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 4, 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 1.01 Entry into a Material Definitive Agreement.

On November 4, 2021, Kezar Life Sciences, Inc. (the "Company") entered into a Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC, a Delaware limited liability company, as lender (the "Lender") and collateral agent (the "Agent"). The Loan Agreement provides for aggregate maximum borrowings of up to $50.0 million (the "Loan"), consisting of (i) a term loan of up to $10.0 million, which was fully funded on November 4, 2021; (ii) at the Company's election, an additional term loan of up to $10.0 million, available for borrowing from July 1, 2022 to December 30, 2022; (iii) upon the Company achieving positive topline data in its MISSION Phase 2 clinical trial sufficient to advance the program into Phase 2(b) or a registration-enabling trial, an additional term loan of up to $20.0 million, available for borrowing through the earlier of June 30, 2023 and nine months following achievement of the aforementioned milestone (the "Tranche C Advance"); (iv) upon the Company achieving positive topline data in its PRESIDIO Phase 2 clinical trial sufficient to advance the program into a registration-enabling trial, an additional term loan of up to $20.0 million, available for borrowing through the earlier of June 30, 2023 and nine months following achievement of the aforementioned milestone (the "Tranche D Advance"); and (v) following drawing either the Tranche C Advance or the Tranche D Advance and upon the Company achieving positive safety and tolerability data from the dose escalation portion of the Phase 1 clinical trial for KZR-261 in oncology indications sufficient to advance the program into the dose expansion portion of clinical trials, an additional term loan of up to $20.0 million, available for borrowing through the earlier of December 31, 2023 and nine months following achievement of the aforementioned milestone. The aggregate maximum borrowings under the Loan Agreement are capped at $50.0 million, irrespective of which tranches are drawn. The final maturity date of the Loan Agreement is November 1, 2026.

Initially, through November 30, 2021, the Loan will bear interest at a per annum rate of 7.9575%. Thereafter, the Loan will bear interest at a floating per annum rate (based on the actual number of days elapsed divided by a year of 360 days) equal to the sum of (a) the greater of (i) the 30-day U.S. LIBOR rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue and (ii) 0.08%, plus (b) 7.87%. The Loan Agreement also provides for the selection of an alternative benchmark rate in the event of the discontinuance of LIBOR or any subsequent benchmark rate. The Company is permitted to prepay the Loan in full or in part at any time upon 10 business days' written notice to the Lender, subject to the applicable Prepayment Fee (as defined below). Upon the earliest to occur of the maturity date, acceleration of the Loan or prepayment of the Loan, the Company is required to make a final payment equal to 6.5% of the aggregate principal amount of the Loan (the "Final Fee"). Any prepayments of the Loan, whether mandatory or voluntary, must include an amount equal to the sum of (a) the portion of the outstanding principal of the Loan being prepaid plus accrued and unpaid interest thereon through the prepayment date, (b) the Final Fee, (c) the Lender's expenses and all other obligations that are due and payable to the Lender, and (d) a prepayment fee of (i) 2% of the portion of the Loan being prepaid if the repayment is on or before the second anniversary of the funding date of such term loan or (ii) 1.0% of the portion of the Loan being prepaid if the repayment is after the second anniversary of the funding date but on or before the third anniversary of the funding date of such term loan (the "Prepayment Fee"). There is no Prepayment Fee for any prepayments occurring after the third anniversary of the funding date of such term loan.

The Company is required to make monthly interest-only payments prior to the amortization date of January 1, 2025, which amortization date will extend to January 1, 2026 if the Company elects to borrow the Tranche C Advance or Tranche D Advance.

The Company's obligations under the Loan Agreement are secured by a security interest in all of the assets of the Company, other than the Company's intellectual property, which is subject to a negative pledge. The Loan Agreement contains customary representations and covenants that, subject to exceptions, restrict the Company's ability to, among other things: declare dividends or redeem or repurchase equity interests; incur additional liens; make loans and investments; incur additional indebtedness; engage in mergers, acquisitions and asset sales; transact with affiliates; undergo a change in control; add or change business locations; and engage in businesses that are not related to its existing business.

Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. Events of default under the Loan Agreement include customary events of default, including, but not limited to: (i) failure to (a) make any payment of principal or interest

on its due date, or (b) pay any other obligations within three business days after such obligations are due and payable; (ii) failure to perform any obligation under specified covenants; (iii) the occurrence of a material adverse change; (iv) the Company or any of its subsidiaries being or becoming insolvent, beginning an insolvency proceeding, or becoming subject to an insolvency proceeding that is not dismissed or stayed within 45 days; (v) a default under any agreement with a third party resulting in a right by such third party to accelerate the maturity of any indebtedness in an amount in excess of $500,000 or that could reasonably be expected to have a material adverse change; (vi) the rendering of judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least $500,000 that remain unsatisfied, unvacated, or unstayed for a period of 10 days after the entry thereof; (vii) revocation, rescission, suspension or adverse modification of any governmental approval, or non-renewal of a governmental approval in the ordinary course for a full term, that could reasonably be expected to result in a material adverse change; (viii) failure of a lien created under the Loan Agreement or any other loan document to constitute a valid and perfected lien on any of the collateral purported to be secured thereby, subject to no prior or equal lien, other than permitted liens; and (ix) the delisting of the Company's shares of common stock.

The foregoing description of the Loan Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the Loan Agreement, a copy of which the Company will file as an exhibit to its Annual Report on Form 10-K for the year ending December 31, 2021.

Item 2.02. Results of Operations and Financial Condition.

On November 9, 2021, the Company issued a press release announcing its financial results for the fiscal quarter ended September 30, 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 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information in Item 1.01 relating to the Loan Agreement is hereby incorporated by reference into this Item 2.03.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release of the Company, dated November 9, 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: November 9, 2021

Exhibit 99.1

Kezar Reports Third Quarter Financial Results and Provides Business Update

- *Target enrollment met in the MISSION Phase 2 trial evaluating KZR-616 for lupus nephritis*
- *First patient dosed in Phase 1 trial of KZR-261 for the treatment of advanced solid tumor malignancies*
- *Company to host virtual Investor and Analyst Day on Monday, November 15, 2021, at 4:30 p.m. ET to discuss KZR-616, including MISSION interim results, and KZR-261*
- *New credit facility provides up to $50 million of available funding*

SOUTH SAN FRANCISCO, Calif. – (BUSINESS WIRE) – November 9, 2021 – 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 third quarter ended September 30, 2021 and provided a business update.

“Excellent progress continues across our programs, as we reached target enrollment in both of our Phase 2 trials with KZR-616 and announced our first patient dosed with KZR-261. Achieving full enrollment in our MISSION and PRESIDIO studies is an important milestone for KZR-616 as a potentially differentiated treatment option for patients suffering from lupus nephritis, dermatomyositis and polymyositis. We look forward to sharing interim results from MISSION at our upcoming event this month, with topline results from both studies expected in the second quarter of 2022,” said John Fowler, Kezar’s Co-founder and Chief Executive Officer.

Clinical Highlights & Updates

KZR-616: Selective Immunoproteasome Inhibitor

MISSION – Phase 2 clinical trial in patients with lupus nephritis (LN) (NCT03393013)

- Kezar’s upcoming Investor and Analyst Day, scheduled for Monday, November 15, 2021, at 4:30 p.m. ET/1:30 p.m. PT, will include a presentation featuring interim MISSION data, as well as a presentation from Samir V. Parikh, MD, Associate Professor of Medicine, Nephrology, The Ohio State University Wexner Medical Center.

- The MISSION Phase 2 open-label trial in patients with active, proliferative LN has reached target enrollment of 20 subjects. The primary efficacy endpoint for the trial is the number of patients with a 50% reduction in urine protein/creatine ratio (UPCR) after 24 weeks of treatment when compared to baseline.

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

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

- The PRESIDIO Phase 2, placebo controlled, cross-over trial of KZR-616 in DM and PM has completed target enrollment of 24 subjects. The primary efficacy endpoint for the trial is the

mean change from start to end of KZR-616 treatment in the Total Improvement Score (TIS), which ranges from 0 to 100.

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

- The PRESIDIO open-label extension study is available for patients completing the PRESIDIO trial, which evaluates KZR-616 for up to a maximum of 96 weeks (NCT04628936).

KZR-261: Protein Secretion Inhibitor

KZR-261-101 – Phase 1 clinical trial in patients with locally advanced or metastatic solid malignancies (NCT05047536)

- In August, Kezar announced an IND submission for KZR-261 for the treatment of advanced solid malignant tumors, and in October, the first patient was dosed in its Phase 1 clinical trial.

- KZR-261 is a novel, broad-spectrum, anti-tumor agent that acts through direct interaction and inhibition of the Sec61 translocon.

