Kezar Life Sciences Reports Third Quarter 2023 Financial Results and Provides Business Update

November 13, 2023

- *Strategic restructuring extends cash runway to fund PALIZADE global Phase 2b clinical trial evaluating zetomipzomib in lupus nephritis*
- *Collaboration and license agreement with Everest Medicines to develop and commercialize zetomipzomib in Greater China, South Korea and Southeast Asia*
- *Kezar Co-Founder and Board Director, Christopher Kirk, Ph.D., appointed as Chief Executive Officer*
- *Cash, cash equivalents and marketable securities totaled $218.2 million as of September 30, 2023*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 13, 2023-- Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company developing breakthrough treatments for immune-mediated and oncologic disorders, today reported financial results for the third quarter ended September 30, 2023 and provided a business update.

“During the third quarter, we made important progress in streamlining our operations and sharpening our focus on the zetomipzomib and KZR-261 programs,” said Christopher Kirk, Ph.D., co-founder and Chief Executive Officer of Kezar. “Our progress has been bolstered by a strategic collaboration and license agreement with Everest Medicines to develop and commercialize zetomipzomib in China, South Korea and Southeast Asia. Looking ahead, our strategic realignment and strong balance sheet provide cash runway to reach and extend beyond important clinical inflection points over the next three years for both our immunology and oncology programs.”

Corporate Update

Christopher Kirk, Ph.D. was appointed and began serving as Kezar’s Chief Executive Officer on November 7, 2023. Dr. Kirk is a co-founder and member of the Board of Directors and previously served as Kezar’s President and Chief Scientific Officer. John Fowler, co-founder and departing CEO, will continue serving as a member of the Board of Directors. In addition, Kezar recently announced a strategic restructuring to prioritize long-term growth and focus resources on its clinical-stage programs. Actions to prioritize clinical programs and implement cost saving measures are expected to extend Kezar’s cash runway into late 2026. These measures will focus resources on achieving important clinical data readouts for zetomipzomib in lupus nephritis (LN) and autoimmune hepatitis and KZR-261 in solid tumors. All research and drug discovery activities have been paused, and Kezar is exploring strategic alternatives for its protein secretion platform and preclinical programs. Kezar anticipates initial data from its KZR-261 Phase 1 clinical trial in 2024, topline data from its PORTOLA Phase 2a clinical trial in mid-2025 and topline data from its PALIZADE Phase 2b clinical trial mid-2026.

Zetomipzomib: Selective Immunoproteasome Inhibitor

Collaboration with Everest Medicines:

In September 2023, Kezar entered into a collaboration and license agreement with Everest Medicines to develop and commercialize zetomipzomib in Greater China, South Korea and Southeast Asia. Everest Medicines is joining Kezar on PALIZADE, a global, placebo-controlled Phase 2b clinical trial evaluating zetomipzomib in patients with active LN, and will contribute their local regulatory and clinical trial expertise to potentially accelerate enrollment in these geographies. In addition to PALIZADE, Kezar and Everest Medicines have the opportunity to collaborate on future clinical trials and indications for the continued development of zetomipzomib.

Clinical Development:

PALIZADE – Phase 2b clinical trial of zetomipzomib in patients with active LN (ClinicalTrials.gov: NCT05781750)

- PALIZADE is a global, placebo-controlled, randomized, double-blind Phase 2b clinical trial evaluating the efficacy and safety of two dose-levels of zetomipzomib in patients with active LN. Target enrollment will be 279 patients, randomly assigned (1:1:1) to receive 30 mg of zetomipzomib, 60 mg of zetomipzomib or placebo subcutaneously once weekly for 52 weeks, in addition to standard background therapy. Background therapy can, but will not be mandated to, include standard induction therapy. Over the initial 16 weeks, there will be a mandatory corticosteroid taper to 5 mg per day or less. End-of-treatment assessments will occur at Week 53. The primary efficacy endpoint is the proportion of patients who achieve a complete renal response (CRR) at Week 37, including a urine protein-to-creatine ratio (UPCR) of 0.5 or less without receiving rescue or prohibited medications.

PORTOLA – Phase 2a clinical trial of zetomipzomib in patients with autoimmune hepatitis (AIH) who have not benefited from standard-of-care treatment (ClinicalTrials.gov: NCT05569759)

- PORTOLA is a placebo-controlled, randomized, double-blind Phase 2a clinical trial evaluating the efficacy and safety of zetomipzomib in patients with AIH that are insufficiently responding to standard of care or have relapsed. Target enrollment will be 24 patients, randomized (2:1) to receive 60 mg of zetomipzomib or placebo in addition to background corticosteroid

therapy for 24 weeks, with a protocol-mandated steroid taper by Week 14. The primary efficacy endpoint will measure the proportion of patients who achieve a complete response measured as normalization of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels with a successful corticosteroid taper by Week 24.

PRESIDIO Open-Label Extension (OLE) – Dr. Rohit Aggarwal, M.D., an investigator at the University of Pittsburgh, will present results from the OLE portion of the Phase 2 PRESIDIO trial in patients with dermatomyositis (DM) and polymyositis (PM) showing zetomipzomib demonstrates long-term safety and tolerability without signs of immunosuppression at the American College of Rheumatology (ACR) Convergence 2023, which is taking place November 10 – 15, 2023, in San Diego, Calif.

MISSION – Kezar will present an encore poster presentation of the results from the open-label Phase 2 MISSION trial of zetomipzomib in LN at the upcoming 25th Asia-Pacific League of Associations for Rheumatology (APLAR) Congress, which is taking place December 7 – 11, 2023, in Thailand.

