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 1, 2022**

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 Stock Market LLC (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 November 1, 2022, Kiniksa Pharmaceuticals, Ltd. issued a press release announcing financial results for the quarter ended September 30, 2022. 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 1, 2022
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 1, 2022

By: /s/ Madelyn Zeylikman
Madelyn Zeylikman
Senior Vice President, General Counsel and Secretary

Exhibit 99.1

Kiniksa Pharmaceuticals Reports Third Quarter 2022 Financial Results and Provides Corporate Update

– ARCALYST® (rilonacept) Q3 2022 net revenue of $33.4 million –
– RHAPSODY long-term extension data demonstrated rilonacept treatment beyond 18 months resulted in continued treatment response (Hazard Ratio = 0.018, p<0.0001) –
– KPL-404 Phase 2 data in rheumatoid arthritis expected in 1H 2024 –
– Cash reserves of $200.7 million expected to fund operations into at least 2025 –
– Conference call and webcast scheduled for 8:30 am ET today –

HAMILTON, BERMUDA – November 1, 2022 – Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) (Kiniksa), a biopharmaceutical company with a portfolio of assets designed to modulate immunological pathways across a spectrum of diseases, today reported third quarter 2022 financial results and provided a corporate update.

"Physician adoption, patient satisfaction, and payer access drove continued strong ARCALYST performance in the third quarter. We remain focused on positioning ARCALYST as the standard of care for recurrent pericarditis, with the goal of broadening our reach and helping even more patients," said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. "Additionally, with the profitable ARCALYST collaboration and initial proceeds from the global license agreement with Genentech for the rights to develop and commercialize vixarelimab, we are well-positioned to execute on synergistic growth opportunities across our portfolio, including the expansion of our ARCALYST cardiovascular franchise."

Corporate Update

- In September 2022, Kiniksa announced the closing of its global license agreement with Roche and Genentech, a member of the Roche Group (Genentech), for the rights to develop and commercialize vixarelimab in exchange for $100 million in upfront and near-term payments, approximately $600 million in clinical, regulatory, and sales-based milestones before fulfilling upstream obligations, and royalties on annual net sales.

Portfolio Execution

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

- ARCALYST net revenue was $33.4 million for the third quarter of 2022.
  - Greater than 650 prescribers have written ARCALYST prescriptions for recurrent pericarditis since launch.

- Greater than 90% payer approval rate of completed patient cases for recurrent pericarditis in the third quarter of 2022.
- As of the end of the third quarter of 2022, the average duration of initial therapy in the commercial setting was approximately 12 months, and approximately 35% of recurrent pericarditis patients who had discontinued ARCALYST therapy restarted treatment.

KPL-404 (monoclonal antibody inhibitor of CD40-CD154 interaction)

- Kiniksa is enrolling the second and final cohort of the multiple ascending dose portion of the Phase 2 clinical trial of KPL-404 in rheumatoid arthritis. Following completion of this portion of the trial, the proof-of-concept portion will begin. The company expects data from the trial in the first half of 2024.

Mavrilimumab (monoclonal antibody inhibitor targeting GM-CSFRα)

- Kiniksa is pursuing collaborative study agreements to evaluate the potential of mavrilimumab in rare cardiovascular diseases where the granulocyte macrophage colony stimulating factor (GM-CSF) mechanism has been implicated.

Upcoming Scientific Conference Presentation

- Kiniksa today announced that an abstract highlighting long-term extension (LTE) data from RHAPSODY, the pivotal Phase 3 clinical trial of rilonacept in recurrent pericarditis, has been accepted for presentation at the American Heart Association (AHA) Scientific Sessions 2022.[1,2]
- LTE data included in the abstract demonstrated rilonacept treatment beyond 18 months resulted in continued treatment response.
    - The median [maximum at end of LTE] duration of continuous rilonacept therapy for all patients in RHAPSODY was 18 [27] months for US patients (n=45) and 27 [33] months for non-US patients (n=29).[3]
    - The annualized incidence of pericarditis recurrences while on therapy for all patients (n=74) during the first 18 months of the LTE portion of the trial was 0.04 events per patient-year.
    - Patients were given the option at 18 months from their most recent pericarditis recurrence to continue or suspend rilonacept treatment for observation.

[1] Dr. Massimo Imazio of University Hospital Santa Maria della Misericordia, Udine, will present a poster presentation entitled *Prolonged Rilonacept Treatment in RHAPSODY Long-Term Extension Provided Persistent Reduction of Pericarditis Recurrence Risk* on Sunday, November 6, 2022, from 3:45 to 4:45 p.m. Central Time (4:45 – 5:45 p.m. Eastern Time).

[2] Data in the abstract are as of the abstract cutoff date; final data are under embargo until the poster presentation.

[3] Upon commercial availability of ARCALYST for recurrent pericarditis in April 2021, the LTE portion in the US ended, and patients continuing therapy transitioned to commercial ARCALYST. Non-US patients remained in the LTE without interruption until the LTE closed in June 2022.