- The Phase 1 clinical trial of KZR-261 will be conducted in two parts: dose escalation in subjects with locally advanced or metastatic solid malignancies for whom no therapeutics are available and dose expansion in subjects with selected tumor types. The trial will assess safety and tolerability, including determination of a recommended Phase 2 dose, evaluate pharmacokinetics and pharmacodynamics, and explore the preliminary anti-tumor activity.

Officer Appointment

In October, Gitanjali Jain was appointed as Kezar's Vice President, Investor Relations and External Affairs, joining with nearly 15 years of healthcare industry and investor relations experience. As a member of the management team and executive committee, Ms. Jain will lead Kezar's overall investor relations and public relations corporate efforts.

Credit Facility

On November 4, 2021, Kezar entered into a credit facility with Oxford Finance. Under the terms of the loan agreement, Oxford Finance will provide Kezar with borrowing capacity of up to $50 million across five potential tranches. The initial $10 million funded at closing, and an additional $10 million will be available at Kezar's option in the second half of 2022. Additional tranches would become available upon achieving milestones related to the MISSION Phase 2 clinical trial, PRESIDIO Phase 2 clinical trial and/or KZR-261 Phase 1 clinical trial. There are no warrants or financial covenants associated with the credit facility. Capital Advisors Group, Inc acted as financial advisor to Kezar.

Third Quarter 2021 Financial Results

- **Cash, cash equivalents and marketable securities** totaled $120.8 million as of September 30, 2021, compared to $140.4 million as of December 31, 2020. The decrease in cash, cash equivalents and marketable securities was primarily attributable to cash used by the company in operations to advance its clinical-stage programs, offset by $11.7 million of net proceeds from the

issuance of common stock through September 30, 2021, under the company's "at-the-market" sales program. In October, Kezar received an additional $4.4 million of net proceeds from the issuance of additional common stock under the ATM program.

- **Research and development expenses** for the third quarter of 2021 increased by $2.2 million to $10.5 million compared to $8.3 million in the third quarter of 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 third quarter of 2021 increased by $0.7 million to $4.0 million compared to $3.3 million in the third quarter of 2020. The increase was primarily due to an increase in stock-based compensation and personnel and recruiting expenses as a result of an increase in headcount and salaries.

- **Net loss** for the third quarter of 2021 was $14.5 million, or $0.28 per basic and diluted common share, compared to a net loss of $11.3 million, or $0.23 per basic and diluted common share, for the third quarter of 2020.

- **Total shares of common stock outstanding** were 48.6 million shares as of September 30, 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 $5.85 per share, each as of September 30, 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 multiple 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 the 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. KZR-261 has demonstrated several encouraging properties that lead to its potential to be an anti-cancer agent, and a Phase 1 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

In mammalian cells, the secretion of proteins such as cytokines and growth factors and the expression of cell surface transmembrane proteins such as receptor tyrosine kinases and immune checkpoint molecules involve a process called cotranslational translocation. For most proteins, this process occurs via the Sec61 translocon, a highly conserved multi-subunit protein complex found in the membrane of the endoplasmic reticulum of all cells. Kezar scientists have been researching the protein secretion pathway and ways to drug this important cellular pathway for more than five years and developed novel and robust assays to discover and develop small molecule inhibitors of Sec61. As a result, Kezar has established a broad library of protein secretion inhibitors for potential development across a wide range of diseases.

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. KZR-616, its lead development asset, is a selective immunoproteasome inhibitor being evaluated in Phase 2 clinical trials in lupus nephritis, dermatomyositis and polymyositis. This asset 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 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 unexpected safety or efficacy data observed during clinical studies, clinical trial site activation or enrollment rates that are lower than expected, the impacts of the COVID-19 pandemic 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)

	September 30, 2021	December 31, 2020
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 120,759	$ 140,447
Total assets	130,889	151,842
Total current liabilities	7,872	6,442
Total stockholders' equity	119,481	140,978

Summary of Operations Data

(In thousands except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	$10,527	$8,259	$29,154	$22,864
General and administrative	3,972	3,292	11,402	9,018
Total operating expenses	14,499	11,551	40,556	31,882
Loss from operations	(14,499)	(11,551)	(40,556)	(31,882)
Interest income	37	262	138	1,081
Net loss	($14,462)	($11,289)	($40,418)	($30,801)
Net loss per common share, basic and diluted	($0.28)	($0.23)	($0.78)	($0.73)
Weighted-average shares used to compute net loss per common share, basic and diluted	52,048,563	49,999,239	51,674,063	41,964,042

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