Kezar Life Sciences Reports Second Quarter 2020 Financial Results and Provides Clinical and Business Update

August 5, 2020

Conference call and webcast today at 4:30pm EDT

SAN FRANCISCO--(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 announced its second quarter 2020 financial results and corporate highlights.

“Our excitement continues to build around the novel mechanism of KZR-616 and supports our conviction that targeting master regulators of cellular function – like the immunoproteasome – can benefit patients in need,” said John Fowler, Kezar’s Chief Executive Officer. “Our recent fundraising has established a strong balance sheet to allow us to prosecute our robust pipeline.”

Noreen Henig, M.D., Kezar’s Chief Medical Officer added, “We are encouraged by the striking early signs of efficacy and the favorable safety and tolerability we’ve seen with KZR-616 and believe in its potential to be a profound treatment option for a wide array of autoimmune diseases. Based on recent events, we plan to adjust our clinical development plans to optimize and expedite the development pathway for KZR-616. In addition, activities related to KZR-261, the first molecule to come forward from our protein secretion inhibition platform, continue as planned for an IND submission in the first quarter of 2021.”

Clinical Highlights & Updates

KZR-616 – Selective Immunoproteasome Inhibitor

KZR-616 is currently being evaluated for the treatment of severe autoimmune diseases.

- On June 3, 2020, Kezar provided a data update from the Phase 1b portion of the MISSION study. Overall, improvements were seen across seven measures of disease activity in a majority of patients, and two of two patients with lupus nephritis (LN) experienced a greater than 50% reduction in proteinuria, a biomarker of disease severity. A positive safety and tolerability profile was observed with step-up dosing of KZR-616. The Phase 1b dataset builds on the safety and tolerability evaluation performed in 100 healthy subjects from two Phase 1a studies.
- Based upon the positive results from the Phase 1b portion of MISSION and acknowledging the recent slowdown in recruitment activities across clinical trials due to the COVID-19 pandemic, Kezar has reviewed and adapted its clinical plans to optimize the development pathway for KZR-616. Kezar will be focusing all development efforts on 60 mg and 45 mg once-weekly subcutaneous dosing of KZR-616. This decision is based on the positive safety and tolerability, pharmacology, and clinical activity results seen to date.
- The revised clinical plan for the MISSION Phase 2 trial in patients with active, proliferative lupus nephritis include the following updates:
    - The Phase 2 protocol has been amended, and the primary endpoint has been changed from safety and tolerability to an efficacy endpoint of renal response measured by 50% or greater reduction in urine protein to creatinine ratio (UPCR) at six months. This study is now open for enrollment under the amended protocol.
        - The inclusion/exclusion criteria of the study have been expanded to include LN patients with histologic Class III or IV +/- Class V being treated with current standard-of-care. The open-label clinical trial is designed to enroll 20 patients with a single treatment arm evaluating a 60 mg dose (with first dose of 30 mg) of KZR-616 administered subcutaneously once weekly for 24 weeks.
    - Interim data are expected in late 2021. To allow for responding patients to continue treatment with KZR-616, a 12-month extension study is being planned.
- The PRESIDIO Phase 2 trial of KZR-616 in dermatomyositis and polymyositis continues to enroll. A 12-month open-label extension study is being planned and will be available for patients completing the trial.
- The MARINA study in patients with autoimmune hemolytic anemia and immune thrombocytopenia has been withdrawn. A combination of COVID-related slowdowns in screening activities and a need to substantially amend the current protocol to reduce high screen failure rates factored into this decision. No new clinical data has informed this decision, and Kezar’s scientific conviction level remains high that KZR-616 could be an important new therapy for patients with these serious diseases. Data from KZR-616 in other studies will inform the optimal strategy for the development of this product candidate in these indications.

