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): **April 28, 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 April 28, 2020, Kiniksa Pharmaceuticals, Ltd. (the "Company") issued a press release announcing financial results for the quarter ended March 31, 2020. 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, 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	Q1 Earnings Press Release issued by Kiniksa Pharmaceuticals, Ltd. dated April 28, 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: April 28, 2020

By: /s/ Thomas Beetham
Thomas Beetham
Executive Vice President, Chief Legal Officer

Exhibit 99.1

Kiniksa Reports First Quarter 2020 Financial Results and Highlights Recent Corporate and Pipeline Activity

- *Financial guidance and clinical timelines for rilonacept, mavrilimumab, vixarelimab and KPL-404 remain intact amid COVID-19 pandemic*
- *Mavrilimumab treatment protocol in COVID-19 pneumonia and hyperinflammation shows evidence of treatment response in all 13 non-ventilated patients dosed*
- *Preparing registrational development program of mavrilimumab in patients with COVID-19 pneumonia and hyperinflammation*
- *Phase 2 trial of vixarelimab in prurigo nodularis met primary efficacy endpoint: statistically significant reduction of weekly average WI-NRS at Week 8*

HAMILTON, BERMUDA – April 28, 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 first quarter 2020 financial results and highlighted recent corporate and pipeline activity.

"Kiniksa continued to advance its clinical-stage pipeline in the first quarter despite the COVID-19 pandemic," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "Our projected cash runway extends into the second half of 2021, and our clinical timelines remain on track. Our evaluation of mavrilimumab in COVID-19 pneumonia and hyperinflammation is progressing, and we continue to expect further clinical data from vixarelimab in the first half of 2020 as well as data from rilonacept, mavrilimumab and KPL-404 in the second half of the year."

Corporate Activity

- Kiniksa continues to monitor its daily operations and program timelines during the evolving coronavirus 2019 (COVID-19) pandemic. The health and safety of Kiniksa's employees as well as the patients and people participating in and operating the company's clinical trials are of paramount importance.

    - Kiniksa assembled an internal working group to identify business-critical activities through year-end 2020 and to develop contingencies for these activities.

    - COVID-19 has not impacted Kiniksa's financial guidance or changed the company's timelines for clinical data in 2020, to date.

Pipeline Activity

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

- Kiniksa completed enrollment in RHAPSODY, a pivotal Phase 3 trial of rilonacept in patients with recurrent pericarditis, a painful autoinflammatory cardiovascular disease. The company continues to expect data in the second half of 2020.

- Kiniksa is preparing for the commercialization of rilonacept in recurrent pericarditis by generating evidence on 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 completed enrollment in a Phase 2a proof-of-concept trial of mavrilimumab in patients with giant cell arteritis (GCA), a chronic inflammatory disease of medium-to-large arteries. The company continues to expect data in the second half of 2020.

- Kiniksa recently announced evidence of treatment response with mavrilimumab from an open-label treatment protocol in 6 non-mechanically ventilated patients with severe COVID-19 pneumonia and hyperinflammation in Italy [1] . All 6 of these patients showed an early resolution of fever and improvement in oxygenation within 1-3 days, none of the patients progressed to require mechanical ventilation, and 3 of the patients were discharged from the hospital within 5 days. Mavrilimumab was well-tolerated.

  - An additional 7 non-mechanically ventilated patients with COVID-19 pneumonia and hyperinflammation have since been treated with mavrilimumab. The results from these patients are consistent with the first 6 patients treated. One of the 7 patients was electively intubated and subsequently returned to low-level supplemental oxygen. All 13 patients improved clinically, and 12 out of 13 patients returned home.

- Kiniksa has engaged with the U.S. Food and Drug Administration (FDA) and is preparing for a potential registrational development program for mavrilimumab in COVID-19 pneumonia and hyperinflammation. In parallel, academic investigators in the U.S. and Italy are planning investigator-initiated placebo-controlled studies.

- Kiniksa and Kite, a Gilead company, expect to commence a Phase 2 trial evaluating the investigational combination of Yescarta ® (axicabtagene ciloleucel) and mavrilimumab in relapsed or refractory large B-cell lymphoma in the second half of 2020. The objective of the trial is to determine the effect of mavrilimumab on the safety of Yescarta. 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.

