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): **October 28, 2019**

Kiniksa Pharmaceuticals, Ltd.
(Exact name of Registrant as Specified in Its Charter)

Bermuda	**001-730430**	**98-1327726**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

Kiniksa Pharmaceuticals, Ltd.
Clarendon House
2 Church Street
Hamilton HM11, Bermuda
(808) 451-3453
(Address, zip code and telephone number, including area code of principal executive offices)

Kiniksa Pharmaceuticals Corp.
100 Hayden Avenue
Lexington, MA, 02421
(781) 431-9100
(Address, zip code and telephone number, including area code of agent for service)

N/A
(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

- ☐ 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(s)**	**Name of each exchange on which registered**
Class A Common Shares $0.000273235 par value	KNSA	The Nasdaq Global Select Market

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 October 28, 2019, Kiniksa Pharmaceuticals, Ltd. (the "Company") issued a press release announcing financial results for the quarter ended September 30, 2019. A copy of the press release is furnished with this Current Report on Form 8-K as Exhibit 99.1.

The information contained in this Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 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 in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, regardless of any general incorporation language in such filing and except as expressly provided by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Q3 Earnings Press Release issued by Kiniksa Pharmaceuticals, Ltd. dated October 28, 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.

KINIKSA PHARMACEUTICALS, LTD.

Date: October 28, 2019

By: /s/ Thomas Beetham
Thomas Beetham
Chief Legal Officer

Exhibit 99.1

Kiniksa Reports Third Quarter 2019 Financial Results and Highlights Recent Corporate and Pipeline Activity

— Clinical data readouts expected throughout 2020 for rilonacept, mavrilimumab, KPL-716 and KPL-404 —

— Operating plan funded into 2H 2021; no current plan to raise additional capital prior to delivering clinical data readouts —

— Final rilonacept Phase 2 data to be presented at the American Heart Association Scientific Sessions 2019 —

— First subject dosed in first-in-human trial of KPL-404 —

HAMILTON, BERMUDA — October 28, 2019 — Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) ("Kiniksa"), a biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutic medicines for patients with significant unmet medical need, today reported third quarter 2019 financial results and highlighted recent corporate and pipeline activity.

"We expect 2020 to be a pivotal year for Kiniksa," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "Our resources are focused on the lead indications for our clinical-stage assets and we expect clinical data readouts from each of them in 2020, including pivotal Phase 3 data for rilonacept in recurrent pericarditis, Phase 2 data for mavrilimumab in giant cell arteritis and Phase 2a data for KPL-716 in prurigo nodularis. Importantly, our projected cash runway extends into the second half of 2021 and we do not anticipate raising additional capital before delivering these clinical milestones."

Pipeline Activity

Rilonacept (IL-1α and IL-1β cytokine trap)

- Kiniksa is advancing rilonacept for the potential treatment of recurrent pericarditis, a painful autoinflammatory cardiovascular disease.

- Kiniksa is enrolling RHAPSODY, a global, randomized-withdrawal design, pivotal Phase 3 clinical trial of rilonacept in patients with recurrent pericarditis in the U.S., Australia, Israel and Italy. Top-line data are expected in the second half of 2020.

- Kiniksa continues to advance its launch readiness activities for rilonacept, including generation of evidence on unmet need and disease burden, and research and education with payers, physicians and advocacy groups.

Mavrilimumab (monoclonal antibody inhibitor targeting GM-CSFRα)

- Kiniksa is advancing mavrilimumab for the potential treatment of giant cell arteritis (GCA), a chronic inflammatory disease of medium-large arteries.

    - Kiniksa is enrolling a global Phase 2 proof-of-concept clinical trial of mavrilimumab in patients with GCA in fifteen countries. Top-line data are expected in the second half of 2020.

KPL-716 (monoclonal antibody inhibitor of signaling through OSMRβ)

- Kiniksa is advancing KPL-716 for the potential treatment of a variety of pruritic diseases, including prurigo nodularis, a chronic inflammatory skin condition.

    - Kiniksa is enrolling a Phase 2a clinical trial of KPL-716 in patients with prurigo nodularis. Top-line data are expected in the first half of 2020.

    - Kiniksa is enrolling an exploratory Phase 2 clinical trial of KPL-716 in diseases characterized by chronic pruritus and plans to have interim data in a limited number of cohorts in the first half of 2020.

