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): **November 5, 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 x

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. x

Item 2.02. Results of Operations and Financial Condition.

On November 5, 2020, Kiniksa Pharmaceuticals, Ltd. (the "Company") issued a press release announcing financial results for the quarter ended September 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	Q3 Earnings Press Release issued by Kiniksa Pharmaceuticals, Ltd. dated November 5, 2020
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

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: November 5, 2020

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

Exhibit 99.1

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

- *Rilonacept commercial launch in recurrent pericarditis anticipated in 1H 2021, if approved by the FDA*
- *Mavrilimumab Phase 2 trial in GCA achieved primary and secondary efficacy endpoints with statistical significance*
- *All cohorts have been dosed in the KPL-404 (anti-CD40) Phase 1 study*
- *Cash reserves of approximately $364 million expected to fund current operating plan into 2023*

HAMILTON, BERMUDA – November 5, 2020 – Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) ("Kiniksa"), a biopharmaceutical company with a pipeline of assets designed to modulate immunological pathways across a spectrum of diseases, today reported third quarter 2020 financial results and highlighted recent pipeline and corporate activity.

"Kiniksa continues to execute across its pipeline," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "We are preparing for the commercial launch of rilonacept in recurrent pericarditis in the first half of 2021, if approved by the FDA. The primary and secondary efficacy endpoints of the mavrilimumab Phase 2 trial in giant cell arteritis achieved statistical significance, further demonstrating the potential broad utility of the molecule. Additionally, all cohorts have been dosed in the Phase 1 study of KPL-404, our anti-CD40 program, and we expect data from the first cohorts this quarter."

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

- Kiniksa anticipates the commercial launch of rilonacept in recurrent pericarditis in the first half of 2021, if approved by the U.S. Food and Drug Administration (FDA) assuming priority review.

- If rilonacept is approved for recurrent pericarditis by the FDA, Kiniksa will commence the sales and distribution of rilonacept for the approved indications in the United States and evenly split profits on sales with Regeneron Pharmaceuticals, Inc. (Regeneron).

- Kiniksa is obligated to pay regulatory milestones to Regeneron of up to an aggregate of $27.5 million through the potential approval of rilonacept in recurrent pericarditis.

· Kiniksa expects data from RHAPSODY, the pivotal Phase 3 clinical trial of rilonacept in recurrent pericarditis, to be presented at the late-breaking science session during the American Heart Association (AHA) Scientific Sessions 2020.

- Dr. Allan Klein, MD, of Cleveland Clinic and co-principal investigator for RHAPSODY, will deliver a virtual presentation entitled *RHAPSODY: Rilonacept an IL-1α and IL-1β Trap Resolves Pericarditis Episodes and Reduces Risk of Recurrence in a Phase 3 Trial of Patients with Recurrent Pericarditis* on Monday, November 16, 2020 at 7:34 p.m. Central Time.

Mavrilimumab (monoclonal antibody inhibitor targeting GM-CSFRα)

· Kiniksa recently announced positive data from the global Phase 2 clinical trial of mavrilimumab in giant cell arteritis (GCA).

- Both the primary efficacy endpoint of time-to-first adjudicated GCA flare by Week 26 in all treated patients (Hazard Ratio = 0.38, p=0.0263) and the secondary efficacy endpoint of sustained remission at Week 26 in all treated patients (p=0.0038) were statistically significant. Additionally, while the trial was not powered for disease cohorts, there was a consistent trend of efficacy across the new onset and relapsing/refractory cohorts.

· Kiniksa expects data from the global Phase 2 clinical trial of mavrilimumab in GCA to be presented at the late-breaking abstracts session during the American College of Rheumatology (ACR) Convergence 2020.

- Dr. Maria Cid of Hospital Clínic, University of Barcelona, IDIBAPS and co-principal investigator for the trial, will deliver a virtual presentation entitled *Mavrilimumab (Anti GM-CSF Receptor α Monoclonal Antibody) Reduces Risk of Flare and Increases Sustained Remission in a Phase 2 Trial of Patients with Giant Cell Arteritis* on Monday, November 9, 2020 at 11:30 a.m. Eastern Time.

- Kiniksa announced that the FDA granted Orphan Drug Designation to mavrilimumab for the treatment of GCA.

- Kiniksa is evaluating mavrilimumab in severe COVID-19 pneumonia and hyperinflammation and is enrolling the Phase 2 portion of a global, randomized, double-blind, placebo-controlled adaptive design Phase 2/3 clinical trial. Additionally, data are expected from a randomized, double-blind, placebo-controlled investigator-initiated study in the U.S. in the fourth quarter of 2020.

- Kiniksa disclosed the discontinuation of the clinical collaboration with Kite, a Gilead company, evaluating mavrilimumab in combination with Yescarta® (axicabtagene ciloleucel) in relapsed or refractory large B-cell lymphoma, due to a portfolio strategy review by Kite that impacted the planned trial.

Vixarelimab (monoclonal antibody inhibitor of signaling through OSMRβ)

- Data from the Phase 2a clinical trial of vixarelimab in prurigo nodularis were presented at the European Academy of Dermatology and Venereology (EADV) Virtual Congress.