KZR-261 – Protein Secretion Program

- KZR-261, a first-in-class protein secretion inhibitor, targets the Sec61 translocon and has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies. Additional preclinical data further detailing the ability of novel Sec61 inhibitors to exhibit broad anti-cancer activity with minimal toxicity *in vitro* and *in vivo* was presented in an e-poster during the American Society of Clinical Oncology (ASCO20) Virtual Scientific Program at the end of May.
- An Investigational New Drug application for KZR-261 is planned for submission in the first quarter of 2021. The first-in-human clinical trial will evaluate dose escalation and safety and tolerability in patients with solid tumors.

Business Update

- On June 11, 2020, Kezar closed an underwritten public offering with gross proceeds of approximately $46.7 million, before deducting underwriting discounts and commissions and offering expenses. In the public offering, Kezar issued and sold 7,590,909 shares of common stock at $5.50 per share and pre-funded warrants to purchase 909,091 shares of common stock at $5.499 per share, with an exercise price of $0.001 per share. In July, Kezar issued and sold an additional 427,707 shares of common stock at $5.50 per share, pursuant to the exercise by the underwriters of their option to purchase additional shares, with gross proceeds of approximately $2.4 million.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled $157.5 million as of June 30, 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 in February and June 2020, 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 second quarter of 2020 increased by $0.2 million to $7.1 million, compared to $6.9 million in the second quarter of 2019. This increase was primarily related to advancing the protein secretion preclinical program.
- **General and administrative expenses** for the second quarter of 2020 increased by $0.3 million to $2.7 million, compared to $2.4 million in the second quarter of 2019. The increase was primarily due to an increase in personnel expenses, including non-cash stock-based compensation.
- **Net loss** for the second quarter of 2020 was $9.5 million, or $0.22 per basic and diluted common share, compared to a net loss of $8.7 million, or $0.46 per basic and diluted common share, for the second quarter of 2019.
- **Total shares of common stock outstanding** were 45.8 million as of June 30, 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 $6.09 per share as of June 30, 2020.

Conference Call and Webcast Information

Kezar will be a hosting a conference call and webcast at 4:30 EDT today. To access the live conference call via phone, dial 877-407-9711 (U.S. toll-free) or 412-902-1014 (toll). No conference ID is required. Additionally, a live webcast of the call will be available under the Events section of Kezar's Investor Relations (IR) site at http://investors.kezarlifesciences.com/. An archived replay of the call will be available on the company's IR site for 90 days following the live call.

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 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 at 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. IND-enabling activities are currently underway, and an IND submission in solid tumors is expected to be filed in the first quarter of 2021.

About Kezar Life Sciences

Based in South San Francisco, Kezar Life Sciences is combining courage, conviction and cutting-edge science to develop 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 and inhibit multiple drivers of disease via a single target. KZR-616, a first-in-class selective immunoproteasome inhibitor, is being evaluated in severe and underserved autoimmune diseases. Additionally, KZR-261, the first clinical candidate for the treatment of cancer from the company's protein secretion program targeting the Sec61 translocon, 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, the design, progress, timing, scope and results of clinical trials, the anticipated timing of disclosure of results of clinical trials, 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. 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)

	June 30, 2020	December 31, 2019
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 157,471	$ 78,206
Total assets	168,323	89,513
Total current liabilities	5,045	6,003
Total stockholders' equity	158,318	78,046

KEZAR LIFE SCIENCES, INC.
Condensed Consolidated Statements of Operations
(Unaudited, In thousands except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	$7,148	$6,925	$14,605	$12,852
General and administrative	2,705	2,430	5,726	4,812
Total operating expenses	9,853	9,355	20,331	17,664
Loss from operations	(9,853)	(9,355)	(20,331)	(17,664)
Interest income	353	637	819	1,304
Net loss	($9,500)	($8,718)	($19,512)	($16,360)
Net loss per common share, basic and diluted	($0.22)	($0.46)	($0.51)	($0.86)
Weighted-average shares used to compute net loss per common share, basic and diluted	42,936,991	19,073,830	37,902,294	19,058,263

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