
**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):
May 7, 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 May 7, 2020, Kezar Life Sciences, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended March 31, 2020. 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 May 7, 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: May 7, 2020

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

- *Noreen R. Henig, MD appointed as Chief Medical Officer*
- *Additional data from the ongoing Phase 1b portion of the MISSION study to be presented before the end of Q2 2020*
- *IND submission for KZR-261, a first-in-class protein secretion inhibitor, is on track for Q1 2021*
- *Cash, cash equivalents and marketable securities of \$123 million as of March 31, 2020*

SAN FRANCISCO, Calif., May 7, 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 first quarter 2020 financial results and corporate highlights.

“During this unprecedented health crisis, I’ve been deeply impressed by our team’s focus and continued execution across both of our programs,” said John Fowler, Kezar’s Chief Executive Officer. “We are working closely with all the sites participating in our trials with KZR-616 and look forward to sharing new data from the Phase 1b portion of our MISSION study next month. In addition, we will present more preclinical data on our novel protein secretion inhibitor, KZR-261, in an e-poster during ASCO 2020 and remain on track for an IND submission in the first quarter of 2021.”

Recent Clinical and Business Highlights

Appointment of Chief Medical Officer

Kezar appointed Noreen Roth Henig, MD as Chief Medical Officer. Dr. Henig is a seasoned leader whose career spans clinical practice, academic medicine, translational science, clinical development, medical and regulatory affairs. As an integral member of the Company’s Executive Leadership team, Dr. Henig will oversee all aspects of the Company’s clinical development, regulatory strategy, and medical affairs.

KZR-616 – Selective Immunoproteasome Inhibitor

On April 9, 2020, Kezar provided a statement on the impact of the COVID-19 pandemic to its clinical operations relating to KZR-616:

- Kezar’s three clinical trials with KZR-616 (MISSION, MARINA, and PRESIDIO) remain active, but due to the unprecedented impact of the COVID-19 pandemic on the healthcare system, delays are anticipated for Phase 2 clinical development and data release milestones.
 - Kezar’s clinical team is working closely with clinical trial sites around the world to provide them with guidance for patients to safely enroll and continue on study.
 - Home health care services are available for patients participating in clinical trials with KZR-616.
 - Virtual site initiations and patient visits are being conducted where applicable.
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- As the Phase 1b portion of the MISSION study is open-label, the next updated data release is expected by the end of the second quarter in conjunction with a major medical conference.

KZR-261 – Protein Secretion Program

- KZR-261, a first-in-class protein secretion inhibitor, has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies. Additional preclinical data will be presented in an e-poster during the American Society of Clinical Oncology (ASCO20) Virtual Scientific Program at the end of May.
- Preclinical work with KZR-261 remains on track towards the anticipated submission of an Investigational New Drug application in the first quarter of 2021.

Business Update

- On February 4, 2020, Kezar closed an underwritten public offering with gross proceeds of approximately \$56.8 million, before deducting underwriting discounts and offering expenses. In the public offering, Kezar sold 16,115,385 shares of common stock at \$2.60 per share and pre-funded warrants to purchase 2,884,615 shares of common stock at \$2.599 per share, each with an exercise price of \$0.001 per share. In addition, the underwriters exercised in full an option to purchase an additional 2,850,000 shares of common stock in the offering.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled \$123.4 million as of March 31, 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 offering in February 2020, net of cash used by the Company in operations to advance its clinical stage programs and preclinical research and development. The Company believes that its current cash, cash equivalent and marketable securities are sufficient to fund planned operations into the third quarter of 2022.
 - **Research and development expenses** for the first quarter of 2020 increased by \$1.6 million to \$7.5 million, compared to \$5.9 million in the first quarter of 2019. 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 first quarter of 2020 increased by \$0.6 million to \$3.0 million, compared to \$2.4 million in the first quarter of 2019. The increase was primarily due to an increase in personnel expenses, including non-cash stock-based compensation.
 - **Net loss** for the first quarter of 2020 was \$10.0 million, or \$0.30 per basic and diluted common share, compared to a net loss of \$7.6 million, or \$0.40 per basic and diluted common share, for the first quarter of 2019.
 - **Total shares of common stock outstanding** were 38.2 million as of March 31, 2020. Additionally, there were outstanding pre-funded warrants to purchase 2.9 million shares of common stock at an exercise price of \$0.001 per share and options to purchase 4.1 million shares of common stock at a weighted average exercise price of \$6.21 per share as of March 31, 2020.
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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 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), dermatomyositis and polymyositis (PRESIDIO), and autoimmune hemolytic anemia and immune thrombocytopenia (MARINA).

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 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 undergoing into 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 cash runway, the timing and amount of future operating expense, 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.

CONTACT:

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KEZAR LIFE SCIENCES, INC.

Selected Balance Sheets Data

(in thousands)

	<u>March 31, 2020</u>	<u>December 31, 2019</u>
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 123,350	\$ 78,206
Total assets	134,644	89,513
Total current liabilities	6,771	6,003
Total stockholders' equity	122,654	78,046

KEZAR LIFE SCIENCES, INC.

Condensed Consolidated Statements of Operations

(Unaudited, in thousands except share and per share data)

	Three Months Ended	
	March 31,	
	<u>2020</u>	<u>2019</u>
Operating expenses:		
Research and development	\$7,457	\$5,927
General and administrative	3,021	2,382
Total operating expenses	10,478	8,309
Loss from operations	(10,478)	(8,309)
Interest income	466	667
Net loss	(\$10,012)	(\$7,642)
Net loss per common share, basic and diluted	(\$0.30)	(\$0.40)
Weighted-average shares used to compute net loss per common share, basic and diluted	32,867,597	19,042,524