cohorts. Weekly (QW) subcutaneous (SC) administration of KZR-616 at both 45 mg and at 60 mg (following step-up dosing) appeared to be well tolerated and demonstrated rapid and broad immunomodulatory activity as consistently evidenced by positive efficacy data across multiple measures of disease activity, including patient reported outcomes. Consistent PD was seen between 45 mg and 60 mg step-up with target levels of immunoproteasome inhibition achieved. Patients receiving KZR-616 did not experience the hematologic or constitutional toxicities associated with approved non-specific proteasome inhibitors. The favorable safety profile of KZR-616 supports the dose levels for the Phase 2 portion of the MISSION study.

Results from the Cohorts 1, 2, and 2a of the Phase 1b portion of the MISSION study are summarized below:

Primary Endpoint(s)	
Safety	No prolonged hematologic or constitutional AEs (including peripheral neuropathy) as seen with nonselective proteasome inhibitors. Two serious adverse events were reported: one patient in cohort 2 had thrombotic microangiopathy and one patient in Cohort 2a had localized herpes zoster (patient resumed KZR-616 after resolution and completed the KZR-616 treatment period)
Tolerability	Repeat dose administration at 45 mg and step-up to 60 mg SC QW was well tolerated for 13 weeks; 60 mg dosed without step-up induced cases of nausea and vomiting
Secondary Endpoint(s)	
Pharmacokinetics (PK)	Consistent dose proportional PK was seen
Determine Phase 2 doses	30 mg and 45 mg will be utilized in Phase 2; efforts ongoing to further evaluate 60 mg step-up dosing
Exploratory Endpoint(s)	
Efficacy	Consistent and broad improvement seen across all measures of disease activity at Week 13
Pharmacodynamics (PD)	Target levels of immunoproteasome inhibition reached with 45 mg and 60 mg step-up doses

“Lupus and lupus nephritis are serious, potentially life threatening diseases where treatment options have been limited. Evaluating novel mechanisms to treat these and other autoimmune diseases of high unmet need is crucial as we work towards improving the overall treatment paradigm. The early data seen with KZR-616 suggest broad immunomodulatory activity, and the lack of prolonged hematologic or constitutional adverse events associated with dual proteasome inhibitors is encouraging,” said Richard Furie, MD, Chief, Division of Rheumatology, Northwell Health in New York.

Conference Call and Webcast Information

To access the live conference call via phone, dial 866-996-5384 (U.S. toll-free) or 270-215-9573 (international). The conference ID number for the live call is 6465657. Additionally, a live webcast of the call will be available under the Events section of the Company’s website 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 at http://investors.kezarlifesciences.com/events 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. Nonclinical research demonstrates that selective immunoproteasome inhibition results in a broad anti-inflammatory response in animal models of several autoimmune diseases, while avoiding immunosuppression. Phase 1a clinical trial results in healthy volunteers provide 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. A Phase 1b trial in systemic lupus erythematosus (SLE) is currently underway, with a Phase 2 trial in lupus nephritis (LN) expected to initiate during the second quarter of 2019. Phase 2 trials in dermatomyositis (DM), polymyositis (PM), autoimmune hemolytic anemia (AIHA), and immune thrombocytopenia (ITP) are expected to commence the second half of 2019.

About the MISSION Study (Modulator of the Immunoproteasome for Systemic Lupus with and without Nephritis)

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 and 45 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 plans to nominate an initial clinical candidate for the treatment of cancer from its protein secretion program before the end of the year. 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,” 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. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, (i) the discovery and development of new product candidates, and (ii) the association of data with treatment outcomes, (iii) the likelihood data will support future development and (iv) the timing of results and initiation of future clinical trials of the Company’s product candidates. 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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