
**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):
March 12, 2020**

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 March 12, 2020, Kezar Life Sciences, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal year and quarter ended December 31, 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 March 12, 2020

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: March 12, 2020

Kezar Life Sciences Reports Fourth Quarter and Year End 2019 Financial Results and Provides Business Update

- *Phase 2 MARINA, MISSION and PRESIDIO trials with KZR-616 are progressing*
- *Additional data from the ongoing Phase 1b portion of the MISSION study to be presented during various medical conferences throughout the course of 2020*
- *KZR-261, a first-in-class protein secretion inhibitor, is currently undergoing IND-enabling activities towards filing in Q1 2021*

SAN FRANCISCO, Calif., March 12, 2020 -- 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 fourth quarter and year end 2019 financial results and corporate highlights.

“2019 marked several key milestones for Kezar, and I’m grateful for our team’s skill and hard work moving both of our programs forward. Our selective immunoproteasome inhibitor, KZR-616, entered Phase 2 trials in five different autoimmune diseases of high unmet need, building upon encouraging data from our ongoing Phase 1b study. We also nominated KZR-261, the first clinical candidate from our protein secretion program, and expect an IND filing in early 2021”, said John Fowler, Chief Executive Officer. “This year we look forward to sharing updates from the Phase 1b portion of our MISSION study, as well as an interim analysis from our MARINA trial in AIHA and ITP. Finally, after our successful financing last month, we have a strong cash position that takes us beyond all of our KZR-616 Phase 2 readouts as well as data with KZR-261 in multiple tumor types.”

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.

- Additional data from the Phase 1b portion of MISSION will be presented during various medical conferences throughout the course of 2020.
 - The Phase 2 portion of MISSION is a randomized, placebo-controlled, double-blind trial to evaluate the safety and efficacy of KZR-616 in patients with active proliferative lupus nephritis. The primary endpoints of this portion of the MISSION trial are safety and tolerability. Secondary and exploratory endpoints include pharmacokinetics (PK), pharmacodynamics (PD), biomarker assessments and additional measures of efficacy. This trial includes four treatment arms evaluating KZR-616 administered subcutaneously once weekly for 24 weeks at dose levels of 30 mg, 45 mg and 60 mg, compared to placebo. The trial is designed to enroll up to 64 patients.
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MARINA Study

The Phase 2 MARINA study in patients with autoimmune hemolytic anemia (AIHA) or immune thrombocytopenia (ITP) is currently ongoing.

- MARINA is a Phase 2 randomized, dose-blind, multicenter trial designed to evaluate the safety, tolerability, efficacy, PK and PD of KZR-616 in patients with active AIHA or ITP. Patients with AIHA or ITP will be randomized to receive either 30 mg or 45 mg of KZR-616 subcutaneously once weekly for 13 weeks, followed by 12 weeks of follow-up. The trial is designed to enroll up to 40 patients. Kezar believes that whole blood RNASeq data from the Phase 1b portion of MISSION, which showed a decrease in multiple inflammatory gene signature and prolonged increase in erythropoietic gene signatures in SLE patients, support the broad potential anti-inflammatory activity of KZR-616 and therapeutic potential in patients with AIHA.

PRESIDIO Study

The Phase 2 PRESIDIO study in patients with polymyositis (PM) or dermatomyositis (DM) is currently ongoing.

- PRESIDIO is a Phase 2 randomized, placebo-controlled, double-blind, crossover, multicenter trial to evaluate the safety, tolerability, efficacy, PK and PD of KZR-616 in patients with active PM or DM. During the 32-week treatment period, patients receive either 45 mg of KZR-616 or placebo subcutaneously once weekly for 16 weeks followed by a crossover to the other treatment arm for an additional 16 weeks. The trial is designed to enroll up to 24 patients. Kezar believes that KZR-616 has the potential to be developed into a treatment for patients with DM and PM, which is in-part supported by preclinical data in a mouse model of PM and DM that demonstrated immunoproteasome inhibition and improved muscle function.

