

**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 28, 2026**

Kiniksa Pharmaceuticals International, plc

(Exact name of Registrant as Specified in Its Charter)

England and Wales
(State or other jurisdiction of
incorporation or organization)

001-730430
(Commission
File Number)

98-1795578
(I.R.S. Employer
Identification No.)

Kiniksa Pharmaceuticals International, plc
105 Piccadilly, Second Floor
London, W1J 7NJ
England, United Kingdom
(781) 431-9100

(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 Ordinary Shares \$0.000273235 nominal 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 28, 2026, Kiniksa Pharmaceuticals International, plc issued a press release announcing financial results for the quarter ended June 30, 2026. A copy of the press release is furnished with this Current Report on Form 8-K as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Kiniksa Pharmaceuticals International, plc, dated July 28, 2026
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 INTERNATIONAL, PLC

Date: July 28, 2026

By: /s/ Douglas Barry

Douglas Barry

Senior Vice President, Chief Legal Officer and Secretary



Kiniksa Pharmaceuticals Reports Second Quarter 2026 Financial Results and Recent Portfolio Execution

- ARCALYST® (rilonacept) Q2 2026 net product revenue of \$243.6 million, representing ~55% year-over-year growth –
- ARCALYST 2026 expected net product revenue increased to \$980 - \$995 million –
- KPL-387 Phase 2 data demonstrated rapid and sustained reductions in pain and inflammation at 300 mg SC once-monthly, the dose level selected for Phase 3 –
- KPL-387 pivotal Phase 3 trial in recurrent pericarditis now enrolling and dosing patients –
- Conference call and webcast scheduled for 8:30 am ET today –

LONDON – July 28, 2026 – Kiniksa Pharmaceuticals International, plc (Nasdaq: KNSA) (Kiniksa), a biopharmaceutical company developing and commercializing novel therapies for diseases with unmet need, with a focus on cardiovascular indications, today reported second quarter 2026 financial results and recent portfolio execution.

“In the second quarter, Kiniksa continued to drive growth in new and repeat prescribers of ARCALYST in recurrent pericarditis, which led to a meaningful increase in patients on therapy. As a result, we have raised our 2026 ARCALYST net sales guidance to between \$980 and \$995 million,” said Sanj K. Patel, Chairman & Chief Executive Officer of Kiniksa. “In our clinical portfolio, KPL-387 Phase 2 data supported initiation of the pivotal Phase 3 trial, PASTORALE, which is now enrolling and dosing patients. We are excited to advance KPL-387 with its target product profile of once-monthly subcutaneous dosing in a liquid formulation. We expect to bring this potential additional treatment option to patients in the 2028/2029 timeframe. Additionally, we continue to develop KPL-1161 with a target profile of once-quarterly dosing and are on track to initiate a Phase 1 trial by the end of this year.”

Portfolio Execution

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

- ARCALYST net product revenue was \$243.6 million for the second quarter of 2026.
- As of the end of the second quarter of 2026, approximately 21% of the 14,000 multiple-recurrence patients were actively on ARCALYST treatment.

- Since launch, more than 5,000 prescribers have written ARCALYST prescriptions for recurrent pericarditis.
- As of the end of the second quarter of 2026, average total duration of ARCALYST therapy in recurrent pericarditis was approximately 3 years, in line with the median duration of disease.

KPL-387 (monoclonal antibody IL-1 receptor antagonist)

