
**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 6, 2019**

KEZAR LIFE SCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(state or other jurisdiction
of incorporation)

001-38542
(Commission
File Number)

47-3366145
(I.R.S. Employer
Identification No.)

4000 Shoreline Court, Suite 300
South San Francisco, California
(Address of principal executive offices)

94080
(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 November 6, 2019, Kezar Life Sciences, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2019. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of the Company, dated November 6, 2019.

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 6, 2019

Kezar Life Sciences Reports Third Quarter 2019 Financial Results and Provides Business Update

- *Additional data from the ongoing Phase 1b portion of the MISSION study to be presented at the 2019 ACR/ARP Meeting in Atlanta, GA*
- *Phase 2 MISSION, PRESIDIO, and MARINA trials with KZR-616 are progressing*
- *KZR-261 nominated as the first oncology clinical candidate from the Protein Secretion Program*
- *Protein Secretion Program to be featured in oral and poster presentations at SITC and ASH*

SAN FRANCISCO, Calif., November 6, 2019 -- Kezar Life Sciences, Inc. (Nasdaq: [KZR](#)), a clinical-stage biotechnology company discovering and developing novel small molecule therapeutics to treat unmet needs in autoimmunity and cancer, today announced its third quarter 2019 financial results and corporate highlights.

“I commend our team’s continued execution across our clinical and preclinical programs here at Kezar. Our three Phase 2 trials with KZR-616 in severe autoimmune diseases are progressing on track, and we look forward to disclosing additional data from our MISSION study at the ACR meeting next week”, said John Fowler, Chief Executive Officer. “Additionally, the nomination of the first clinical candidate from our protein secretion program is a pivotal step for the company and underscores the depth and breadth of our R&D capabilities. Our small molecule approach to targeting the Sec61 translocon represents a highly compelling new therapeutic approach, and the preclinical data generated with KZR-261 gives us confidence that it may prove effective in treating a variety of tumor types. We are excited to share more about this highly novel target and illustrate the broad platform potential of this approach.”

Recent Clinical and Business Highlights

KZR-616 – Selective Immunoproteasome Inhibitor

MISSION Study

The Phase 1b/2 MISSION study in systemic lupus erythematosus (SLE) patients with and without nephritis is currently ongoing.

- On October 1, 2019, we presented a corporate and strategic update, including a protocol amendment for the Phase 2 portion of the MISSION study ([NCT03393013](#)). The updated protocol is designed to generate more robust and meaningful data around the safety and efficacy of KZR-616 in lupus nephritis, including the evaluation of three dose levels of KZR-616 (administered with background medication) for a treatment period of six months.
 - The Phase 1b portion of the MISSION study is ongoing and additional data will be presented during a poster session at the 2019 American College of Rheumatology (ACR) Meeting in Atlanta, GA on November 12, 2019.
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PRESIDIO Study

- In August 2019, we announced the initiation of the PRESIDIO study ([NCT04033926](#)), a Phase 2 randomized, double-blind, placebo-controlled, crossover, multicenter study to evaluate the safety, tolerability, efficacy, PK and PD of treatment with KZR-616 in patients with active dermatomyositis (DM) or polymyositis (PM). This trial is expected to enroll 24 patients with either DM or PM.

MARINA Study

- In August 2019, we announced the initiation of the MARINA study ([NCT04039477](#)), a Phase 2 randomized, dose-blind, multicenter study to evaluate the safety and efficacy of KZR-616 in the treatment of patients with autoimmune hemolytic anemia (AIHA) and immune thrombocytopenia (ITP). This trial is expected to enroll 40 patients with either AIHA or ITP.

KZR-261 – Protein Secretion Program

- Our research and discovery efforts targeting the protein secretion pathway have progressed significantly, and today, we announce the nomination of KZR-261 as our first oncology clinical candidate. KZR-261 has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies, and we have initiated laboratory studies and manufacturing activities towards an Investigational New Drug (IND) filing for a Phase 1 study in solid tumors, which we anticipate occurring in Q1 2021.
- Additionally, this novel program and pathway will be featured in four separate presentations during two major medical and scientific conferences: the Society for Immunotherapy of Cancer (SITC) and the 61st American Society of Hematology Meeting & Exposition (ASH). The abstract titles are summarized below.

