

**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, 2021**

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
(I.R.S. 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 (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 2.02. Results of Operations and Financial Condition.

On May 12, 2021, Kezar Life Sciences, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended March 31, 2021. 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 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, 2021
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 hereunto duly authorized.

KEZAR LIFE SCIENCES, INC.

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

Dated: May 12, 2021

Kezar Life Sciences Reports First Quarter Financial Results and Provides Business Updates

- *KZR-616 clinical development in three severe autoimmune diseases is advancing with several data readouts expected in 2021 and 2022*
- *KZR-261 IND submission expected mid-2021, with Phase 1 trial in solid tumors expected to initiate before year-end*
- *Cash, cash equivalents and marketable securities of \$142 million as of March 31, 2021*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE) – May 12, 2021 – Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company discovering and developing breakthrough treatments for immune-mediated and oncologic disorders, today announced its first quarter 2021 financial results and corporate highlights.

“Last quarter saw excellent execution by the Kezar team across both of our programs. We look forward to sharing data this June from the completed Phase 1b portion of the MISSION study of KZR-616 in SLE patients, followed by an interim review of the Phase 2 portion of MISSION in LN patients in the fourth quarter. Our conviction continues to deepen that immunoproteasome inhibition has the potential to be a powerful, differentiated treatment approach for patients with autoimmune diseases,” said John Fowler, Kezar’s Co-founder and Chief Executive Officer. “In addition, we are on track to submit an IND for KZR-261, our first-in-class protein secretion inhibitor, in mid-2021 and commence a Phase 1 study in solid tumors shortly thereafter.”

Clinical Highlights & Updates

KZR-616: Selective Immunoproteasome Inhibitor

MISSION – Phase 1b/2 clinical trial in patients with systemic lupus erythematosus (SLE) and lupus nephritis (LN), respectively ([NCT03393013](#))

- The last patient from the MISSION Phase 1b completed treatment in February 2021, and final clinical data from this 25-week safety and tolerability study of up to 75 mg weekly of KZR-616 in 47 patients with SLE will be presented during the European Congress of Rheumatology (EULAR 2021) in June.
- The amended Phase 2 open-label portion of the MISSION trial in patients with active, proliferative lupus nephritis opened for enrollment in August 2020 and is actively recruiting. The primary efficacy endpoint for the trial is the proportion of patients achieving a renal response measured by a 50% or greater reduction in urine protein to creatinine ratio (UPCR) at six months.
 - Interim data are expected in late 2021, and topline data are expected in the first half of 2022.

PRESIDIO – Phase 2 clinical trial in patients with dermatomyositis (DM) and polymyositis (PM) ([NCT04033926](#))

- The PRESIDIO Phase 2, placebo controlled cross-over trial of KZR-616 in DM and PM is actively enrolling. Additionally, a 12-month open-label extension study is open to patients completing the 32-week placebo-controlled trial ([NCT04628936](#)).
 - Topline data are expected in the first half of 2022.

Protein Secretion Program

- KZR-261 is a first-in-class protein secretion inhibitor which targets the Sec61 translocon and has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies.
 - Pending successful completion of drug product manufacturing, submission of an Investigational New Drug (IND) application for KZR-261 is anticipated in mid-2021. The Phase 1 clinical trial will evaluate pharmacokinetics, safety, and tolerability in patients with solid tumors as well as preliminary signs of efficacy in tumor-specific expansion cohorts. The trial is expected to commence shortly after the IND becomes effective.
 - Two abstracts featuring Kezar's small molecule inhibitors of the Sec61 translocon were presented in April during the American Association of Cancer Research (AACR) 2021 Virtual Annual Meeting.

Corporate Update

- In May 2021, Kezar was recognized as a winner of the 2021 Bay Area Best Places to Work, an awards program presented by the San Francisco Business Times and the Silicon Valley Business Journal.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled \$142.3 million as of March 31, 2021, compared to \$140.4 million as of December 31, 2020. The increase in cash, cash equivalents and marketable securities was primarily attributable to the net proceeds from the issuance of common stock under the "at-the-market" Sales Agreement with Cowen and Company, LLC, offset by 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 2021 increased by \$1.8 million to \$9.3 million compared to \$7.5 million in the first quarter of 2020. This increase was primarily related to advancing the KZR-616 clinical program in multiple indications and the protein secretion preclinical program.
 - **General and administrative expenses** for the first quarter of 2021 increased by \$0.8 million to \$3.8 million compared to \$3.0 million in the first quarter of 2020. The increase was primarily due to an increase in personnel expenses and stock-based compensation as a result of an increase in headcount and salaries and an increase in the cost of directors' and officers' liability insurance.
-

- **Net loss** for the first quarter of 2021 was \$13.0 million, or \$0.25 per basic and diluted common share, compared to a net loss of \$10.0 million, or \$0.30 per basic and diluted common share, for the first quarter of 2020.
- **Total shares of common stock outstanding** were 48.1 million shares as of March 31, 2021. 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 7.1 million shares of common stock at a weighted-average exercise price of \$5.90 per share as of March 31, 2021.

