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): **July, 30, 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

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 July 30, 2020, Kiniksa Pharmaceuticals, Ltd. (the "Company") issued a press release announcing financial results for the quarter ended June 30, 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	Q2 Earnings Press Release issued by Kiniksa Pharmaceuticals, Ltd. dated July 30, 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: July 30, 2020

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

Exhibit 99.1

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

- *Rilonacept pivotal Phase 3 trial in recurrent pericarditis met statistical significance for primary and all major secondary efficacy endpoints; sBLA submission expected this year*
- *Mavrilimumab global Phase 2/3 adaptive design trial in severe COVID-19 pneumonia and hyperinflammation enrolling and dosing patients*
- *Data from mavrilimumab global Phase 2 trial in GCA and KPL-404 Phase 1 trial expected in Q4 2020*
- *Initiation of dose-ranging Phase 2b trial of vixarelimab in prurigo nodularis expected in Q4 2020*
- *Recent public offerings and concurrent private placements raised a total of ~$220 million in net proceeds; cash reserves expected to fund current operating plan into 2023*

HAMILTON, BERMUDA – July 30, 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 second quarter 2020 financial results and highlighted recent pipeline and corporate activity.

"Kiniksa had a brilliant first half of 2020, marked by statistically significant results from the pivotal Phase 3 study of rilonacept in recurrent pericarditis and the Phase 2a study of vixarelimab in prurigo nodularis as well as the COVID-19 mavrilimumab data published in *The Lancet Rheumatology*," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "The second half of the year is also expected to be catalyst-filled. We are committed to submitting an sBLA to the FDA for rilonacept in recurrent pericarditis this year and look forward to bringing this potential treatment to patients as soon as possible. Our evaluations of mavrilimumab in severe COVID-19 pneumonia and vixarelimab in prurigo nodularis are also progressing, and we continue to expect data in the fourth quarter from the mavrilimumab GCA trial and from our anti-CD40 program, KPL-404. We expect the recent capital raises and continued financial discipline to extend our cash runway into 2023."

Pipeline Activity

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

- Kiniksa announced data from RHAPSODY, a global, randomized withdrawal design, pivotal Phase 3 clinical trial of rilonacept in recurrent pericarditis, a painful autoinflammatory cardiovascular disease. The primary efficacy endpoint of time-to-first adjudicated pericarditis recurrence in the randomized withdrawal period was highly statistically significant: rilonacept treatment resulted in a 96% reduction in risk of recurrent pericarditis events (Hazard Ratio = 0.04, $p<0.0001$). All major secondary endpoints were also highly statistically significant.

  - Based on the data from RHAPSODY, the Biologic License Application (BLA) for Cryopyrin-Associated Periodic Syndromes (CAPS) will transfer to Kiniksa from Regeneron Pharmaceuticals, Inc. (Regeneron). Kiniksa plans to submit a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) in recurrent pericarditis this year. Upon receipt of FDA approval for rilonacept in recurrent pericarditis, Kiniksa will assume the sales and distribution of rilonacept for the approved indications in the United States and evenly split profits on sales with Regeneron.

- Kiniksa announced the FDA granted Orphan Drug designation for rilonacept for the treatment of pericarditis, which includes recurrent pericarditis.

- 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 expects data from a global Phase 2 clinical trial of mavrilimumab in patients with giant cell arteritis (GCA), a chronic inflammatory disease of medium-to-large arteries, in the fourth quarter of 2020.

- Kiniksa is enrolling and dosing the global, randomized, double-blind, placebo-controlled Phase 2 portion of an adaptive design Phase 2/3 clinical trial of mavrilimumab in severe coronavirus disease 2019 (COVID-19) pneumonia and hyperinflammation. Additionally, a randomized, double-blind, placebo-controlled investigator-initiated study in the U.S. is enrolling and dosing patients.

  - Kiniksa announced clinical outcomes data from the open-label treatment protocol[1] with mavrilimumab in severe COVID-19 pneumonia and hyperinflammation. Mavrilimumab-treated patients experienced earlier and improved clinical outcomes compared to control-group patients, including earlier weaning from supplemental oxygen, shorter hospitalizations, and no deaths. These data were presented at the European E-Congress of Rheumatology (EULAR) 2020 and published in *The Lancet Rheumatology*.

