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): **October 28, 2025**

Kiniksa Pharmaceuticals International, plc
(Exact name of Registrant as Specified in Its Charter)

England and Wales	**001-730430**	**98-1795578**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

23 Old Bond Street, Floor 3
London, W1S 4PZ
England, United Kingdom
(Address of principal executive offices, including zip code)

(781) 431-9100
(Registrant's telephone number, including area code)

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 October 28, 2025, Kiniksa Pharmaceuticals International, plc issued a press release announcing financial results for the quarter ended September 30, 2025. 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	Earnings Press Release issued by Kiniksa Pharmaceuticals International, plc, dated October 28, 2025
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: October 28, 2025

By: /s/ Douglas Barry
Douglas Barry
Senior Vice President, Chief Legal Officer and Secretary

Kiniksa Pharmaceuticals Reports Third Quarter 2025 Financial Results and Recent Portfolio Execution

– ARCALYST® (rilonacept) Q3 2025 net product revenue of $180.9 million, representing 61% year-over-year growth –

– ARCALYST 2025 expected net product revenue raised to $670 - $675 million –

– KPL-387 granted Orphan Drug Designation for the treatment of pericarditis –

– Cash balance increased by $44.3 million in Q3 2025 to $352.1 million –

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

LONDON – October 28, 2025 – 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 third quarter 2025 financial results and recent portfolio execution.

"Year to date, ARCALYST revenue has continued to grow, with the expanding adoption of IL-1α & IL-1β inhibition for recurrent pericarditis driving a significant increase in active commercial patients and duration of therapy. As a result, we are raising our 2025 ARCALYST net sales guidance to between $670 million and $675 million from between $625 million and $640 million," said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. "In our clinical portfolio, we believe the development of KPL-387 positions our IL-1α & IL-1β inhibition franchise for continued success and could offer an important advancement in the treatment options available to patients with recurrent pericarditis, potentially expanding penetration into the addressable market. We are on-track for data from the Phase 2 dose-focusing portion of the KPL-387 Phase 2/3 recurrent pericarditis trial in the second half of 2026."

Portfolio Execution

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

- ARCALYST net product revenue was $180.9 million for the third quarter of 2025.
- Since launch, more than 3,825 prescribers have written ARCALYST prescriptions for recurrent pericarditis.
- As of the end of the third quarter of 2025, average total duration of ARCALYST therapy in recurrent pericarditis increased to approximately 32 months, compared to approximately 27 months at the end of 2024.

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

- Kiniksa expects data from the dose-focusing portion of the Phase 2/3 clinical trial of KPL-387 in recurrent pericarditis in the second half of 2026. Subsequently, Kiniksa plans to initiate the pivotal portion of the trial.
- Kiniksa continues to plan to conduct a supplemental Phase 2 Transition to KPL-387 Monotherapy Dosing & Administration Study evaluating the efficacy and safety of the dosing regimens used to transition patients from standard therapies to KPL-387 monotherapy.
- Kiniksa announced that the Food and Drug Administration (FDA) granted Orphan Drug Designation to KPL-387 for the treatment of pericarditis.

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

- Kiniksa is conducting Investigational New Drug (IND)-enabling development activities with KPL-1161 with a target profile of quarterly subcutaneous (SC) dosing.

Financial Results

- Total revenue for the third quarter of 2025 was $180.9 million, compared to $112.2 million for the third quarter of 2024.
- Total operating expenses for the third quarter of 2025 were $156.8 million, compared to $121.9 million for the third quarter of 2024.
  - Total operating expenses for the third quarter of 2025 included $63.3 million in collaboration expenses, which are driven by ARCALYST collaboration profitability, compared to $29.3 million for the third quarter of 2024.
  - Total operating expenses for the third quarter of 2025 included $10.1 million in non-cash, share-based compensation expense, compared to $7.8 million for the third quarter of 2024.
- Net income for the third quarter of 2025 was $18.4 million, compared to a net loss of $12.7 million for the third quarter of 2024.
- As of September 30, 2025, Kiniksa had $352.1 million of cash, cash equivalents, and short-term investments and no debt.

Financial Guidance

- Kiniksa expects 2025 ARCALYST net product revenue of between $670 million and $675 million, compared to prior guidance of between $625 million and $640 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, October 28, 2025, to discuss third quarter 2025 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-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 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-1α and IL-1β. 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 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-1α and IL-1β, with a target profile of quarterly SC dosing. Kiniksa is currently engaging in IND-enabling 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 2025 net product revenue will increase to between $670 million and $675 million; our belief that the development of KPL-387 positions our IL-1α & IL-1β inhibition franchise for continued success and could offer an important advancement in the treatment options available to patients with recurrent pericarditis, potentially expanding penetration into the addressable market; our expectation that we are on track to have data from the Phase 2 dose-focusing portion of the KPL-387 Phase 2/3 recurrent pericarditis trial in the second half of 2026, and our plan to initiate the pivotal portion of the trial thereafter; our plan to conduct a supplemental Phase 2 Transition to KPL-387 Monotherapy Dosing & Administration Study evaluating the efficacy and safety of the dosing regimens used to transition patients from standard therapies to KPL-387 monotherapy; our expectation that our current operating plan will remain cash flow positive on an annual basis; our target profile of monthly dosing via a single subcutaneous injection in a liquid formulation for KPL-387; our target profile of quarterly subcutaneous dosing for KPL-1161; our beliefs about the mechanisms of our assets and potential impact of their approach; 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; 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; 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; 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; 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.

Every Second Counts! ®

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue:				
Product revenue, net	$ 180,855	$ 112,214	$ 475,437	$ 294,493
License and collaboration revenue	—	—	—	6,210
Total revenue	180,855	112,214	475,437	300,703
Operating expenses:				
Cost of goods sold	20,257	20,109	56,728	43,014
Collaboration expenses	63,307	29,307	159,515	80,122
Research and development	24,166	26,057	62,244	76,408
Selling, general and administrative	49,104	46,399	139,497	127,476
Total operating expenses	156,834	121,872	417,984	327,020
Income (loss) from operations	24,021	(9,658)	57,453	(26,317)
Other income	3,136	2,457	8,146	7,144
Income (loss) before income taxes	27,157	(7,201)	65,599	(19,173)
Provision for income taxes	(8,722)	(5,492)	(20,793)	(15,132)
Net income (loss)	$ 18,435	$ (12,693)	$ 44,806	$ (34,305)
Net income (loss) per share attributable to ordinary shareholders—basic	$ 0.25	$ (0.18)	$ 0.61	$ (0.48)
Net income (loss) per share attributable to ordinary shareholders—diluted	$ 0.23	$ (0.18)	$ 0.57	$ (0.48)
Weighted average ordinary shares outstanding—basic	74,714,846	71,726,685	73,605,690	71,123,658
Weighted average ordinary shares outstanding—diluted	80,035,400	71,726,685	78,027,370	71,123,658

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

	As of	
	September 30, 2025	December 31, 2024
Cash, cash equivalents, and short-term investments	$ 352,102	$ 243,627
Working capital	351,938	231,178
Total assets	712,333	580,553
Accumulated deficit	(476,337)	(521,143)
Total shareholders' equity	535,383	438,436