- Kiniksa announced interim data from a repeated-single-dose Phase 1b clinical trial of KPL-716 in patients with moderate-to-severe atopic dermatitis. The data showed a rapid and sustained reduction in pruritus throughout the 12-week treatment period. There were no serious adverse events. However, there were more atopic dermatitis flares in the KPL-716-treated population versus placebo. All flares were successfully managed with topical corticosteroids. KPL-716 was otherwise well-tolerated by all patients.

KPL-404 (monoclonal antibody inhibitor of signaling between CD40 and CD40L)

- Kiniksa is enrolling and dosing subjects in a single-ascending-dose Phase 1 clinical trial in healthy volunteers. The first-in-human trial will measure safety

and pharmacokinetics as well as receptor occupancy and T-cell Dependent Antibody Responses (TDAR). CD40-CD40 ligand (CD40L) interaction is an attractive target for blocking T-cell mediated B-cell driven autoimmunity. External proof-of-concept for inhibition of this pathway has been previously established in patients with a broad range of autoimmune diseases. Top-line data are expected in the second half of 2020.

KPL-045 (monoclonal antibody inhibitor of the CD30L co-stimulatory molecule)

- Kiniksa is evaluating the progression of KPL-045, a monoclonal antibody inhibitor of the CD30 ligand (CD30L) co-stimulatory molecule, based on preclinical data from the program in the context of the company's portfolio.

Third Quarter 2019 Financial Results

- For the third quarter of 2019, Kiniksa reported a net loss of $27.1 million, compared to a net loss of $24.4 million for the third quarter of 2018.
- Total operating expenses for the third quarter of 2019 totaled $30.4 million, compared to $26.2 million for the third quarter of 2018. Non-cash share-based compensation expense totaled $3.8 million for the third quarter of 2019, compared to $1.5 million for the third quarter of 2018.
- Cash, cash equivalents and short-term investments totaled $258.7 million as of September 30, 2019, compared to $287.4 million as of June 30, 2019.

Financial Guidance

- Kiniksa expects that its cash, cash equivalents and short-term investments will fund its operating plan into the second half of 2021.
    - Kiniksa expects to end 2019 with more than $225 million in cash, cash equivalents and short-term investments.

Scientific Conference Presentations

- Kiniksa recently presented at the following scientific conferences:
    - European Society of Cardiology (ESC) in September 2019; rilonacept Phase 3 methods.

- American College of Epidemiology (ACE) in September 2019; retrospective claims analysis of recurrent pericarditis epidemiology in the U.S.
- European Society for Dermatological Research (ESDR) in September 2019; preclinical data analyzing expression of oncostatin M receptor beta (OSMRβ) in chronic pruritic diseases.
- European Academy of Dermatology and Venerology (EADV) in October 2019; preclinical data from a longitudinal observational study in prurigo nodularis (LOTUS-PN).
- American Conference on Pharmacometrics (ACoP) in October 2019; pharmacokinetic/pharmacodynamic modeling for KPL-716.

- Kiniksa plans to present at the following scientific conferences:
  - American College of Rheumatology (ACR) in November 2019; preclinical data analyzing the role of granulocyte macrophage colony stimulating factor (GM-CSF) in GCA.
  - American Heart Association (AHA) in November 2019; final data from an open-label, multicenter Phase 2 clinical trial of rilonacept in a range of pericarditis populations.
  - World Congress on Itch (WCI) in November 2019; preclinical data on the role of the oncostatin M (OSM) and interleukin-31 (IL-31) in the pathogenesis of prurigo nodularis.

About Kiniksa

Kiniksa is a biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need. Kiniksa has a pipeline of product candidates across various stages of development, focused on autoinflammatory and autoimmune conditions. For more information, please visit www.kiniksa.com.

About Rilonacept

Rilonacept is a weekly, subcutaneously-injected, recombinant fusion protein that blocks interleukin-1α (IL-1α) and interleukin 1β (IL-1β) signaling. Rilonacept was discovered and developed by Regeneron Pharmaceuticals, Inc. (Regeneron) and is approved by the FDA under the brand name ARCALYST® for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), which includes Familial Cold Autoinflammatory

Syndrome and Muckle-Wells Syndrome. IL-1 blockade may interfere with immune response to infections. Serious, life-threatening infections have been reported in patients taking ARCALYST. ARCALYST should be discontinued if a patient develops a serious infection. Taking ARCALYST with TNF inhibitors is not recommended because this may increase the risk of serious infections. Kiniksa exclusively licensed rilonacept from Regeneron for recurrent pericarditis and certain other indications. Rilonacept in recurrent pericarditis is an investigational drug.