- 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 expects to initiate a dose-ranging Phase 2b clinical trial of vixarelimab in prurigo nodularis, a chronic inflammatory skin condition, in the fourth quarter of 2020.
    - Kiniksa's Phase 2a clinical trial of vixarelimab in patients with prurigo nodularis 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 announced data from an exploratory Phase 2 trial of vixarelimab in diseases characterized by chronic pruritus, including plaque psoriasis, chronic idiopathic pruritus, lichen simplex chronicus, chronic idiopathic urticaria and lichen planus. The plaque psoriasis cohort achieved a statistically significant reduction in weekly-average WI-NRS at Week 8. Additionally, the lichen simplex chronicus, chronic idiopathic urticaria and lichen planus cohorts showed encouraging efficacy results as measured by percent change from baseline in weekly-average WI-NRS at Week 8.

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

- Kiniksa expects data from a single-ascending-dose Phase 1 clinical trial of KPL-404 in healthy volunteers in the fourth quarter of 2020. The first-in-human trial will provide safety data and pharmacokinetics as well as receptor occupancy and T-cell Dependent Antibody Response (TDAR).

Corporate Activity

- In May of 2020, Kiniksa completed a public offering of 2,760,000 Class A common shares at a public offering price of $18.25 per share, which included the exercise in full by the underwriters of their option to purchase additional shares. Concurrent with the public offering, Kiniksa sold 1,600,000 Class A1 common shares to certain existing shareholders affiliated with certain of Kiniksa's directors at a sale price equal to the price of the public offering. The aggregate net proceeds to Kiniksa from these offerings after deducting underwriting discounts, commissions and other offering costs were approximately $74.5 million.

- In July of 2020, Kiniksa completed a public offering of 5,952,381 Class A common shares at a public offering price of $21.00 per share. Concurrent with the public offering, Kiniksa sold 1,428,572 Class A1 common shares to certain existing shareholders affiliated with certain of Kiniksa's directors at a sale price equal to the price of the public offering. The estimated aggregate net proceeds to Kiniksa from these offerings after deducting underwriting discounts, commissions and other offering costs were approximately $145.9 million.

Financial Results

- For the second quarter of 2020, Kiniksa reported a net loss of $37.5 million, compared to a net loss of $37.2 million for the second quarter of 2019.

- Total operating expenses for the second quarter of 2020 totaled $31.9 million, compared to $39.3 million for the second quarter of 2019. Non-cash share-based compensation expense totaled $4.9 million for the second quarter of 2020, compared to $3.5 million for the second quarter of 2019.

- As of June 30, 2020, the company had cash, cash equivalents and short-term investments of $252.4 million and no debt.

  - Kiniksa had proforma cash reserves[2] of $398.3 million as of June 30, 2020, which includes approximately $252.4 million of cash, cash equivalents and short-term investments as of June 30, 2020 and approximately $145.9 million of estimated net proceeds from our July 2020 public offering and concurrent private placement as though we had closed on these financings in the second quarter of 2020.

Financial Guidance

- Kiniksa expects that its cash, cash equivalents and short-term investments, inclusive of the estimated net proceeds from its recent public offering and concurrent private placement, will fund its current operating plan into 2023.

[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.

[2] Proforma cash reserves is a non-GAAP measure, please refer to "Use of Non-GAAP Measures" in this press release for an explanation of our use of this measure.

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 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 and is approved by the FDA under the brand name ARCALYST® for the treatment of CAPS, specifically Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome. Rilonacept for the treatment of deficiency of the interleukin-1 receptor antagonist (DIRA) is currently pending FDA approval following the submission of an sBLA in June 2020. Rilonacept in recurrent pericarditis is an investigational drug. The FDA granted Breakthrough Therapy designation to rilonacept for recurrent pericarditis in 2019 and Orphan Drug designation to rilonacept for pericarditis in 2020.

Important information about ARCALYST® (rilonacept) Injection
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.

