

November 9, 2021



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)-- [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/creatinine 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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