
**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 5, 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 November 5, 2020, Kezar Life Sciences, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended September 30, 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 November 5, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 5, 2020

Kezar Life Sciences Reports Third-Quarter 2020 Financial Results and Provides Business Updates

- *FDA grants two Orphan Drug Designations to KZR-616 for the treatment of Dermatomyositis (DM) and Polymyositis (PM)*
- *KZR-616 clinical and pre-clinical data continues to support its potential to positively affect multiple drivers of immune-mediated diseases*
- *KZR-261 IND submission on-track for Q1 2021*

SOUTH SAN FRANCISCO, Calif., November 5, 2020 -- Kezar Life Sciences, Inc. (Nasdaq: KZR), a clinical-stage biotechnology company discovering and developing breakthrough treatments for immune-mediated and oncologic disorders, today announced its third-quarter 2020 financial results and corporate highlights.

“The third quarter of 2020 saw continued momentum for Kezar, punctuated by the U.S. FDA granting Orphan Drug Designations for our lead candidate KZR-616 for the treatment of polymyositis and dermatomyositis,” said John Fowler, Kezar’s Co-Founder and Chief Executive Officer. “In addition, our presentations at a number of medical and scientific meetings this fall highlight the compelling therapeutic potential of our two highly novel programs in immunoproteasome inhibition and the protein secretion pathway. With each step forward, our conviction deepens that Kezar’s novel small molecule approaches autoimmunity and oncology could have profound impacts on a wide array of diseases with high unmet need.”

Clinical Highlights & Updates

KZR-616: Selective Immunoproteasome Inhibitor

KZR-616 is currently being evaluated for the treatment of severe autoimmune diseases.

- In October 2020, Orphan Drug Designations (ODD) were granted for KZR-616 in both dermatomyositis (DM) and polymyositis (PM) by the U.S. Food and Drug Administration (FDA). Both orphan diseases are autoimmune inflammatory myopathies that are chronic and debilitating diseases characterized by marked morbidity and mortality. The estimated prevalence of DM and PM in the United States is up to 71,000 and 51,000, respectively. Orphan Drug Designation can provide certain benefits for the development of KZR-616, including a period of marketing exclusivity for the first marketing application, if approved for the designated indication, certain tax credits and waiver of certain administrative fees.
 - The MISSION Phase 2 trial in patients with active, proliferative lupus nephritis (LN) opened for enrollment under a new protocol in August 2020. The primary efficacy endpoint for the trial is the number of patients achieving a renal response measured by a 50% or greater reduction in urine protein to creatinine ratio (UPCR) at six months.
 - Interim data are expected in late 2021, and topline data are expected in the first half of 2022. To allow for responding patients to continue treatment with KZR-616, a 12-month extension study will also be made available.
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- Updated results from the MISSION Phase 1b portion were presented at the American College of Rheumatology Annual Meeting (ACR Convergence 2020) in November 2020. These results indicate that KZR-616 60mg administered subcutaneously weekly is well-positioned for development as a long-term treatment option in autoimmune disease.
- The PRESIDIO Phase 2 trial of KZR-616 in polymyositis (PM) and dermatomyositis (DM) continues to enroll. A 12-month open-label extension study has been initiated for patients completing the placebo-controlled trial.
 - Topline data are expected in the first half of 2022.
 - Pre-clinical results of KZR-616 in a murine model of polymyositis were presented during ACR Convergence 2020. The results provide a rationale for targeting selective immunoproteasome inhibition for the treatment of polymyositis.

KZR-261: Protein Secretion Program

- KZR-261, a first-in-class protein secretion inhibitor, targets the Sec61 translocon and has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies. Additional preclinical data further detailing the ability of novel small molecule Sec61 inhibitors to target multiple checkpoint proteins on various cell populations, thereby offering the potential of combination therapy in a single compound, are being presented during the 8th Annual Meeting of the International Cytokine & Interferon Society (Cytokines 2020) and the Society for the Immunotherapy of Cancer (SITC) in November 2020.
- An Investigational New Drug (IND) application for KZR-261 is on-track for a planned submission in the first quarter of 2021. The Phase 1 clinical trial will evaluate dose escalation and safety and tolerability in patients with solid tumors to begin shortly after IND acceptance.

Third-Quarter 2020 Financial Results

- **Cash, cash equivalents and marketable securities** totaled \$150.0 million as of September 30, 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 Kezar's underwritten public offerings in February and June 2020, net of cash used by the Company in operations to advance its clinical stage programs and preclinical research and development.
 - **Research and development expenses** for the third quarter of 2020 increased by \$1.2 million to \$8.3 million, compared to \$7.1 million in the third 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 third quarter of 2020 increased by \$0.7 million to \$3.3 million, compared to \$2.6 million in the third quarter of 2019. The increase was primarily due to an increase in personnel expenses, including non-cash stock-based compensation, legal and professional fees.
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- **Net loss** for the third quarter of 2020 was \$11.3 million, or \$0.23 per basic and diluted common share, compared to a net loss of \$9.1 million, or \$0.48 per basic and diluted common share, for the third quarter of 2019.
- **Total shares of common stock outstanding** were 46.3 million as of September 30, 2020. Additionally, there were outstanding pre-funded warrants to purchase 3.8 million shares of common stock at an exercise price of \$0.001 per share and outstanding options to purchase 4.5 million shares of common stock at a weighted average exercise price of \$6.12 per share as of September 30, 2020.

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 clinical trials provide evidence that KZR-616 exhibits a favorable safety and tolerability profile for development in severe, chronic autoimmune diseases. Phase 2 trials are underway in severe autoimmune diseases.

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 by 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 combining courage, conviction and cutting-edge science to develop breakthrough treatments for immune-mediated and oncologic disorders. The company is pioneering first-in-class, small-molecule therapies that harness master regulators of cellular function and inhibit multiple drivers of disease via a single target. KZR-616, a first-in-class selective immunoproteasome inhibitor, is being evaluated in severe and underserved autoimmune diseases. Additionally, KZR-261, the first clinical candidate for the treatment of cancer from the company's protein secretion program targeting the Sec61 translocon, is undergoing IND-enabling activities. 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, plans for initiating future clinical trials and extension studies, 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. Orphan Drug Designation does not provide any assurance of regulatory approval or expedite regulatory review. 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>September 30, 2020</u>	<u>December 31, 2019</u>
	(unaudited)	
Cash, cash equivalents and marketable securities	\$ 149,954	\$ 78,206
Total assets	161,210	89,513
Total current liabilities	6,193	6,003
Total stockholders' equity	150,323	78,046

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

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
	<u>(unaudited)</u>		<u>(unaudited)</u>	
Operating expenses:				
Research and development	\$8,259	\$7,080	\$22,864	\$19,932
General and administrative	3,292	2,601	9,018	7,413
Total operating expenses	11,551	9,681	31,882	27,345
Loss from operations	(11,551)	(9,681)	(31,882)	(27,345)
Interest income	262	533	1,081	1,837
Net loss	<u>(\$11,289)</u>	<u>(\$9,148)</u>	<u>(\$30,801)</u>	<u>(\$25,508)</u>
Net loss per common share, basic and diluted	<u>(\$0.23)</u>	<u>(\$0.48)</u>	<u>(\$0.73)</u>	<u>(\$1.34)</u>
Weighted-average shares used to compute net loss per common share, basic and diluted	<u>49,999,239</u>	<u>19,095,870</u>	<u>41,964,042</u>	<u>19,070,937</u>