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): **February 26, 2020**

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 February 26, 2020, Kiniksa Pharmaceuticals, Ltd. (the "Company") issued a press release announcing financial results for the quarter and year ended December 31, 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	Q4 and FY2019 Earnings Press Release issued by Kiniksa Pharmaceuticals, Ltd. dated February 26, 2020

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: February 26, 2020

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

Exhibit 99.1

Kiniksa Reports Fourth Quarter and Full-Year 2019 Financial Results and Highlights Recent Pipeline Activity

- Clinical data readouts expected throughout 2020 for rilonacept, mavrilimumab, KPL-716 and KPL-404 -
- Year-end 2019 cash reserves of $233 million -

HAMILTON, BERMUDA – February 26, 2020 – 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 fourth quarter and full-year 2019 financial results and highlighted recent pipeline activity.

"We have the potential to generate data-driven value from multiple clinical-stage assets in 2020," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "Near-term, given the anti-pruritic response shown in both cohorts of our KPL-716 Phase 1b study as well as recent external mechanistic validation, we are enabling an interim readout from our KPL-716 Phase 2a trial in prurigo nodularis. Data are expected by the end of April."

Pipeline Activity

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

- Kiniksa is evaluating rilonacept for the potential treatment of recurrent pericarditis, a painful autoinflammatory cardiovascular disease.
  - Kiniksa expects top-line data from RHAPSODY, a pivotal Phase 3 trial of rilonacept in patients with recurrent pericarditis, in the second half of 2020.
- Kiniksa recently announced the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for rilonacept for the treatment of recurrent pericarditis. Kiniksa's Breakthrough Therapy application was based on final data from an open-label Phase 2 clinical trial of rilonacept in a range of recurrent pericarditis populations.
- Kiniksa continues to prepare for the commercialization of rilonacept in recurrent pericarditis by generating evidence on unmet need and disease burden, building disease awareness with payers, physicians and advocacy groups, and establishing core capabilities such as distribution, patient services and data management.

Mavrilimumab (monoclonal antibody inhibitor targeting GM-CSFRα)

- Kiniksa is evaluating mavrilimumab for the potential treatment of giant cell arteritis (GCA), a chronic inflammatory disease of medium-to-large arteries.
    - Kiniksa expects top-line data from a global Phase 2 proof-of-concept trial of mavrilimumab in patients with GCA in the second half of 2020.
- Kiniksa and Kite, a Gilead company, recently announced a clinical collaboration evaluating the investigational combination of axicabtagene ciloleucel and mavrilimumab in relapsed or refractory large B-cell lymphoma. The objective of the trial is to determine the effect of mavrilimumab on the safety of axicabtagene ciloleucel. Preclinical evidence shows the potential for interruption of granulocyte macrophage colony stimulating factor (GM-CSF) signaling to disrupt chimeric antigen receptor T (CAR T) cell-mediated inflammation without disrupting anti-tumor efficacy. The Phase 2 trial is expected to commence in the second half of 2020.

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

- Kiniksa is evaluating KPL-716 for the potential treatment of a variety of pruritic diseases, including prurigo nodularis, a chronic inflammatory skin condition.
    - Kiniksa expects data from a Phase 2a trial of KPL-716 in patients with prurigo nodularis by the end of April 2020.
    - Kiniksa expects interim data from cohorts of an exploratory Phase 2 trial of KPL-716 in diseases characterized by chronic pruritus in the first half of 2020.

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

- Kiniksa is enrolling a single-ascending-dose Phase 1 clinical trial of KPL-404 in healthy volunteers. The first-in-human trial will provide safety data and pharmacokinetics as well as receptor occupancy and T-cell Dependent Antibody Response (TDAR). Top-line data are expected in the second half of 2020.

Financial Results

- For the fourth quarter of 2019, Kiniksa reported a net loss of $31.8 million, compared to a net loss of $42.6 million for the fourth quarter of 2018.
- For the full-year 2019, Kiniksa reported a net loss of $161.9 million, compared to a net loss of $103.2 million for the full-year 2018.
- Total operating expenses for the fourth quarter of 2019 totaled $32.6 million, compared to $44.1 million for the fourth quarter of 2018. Non-cash share-based compensation expense totaled $5.0 million for the fourth quarter of 2019, compared to $2.6 million for the fourth quarter of 2018.
- Total operating expenses for the full-year 2019 totaled $170.0 million, compared to $108.2 million for the full-year 2018. Non-cash share-based compensation expense totaled $15.1 million for the full-year 2019, compared to $5.7 million for the full-year 2018.
- As of December 31, 2019, the company had cash, cash equivalents and short-term investments of $233.4 million and no outstanding debt.