- § 75% of patients who suspended treatment (n=8) experienced pericarditis recurrence (n=6). The median [interquartile range (IQR)] time-to-event was 11.8 [3.7, Not-Estimable (NE)] weeks.
- § There was a 98.2% reduction in risk of recurrent pericarditis events in patients who continued rilonacept treatment beyond 18 months (Hazard Ratio = 0.018, p<0.0001).

Financial Results

- Total revenue for the third quarter of 2022 was $99.1 million, compared to $12.1 million for the third quarter of 2021.
  - Total revenue for the third quarter of 2022 included $33.4 million in ARCALYST net product revenue and $65.7 million in license and collaboration revenue from the vixarelimab global license agreement with Genentech. Kiniksa did not report license and collaboration revenue in the third quarter of 2021.
- Total operating expenses for the third quarter of 2022 were $52.7 million, compared to $42.8 million for the third quarter of 2021.
  - Total operating expenses for the third quarter of 2022 included $4.6 million in collaboration expense. Kiniksa did not report collaboration expense in the third quarter of 2021.
  - Total operating expenses for the third quarter of 2022 included $6.0 million of non-cash, share-based compensation expense, compared to $6.2 million for third quarter of 2021.
- Net income for the third quarter of 2022 was $224.1 million, compared to a net loss of $30.5 million for the third quarter of 2021.
  - Net income for the third quarter of 2022 included a $177.4 million tax benefit primarily due to the release of a valuation allowance on non-cash deferred tax assets.
- As of September 30, 2022, the company had $200.7 million of cash, cash equivalents, and short-term investments and no debt.

Financial Guidance

- Kiniksa continues to expect ARCALYST net revenue for the full-year 2022 of between $115 million and $130 million.
- Kiniksa expects that its cash and cash equivalents will fund its current operating plan into at least 2025.

Conference Call Information

- Kiniksa will host a conference call and webcast at 8:30 a.m. Eastern Time on Tuesday, November 1, 2022, to discuss third quarter 2022 financial results and to provide a corporate update.
- Individuals interested in participating in the call via telephone may register here. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. To access the webcast, please visit the Investors and Media section of Kiniksa's website. A replay of the event will also be available on Kiniksa's website within approximately 48 hours after the event.

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 portfolio assets, ARCALYST, KPL-404, and mavrilimumab, are based on strong biologic rationale or validated mechanisms, target underserved conditions, and offer the potential for differentiation. These assets are designed to modulate immunological pathways across a spectrum of diseases. For more information, please visit www.kiniksa.com.

About ARCALYST

ARCALYST is a weekly, subcutaneously injected recombinant dimeric fusion protein that blocks interleukin-1 alpha (IL-1α) and interleukin-1 beta (IL-1β) signaling. ARCALYST was discovered by Regeneron and is approved by the U.S. Food and Drug Administration (FDA) for recurrent pericarditis, cryopyrin-associated periodic syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome, and deficiency of IL-1 receptor antagonist (DIRA). The FDA granted Breakthrough Therapy designation to ARCALYST for the treatment of recurrent pericarditis in 2019 and Orphan Drug designation to ARCALYST for the treatment of pericarditis in 2020. The European Commission granted Orphan Drug Designation to ARCALYST for the treatment of idiopathic pericarditis in 2020.

ARCALYST is indicated for:

- Treatment of Recurrent Pericarditis (RP) and reduction in risk of recurrence in adults and pediatric patients 12 years and older.
- Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS) in adults and children 12 years and older.
- Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing 10 kg or more.

IMPORTANT SAFETY INFORMATION ABOUT ARCALYST

- ARCALYST may affect your immune system and can lower the ability of your immune system to fight infections. Serious infections, including life-threatening infections and death, have happened in patients taking ARCALYST. If you have any signs of an infection, call your doctor right away. Treatment with ARCALYST should be stopped if you get a serious infection. You should not begin treatment with ARCALYST if you have an infection or have infections that keep coming back (chronic infection).
- While taking ARCALYST, do not take other medicines that block interleukin-1, such as Kineret® (anakinra), or medicines that block tumor necrosis factor, such as Enbrel® (etanercept), Humira® (adalimumab), or Remicade® (infliximab), as this may increase your risk of getting a serious infection.

- Talk with your doctor about your vaccine history. Ask your doctor whether you should receive any vaccines before you begin treatment with ARCALYST.
- Medicines that affect the immune system may increase the risk of getting cancer.
- Stop taking ARCALYST and call your doctor or get emergency care right away if you have any symptoms of an allergic reaction.
- Your doctor will do blood tests to check for changes in your blood cholesterol and triglycerides.
- Common side effects include injection-site reactions (which may include pain, redness, swelling, itching, bruising, lumps, inflammation, skin rash, blisters, warmth, and bleeding at the injection site), upper respiratory tract infections, joint and muscle aches, rash, ear infection, sore throat, and runny nose.

For more information about ARCALYST, talk to your doctor and see the Product Information.