KZR-261: Broad-Spectrum Sec61 Translocon Inhibitor

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

- The Phase 1 clinical trial of KZR-261 is being conducted in two parts: dose escalation and dose expansion in tumor-specific solid tumors. The study is designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, identify a recommended Phase 2 dose and to explore the preliminary anti-tumor activity of KZR-261 in patients with locally advanced or metastatic disease.
- The KZR-261 trial is currently enrolling Cohort 8 (60 mg/m^2). Previously, Cohort 1 (1.8 mg/m^2) through Cohort 7 (40 mg/m^2) enrolled a total of 29 patients and completed rapid dose escalation without significant safety concerns.
- To date, KZR-261 has shown dose-proportional exposure and no signs of accumulation or altered pharmacokinetics with repeated dosing.

Protein Secretion Platform

Kezar presented results around the quantitative proteomic profiling of KZR-540, an oral small molecule inhibitor that selectively blocks PD-1 expression via inhibition of the Sec61 translocon, at the Society for Immunotherapy of Cancer's (SITC) 38th Annual Meeting which took place November 1– 5, 2023 in San Diego, CA. KZR-540 demonstrates that the Sec61 translocon can be selectively inhibited for specific anti-tumor effects and validates Sec61 inhibition as a platform for selective down-regulation of high-value targets. The poster presentation was made by David Bade, Ph.D., Senior Scientist at Kezar.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled $218.2 million as of September 30, 2023, compared to $276.6 million as of December 31, 2022. The decrease was primarily attributable to cash used in operations to advance clinical-stage programs and preclinical research and development.
- **Revenue** for the third quarter of 2023 was $7.0 million resulting from the upfront payment under the collaboration and license agreement with Everest Medicines.
- **Research and development expenses** for the third quarter of 2023 increased by $9.8 million to $23.7 million compared to $13.9 million in the third quarter of 2022. This increase was primarily due to advancing the zetomipzomib clinical program in multiple indications and the KZR-261 clinical program and an increase in compensation and personnel related expenses, including non-cash stock-based compensation expense, as a result of an increase in headcount.
- **General and administrative (G&A) expenses** for the third quarter of 2023 increased by $3.7 million to $8.8 million compared to $5.1 million in the third quarter of 2022. The increase was primarily due to an increase in legal and professional service expense in connection with the collaboration and license agreement with Everest and an increase in compensation and personnel related expenses, including non-cash stock-based compensation, as a result of an increase in headcount.
- **Net loss** for the third quarter of 2023 was $23.1 million, or $0.32 per basic and diluted common share, compared to a net loss of $17.8 million, or $0.25 per basic and diluted common share, for the third quarter of 2022.
- **Total shares of common stock outstanding** were 72.7 million shares as of September 30, 2023. Additionally, there were options to purchase 13.3 million shares of common stock at a weighted-average exercise price of $2.76 per share and 0.3 million restricted stock units outstanding as of September 30, 2023.

About Kezar Life Sciences

Kezar Life Sciences is a clinical-stage biopharmaceutical company developing novel treatments for immune-mediated and oncologic disorders. Zetomipzomib, a selective immunoproteasome inhibitor, is currently being evaluated in a Phase 2b clinical trial for lupus nephritis and a Phase 2a clinical trial for autoimmune hepatitis. This product candidate also has the potential to address multiple chronic immune-mediated diseases. Kezar's oncology product candidate, KZR-261, targeting the Sec61 translocon and protein secretion pathway, is being evaluated in an open-label dose-escalation Phase 1 clinical trial to assess safety, tolerability and preliminary tumor activity in solid tumors. For more information, visit www.kezarlifesciences.com, and follow us on LinkedIn, Facebook, Twitter and Instagram.

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," "can," "should," "expect," "believe," "potential," "anticipate" 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 company's financial position and cash runway, the timing and amount of future operating expenses, the design, initiation, progress, timing, scope and results of clinical trials, collaboration on clinical trials and development of zetomipzomib in additional indications, the potential acceleration of enrollment of clinical trials, anticipated therapeutic benefit and regulatory development of Kezar's product candidates, 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 clinical trial site activation or enrollment rates that are lower than expected, unexpected safety or efficacy data observed during clinical studies, difficulties enrolling and conducting our clinical trials, disputes or failure to perform under the collaboration and license agreement, 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, 2023	December 31, 2022
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 218,205	$ 276,561
Total assets	249,326	299,568
Total current liabilities	16,672	10,997
Total noncurrent liabilities	16,660	18,699
Total stockholders' equity	215,994	269,872

Summary of Operations Data

(In thousands except share and per share data)

	Three Months Ended September 30		Nine Months Ended September 30	
	2023	2022	2023	2022
	(unaudited)		(unaudited)	
Collaboration revenue	$ 7,000	$ —	$ 7,000	$ —
Operating expenses:				
Research and development	23,738	13,860	63,055	36,150
General and administrative	8,789	5,067	20,780	14,978
Total operating expenses	32,527	18,927	83,835	51,128
Loss from operations	(25,527)	(18,927)	(76,835)	(51,128)
Interest income	2,820	1,390	8,376	1,906
Interest expense	(396)	(310)	(1,151)	(836)
Net loss	$ (23,103)	$ (17,847)	$ (69,610)	$ (50,058)
Net loss per common share, basic and diluted	$ (0.32)	$ (0.25)	$ (0.96)	$ (0.76)
Weighted-average shares used to compute net loss per common share, basic and diluted	72,681,645	72,153,952	72,491,870	65,730,202

View source version on businesswire.com: https://www.businesswire.com/news/home/20231113750324/en/

Investor Contact:
Gitanjali Jain
Vice President, Investor Relations and External Affairs
Kezar Life Sciences, Inc.
gjain@kezarbio.com

Media Contact:
Will Zasadny
Evoke Canale
will.zasadny@evokegroup.com

Source: Kezar Life Sciences, Inc.