Financial Guidance

- Kiniksa expects that its cash, cash equivalents and short-term investments will fund its operating plan into the second half of 2021.

Scientific Conference Presentations

- Kiniksa recently presented at the following scientific conferences:
    - 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.
    - American College of Rheumatology (ACR) in November 2019; preclinical data analyzing the role of GM-CSF in GCA and showing mavrilimumab reduced arterial inflammation in an *in vivo* model.
    - American Heart Association (AHA) in November 2019; final data from an open-label, multicenter Phase 2 clinical trial of rilonacept in a range of recurrent 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.
- Kiniksa plans to present at the following scientific conference:
    - American College of Cardiology (ACC) in March 2020; Phase 2 clinical data providing evidence of the potential for rilonacept to taper or obviate corticosteroid use in recurrent pericarditis.

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's clinical-stage product candidates, rilonacept, mavrilimumab, KPL-716 and KPL-404, are based on strong biologic rationale or validated mechanisms, target underserved conditions and offer the potential for differentiation. These pipeline assets are designed to modulate immunological signaling pathways that are implicated across a spectrum of diseases. For more information, please visit www.kiniksa.com.

About Rilonacept
Rilonacept is a weekly, subcutaneously-injected, recombinant fusion protein that blocks interleukin-1 alpha (IL-1α) and interleukin-1 beta (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. Interleukin-1 (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 tumor necrosis factor (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. The FDA has granted Breakthrough Therapy designation to rilonacept for recurrent pericarditis.

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 (GM-CSFRα). Kiniksa's lead indication for mavrilimumab is GCA, an inflammatory disease of medium to large arteries. Additionally, Kiniksa and Kite have a clinical collaboration to evaluate mavrilimumab in combination with Yescarta® (axicabtagene ciloleucel) in patients with relapsed or refractory large B-cell lymphoma.

About KPL-716
KPL-716 is an investigational fully-human monoclonal antibody that targets oncostatin M receptor beta (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-CD40 ligand (CD40L) interaction, a key T-cell co-stimulatory signal critical for B-cell maturation and immunoglobulin class switching. Kiniksa believes 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 rheumatoid arthritis, Sjogren's syndrome, Graves' disease, systemic lupus erythematosus and solid organ transplant.

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 data readouts; proposed indications for the investigation of our product candidates; our beliefs about the mechanisms of action of our product candidates and potential impact of their approach; our clinical trial design; plans and timing to report or present preliminary, interim and final top-line or other clinical trial data and the potential impact of that data; and our projected timeframe for funding our operating plan with current cash, cash equivalents and short-term investments.

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 or continuation 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 for lower accrual of events in our clinical trials; 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 or other data we announce; impact of additional data from us or other companies; our potential inability to replicate in later clinical trials positive results from our earlier pre-clinical and clinical trials; drug substance and/or drug product shortages; our reliance on 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 and funding requirements; 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 November 5, 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.

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 December 31,		Years Ended December 31,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 22,886	$ 36,122	$ 135,001	$ 86,597
General and administrative	9,695	8,013	34,962	21,563
Total operating expenses	32,581	44,135	169,963	108,160
Loss from operations	(32,581)	(44,135)	(169,963)	(108,160)
Interest income	1,130	1,727	6,049	4,719
Loss before benefit (provision) for income taxes	(31,451)	(42,408)	(163,914)	(103,441)
Benefit (provision) for income taxes	(346)	(172)	2,047	214
Net loss	$ (31,797)	$ (42,580)	$ (161,867)	$ (103,227)
Net loss per share attributable to common shareholders —basic and diluted	$ (0.58)	$ (0.88)	$ (2.99)	$ (3.49)
Weighted average common shares outstanding—basic and diluted	54,887,689	48,458,892	54,049,477	29,547,427

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

	As of	
	December 31, 2019	December 31, 2018
Cash, cash equivalents, and short-term investments	$ 233,380	$ 307,304
Working capital	213,797	271,196
Total assets	254,534	321,965
Accumulated deficit	(356,092)	(194,225)
Total shareholders' equity	225,423	279,267