Patients should not receive a live vaccine while taking ARCALYST. It is recommended that prior to initiation of therapy with ARCALYST patients receive all recommended vaccinations, as appropriate, including pneumococcal vaccine and inactivated influenza vaccine. In the initial development program for ARCALYST, six serious adverse reactions were reported by four patients: Mycobacterium intracellular infection, gastrointestinal bleeding and colitis, sinusitis and bronchitis and Streptococcus pneumoniae meningitis. The most commonly reported adverse reactions associated with ARCALYST were injection site reaction and upper respiratory tract infection. Patients should be monitored for changes in their lipid profiles and provided with medical treatment if warranted. Treatment with immunosuppressants, including ARCALYST, may result in an increase in risk of malignancies. Hypersensitivity reactions associated with ARCALYST administration in clinical studies have been rare. If a hypersensitivity reaction occurs, administration of ARCALYST should be discontinued and appropriate therapy initiated.

About Mavrilimumab
Mavrilimumab is an investigational fully-human monoclonal antibody that targets granulocyte macrophage colony stimulating factor receptor alpha (GM-CSFRα). 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. Kiniksa's lead indication for mavrilimumab is giant cell arteritis (GCA), an inflammatory disease of medium-to-large arteries. Kiniksa is also evaluating mavrilimumab in COVID-19 pneumonia and hyperinflammation. Additionally, Kiniksa and Kite, a Gilead company, 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
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. Kiniksa's lead indication for vixarelimab is prurigo nodularis, a chronic inflammatory skin condition.

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 the 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 catalysts in the second half of fiscal year 2020; plans and timing of clinical trial data readouts; plans and timing of submitting a supplemental BLA to the FDA in recurrent pericarditis; our beliefs about the potential to bring rilonacept as a potential treatment option for patients with recurrent pericarditis; our beliefs about the mechanisms of action of our product candidates and potential impact of their approach; planned clinical trials and timing thereof, including a potential dose-ranging Phase 2b clinical trial of vixarelimab in prurigo nodularis and a Phase 2 trial evaluating the investigational combination of Yescarta® (axicabtagene ciloleucel) and mavrilimumab in relapsed or refractory large B-cell lymphoma; and our projected timeframe for funding our current 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 the COVID-19 pandemic; 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, 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; 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; changes in our operating plan and funding requirements; 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 May 4, 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.

ARCALYST® is a registered trademark of Regeneron Pharmaceuticals, Inc. and Yescarta® is a registered trademark of Gilead Sciences, Inc., or its related companies.

Use of Non-GAAP Financial Measures
To supplement our financial statements presented in accordance with Generally Accepted Accounting Principles (GAAP) and to provide additional insights into our financial condition, we have presented our pro forma cash reserves as of June 30, 2020, which is not prepared in accordance with GAAP. Management believes that the presentation of pro forma cash reserves as of June 30, 2020 provides useful information to investors regarding our financial condition.

Other companies may define pro forma cash reserves differently and, as a result, our use of this non-GAAP measure may not be directly comparable to pro forma cash reserves used by other companies. Pro forma cash reserves is not intended to be a measure of liquidity nor is it intended to be a measure of our cash, cash equivalents and short-term investments available for discretionary use. You are cautioned not to place undue reliance on this non-GAAP measure.

This measure is supplemental in nature and should not be considered in isolation or as a substitute for the related financial information prepared in accordance with GAAP.

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 June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 22,324	$ 30,848	$ 43,225	$ 90,101
General and administrative	9,536	8,441	18,022	16,835
Total operating expenses	31,860	39,289	61,247	106,936
Loss from operations	(31,860)	(39,289)	(61,247)	(106,936)
Interest income	266	1,724	1,055	3,533
Loss before (provision) benefit for income taxes	(31,594)	(37,565)	(60,192)	(103,403)
(Provision) benefit for income taxes	(5,875)	374	(3,696)	391
Net loss	$ (37,469)	$ (37,191)	$ (63,888)	$ (103,012)
Net loss per share attributable to common shareholders —basic and diluted	$ (0.65)	$ (0.68)	$ (1.13)	$ (1.94)
Weighted average common shares outstanding—basic and diluted	57,914,105	54,475,476	56,618,397	53,225,710

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

	As of	
	June 30, 2020	**December 31, 2019**
Cash, cash equivalents, and short-term investments	$ 252,398	$ 233,380
Working capital	243,941	213,797
Total assets	271,441	254,534
Accumulated deficit	(419,980)	(356,092)
Total shareholders' equity	250,416	225,423