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 25, 2023**

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 July 25, 2023, Kiniksa Pharmaceuticals, Ltd. issued a press release announcing financial results for the quarter ended June 30, 2023. 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 25, 2023
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: July 25, 2023

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

Exhibit 99.1

Kiniksa Pharmaceuticals Reports Second Quarter 2023 Financial Results and Recent Portfolio Execution

– ARCALYST® (rilonacept) Q2 2023 net product revenue of $54.5 million –

– ARCALYST 2023 net product revenue guidance increased to $220 - $230 million, representing ~84% year-over-year growth at the midpoint –

– KPL-404 Phase 2 rheumatoid arthritis data expected in 1H 2024 –

– Cash reserves now expected to fund operations into at least 2027 –

– Conference call and webcast scheduled for 8:30 am ET today –

HAMILTON, BERMUDA – July 25, 2023 – Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) (Kiniksa), a biopharmaceutical company with a pipeline of immune-modulating assets designed to target a spectrum of cardiovascular and autoimmune diseases, today reported second quarter 2023 financial results and recent portfolio execution.

"Kiniksa continues to make significant progress in bringing ARCALYST, the first and only FDA-approved therapy for recurrent pericarditis, to patients in need. As a result of increased call frequency and expanded reach with target prescribers, we are seeing increased prescriber adoption and patient enrollments. We are still in the early stages of building the recurrent pericarditis market and remain encouraged by the high level of patient satisfaction, payer approval rates, and duration of therapy. These key metrics provide conviction in raising our 2023 ARCALYST sales guidance to between $220 million and $230 million," said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. "Within our pipeline, we continue to enroll patients in the KPL-404 Phase 2 trial in rheumatoid arthritis and expect data in the first half of 2024. Additionally, we have a strong financial position and our cash reserves, combined with our continued ARCALYST commercial execution and financial discipline, now provide cash runway into at least 2027."

Portfolio and Collaboration Execution

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

- ARCALYST net product revenue was $54.5 million for the second quarter of 2023.
- Since launch, more than 1,250 prescribers have written ARCALYST prescriptions for recurrent pericarditis.

- As of the end of the second quarter of 2023, average total duration of ARCALYST therapy in recurrent pericarditis was approximately 20 months.
    - Average total duration of therapy includes the approximately 45% of patients who restarted ARCALYST, within an average of 8 weeks, after having discontinued therapy.

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

- Kiniksa is enrolling patients in the Phase 2 clinical trial of KPL-404 in rheumatoid arthritis. 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.

Vixarelimab (monoclonal antibody inhibitor of signaling through OSMRβ)

- In the second quarter of 2023, Kiniksa recognized a $15.0 million development milestone related to a new indication under its global license agreement with Genentech, a member of the Roche Group (Genentech).

Financial Results

- Total revenue for the second quarter of 2023 was $71.5 million, compared to $27.0 million for the second quarter of 2022.
    - Total revenue for the second quarter of 2023 included $54.5 million in ARCALYST net product revenue and $17.0 million in license and collaboration revenue, compared to $27.0 million in ARCALYST net product revenue and $0.0 million in license and collaboration revenue for the second quarter of 2022.
- Total operating expenses for the second quarter of 2023 were $74.6 million, compared to $46.3 million for the second quarter of 2022.
    - Total operating expenses for the second quarter of 2023 included $6.5 million in non-cash, share-based compensation expense, compared to $6.7 million for the second quarter of 2022.
- Net income for the second quarter of 2023 was $15.0 million, compared to a net loss of $20.0 million for the second quarter of 2022.
    - Net income for the second quarter of 2023 included a $16.2 million tax benefit primarily due to the release of a valuation allowance on non-cash deferred tax assets.
- As of June 30, 2023, Kiniksa had $185.0 million of cash, cash equivalents, and short-term investments and no debt.

Financial Guidance

- Kiniksa now expects 2023 ARCALYST net product revenue of between $220 million and $230 million compared to prior guidance of between $200 million and $215 million.

- Kiniksa now expects that its cash and cash equivalents will fund its current operating plan into at least 2027.

Conference Call Information

- Kiniksa will host a conference call and webcast at 8:30 a.m. Eastern Time on Tuesday, July 25, 2023, to discuss second quarter 2023 financial results and recent portfolio execution.

- 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 immune-modulating assets, ARCALYST, KPL-404, and mavrilimumab, are based on strong biologic rationale or validated mechanisms, target a spectrum of underserved cardiovascular and autoimmune conditions, and offer the potential for differentiation. 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 Pharmaceuticals, Inc. (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 2021.

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: our expectation that ARCALYST full-year 2023 net product revenue will be between $220 million and $230 million; our expectation that we will report data from our Phase 2 clinical trial of KPL-404 in rheumatoid arthritis in the first half of 2024; our expectation about our cash reserves funding our current operating plan into at least 2027; 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 current sole manufacturer of ARCALYST; risks arising from our ongoing technology transfer of ARCALYST drug substance manufacturing; raw material, important ancillary product 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; changes in our operating plan, business development strategy or 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. 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 INCOME (LOSS)
(In thousands)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Product revenue, net	$ 54,495	$ 26,972	$ 97,154	$ 49,161
License and collaboration revenue	16,978	—	22,664	10,000
Total revenue	71,473	26,972	119,818	59,161
Costs and operating expenses:				
Cost of goods sold	7,699	5,029	14,735	9,248
Collaboration expenses	13,986	3,672	22,274	11,926
Research and development	23,767	13,798	38,939	34,615
Selling, general and administrative	29,175	23,841	58,220	46,059
Total operating expenses	74,627	46,340	134,168	101,848
Loss from operations	(3,154)	(19,368)	(14,350)	(42,687)
Other income	1,915	103	3,747	137
Loss before income taxes	(1,239)	(19,265)	(10,603)	(42,550)
Benefit (provision) for income taxes	16,211	(716)	13,305	(2,641)
Net income (loss)	$ 14,972	$ (19,981)	$ 2,702	$ (45,191)
Net income (loss) per share attributable to common shareholders—basic	$ 0.21	$ (0.29)	$ 0.04	$ (0.65)
Net income (loss) per share attributable to common shareholders—diluted	$ 0.21	$ (0.29)	$ 0.04	$ (0.65)
Weighted average common shares outstanding—basic	69,918,287	69,289,972	69,835,452	69,213,860
Weighted average common shares outstanding—diluted	71,634,729	69,289,972	71,420,026	69,213,860

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

	As of	
	June 30, 2023	December 31, 2022
Cash, cash equivalents, and short-term investments	$ 184,992	$ 190,608
Working capital	198,568	195,994
Total assets	484,332	459,672
Accumulated deficit	(489,332)	(492,034)
Total shareholders' equity	411,656	396,149