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): March 17, 2022

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)**	**(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 March 17, 2022, Kezar Life Sciences, Inc. (the "Company") issued a press release announcing its financial results for the fiscal year and quarter ended December 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 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.

Exhibit No.	Description
99.1	Press release of the Company, dated March 17, 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: March 17, 2022

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

Exhibit 99.1

Kezar Reports Fourth Quarter and Year-End 2021 Financial Results and Provides Business Update

- *Topline data from two Phase 2 trials of KZR-616 expected in second quarter of 2022*
- *Zetomipzomib assigned as nonproprietary name for lead candidate, KZR-616*
- *Cash, cash equivalents and marketable securities totaled $208.4 million as of year-end 2021*

SOUTH SAN FRANCISCO, Calif. – (BUSINESS WIRE) – March 17, 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 fourth quarter and year ended December 31, 2021 and provided a business update.

"In 2021, we made significant progress in each of our programs, achieving target enrollment in both of our Phase 2 trials with zetomipzomib, sharing positive interim results from our MISSION Phase 2 study, and launching a Phase 1 trial in solid tumors with our novel protein secretion inhibitor, KZR-261," said John Fowler, Kezar's Co-founder and Chief Executive Officer. "We look forward to continued momentum across the company in 2022, including the presentation of topline results from the MISSION and PRESIDIO trials in the second quarter and preparing for the exciting next phase of development with our first-in-class immunoproteasome inhibitor, zetomipzomib."

Zetomipzomib Assigned as Nonproprietary Name for KZR-616

The International Nonproprietary Name (INN) of zetomipzomib has been selected as the proposed nonproprietary name for KZR-616. The established suffix "-ipzomib" is being utilized to convey the compound's mode of action to selectively inhibit the immunoproteasome.

KZR-616: Selective Immunoproteasome Inhibitor

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

- In November 2021, Kezar presented positive interim results from the MISSION Phase 2 clinical trial of KZR-616, in which five patients had reached the end of treatment, and ten patients had reached week 13 of treatment. The interim results showed a clinically meaningful renal response at the end of treatment for this subset of patients. Four of five patients who completed treatment at week 25 with KZR-616 demonstrated clinically meaningful reduction in proteinuria to less than 0.8 urine protein to creatine ratio (UPCR). Clinically meaningful reductions in UPCR were also observed in five of ten patients at week 13 of treatment and included improvements in key disease biomarkers. KZR-616 was well tolerated over the six-month treatment period.
- The MISSION Phase 2 open-label trial in patients with active, proliferative LN reached target enrollment of 20 patients in November 2021. 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 when compared to baseline.
- Kezar expects to report topline data in the second quarter of 2022.

PRESIDIO – Phase 2 clinical trial of KZR-616 in patients with active dermatomyositis (DM) or polymyositis (PM) (NCT04033926)

- The PRESIDIO Phase 2 randomized, placebo-controlled, double-blind, cross-over clinical trial of KZR-616 in patients with DM or PM reached target enrollment of 24 subjects in August 2021. The primary efficacy endpoint of this clinical trial is the mean change from beginning to end of treatment with KZR-616 in the Total Improvement Score (TIS), which ranges from 0 to 100.

- Kezar expects to report topline data in the second quarter of 2022.

- Patients completing the PRESIDIO study have an opportunity to enroll into an open-label extension study to continue receiving KZR-616 treatment for up to a total of 96 weeks (NCT04628936). In December 2021, at-home self-administration of KZR-616 was introduced for patients in the open-label extension study.

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.

- In October 2021, the first patient was dosed in the open-label Phase 1 clinical trial of KZR-261 in patients with solid tumor malignancies.

- 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.

- An abstract featuring Kezar's proprietary small molecule inhibitors of the Sec61 translocon, specifically KZR-834, a working analog of KZR-261, has been selected for presentation at the upcoming American Association of Cancer Research (AACR) 2022 Annual Meeting, taking place April 8–13, 2022 in New Orleans, LA. Details for the AACR presentation are as follows:

    - *Title*: Sec61 inhibitor KZR-834, an anti-cancer agent, exhibits immunomodulatory activity and combines with PD-1 blockade to further enhance immune responses

    - *Abstract Number*: 5592

    - *Session Title*: Immunology, Preclinical Immunotherapy

    - *Date/Time*: Available on demand [Friday, April 8, 2022, 8:30 a.m. ET]

    - *Presenter*: Jennifer Whang, Associate Director, Biology

Board Appointment

Courtney Wallace, a strategic business development executive, was appointed to Kezar's Board of Directors in December 2021, bringing over a decade of business experience in healthcare.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled $208.4 million as of December 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 company's "at-the-market" sales program, net of cash used by the company in operations to advance its clinical-stage programs.

- **Research and development expenses** for the fourth quarter of 2021 increased by $1.7 million to $9.8 million compared to $8.1 million in the fourth quarter of 2020. Full year R&D expenses increased by $7.9 million to $38.9 million in 2021, compared to $31.0 million in 2020. This increase was primarily related to advancing the KZR-616 clinical program in multiple indications and the KZR-261 clinical program.

- **General and administrative expenses** for the fourth quarter of 2021 increased by $1.3 million to $4.3 million compared to $3.0 million in the fourth quarter of 2020. Full year G&A expenses increased by $3.7 million to $15.7 million in 2021, compared to $12.0 million in 2020. The increase was primarily due to an increase in stock-based compensation and personnel expenses as a result of an increase in headcount and salaries.

- **Net loss** for the fourth quarter of 2021 was $14.2 million, or $0.25 per basic and diluted common share, compared to a net loss of $10.9 million, or $0.22 per basic and diluted common share, for the fourth quarter of 2020. Net loss for 2021 was $54.6 million, or $1.04 per basic and diluted common share, compared to $41.7 million, or $0.95 per basic and diluted common share, in 2020.

- **Total shares of common stock outstanding** were 56.3 million shares as of December 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 6.9 million shares of common stock at a weighted-average exercise price of $5.95 per share, each as of December 31, 2021.

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 1a and 1b clinical trials provide evidence that zetomipzomib exhibits a favorable safety and tolerability profile for development in severe, chronic autoimmune diseases. Phase 2 trials are underway in multiple severe autoimmune diseases.

About KZR-261

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.

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 Dermatomyositis and Polymyositis

Dermatomyositis (DM) and Polymyositis (PM) 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 Inhibition of Protein Secretion

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 Phase 2 clinical trials in lupus nephritis, dermatomyositis and polymyositis. 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, the 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 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)

	December 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 208,355	$ 140,447
Total assets	217,933	151,842
Total current liabilities	8,212	6,442
Total noncurrent liabilities	12,845	4,422
Total stockholders’ equity	196,876	140,978

Summary of Operations Data
(in thousands except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$9,781	$8,117	$38,935	$30,981
General and administrative	4,322	2,951	15,724	11,969
Total operating expenses	14,103	11,068	54,659	42,950
Loss from operations	(14,103)	(11,068)	(54,659)	(42,950)
Interest expense	(159)	-	(159)	-
Interest income	50	127	188	1,208
Net loss	($14,212)	($10,941)	($54,630)	($41,742)
Net loss per common share, basic and diluted	($0.25)	($0.22)	($1.04)	($0.95)
Weighted-average shares used to compute net loss per common share, basic and diluted	55,979,764	50,080,283	52,759,335	44,004,190

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