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):
January 30, 2020

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** **(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 8.01 Other Events.

On January 30, 2020, Kezar Life Sciences, Inc. (the "Company") filed with the Securities and Exchange Commission (the "SEC") a preliminary prospectus supplement in connection with a proposed public offering of shares of the Company's common stock, par value $0.001 per share ("Common Stock"), and pre-funded warrants to purchase shares of its Common Stock. The preliminary prospectus supplement contains an updated description of certain aspects of the Company's business and certain risk factors. Accordingly, the Company is filing this information with this Current Report on Form 8-K for the purpose of supplementing and updating disclosures contained in the Company's prior filings with the SEC, including those discussed under the heading "Item 1A. Risk Factors," in the Company's most recent Annual Report on Form 10-K for the ended December 31, 2018, filed with the SEC on March 26, 2019. The updated disclosures are filed herewith as Exhibit 99.1 and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Updated Company Disclosures.

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: January 30, 2020

As used in this Exhibit 99.1, unless the context indicates otherwise, references to "Kezar," "the Company," "we," "us," "our" and similar references refer to Kezar Life Sciences, Inc. and its wholly owned Australian subsidiary, Kezar Life Sciences Australia Pty Ltd.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Exhibit 99.1 contains forward-looking statements. In some cases, you can identify these statements by forward-looking words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "should," "would," "potential," "project," "plan," "expect," "seek," "should," "target" or similar expressions, or the negative or plural of these words or expressions. These forward-looking statements include statements concerning the following:

- our plans to develop and commercialize our product candidates;
- the initiation, timing, progress and expected results of our current and future clinical trials and our research and development programs;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to successfully acquire or in-license additional product candidates or other technology on reasonable terms;
- our ability to maintain and establish collaborations or strategic relationships or obtain additional funding;
- the timing and likelihood of obtaining regulatory approval of our current and future product candidates;
- our expectations regarding the potential market size and the rate and degree of market acceptance of such product candidates;
- our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources;
- the implementation of our business model and strategic plans for our business and product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights and the duration of our patent rights covering our product candidates;
- developments or disputes concerning our intellectual property or other proprietary rights;
- the scalability and commercial viability of our manufacturing methods and processes;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to compete in the markets for our product candidates;
- the impact of government laws and regulations;
- developments relating to our competitors and our industry; and
- the factors that may impact our financial results.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. Discussions containing these forward-looking statements may be found, among other places, in the sections titled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" incorporated by reference from our most recent Annual Report on Form 10-K and most recent Quarterly Report on Form 10-Q, as well as any amendments thereto, filed with the SEC. You should not rely upon forward-looking statements as predictions of future events.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we are under no duty to update or revise any of the forward-looking statements in this Exhibit 99.1, whether as a result of new information, future events or otherwise.

Company Overview

We are a clinical-stage biotechnology company, discovering and developing novel small molecule therapeutics to treat unmet needs in autoimmunity and cancer. Our lead product candidate, KZR-616, a first-in-class selective immunoproteasome inhibitor, has completed testing in healthy volunteers, and we are now enrolling patients in both phases of the MISSION trial, a Phase 1b/2 clinical trial in systemic lupus erythematosus, also known as lupus or SLE, and lupus nephritis. We believe that the immunoproteasome is a validated target for the treatment of a wide variety of autoimmune diseases given the compelling published activity seen with non-selective proteasome inhibitors administered to patients with severe autoimmune diseases. Based on results from our Phase 1a studies in healthy volunteers and the preliminary results from the Phase 1b portion of the MISSION trial, KZR-616 has largely avoided adverse effects associated with currently marketed non-selective proteasome inhibitors, as exhibited in clinical studies conducted by third parties, including side effects which we believe prevent them from being utilized as a chronic treatment in autoimmune disorders. We intend to develop KZR-616 to address underserved autoimmune diseases. The Phase 2 portion of the MISSION trial is evaluating KZR-616 for the treatment of lupus nephritis, for which there are currently no drugs approved by the Food and Drug Administration, or FDA. We are also leveraging the broad therapeutic potential of KZR-616 to develop the product candidate in four additional autoimmune indications: dermatomyositis, or DM, polymyositis, or PM, autoimmune hemolytic anemia, or AIHA, and immune thrombocytopenia, or ITP.