Vixarelimab (monoclonal antibody inhibitor of signaling through OSMRβ)

- Kiniksa recently announced data from a Phase 2a trial of vixarelimab in patients with prurigo nodularis, a chronic inflammatory skin condition. The trial met its primary efficacy endpoint: the reduction in weekly-average Worst-Itch Numeric Rating Scale (WI-NRS) from baseline at Week 8 was statistically significantly greater in patients who received vixarelimab versus those who received placebo. Additionally, a statistically significantly greater percentage of vixarelimab recipients achieved a prurigo nodularis-investigator's global assessment (PN-IGA) score of 0/1 at Week 8 compared to placebo recipients.

- Kiniksa continues to expect data from cohorts of an exploratory Phase 2 trial of vixarelimab 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 conducting 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). The company continues to expect data in the second half of 2020.

Financial Results

- For the first quarter of 2020, Kiniksa reported a net loss of $26.4 million, compared to a net loss of $65.8 million for the first quarter of 2019.

- Total operating expenses for the first quarter of 2020 totaled $29.4 million, compared to $67.6 million for the first quarter of 2019. Non-cash share-based compensation expense totaled $4.2 million for the first quarter of 2020, compared to $2.9 million for the first quarter of 2019.

- As of March 31, 2020, the company had cash, cash equivalents and short-term investments of $204.2 million and no 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.

[1] The treatment protocol with the investigational drug mavrilimumab was conducted by Professor Lorenzo Dagna, MD, FACP, Head, Unit of Immunology, Rheumatology, Allergy and Rare Diseases IRCCS San Raffaele Scientific Institute and Vita-Salute San Raffaele University in Milan, Italy within a COVID-19 Program directed by Professor Alberto Zangrillo, Head of Department of Anesthesia and Intensive Care of the Scientific Institute San Raffaele Hospital and Professor in Anesthesiology and Intensive Care, Università Vita-Salute San Raffaele.

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, vixarelimab 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. Mavrilimumab was dosed in over 550 patients with rheumatoid arthritis through Phase 2b clinical studies in Europe and achieved prospectively-defined primary endpoints of efficacy and safety. 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 Vixarelimab (KPL-716)

Vixarelimab is an investigational fully-human monoclonal antibody that targets oncostatin M receptor beta (OSMRβ), which mediates signaling of interleukin-31 (IL-31) and oncostatin M (OSM), two key cytokines implicated in pruritus, inflammation and fibrosis. Kiniksa believes vixarelimab 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; our beliefs about the mechanisms of action of our product candidates and potential impact of their approach; planned and preparations for potential clinical trials, including a potential registrational development program for mavrilimumab in COVID-19 pneumonia and hyperinflammation and a Phase 2 trial evaluating the investigational combination of Yescarta ® (axicabtagene ciloleucel) and mavrilimumab in relapsed or refractory large B-cell lymphoma, and the timing thereof; plans and timing to report or present preliminary, interim and final top-line or other clinical trial 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 low 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; potential impact of the COVID-19 pandemic, and measures taken in response to the pandemic, on our business and operations as well as the business and operations of our manufacturers, CROs upon whom we rely to conduct our clinical trials, and other third parties with whom we conduct business or otherwise engage, including the FDA and other regulatory authorities; and our ability to attract and retain qualified personnel.

These and other important factors discussed under the caption “Risk Factors” in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 5, 2020 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 March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 20,901	$ 59,253
General and administrative	8,486	8,394
Total operating expenses	29,387	67,647
Loss from operations	(29,387)	(67,647)
Interest income	789	1,809
Loss before benefit for income taxes	(28,598)	(65,838)
Benefit for income taxes	2,179	17
Net loss	$ (26,419)	$ (65,821)
Net loss per share attributable to common shareholders — basic and diluted	$ (0.48)	$ (1.27)
Weighted average common shares outstanding — basic and diluted	55,322,690	51,758,353

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

	As of	
	March 31, 2020	**December 31, 2019**
Cash, cash equivalents, and short-term investments	$ 204,206	$ 233,380
Working capital	193,713	213,797
Total assets	226,108	254,534
Accumulated deficit	(382,511)	(356,092)
Total shareholders' equity	205,834	225,423