    - Dr. Howard Sofen, MD, of the David Geffen UCLA School of Medicine, delivered a virtual presentation entitled *Vixarelimab Reduced Pruritus, Improved Nodules, and was Well-Tolerated in Patients with Prurigo Nodularis in a Phase 2a, Randomized, Double-Blind, Placebo-Controlled Study.*

- Kiniksa expects to initiate a dose-ranging Phase 2b clinical trial of vixarelimab in prurigo nodularis in the fourth quarter of 2020.

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

- Kiniksa today announced that all cohorts in the single-ascending-dose Phase 1 clinical trial of KPL-404 in healthy volunteers have been dosed. All dose escalations occurred as per protocol with no dose limiting safety findings. The data to-date support continued clinical development.

    - The study is divided into two parts: single doses of KPL-404 0.03 mg/kg, 0.3 mg/kg, 1 mg/kg, 3 mg/kg or 10 mg/kg intravenous (IV) and single doses of KPL-404 1 mg/kg or 5 mg/kg subcutaneous.

    - Pharmacokinetic, receptor occupancy and T-cell Dependent Antibody Response data from the first cohorts, including the 3 mg/kg IV dose level, are expected in the fourth quarter of 2020. Final data and safety follow-up from all cohorts are expected in the first half of 2021.

- The CD40-CD40 ligand (CD40L) interaction has been implicated in diseases such as rheumatoid arthritis, Sjogren's syndrome, Graves' disease, systemic lupus erythematosus and solid organ transplant, where external proof-of-concept has been previously demonstrated.

Corporate Activity

- 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 aggregate net proceeds to Kiniksa from these offerings after deducting underwriting discounts and commissions, private placement fees and other offering costs were approximately $146.0 million.

Financial Results

- For the third quarter of 2020, Kiniksa reported a net loss of $43.8 million, compared to a net loss of $27.1 million for the third quarter of 2019.

- Total operating expenses for the third quarter of 2020 totaled $43.2 million, compared to $30.4 million for the third quarter of 2019. Non-cash share-based compensation expense totaled $5.6 million for the third quarter of 2020, compared to $3.8 million for the third quarter of 2019.

- As of September 30, 2020, the company had cash, cash equivalents and short-term investments of $364.4 million and no debt.

Financial Guidance

- Kiniksa expects that its cash, cash equivalents and short-term investments will fund its current operating plan into 2023.

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 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 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). Rilonacept was discovered and developed by Regeneron and is approved by the FDA under the brand name ARCALYST® for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), specifically Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome. Rilonacept for the treatment of deficiency of the interleukin1 receptor antagonist (DIRA) is currently pending FDA approval following the submission of a Supplemental Biologics License Application (sBLA) in June 2020. Rilonacept in recurrent pericarditis is an investigational drug. The FDA granted Breakthrough Therapy designation to rilonacept for the treatment of recurrent pericarditis in 2019 and Orphan Drug designation to rilonacept for the treatment of 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 GCA, a rare inflammatory disease of medium-to-large arteries. Kiniksa is also evaluating mavrilimumab in COVID-19 pneumonia and hyperinflammation. The FDA granted Orphan Drug designation to mavrilimumab for the treatment of GCA in 2020.

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-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: plans and timing of clinical trial data readouts; our beliefs about research, pre-clinical and clinical trial data supporting continued clinical development; anticipated timing of our potential commercial launch of rilonacept in recurrent pericarditis, if approved by the FDA under priority review; planned clinical trials and timing thereof, including a potential dose-ranging Phase 2b clinical trial of vixarelimab in prurigo nodularis; regulatory milestones and related payments under our License Agreement with Regeneron upon achievement of certain specified events; 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; 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: 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; 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 applicable regulatory authorities to not accept our BLA or sBLA filings or to delay or deny approval of any of our product candidates or to require additional trials to support any such approval; potential for changes between final data and any preliminary, interim, top-line or other data from clinical trials conducted by us or third parties, including from investigator initiated studies; impact of additional data from us or other companies; potential inability to replicate in later clinical trials positive results from earlier pre-clinical and clinical trials or studies of our product candidates potential in subsequent clinical trials conducted by us or third parties, including investigator-initiated studies; 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; 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 August 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.

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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 31,419	$ 22,014	$ 74,644	$ 112,115
General and administrative	11,799	8,432	29,821	25,267
Total operating expenses	43,218	30,446	104,465	137,382
Loss from operations	(43,218)	(30,446)	(104,465)	(137,382)
Interest income	49	1,386	1,104	4,919
Loss before benefit (provision) for income taxes	(43,169)	(29,060)	(103,361)	(132,463)
Benefit (provision) for income taxes	(667)	2,002	(4,363)	2,393
Net loss	$ (43,836)	$ (27,058)	$ (107,724)	$ (130,070)
Net loss per share attributable to common shareholders —basic and diluted	$ (0.66)	$ (0.49)	$ (1.80)	$ (2.42)
Weighted average common shares outstanding—basic and diluted	65,958,513	54,831,308	59,754,495	53,767,003

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

	As of	
	September 30, 2020	December 31, 2019
Cash, cash equivalents, and short-term investments	$ 364,395	$ 233,380
Working capital	353,521	213,797
Total assets	384,413	254,534
Accumulated deficit	(463,816)	(356,092)
Total shareholders' equity	358,509	225,423