Additionally, we are advancing our novel research platform targeting the Sec61 translocon and the protein secretion pathway to discover and develop small molecule therapeutics targeting oncology indications. We believe this discovery platform has the potential to yield oral small molecule candidates that, if successfully developed and approved, could serve as 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. Our first clinical candidate in this program, KZR-261, has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies. KZR-261 is undergoing laboratory studies and manufacturing activities in support of an investigational new drug, or IND, application, which we anticipate submitting to the FDA in the first quarter of 2021 for a Phase 1 clinical trial in solid tumors.

KZR-616: Selective Immunoproteasome Inhibitor

We believe that KZR-616 has potential to be developed for the treatment of multiple autoimmune disease indications. In the last decade, research directed by our Chief Scientific Officer, along with work performed in multiple academic laboratories, has led to over 15 peer-reviewed publications showing that selective immunoproteasome inhibition resulted in a broad anti-inflammatory response, reducing autoimmune disease in animal models of lupus, lupus nephritis, rheumatoid arthritis, inflammatory bowel disease, multiple sclerosis, Type 1 diabetes and other indications. This immunomodulatory response was broadly seen across many cell types of the immune system, including both T cells and B cells, and was demonstrated in a safe and non-immunosuppressive manner. This is distinct from other agents currently used to treat autoimmunity, which typically target a single cytokine or immune cell type or are broadly immunosuppressive.

Autoimmunity and Selective Inhibition of the Immunoproteasome

Autoimmune disease is an immune response directed against the body's own healthy cells and tissues. Approximately 50 million people in the United States suffer from more than 100 diagnosed autoimmune diseases according to the American Autoimmune Related Diseases Association, Inc. In indications large and small, there remain significant unmet medical needs and indications with no approved drugs beyond broadly prescribed corticosteroids and similar immunosuppressive regimens. These result in increased risk of infection and malignancy and a wide variety of side effects. In diseases such as lupus nephritis, these regimens do not induce high rates of clinically meaningful responses.

Found in all cells of the body, proteasomes regulate intracellular protein degradation and are essential for many cellular processes such as cell division, cell differentiation and cytokine production. There are two main forms of the proteasome: the constitutive proteasome and the immunoproteasome. In most tissues of the body, the constitutive proteasome is the predominant form. In cells of the immune system, the immunoproteasome is the predominant form. While both forms of the proteasome mediate protein degradation, the two forms of the proteasome accomplish this utilizing different active sites. These active sites are responsible for cleaving and degrading proteins. Selective inhibition of the immunoproteasome has the potential to reduce inflammation by targeting dysfunctional immune cells involved in autoimmunity, such as T cells and B cells, without causing widespread immunosuppression.

Safety and Efficacy of Approved Proteasome Inhibitors

The three proteasome inhibitors approved for the treatment of multiple myeloma, Velcade® (bortezomib), Kyprolis® (carfilzomib) and Ninlaro® (ixazomib), are potent "dual inhibitors" of both the immunoproteasome and the constitutive proteasome. This dual-targeting profile is necessary to make them effective treatments for multiple myeloma. However, dual proteasome inhibition is associated with hematologic issues such as thrombocytopenia, neutropenia and anemia, as well as constitutional toxicities such as fatigue and myalgia. In addition, Velcade and Ninlaro are associated with risk of peripheral neuropathy, likely due to the off-target activity of these drugs against proteins found in peripheral neurons.

Velcade has demonstrated clinical activity in several autoimmune diseases, including lupus, lupus nephritis, rheumatoid arthritis, immune thrombocytopenia, autoimmune hemolytic anemia, primary Sjögren's syndrome and graft-versus-host disease. In preclinical models, proteasome inhibition with Velcade blocked production of most inflammatory cytokines, including many of those targeted by current biologic drugs. However, long-term, chronic administration of Velcade in the setting of autoimmune diseases is not considered feasible due to its side effect profile, in particular hematologic toxicities and risk of peripheral neuropathy. As a result, we believe that this promising drug target has remained untapped for use in the chronic treatment of autoimmune diseases.

We believe we are the only company with a selective immunoproteasome inhibitor that is in clinical trials for the treatment of autoimmune disorders. In addition, we believe that KZR-616, if successfully developed and approved, may have the ability to become the standard of care across a broad range of autoimmune diseases based on the following expected key attributes:

- broad immunomodulatory activity that may allow it to outperform approved therapies and to work in indications where other drugs have failed;
- low infection rates observed in clinical trials to date, which indicates a potential lack of immunosuppression, a key drawback to other approved therapies in autoimmunity; and
- avoidance of systemic toxicities associated with dual proteasome inhibitors and the peripheral neuropathy associated with Velcade and Ninlaro.