- Kiniksa today announced data from an interval analysis of the ongoing KPL-387 Phase 2/3 trial in recurrent pericarditis. The Phase 2 dose-focusing portion of the trial is designed to evaluate the dose response and safety of different subcutaneously (SC) administered KPL-387 dose regimens and to support dose selection for the pivotal Phase 3 portion of the trial.
 - Participants in the KPL-387 300 mg SC monthly dose group experienced rapid and sustained reductions in Numeric Rating Scale (NRS) pain and inflammation as soon as after the first dose:
 - Primary Efficacy Endpoint^{*}
 - Time to Treatment Response¹: 4.0 (3.0, 6.0) days.
 - Secondary Efficacy Endpoints^{*}
 - Time to Pain Response: 4.0 (3.0, 6.0) days.
 - Time to C-Reactive Protein (CRP) Normalization²: 8.0 (7.0, 9.0) days.
 - KPL-387 efficacy was durable throughout the monthly dosing interval.
 - KPL-387 was generally well-tolerated, consistent with the well-known safety profile of interleukin-1 (IL-1) pathway inhibition.
- Kiniksa is enrolling and dosing patients in PASTORALE, the pivotal Phase 3 portion of the Phase 2/3 clinical trial.
 - PASTORALE is an event-driven, double-blind, placebo controlled, randomized withdrawal (RW) study enrolling up to approximately 85 participants with recurrent pericarditis. PASTORALE is evaluating the efficacy and safety of KPL-387 300 mg SC administered once-monthly in a liquid formulation.
 - The primary endpoint is time to first adjudicated pericarditis recurrence during the RW period.
- Kiniksa is also conducting a supplemental Phase 2 Transition to KPL-387 Monotherapy Dosing & Administration Study evaluating the efficacy and safety of dosing regimens used to transition patients from standard therapies to KPL-387 monotherapy.

KPL-1161 (Fc-modified monoclonal antibody IL-1 receptor antagonist)

- Kiniksa is conducting preclinical development activities with KPL-1161 with a target profile of quarterly SC dosing. The company expects to initiate a Phase 1 first-in-human clinical trial by the end of 2026.

* Reported as median (95% confidence interval).

¹ Treatment Response is defined as Pain Response (NRS score ≤ 2 on the 11-point daily pericarditis pain NRS pain scale) and at least one CRP level ≤ 0.5 mg/dL within 7 days before or after the Pain Response.

² CRP Normalization is defined as CRP ≤ 0.5 mg/dL.

Financial Results

- Total revenue for the second quarter of 2026 was \$243.6 million, compared to \$156.8 million for the second quarter of 2025.
- Total operating expenses for the second quarter of 2026 were \$216.4 million, compared to \$136.6 million for the second quarter of 2025, and comprised the following:
 - Cost of Goods Sold (COGS) expenses of \$23.6 million, compared to \$18.6 million for the second quarter of 2025. The increase in COGS expenses was primarily due to costs associated with increased sales of ARCALYST.
 - Collaboration expenses of \$88.1 million, compared to \$52.4 million for the second quarter of 2025. Collaboration expenses are driven primarily by ARCALYST collaboration profitability.
 - Research and Development (R&D) expenses of \$40.9 million, compared to \$18.8 million for the second quarter of 2025. The increase in R&D expenses was primarily due to increased KPL-387 clinical and manufacturing activity as well as increased preclinical development investment.
 - Selling, General, and Administrative (SG&A) expenses of \$63.9 million, compared to \$46.9 million for the second quarter of 2025. The increase in SG&A expenses was primarily due to investment associated with the commercialization of ARCALYST.
 - Total operating expenses for the second quarter of 2026 included \$11.6 million in non-cash, share-based compensation expense, compared to \$8.9 million for the second quarter of 2025.
- Net income for the second quarter of 2026 was \$25.4 million, compared to \$17.8 million for the second quarter of 2025.
- As of June 30, 2026, Kiniksa had \$525.9 million of cash, cash equivalents, and short-term investments and no debt.

Financial Guidance

- Kiniksa expects 2026 ARCALYST net product revenue of between \$980 million and \$995 million, compared to prior guidance of between \$930 million and \$945 million.
- Kiniksa expects its current operating plan to remain cash flow positive on an annual basis.

Conference Call Information

- Kiniksa will host a conference call and webcast at 8:30 a.m. Eastern Time on Tuesday, July 28, 2026, to discuss second quarter 2026 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 dedicated to improving the lives of patients suffering from debilitating diseases by discovering, acquiring, developing, and commercializing novel therapies for diseases with unmet need, with a focus on cardiovascular indications. Kiniksa's portfolio of assets is based on strong biologic rationale or validated mechanisms and offers 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-1 α) and interleukin-1 beta (IL-1 β) 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 exclusivity to ARCALYST in 2021 for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and pediatric patients 12 years and older. 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-387

KPL-387 is an independently developed, investigational, fully human immunoglobulin G2 (IgG2) monoclonal antibody that binds human interleukin-1 receptor 1 (IL-1R1), inhibiting the signaling of the cytokines IL-1 α and IL-1 β . Kiniksa believes KPL-387 could expand the treatment options for recurrent pericarditis patients by potentially enabling dosing with a single monthly SC self-injection in a liquid formulation. In October 2025, the FDA granted Orphan Drug Designation to KPL-387 for the treatment of pericarditis.