About KPL-404

KPL-404 is an investigational humanized monoclonal antibody that is designed to inhibit CD40-CD154 (CD40 ligand) interaction, a key T-cell co-stimulatory signal critical for B-cell maturation and immunoglobulin class switching and Type 1 immune responses. Kiniksa believes disrupting the CD40-CD154 interaction is an attractive approach to address multiple autoimmune disease pathologies.

About Mavrilimumab

Mavrilimumab is an investigational fully human monoclonal antibody that blocks activity of GM-CSF by specifically binding to the alpha subunit of the GM-CSF receptor (GM-CSFRα). Phase 2 clinical trials of mavrilimumab in rheumatoid arthritis and giant cell arteritis achieved their primary and secondary endpoints with statistical significance. Kiniksa is evaluating the development of mavrilimumab in rare cardiovascular diseases where the GM-CSF mechanism has been implicated.

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: positioning ARCALYST as the standard of care for recurrent pericarditis with the goal of broadening our reach and helping even more patients; our ability to execute on synergistic growth opportunities across our portfolio, including the expansion of our ARCALYST cardiovascular franchise; our expectation that (i) the proof-of-concept portion of the Phase 2 clinical trial of KPL-404 in rheumatoid arthritis will begin after completion of the multiple ascending dose portion of such trial, and (ii) we will report data from such Phase 2 clinical trial in the first half of 2024; our pursuit of collaborative study agreements to evaluate the potential of mavrilimumab in rare cardiovascular diseases where the GM-CSF mechanism has been implicated; our expectation that ARCALYST net revenue for full-year 2022 will be between $115 million and $130 million; our expectation about our cash reserves funding our current operating plan into at least 2025; our beliefs about the mechanisms of action of our product candidates and potential impact of their approach, including that using KPL-404 to disrupt the CD40-CD154 interaction is an attractive approach to address multiple autoimmune disease pathologies; and our belief that all of our product candidates offer the potential for differentiation.

These forward-looking statements are based on management's current 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; delays or difficulty in completing our clinical trials as originally designed; potential for changes between final data and any preliminary, interim, top-line or other data from clinical trials; our inability to replicate results from our earlier clinical trials or studies; impact of additional data from us or other companies, including the potential for our data to produce negative, inconclusive or commercially uncompetitive results; potential undesirable side effects caused by our products and product candidates; our inability to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities; potential for applicable regulatory authorities to not accept our filings, delay or deny approval of any of our product candidates or require additional data or trials to support approval; inability to successfully execute on our commercial strategy for ARCALYST; our reliance on third parties as the sole source of supply of the drug substance and drug product used in our products and product candidates; our reliance on Regeneron as the sole manufacturer of ARCALYST; raw materials, important ancillary products and drug substance and/or drug product shortages; our reliance on third parties to conduct research, clinical trials, and/or certain regulatory activities for our product candidates; complications in coordinating requirements, regulations and guidelines of regulatory authorities across jurisdictions for our clinical trials; the impact of the COVID-19 pandemic and any subsequent pandemic and measures taken in response to such pandemics 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 existing or new competition.

These and other important factors discussed in our filings with the U.S. Securities and Exchange Commission, including under the caption "Risk Factors" contained therein, 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 estimates as of the date of this press release. Except as required by law, we disclaim any intention or obligation to update or revise any forward-looking statements. 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. All other trademarks are the property of their respective owners.

Every Second Counts!®

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KINIKSA PHARMACEUTICALS, LTD.
SELECTED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
Product revenue, net	$ 33,424	$ 12,095	$ 82,585	$ 19,799
License and collaboration revenue	65,711	—	75,711	—
Total revenue	99,135	12,095	158,296	19,799
Costs and operating expenses:				
Cost of goods sold	6,937	2,767	16,185	5,233
Collaboration expenses	4,623	—	16,549	—
Research and development	16,485	19,236	51,100	71,864
Selling, general and administrative	24,677	20,759	70,736	63,207
Total operating expenses	52,722	42,762	154,570	140,304
Income (loss) from operations	46,413	(30,667)	3,726	(120,505)
Interest income	322	5	459	20
Income (loss) before income taxes	46,735	(30,662)	4,185	(120,485)
Benefit (provision) for income taxes	177,358	118	174,717	(1,106)
Net income (loss)	$ 224,093	$ (30,544)	$ 178,902	$ (121,591)
Net income (loss) per share attributable to common shareholders—basic	$ 3.23	$ (0.44)	$ 2.58	$ (1.78)
Net income (loss) per share attributable to common shareholders—diluted	$ 3.18	$ (0.44)	$ 2.55	$ (1.78)
Weighted average common shares outstanding—basic	69,445,071	68,662,673	69,305,755	68,444,061
Weighted average common shares outstanding—diluted	70,552,018	68,662,673	70,286,444	68,444,061

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

	As of	
	September 30, 2022	December 31, 2021
Cash, cash equivalents, and short-term investments	$ 200,724	$ 182,201
Working capital	185,323	151,622
Total assets	459,953	232,800
Accumulated deficit	(496,495)	(675,397)
Total shareholders' equity	384,008	185,037