Clinical Development of KZR-616

We are focusing our initial development of KZR-616 in severe orphan autoimmune diseases where limited treatment options exist. Currently, there are no approved treatments for lupus nephritis or AIHA in the United States or Europe, and there are limited approved treatments for DM, PM, and ITP in the United States and Europe. We estimate the addressable patient population in the United States for lupus, lupus nephritis, DM/PM and AIHA/ITP to be 460,000, 100,000 to 200,000, 70,000 and 140,000, respectively.

We have opened three Phase 2 trials across five separate autoimmune diseases of high unmet need: the MISSION trial in patients with lupus nephritis; the PRESIDO trial in patients with DM and PM; and the MARINA trial in patients with AIHA and ITP.

Phase 2 Clinical Trials

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, or PK, pharmacodynamics, or 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. We expect to enroll 64 patients.

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. We expect to enroll 24 patients in the trial. We believe 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.

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. We expect to enroll 40 patients in the trial. We believe that whole blood RNASeq data from 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 an application in patients with AIHA.

Phase 1 Clinical Trials

We have conducted and presented at medical conferences the results of two Phase 1a studies evaluating KZR-616 in healthy volunteers. Results from these studies, involving administration of two different formulations of KZR-616 to a total of 100 healthy volunteers, demonstrated that KZR-616 was well tolerated in up to 75 mg (the highest tested dose). We believe that these results support development of KZR-616 in autoimmune disorders based on the following observations:

- consistent and reproducible pharmacology;
- a distinct safety profile from dual proteasome inhibitors as a class; and
- an encouraging safety and tolerability profile.

The Phase 1b portion of MISSION is an open-label, dose escalation and dose-finding study in patients with active lupus with or without lupus nephritis who have received at least one standard therapeutic regimen. Patients receive 13 weeks of weekly subcutaneous treatment, followed by 12 weeks of follow-up. Preliminary data generated from the Phase 1b portion of the MISSION trial, almost exclusively in SLE patients, continues to support the advancement of KZR-616 into Phase 2 trials across multiple autoimmune indications. As of the September 2019 data cutoff, the Phase 1b portion of MISSION enrolled 32 patients across four cohorts. Results presented at both the European League Against Rheumatism (EULAR) and American College of Rheumatology (ACR) Conferences in 2019 showed that KZR-616:

- was well tolerated for 13 weeks of treatment;
- largely avoided toxicities seen with dual proteasome inhibitors in third-party clinical trials;
- exhibited low rates of infection (which suggest immunomodulatory activity without inducing immunosuppressive side effects);
- induced broad improvement across seven measured parameters of disease activity across organ systems;
- showed a broad anti-inflammatory gene expression response as evidenced by whole blood RNASeq data;
- demonstrated consistent, dose proportional PK; and
- reached target levels of immunoproteasome inhibition with all dose levels.

Broad and consistent improvements were seen across multiple measures and assessments of disease activity. Of the 16 patients completing 13 weeks of treatment:

- 94% had a numerical improvement on at least four measured parameters or assessments of disease activity;
- 75% had at least a two-point decrease in Systemic Lupus Erythematosus Disease Activity Index 2000, or SLEDAI;

- 67% had at least a four-point decrease in Cutaneous Lupus Erythematosus Severity Index-Activity, or CLASI-A (where baseline was at least four); and
- 56% had at least a 50% improvement in tender joint counts and swollen joint counts.

Additionally, Physician Global Assessment, Patient Global Assessment, and Patient Assessment of Pain were reduced by at least ten points in 50%, 75% and 69% of the 16 patients who completed 13 weeks of treatment, respectively. Step-up dosing to 60 mg exhibited improved tolerability, such that nausea and vomiting were reported in less than 20% of patients, and discontinuation rates declined from 38% to 20% compared to the cohort receiving an initial dose of 60 mg.

A single patient with active proliferative lupus nephritis, who completed the trial following the last data cutoff, was enrolled in the Phase 1b portion of the study and was treated at 45 mg after initial doses of 30 mg. The patient is a 29-year old Asian female who was diagnosed with lupus nephritis in 2015. She entered the study with a positive antinuclear antibody test, low complement levels, proliferative lupus nephritis, a near-nephrotic range of proteinuria with a 3.85 mg/mg urine protein to creatinine ratio, or UPCR, and a baseline SLEDAI score of 17, indicative of severe disease. The UPCR dropped to 0.6 mg/mg at week 17 (four weeks after the last dose of KZR-616), and the SLEDAI score dropped to 8 at week 13, which was maintained through the follow-up period to week 25. The investigator believes that the unexpected drop and maintenance in UPCR was probably due to KZR-616. The patient also experienced one serious adverse event after the first dose of 30 mg, which was related to a first dose effect of fever, thus she was maintained at 45 mg until the end of her treatment.