About Mavrilimumab

Mavrilimumab is an investigational fully-human monoclonal antibody that is designed to antagonize GM-CSF signaling by binding to the alpha subunit of the GM-CSF receptor. Kiniksa's lead indication for mavrilimumab is GCA, an inflammatory disease of medium-large arteries.

About KPL-716

KPL-716 is an investigational fully-human monoclonal antibody that targets OSMRβ, which mediates signaling of IL-31 and OSM, two key cytokines implicated in pruritus, inflammation and fibrosis. Kiniksa believes KPL-716 to be the only monoclonal antibody in development that targets both pathways simultaneously.

About KPL-404

KPL-404 is an investigational humanized monoclonal antibody that is designed to inhibit CD40-CD40L interaction, a key T-cell co-stimulatory signal critical for B-cell maturation and immunoglobulin class switching. Disrupting CD40-CD40L interaction is an attractive approach for blocking T-cell mediated B-cell driven responses, drivers of multiple autoimmune disease pathologies such as Systemic Lupus Erythematosus, Rheumatoid Arthritis, Sjogren's Syndrome and Grave's Disease.

About KPL-045

KPL-045 is an investigational fully-human monoclonal antibody that is designed to inhibit CD30-CD30L interaction, a co-stimulatory signal involved in activating and sustaining memory T-cells.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these

identifying words. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, statements regarding: our expectations for fiscal year 2020; plans and timing to advance our product candidates; proposed indications for the investigation of our product candidates; plans and timing to report or present preliminary, interim and final top-line clinical trial, pre-clinical and other data; expected cash, cash equivalents and short-term investments at fiscal year-end 2019; expected timeframe for funding our operating plan with current cash, cash equivalents and short-term investments; and our having no current plans to raise additional capital prior to delivering our anticipated 2020 clinical trial data readouts.

These forward-looking statements are based on management's current plans, estimates or expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including without limitation, the following: potential delays or difficulty in enrollment of patients in, and activation of sites for, our clinical trials; potential complications in coordinating among requirements, regulations and guidelines of regulatory authorities across a number of jurisdictions for our global clinical trials; potential amendments to our clinical trial protocols initiated by us or required by regulatory authorities; potential delays or difficulty in completing our clinical trials, including as a result of our clinical trial design; potential undesirable side effects caused by our product candidates; our potential inability to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities or otherwise producing negative, inconclusive or commercially uncompetitive results; potential for changes between final data and any preliminary and interim "top-line" data we announce; impact of additional data from us or other companies; our potential inability to replicate in later pre-clinical and clinical trials positive results from our earlier pre-clinical and clinical trials; drug substance and/or drug product shortages caused by issues at our third-party manufacturers' facilities; our reliance on certain third parties as the sole source of supply of the drug substance and drug products used in our product candidates; our reliance on third parties to conduct our research, pre-clinical studies, clinical trials, and other trials for our product candidates; changes in our operating plan; changes in the capital markets; market reaction to our anticipated 2020 clinical trial data readouts; substantial existing or new competition; and our ability to attract and retain qualified personnel.

These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission

("SEC") on August 13, 2019 and our other reports subsequently filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's plans, estimates, or expectations as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

ARCALYST® is a registered trademark of Regeneron Pharmaceuticals, Inc.

Every Second Counts!™

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KINIKSA PHARMACEUTICALS, LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 22,014	$ 20,644	$ 112,115	$ 50,475
General and administrative	8,432	5,515	25,267	13,550
Total operating expenses	30,446	26,159	137,382	64,025
Loss from operations	(30,446)	(26,159)	(137,382)	(64,025)
Interest income	1,386	1,622	4,919	2,992
Loss before benefit for income taxes	(29,060)	(24,537)	(132,463)	(61,033)
Benefit for income taxes	2,002	131	2,393	386
Net loss	$ (27,058)	$ (24,406)	$ (130,070)	$ (60,647)
Net loss per share attributable to common shareholders —basic and diluted	$ (0.49)	$ (0.51)	$ (2.42)	$ (2.62)
Weighted average common shares outstanding—basic and diluted	54,831,308	48,183,424	53,767,003	23,174,841

KINIKSA PHARMACEUTICALS, LTD.
SELECTED CONSOLIDATED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	As of	
	September 30, 2019	**December 31, 2018**
Cash, cash equivalents, and short-term investments	$ 258,745	$ 307,304
Working capital (1)	240,780	271,196
Total assets	281,805	321,965
Accumulated deficit	(324,295)	(194,225)
Total shareholders' equity	251,911	279,267

(1) We define working capital as current assets less current liabilities.