About PASTORALE

PASTORALE is a double-blind, placebo controlled, randomized withdrawal (RW) study enrolling up to approximately 85 patients with recurrent pericarditis. In the first period, a single-blind run-in (RI), all participants will receive KPL-387 while conventional oral pericarditis medications are weaned and discontinued. Participants achieving Clinical Response in the RI period will then be randomized in a 1:1 ratio to receive either KPL-387 300 mg SC once-monthly or placebo in an event-driven, double-blind, RW period. The primary efficacy endpoint is time to first-adjudicated pericarditis recurrence during the RW period. Participants in the RW period may be eligible to enter a long-term extension.

About KPL-1161

KPL-1161 is an independently developed, investigational, Fc-modified IgG2 monoclonal antibody that binds IL-1R1, inhibiting the signaling of the cytokines IL-1 α and IL-1 β , with a target profile of quarterly SC dosing. Kiniksa is currently engaging in preclinical development activities for KPL-1161.

Forward-Looking Statements

This press release contains forward-looking statements. 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 2026 net product revenue will be between \$980 million and \$995 million; our expectation to begin commercialization of KPL-387 in 2028 or 2029; our belief that we are on track to initiate a Phase 1 first-in-human clinical trial of KPL-1161 by the end of 2026; our expectation that our current operating plan will remain cash flow positive on an annual basis; our target profile of quarterly subcutaneous dosing for KPL-1161; our beliefs about the mechanisms of our assets and potential impact of their approach; statements regarding our belief about the future of our commercial opportunities; and our belief that our portfolio of assets offers 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, including the data from the interval analysis of our Phase 2 clinical trial of KPL-387 in recurrent pericarditis; 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; 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; 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; 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; raw material, important ancillary product and drug substance and/or drug product shortages; business development activities and their impact on our financial performance and strategy; changes in our operating plan, business development strategy or funding requirements; existing or new competition; current and future healthcare reforms, including those affecting the delivery of or payment for healthcare products and services; and the impact of global economic policy, including any uncertainty in national and international markets.

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.

***Every Second Counts!*®**

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KINIKSA PHARMACEUTICALS INTERNATIONAL, PLC
SELECTED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2026	2025	2026	2025
Revenue:				
Product revenue, net	\$ 243,600	\$ 156,797	\$ 457,866	\$ 294,582
License and collaboration revenue	—	—	—	—
Total revenue	243,600	156,797	457,866	294,582
Costs and operating expenses:				
Cost of goods sold	23,572	18,603	44,368	36,471
Collaboration expenses	88,069	52,418	163,646	96,208
Research and development	40,899	18,753	68,374	38,078
Selling, general and administrative	63,866	46,863	125,017	90,393
Total operating expenses	216,406	136,637	401,405	261,150
Income from operations	27,194	20,160	56,461	33,432
Other income, net	3,951	2,717	7,365	5,010
Income before income taxes	31,145	22,877	63,826	38,442
Provision for income taxes	(5,713)	(5,045)	(15,802)	(12,071)
Net income	\$ 25,432	\$ 17,832	\$ 48,024	\$ 26,371
Net income per share attributable to ordinary shareholders—basic	\$ 0.33	\$ 0.24	\$ 0.62	\$ 0.36
Net income per share attributable to ordinary shareholders—diluted	\$ 0.30	\$ 0.23	\$ 0.58	\$ 0.34
Weighted average ordinary shares outstanding—basic	77,577,675	73,438,530	77,050,036	73,041,920
Weighted average ordinary shares outstanding—diluted	83,398,051	77,942,082	82,902,904	76,984,393

KINIKSA PHARMACEUTICALS INTERNATIONAL, PLC
SELECTED CONDENSED CONSOLIDATED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	As of	
	June 30, 2026	December 31, 2025
Cash, cash equivalents, and short-term investments	\$ 525,928	\$ 414,074
Working capital	497,386	387,993
Total assets	896,110	763,633
Accumulated deficit	(414,114)	(462,138)
Total shareholders' equity	654,149	567,606