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): August 7, 2019

KEZAR LIFE SCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38542**	**47-3366145**
(state or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

4000 Shoreline Court, Suite 300 South San Francisco, California	**94080**
(Address of principal executive offices)	**(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 August 7, 2019, Kezar Life Sciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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.

Exhibit No.	Description
99.1	Press release of the Company, dated August 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: August 7, 2019

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

- *Promising data reported from the Phase 1b portion of MISSION, a first-in-patient study of KZR-616; Phase 2 portion of MISSION in LN patients has been initiated*
- *Phase 2 PRESIDIO and MARINA trials have been initiated evaluating KZR-616 in DM, PM, AIHA, and ITP patients*
- *Nomination of first oncology clinical candidate from protein secretion program on track before year end*
- *Niti Goel, MD, Chief Medical Officer, will depart to pursue new professional opportunities following a transition period*

SAN FRANCISCO, Calif., August 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 second quarter 2019 financial results and corporate highlights.

“I’m proud of the tremendous progress made by the team over the quarter, culminating with the first-in-patient data reported with KZR-616,” said John Fowler, Chief Executive Officer. “The broad therapeutic potential demonstrated thus far by KZR-616 reinforces our view that selective immunoproteasome inhibition can target multiple autoimmune diseases. To that end, in addition to having initiated the Phase 2 portion of the MISSION study in lupus nephritis patients, we are pleased to announce that the Phase 2 PRESIDIO and MARINA trials have commenced in four additional autoimmune indications—dermatomyositis, polymyositis, autoimmune hemolytic anemia, and immune thrombocytopenia. Furthermore, we remain on-track to nominate the first oncology clinical candidate from our novel protein secretion program before the end of the year.”

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.

- We reported promising data with KZR-616 in patients with SLE at the European League Against Rheumatism (EULAR) 2019 Annual Meeting. Initial data were reported from 3 cohorts of the open-label dose escalation portion of the trial (Phase 1b). The study met its objectives by establishing the safety and tolerability of KZR-616 and identifying doses to advance into our Phase 2 clinical trials.

- Enrollment to the Phase 1b portion of the MISSION study is ongoing and updated data from cohorts testing step-up dosing to a 60 mg dose are expected in Q4 2019.

- The Phase 2 portion of the MISSION study, which is evaluating KZR-616 for the treatment of lupus nephritis (LN), was initiated.

PRESIDIO Study

- We recently initiated the PRESIDIO study (NCT04033926). This is 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). The trial is expected to enroll 24 patients with either DM or PM.

MARINA Study

- We recently initiated the MARINA study (NCT04039477). MARINA is 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). The trial is expected to enroll 40 patients with either AIHA or ITP.

Protein Secretion Program (Sec61 translocon modulation)

- Our research and discovery efforts targeting the protein secretion pathway as a potential therapy for oncology indications is progressing well, and we remain on track to nominate a first clinical candidate before the end of the year.

Management Update

Kezar announced today that Niti Goel, MD, Chief Medical Officer, will be departing the company following a transition period ending October 1, 2019.

“On behalf of the Executive Team and Board of Directors, I would like to sincerely thank Niti for her contributions during her tenure at Kezar,” said John Fowler, Chief Executive Officer. “Niti’s exceptional skill designing innovative clinical trials and her unwavering commitment to patients has positioned KZR-616 for success in our Phase 2 studies and will be missed.”

Financial Results

- **Cash, cash equivalents and marketable securities** totaled $93.4 million as of June 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 second quarter of 2019 increased by $1.7 million to $6.9 million from $5.2 million in the second 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 second quarter of 2019 increased by $0.7 million to $2.4 million from $1.7 million in the second 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 second quarter of 2019 was $8.7 million, or $0.46 per basic and diluted common share, compared to a net loss of $6.8 million, or $3.31 per basic and diluted common share, for the second quarter of 2018.

- **Total shares outstanding** were 19.1 million as of June 30, 2019. Additionally, there were outstanding options to purchase 2.9 million shares of common stock at a $8.02 weighted average exercise price as of June 30, 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. Phase 2 trials have commenced for the treatment of lupus nephritis (MISSION study), dermatomyositis and polymyositis (PRESIDIO study), and autoimmune hemolytic anemia and immune thrombocytopenia (MARINA study).

About Protein Secretion

We are conducting research and discovery efforts targeting protein secretion pathways as potential therapies for oncology and immuno-oncology indications. In mammalian cells, the secretion of proteins such as cytokines and the expression of cell surface transmembrane proteins such as cytokine receptors involve a process called cotranslational translocation. For most proteins, this process occurs via the Sec61 translocon, a highly conserved multi-subunit protein complex found in the membrane of the endoplasmic reticulum of all cells. Inhibition of the Sec61 translocon with small molecules blocks the secretion of some or all proteins, which can result in several physiologic outcomes, including altered cellular function, inhibition of cytokine release and/or cell death. We believe this platform has the potential to yield oral small molecule alternatives to currently marketed biologic therapeutics, to act as cytotoxic anti-cancer agents or to block the secretion of novel targets of interest in immuno-oncology or inflammation.

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, 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. 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:
Celia Economides
SVP, Strategy & External Affairs
ceconomides@kezarbio.com

KEZAR LIFE SCIENCES, INC.
Selected Balance Sheets Data
(In thousands)

	June 30, 2019	December 31, 2018
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 93,423	$ 107,432
Total assets	105,267	114,682
Total current liabilities	4,735	3,337
Total stockholders' equity	94,603	108,797

KEZAR LIFE SCIENCES, INC.

Condensed Consolidated Statements of Operations

(In thousands except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	$6,925	$5,228	$12,852	$8,800
General and administrative	2,430	1,722	4,812	3,236
Total operating expenses	9,355	6,950	17,664	12,036
Loss from operations	(9,355)	(6,950)	(17,664)	(12,036)
Interest income	637	175	1,304	314
Net loss	($8,718)	($6,775)	($16,360)	($11,722)
Net loss per common share, basic and diluted	($0.46)	($3.31)	($0.86)	($8.35)
Weighted-average shares used to compute net loss per common share, basic and diluted	19,073,830	2,044,027	19,058,263	1,404,392