
**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, 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))

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.

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

Item 2.02. Results of Operations and Financial Condition.

On May 7, 2019, Kezar Life Sciences, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 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 May 7, 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: May 7, 2019

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

- *Phase 1b systemic lupus erythematosus (SLE) top-line data release and Phase 2 lupus nephritis (LN) initiation on track in Q2 2019*
- *Site selection underway for Phase 2 trial of KZR-616 for the treatment of dermatomyositis (DM) and polymyositis (PM)—trial on track to begin in 2H 2019*
- *FDA accepts Investigational New Drug (IND) Application for KZR-616 for the treatment of autoimmune hemolytic anemia (AIHA) and immune thrombocytopenia (ITP)—trial to begin in 2H 2019*
- *Nomination of oncology clinical candidate from protein secretion program planned before year end*

SAN FRANCISCO, Calif., May 7, 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 first quarter 2019 financial results and corporate highlights.

“The entire team at Kezar is excited to build on last year’s momentum and advance both of our programs in 2019,” said John Fowler, Kezar’s Chief Executive Officer. “Our strategy of evaluating KZR-616 in Phase 2 trials across multiple autoimmune indications is underway, building our case around the broad therapeutic potential of immunoproteasome inhibition. Pursuant to that goal, we look forward to reporting the first in patient data for KZR-616 at a major medical conference later this quarter. In addition, our novel protein secretion program continues to progress, with our first oncology clinical candidate anticipated to be selected this year.”

First Quarter and Recent Clinical and Business Highlights

- The United States Food and Drug Administration (FDA) accepted an IND for KZR-616 for the treatment of AIHA and ITP. A Phase 2 trial for these indications in addition to a Phase 2 trial in DM and PM are anticipated to begin 2H 2019.
 - Our SLE and LN program is advancing with enrollment continuing in the open-label dose escalation Phase 1b portion in SLE patients. We expect to report data from the first two cohorts of this portion at a major medical conference later this quarter in addition to initiating the Phase 2 portion of the trial in patients with active, proliferative LN.
 - Our protein secretion program (Sec61 translocon modulation) was showcased in two poster presentations at the American Association for Cancer Research (AACR) in Atlanta, GA on April 2,
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2019. We remain on track to nominate a first clinical candidate in oncology before the end of the year.

- In April of this year, we continued to strengthen the depth and breadth of our management team with the appointment of Mark Schiller as Vice President of Legal Affairs.

Financial Results

- **Cash, cash equivalents and marketable securities** totaled \$101.1 million as of March 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 first quarter of 2019 increased by \$2.3 million to \$5.9 million from \$3.6 million in the first quarter of 2018. This increase was primarily related to advancing both the KZR-616 clinical program across indications and the protein secretion preclinical program.
- **General and administrative expenses** for the first quarter of 2019 increased by \$0.9 million to \$2.4 million from \$1.5 million in the first quarter of 2018. The increase was primarily due to an increase in stock-based compensation, personnel expenses, and costs related to operating as a public company.
- **Net loss** for the first quarter of 2019 was \$7.6 million, or \$0.40 per basic and diluted common share, compared to a net loss of \$4.9 million, or \$6.53 per basic and diluted common share, for the first quarter of 2018.
- **Total shares outstanding** were 19.1 million as of March 31, 2019. Additionally, there were 2.8 million outstanding options granted to purchase common stock at a \$7.73 weighted average exercise price as of March 31, 2019.

About KZR-616

KZR-616 is a novel, first-in-class, selective immunoproteasome inhibitor with broad therapeutic potential across multiple autoimmune diseases. Nonclinical 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. A Phase 1b trial in systemic lupus erythematosus (SLE) is currently underway, with a Phase 2 trial in lupus nephritis (LN) expected to initiate during the second quarter of 2019. Phase 2 trials in dermatomyositis (DM), polymyositis (PM), autoimmune hemolytic anemia (AIHA), and immune thrombocytopenia (ITP) are expected to commence the second half of 2019.

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 plans to nominate an initial clinical candidate for the treatment of cancer from its protein secretion program before the end of the year. 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,” 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. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, (i) projected financing needs, (ii) the discovery and development of new product candidates, (iii) the design, progress, timing, scope and results of clinical trials, (iv) the anticipated timing of disclosure of results of clinical trials, (v) the likelihood data will support future development and (vi) the likelihood of obtaining regulatory approval of Kezar’s product candidates. 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>March 31, 2019</u>	<u>December 31, 2018</u>
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 101,134	\$ 107,433
Total assets	113,056	114,683
Total current liabilities	4,758	3,333
Total stockholders' equity	102,145	108,797

KEZAR LIFE SCIENCES, INC.**Condensed Consolidated Statement of Operations**

(In thousands except share and per share data)

	Three Months Ended	
	March 31,	
	2019	2018
	(unaudited)	
Operating expenses:		
Research and development	\$ 5,927	\$ 3,577
General and administrative	2,382	1,511
Total operating expenses	8,309	5,088
Loss from operations	(8,309)	(5,086)
Interest income	667	131
Net loss	\$ (7,642)	\$ (4,947)
Net loss per common share, basic and diluted	\$ (0.40)	\$ (6.53)
Weighted-average shares used to compute net loss per common share, basic and diluted	19,042,524	757,391