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 11, 2021

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 2.02. Results of Operations and Financial Condition.

On March 11, 2021, Kezar Life Sciences, Inc. (the "Company") issued a press release announcing its financial results for the fiscal year and quarter ended December 31, 2020. 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.

Exhibit No.	Description
99.1	Press release of the Company, dated March 11, 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: March 11, 2021

Exhibit 99.1

Kezar Life Sciences Reports Fourth Quarter and Year End 2020 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, subject to developments in the ongoing COVID-19 pandemic.*
- *Upcoming poster presentations at AACR validate that inhibition of Sec61 with a small molecule can target multiple tumor types.*
- *Cash and cash equivalents of $140 million as of December 31, 2020.*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE) – March 11, 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 fourth quarter and year end 2020 financial results and corporate highlights.

“Despite unprecedented circumstances, 2020 was a year of significant corporate and clinical accomplishments, thanks to the excellent execution by the Kezar team,” said John Fowler, Kezar’s Co-Founder and Chief Executive Officer. “We advanced our lead product candidate, KZR-616, in multiple indications, and the early clinical data from MISSION strongly support its continued development for a wide range of severe immune-mediated diseases. We launched the open-label extension study for patients completing PRESIDIO, and KZR-616 was granted Orphan Drug Designations from the FDA for the treatment of polymyositis and dermatomyositis. This year we look forward to reporting the final results of the MISSION Phase 1b study and interim data from the MISSION Phase 2 study in systemic lupus erythematosus and lupus nephritis patients, respectively.”

Fowler continued, “Additionally, we continue to be highly encouraged by the therapeutic potential of KZR-261 and look forward to initiating a Phase 1 trial in solid tumors later this year. The data we’ll be presenting from the protein secretion program in two posters during AACR next month provides further support for inhibiting Sec61 as a target to treat various cancers.”

Clinical Highlights & Updates

KZR-616: Selective Immunoproteasome Inhibitor

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

- The 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, subject to developments in the ongoing COVID-19 pandemic.

- The MISSION Phase 1b 25-week safety and tolerability study of up to 75 mg weekly of KZR-616 in 47 patients with SLE completed enrollment in the fourth quarter of 2020.
    - Final data from the MISSION Phase 1b study are expected to be available in mid-2021.
    - In November 2020, additional data from this study were presented at the American College of Rheumatology Annual Meeting (ACR Convergence 2020). Positive early efficacy and biomarker data suggest that selective inhibition of the immunoproteasome with KZR-616 could have a meaningful clinical impact in patients with severe autoimmune diseases. No new safety signals were observed, and KZR-616 administered subcutaneously once weekly has been consistently well tolerated for up to 13 weeks.

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 enrolling patients completing the 32-week placebo-controlled trial (NCT04628936).
    - Topline data are expected in the first half of 2022, subject to developments in the ongoing COVID-19 pandemic.
    - KZR-616 was granted Orphan Drug Designations (ODD) by the U.S. Food and Drug Administration in October 2020 for both DM and PM, the only investigative drug to have ODD in both indications. The estimated prevalence of DM and PM in the United States is up to 71,000 and 51,000, respectively.
    - During ACR Convergence 2020, preclinical results for KZR-616 were presented in CIM, the mouse model of polymyositis. The results demonstrated that treatment with KZR-616 was associated with significant improvement in muscle function and reduced levels of muscle tissue damage, providing a rationale for targeting selective immunoproteasome inhibition for the treatment of polymyositis.

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.
    - Submission of an Investigational New Drug (IND) application for KZR-261 is anticipated in mid-2021. The Phase 1 clinical trial will evaluate dose escalation and safety and tolerability in patients with solid tumors and is expected to commence shortly after the IND becomes effective.
- Two abstracts featuring Kezar's small molecule inhibitors of the Sec61 translocon have been selected for presentation at the upcoming American Association of Cancer Research (AACR) 2021 Virtual Annual Meeting, taking place April 10-15, 2021 and May 17-21, 2021. Details for the two AACR presentations are as follows:

    Poster Presentations

Title: *Prioritizing tumor types for clinical study of novel Sec61 inhibitors by searching for expression profiles of sensitive cell lines in tumor sample databases*