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. Data generated from Phase 1a and 1b clinical trials provide evidence that KZR-616 exhibits a favorable safety and tolerability profile for development in severe, chronic autoimmune diseases. Phase 2 trials are underway in severe autoimmune diseases.

About KZR-261

KZR-261, a novel, first-in-class protein secretion inhibitor, is the first clinical candidate to be nominated from Kezar's research and discovery efforts targeting protein secretion pathway. KZR-261 is a broad-spectrum anti-tumor agent that acts through direct interaction and inhibition of Sec61 activity. The compound was discovered by Kezar through a robust medicinal chemistry campaign in which several scaffolds were progressed through the company's proprietary platform evaluating Sec61 modulation. As a result, Kezar has established a broad library of protein secretion inhibitors. KZR-261 has demonstrated several encouraging properties that lead to its potential to be an anti-cancer agent for the treatment of solid and hematologic malignancies. An IND submission in solid tumors is expected to be filed in mid-2021.

About Lupus Nephritis

Lupus nephritis is one of the most serious complications of systemic lupus erythematosus. 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 Dermatomyositis and Polymyositis

Dermatomyositis and Polymyositis are two of the five types of autoimmune myositis diseases. Both are chronic, debilitating, inflammatory autoimmune myopathies that are distinguished by inflammation of the muscles as well as the skin (in DM). Approximately 30,000 to 120,000 people in the United States are living with these severe and progressive inflammatory myopathies that are characterized by marked morbidity and associated mortality. While debilitating muscle weakness is the hallmark of these myopathies, including compromised muscles of respiration, other internal organ system dysfunctions can be equally disabling. The aim of treatment for these diseases is to suppress inflammation, increase muscle strength and prevent long-term damage to muscles and extramuscular organs; however, treatment options are limited for DM, and there are currently no approved treatments for PM.

About Kezar Life Sciences

Kezar Life Sciences is a clinical-stage biopharmaceutical company bringing novel treatments to patients with rare autoimmune diseases and cancer. 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. KZR-616, its lead development candidate, is a selective immunoproteasome inhibitor being evaluated in Phase 2 clinical trials in lupus nephritis, dermatomyositis and polymyositis. Additionally, KZR-261, the first anti-cancer clinical candidate from the company's platform targeting the Sec61 translocon and the protein secretion pathway, is undergoing IND-enabling activities. 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, the anticipated timing of disclosure of results of clinical trials, plans for initiating future clinical trials, the likelihood data will support future development, the association of data with treatment outcomes, the likelihood of obtaining regulatory approval of Kezar's product candidates and the timing of regulatory filings. Many factors may cause differences between current expectations and actual results, including the impacts of the COVID-19 pandemic, 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.

KEZAR LIFE SCIENCES, INC.

Selected Balance Sheets Data

(In thousands)

	March 31, 2021		December 31, 2020	
	(unaudited)			
Cash, cash equivalents and marketable securities	\$	142,308	\$	140,447
Total assets		152,337		151,842
Total current liabilities		7,561		6,442
Total stockholders' equity		140,637		140,978

Summary of Operations Data

(Unaudited, in thousands except share and per share data)

	Three Months Ended	
	March 31,	
	2021	2020
Operating expenses:		
Research and development	\$9,286	\$7,457
General and administrative	3,762	3,021
Total operating expenses	13,048	10,478
Loss from operations	(13,048)	(10,478)
Interest income	54	466
Net loss	(\$12,994)	(\$10,012)
Net loss per common share, basic and diluted	(\$0.25)	(\$0.30)
Weighted-average shares used to compute net loss per common share, basic and diluted	51,058,039	32,867,597

Celia Economides
SVP, Strategy & External Affairs
IR@kezarbio.com

Argot Partners
(212)-600-1902
kezar@argotpartners.com