SITC: November 6-10, 2019, National Harbor, MD

- Abstract Number: 815
Title: Targeting multiple immune checkpoint proteins with novel small molecule inhibitors of Sec61-dependent cotranslational translocation
Date: Friday, November 8, 2019
Time: 12:30pm – 2:00pm
Poster Session: Novel Single-Agent Immunotherapies

ASH: December 7-10, 2019, Orlando, FL

Oral Presentations

- Abstract Number: 408
Title: Blocking Protein Secretion with Novel Small Molecule Inhibitors of Sec61 Represents a Potential Treatment Strategy Against Hematologic Malignancies
Date: Sunday, December 8, 2019
Time: 10:45am
Oral Session: 802. Chemical Biology and Experimental Therapeutics: Novel Compounds and Mechanisms of Action
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- Abstract Number: 805
Title: Protein Translocation Inhibitors Overcome Cytokine-Induced Glucocorticoid Resistance in T-Cell Acute Lymphoblastic Leukemia
Date: Monday, December 9, 2019
Time: 4:30 PM
Oral Session: 605. Molecular Pharmacology, Drug Resistance—Lymphoid and Other

Poster Presentation

- Abstract Number: 2076
Title: Proteomic Profiling and Mechanistic Investigating of a Novel Anti-Cancer Small Molecule Inhibitor of Sec61
Date: Saturday, December 7, 2019
Time: 5:30 PM - 7:30 PM
Poster Session: 802. Chemical Biology and Experimental Therapeutics: Poster I

Financial Results

- **Cash, cash equivalents and marketable securities** totaled \$85.2 million as of September 30, 2019, compared to \$107.4 million as of December 31, 2018. 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 as well as preclinical research and development.
- **Research and development expenses** for the third quarter of 2019 increased by \$2.4 million to \$7.1 million compared to \$4.7 million in the third quarter of 2018. This increase was primarily related to advancing both the KZR-616 clinical program in multiple indications and the protein secretion preclinical program.
- **General and administrative expenses** for the third quarter of 2019 increased by \$1.0 million to \$2.6 million compared to \$1.6 million in the third quarter of 2018. The increase was primarily due to an increase in personnel expenses and costs related to operating as a public company.
- **Net loss** for the third quarter of 2019 was \$9.1 million, or \$0.48 per basic and diluted common share, compared to a net loss of \$5.7 million, or \$0.30 per basic and diluted common share, for the third quarter of 2018.
- **Total shares outstanding** were 19.1 million as of September 30, 2019. Additionally, there were outstanding options to purchase 3.3 million shares of common stock at a weighted average exercise price of \$7.39 per share as of September 30, 2019.

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. Phase 1a clinical trial results in healthy volunteers provide evidence that KZR-616 potentially avoids adverse effects caused by currently

marketed non-selective proteasome inhibitors, which we believe prevent them from being utilized as a chronic treatment in autoimmune disorders. Phase 2 trials are underway for the treatment of lupus nephritis (MISSION study), dermatomyositis and polymyositis (PRESIDIO study), and autoimmune hemolytic anemia and immune thrombocytopenia (MARINA study).

About KZR-261

KZR-261, a novel, first-in-class protein secretion inhibitor, is the first clinical candidate to be nominated from our research and discovery efforts targeting protein secretion pathways as potential therapies for oncology, immuno-oncology and autoimmune indications. 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 medicinal chemistry campaign in which several scaffolds were progressed through the company's proprietary work flow of Sec61 modulation. As a result, Kezar has established a unique and broad library of protein secretion inhibitors and a strong patent position around KZR-261 and its analogs. KZR-261 has demonstrated several encouraging features that lend to its potential to be a new anti-cancer agent for the treatment of solid and hematologic malignancies. IND-enabling studies are currently underway, and an IND filing in solid tumors is expected in Q1 2021.

About Kezar Life Sciences

Based in South San Francisco, Kezar Life Sciences is a clinical-stage biotechnology company committed to revolutionizing treatments for patients with autoimmune diseases and cancer. Kezar is translating its innovative research on the immunoproteasome and protein secretion pathways to advance novel therapeutic approaches. KZR-616, a first-in-class selective immunoproteasome inhibitor, is being evaluated in severe and underserved autoimmune diseases. Additionally, Kezar has nominated KZR-261 as its first clinical candidate for the treatment of cancer from its protein secretion program and will now enter into IND-enabling studies for the program. 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, 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, and the discovery and development of new product candidates. Many factors may cause differences between current expectations and actual results, including 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.

CONTACTS:

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KEZAR LIFE SCIENCES, INC.

Selected Balance Sheets Data

(In thousands)

	September 30, 2019		December 31, 2018	
	(unaudited)			
Cash, cash equivalents and marketable securities	\$	85,243	\$	107,430
Total assets		97,523		114,680
Total current liabilities		5,327		3,330
Total stockholders' equity		86,497		108,790

KEZAR LIFE SCIENCES, INC.

Condensed Consolidated Statements of Operations

(In thousands except share and per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	\$7,080	\$4,664	\$19,932	\$13,400
General and administrative	2,601	1,600	7,413	4,800
Total operating expenses	9,681	6,264	27,345	18,300
Loss from operations	(9,681)	(6,264)	(27,345)	(18,300)
Interest income	533	601	1,837	900
Net loss	(\$9,148)	(\$5,663)	(\$25,508)	(\$17,380)
Net loss per common share, basic and diluted	(\$0.48)	(\$0.30)	(\$1.34)	(\$2.30)
Weighted-average shares used to compute net loss per common share, basic and diluted	19,095,870	18,955,384	19,070,937	7,319,000