Presenter/s: **Eric Lowe, R**. Andrea Fan, Henry W. B. Johnson, Christopher J. Kirk, Dustin McMinn, Yu Qian, Brian Tuch

Session: Genomic Profiling of Tumors – Abstract #2226

Date and time: Available on demand [8:30AM ET, Saturday, April 10, 2021]

Title: *Quantitative proteomic profiling of novel anti-cancer small molecule inhibitors of Sec61: Mechanistic investigation and biomarker discovery*

Presenter/s: Yu Qian, Jennifer Whang, Janet Anderl, Andrea Fan, Henry W. B. Johnson, Christopher J. Kirk, Eric Lowe, Dustin McMinn, Beatriz Millare, Tony Muchamuel and Jinhai Wang; Kezar Life Sciences

Session: Proteomics and Biomarker Discovery – Abstract #2816

Date and time: Available on demand [8:30AM ET, Saturday, April 10, 2021]

- Additional preclinical data further detailing the ability of novel small molecule Sec61 inhibitors to target multiple checkpoint proteins on various cell populations, thereby offering the potential of combination therapy in a single compound, were presented during the 8th Annual Meeting of the International Cytokine & Interferon Society (Cytokines 2020) and the Society for the Immunotherapy of Cancer (SITC) in November 2020.

Corporate Update

- Kezar was added to the NASDAQ Biotechnology Index® (NASDAQ: NBI) on December 21, 2020.

Financial Results

- **Cash, cash equivalents and marketable securities**totaled $140.4 million as of December 31, 2020, compared to $78.2 million as of December 31, 2019. The increase in cash, cash equivalents and marketable securities was primarily attributable to the net proceeds from the underwritten public offerings, net of cash used by the company in operations to advance its clinical stage programs and preclinical research and development.

- **Research and development expenses** for the fourth quarter of 2020 increased by $0.7 million to $8.1 million compared to $7.4 million in the fourth quarter of 2019. Full year R&D expenses increased by $3.6 million in 2020 compared to 2019. 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 fourth quarter of 2020 increased by $0.4 million to $3.0 million compared to $2.6 million in the fourth quarter of 2019. Full year G&A expenses increased by $1.9 million in 2020 compared to 2019. The increase was primarily due to an increase in personnel expenses, professional fees and costs of directors and officers liability insurance.

- **Net loss** for the fourth quarter of 2020 was $10.9 million, or $0.22 per basic and diluted common share, compared to a net loss of $9.6 million, or $0.50 per basic and diluted common share, for the fourth quarter of 2019. Net loss for 2020 was $41.7 million, or $0.95 per basic and diluted common share, compared to $35.1 million, or $1.84 per basic and diluted common share, in 2019.

- **Total shares of common stock outstanding** were 46.4 million as of December 31, 2020. 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 4.5 million shares of common stock at a weighted average exercise price of $6.14 per share as of December 31, 2020.

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 pathways. 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 (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 about 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

Polymyositis and Dermatomyositis 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). An approximate 30,000-120,000 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 and extension studies, 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, the timing of regulatory filings, and the discovery and development of new product candidates. Orphan Drug Designation does not provide any assurance of regulatory approval or expedite regulatory review. Many factors may cause differences between current expectations and actual results, including the impacts of the COVID-19 pandemic on the company's business, clinical trials and financial position, 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)

	December 31, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	$ 140,447	$ 78,206
Total assets	151,842	89,513
Total current liabilities	6,442	6,003
Total stockholders' equity	140,978	78,046

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$8,117	$7,431	$30,981	$27,363
General and administrative	2,951	2,566	11,969	9,979
Total operating expenses	11,068	9,997	42,950	37,342
Loss from operations	(11,068)	(9,997)	(42,950)	(37,342)
Interest income	127	418	1,208	2,255
Net loss	($10,941)	($9,579)	($41,742)	($35,087)
Net loss per common share, basic and diluted	($0.22)	($0.50)	($0.95)	($1.84)
Weighted-average shares used to compute net loss per common share, basic and diluted	50,080,283	19,122,074	44,004,190	19,083,826

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