We caution that these data from the Phase 1b portion of the MISSION trial are preliminary, particularly with respect to the single patient described above, and will require confirmation in additional patients as well as longer follow-up to draw any clinical conclusion. In addition, these preliminary data should not be viewed as an indication, belief or guarantee that other patients enrolled in the MISSION trial will achieve similar results or that the preliminary results from this patient will be maintained. For more information about the risks of preliminary clinical data, including the risk that the preliminary data from this single patient enrolled in the MISSION trial to date may not be maintained or replicated in that patient or in any other enrolled patients, see "Risks Related to the Development and Commercialization of Our Product Candidates—*Interim top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data*."

Protein Secretion and the Sec61 Translocon

We are conducting research and discovery efforts targeting protein secretion pathways as potential therapies for oncology and immuno-oncology indications. We believe that targeting this pathway has the potential to inhibit multiple therapeutically relevant targets with a single small molecule.

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 nearly all secreted and transmembrane proteins (approximately 5,000 to 7,000 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. Our scientists have been researching the protein secretion pathway and ways to therapeutically target this key aspect of cellular function for more than five years. We have developed several novel experimental platforms to study small molecule inhibitors of Sec61, 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 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 inflammation or immuno-oncology.

In December 2019, we highlighted our work from the protein secretion platform during the 61st American Society of Hematology (ASH) Annual Meeting. Our preclinical research on the Sec61 transolocon demonstrated high degrees of potency against a large number of therapeutically relevant oncology and immuno-oncology targets that are Sec61 client proteins, translating into broad anti-tumor activity. Our discovery-stage Sec61 inhibitors have shown to induce anti-tumor activity against multiple hematologic tumor types without inducing cell death in normal cells or significant toxicity in animals. Genomic and proteomic analysis reveal a proteotoxic stress response as a potential biomarker for sensitivity across multiple tumor types, and we have observed synergy with proteasome inhibitors in multiple myeloma models.

KZR-261

KZR-261, a novel, first-in-class protein secretion inhibitor, is the first clinical candidate to be nominated from our 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 medicinal chemistry campaign in which several scaffolds were progressed through our proprietary workflow of protein secretion assays. As a result, we have established a unique and broad library of protein secretion inhibitors and a strong patent position around KZR-261 and its analogs. We have observed encouraging data with KZR-261 that exhibit its potential to be a new anti-cancer agent for the treatment of solid and hematologic malignancies. It has been shown to induce simultaneous inhibition of multiple, clinically relevant proteins including oncogenic drivers, angiogenic factors and immune checkpoints. The preclinical data generated with KZR-261 increases our confidence that inhibiting the Sec61 translocon may treat a variety of solid and hematologic tumor types. IND-enabling studies are currently underway, and we expect to file an IND application for the treatment of solid tumors in the first quarter of 2021.

Our Pipeline

The following table sets forth the status and initial focus of our lead product candidate and protein secretion program:

Compound	Therapeutic Indication	Development Stage				Anticipated Milestones
		Preclinical	Ph1	Ph2	Ph3	
Selective Immunoproteasome Inhibition						
KZR-616	Autoimmune Hemolytic Anemia (AIHA)/ Immune Thrombocytopenia (ITP)			MARINA		Interim: Q4 '20 Final Data: 1H '21
	Lupus Nephritis (LN)			MISSION		Interim: 1H '21 Final Data: 2H '21
	Dermatomyositis (DM)/ Polymyositis (PM)			PRESIDIO		Final Data: 2H '21
Protein Secretion Inhibition						
KZR-261	Oncology					IND Solid Tumors: Q1 '21
KZR-TBD	Oncology & Autoimmunity					

Risks Related to the Development and Commercialization of Our Product Candidates

Interim top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Preliminary or top-line data may include, for example, data regarding a small percentage of the patients enrolled in a clinical trial, and such preliminary data should not be viewed as an

indication, belief or guarantee that other patients enrolled in such clinical trial will achieve similar results or that the preliminary results from such patients will be maintained. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.