KZR-261 – Protein Secretion Program

- Research and discovery efforts targeting the protein secretion pathway have progressed significantly, and this novel program and pathway was featured in four separate presentations during two major medical and scientific conferences in 2019: the Society for Immunotherapy of Cancer (SITC) and the 61st American Society of Hematology Meeting & Exposition (ASH).
- KZR-261, our first oncology clinical candidate and a first-in-class protein secretion inhibitor, has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies. Kezar anticipates filing an Investigational New Drug (IND) application for a Phase 1 study of KZR-261 in solid tumors in the first quarter of 2021.

Business Update

On February 4, 2020, Kezar completed an underwritten public offering of 18,965,385 shares of its common stock, which includes the full exercise of the underwriters' option, and pre-funded warrants to purchase 2,884,615 shares of its common stock at an exercise price of \$0.001 per share. The public offering price of the common stock was \$2.60 per share and the public offering price of each pre-funded warrant was \$2.599 per underlying share. The gross proceeds from the public offering were approximately \$56.8 million, before deducting underwriting discounts and offering expenses.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled \$78.2 million as of December 31, 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 fourth quarter of 2019 increased by \$2.7 million to \$7.4 million compared to \$4.7 million in the fourth quarter of 2018. Full year R&D expenses increased by \$9.2 million in 2019 compared to 2018. This increase was primarily related to advancing the KZR-616 clinical program in multiple indications and the protein secretion preclinical program.
- **General and administrative expenses** for the fourth quarter of 2019 increased by \$0.8 million to \$2.6 million compared to \$1.8 million in the fourth quarter of 2018. Full year G&A expenses increased by \$3.4 million in 2019 compared to 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 fourth quarter of 2019 was \$9.6 million, or \$0.50 per basic and diluted common share, compared to a net loss of \$5.8 million, or \$0.30 per basic and diluted common share, for the fourth quarter of 2018. Net loss for 2019 was \$35.1 million, or \$1.84 per basic and diluted common share, compared to \$23.2 million, or \$2.26 per basic and diluted common share, in 2018.
- **Total shares outstanding** were 19.2 million as of December 31, 2019. Additionally, there were outstanding options to purchase 3.1 million shares of common stock at a weighted average exercise price of \$7.19 per share as of December 31, 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 Kezar believes 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), autoimmune hemolytic anemia and immune thrombocytopenia (MARINA study), and dermatomyositis and polymyositis (PRESIDIO study).

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 application 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 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 is now undergoing IND-enabling activities 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 company's financial position and the timing and amount of future operating expenses, 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, unexpected litigation or other disputes, and the potential disruption of our business and clinical trials from the global outbreak of the novel strain of coronavirus. 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 Sheet Data**

(In thousands)

	<u>December 31, 2019</u>	<u>December 31, 2018</u>
Cash, cash equivalents and marketable securities	\$ 78,206	\$ 107,432
Total assets	89,513	114,682
Total current liabilities	6,003	3,337
Total stockholders' equity	78,046	108,797

KEZAR LIFE SCIENCES, INC.**Summary of Operations Data**

(In thousands except share and per share data)

	<u>Three Months Ended</u>		<u>Year Ended</u>	
	<u>December 31,</u>		<u>December 31,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Operating expenses:				
Research and development	\$7,431	\$4,673	\$27,363	\$18,111
General and administrative	2,566	1,753	9,979	6,500
Total operating expenses	9,997	6,426	37,342	24,711
Loss from operations	(9,997)	(6,426)	(37,342)	(24,721)
Interest income	418	644	2,255	1,500
Net loss	\$(9,579)	\$(5,782)	\$(35,087)	\$(23,161)
Net loss per common share, basic and diluted	\$(0.50)	\$(0.30)	\$(1.84)	\$(2.21)
Weighted-average shares used to compute net loss per common share, basic and diluted	19,122,074	19,005,250	19,083,826	10,264,500