



Kiniksa Pharmaceuticals Reports Fourth Quarter and Full Year 2024 Financial Results and Recent Portfolio Execution

February 25, 2025

- ARCALYST® (rilonacept) Q4 2024 and full year 2024 net product revenue of \$122.5 million and \$417.0 million, respectively –
 - ARCALYST 2025 net product revenue expected to be \$560 - \$580 million –
- KPL-387 Phase 2/3 clinical trial in recurrent pericarditis expected to initiate in mid-2025; Phase 2 data expected in 2H 2026 –
 - Abiprubart development in Sjögren's Disease to be discontinued –
 - Current operating plan expected to remain cash flow positive on an annual basis –
 - Conference call and webcast scheduled for 8:30 am ET today –

LONDON, Feb. 25, 2025 (GLOBE NEWSWIRE) -- [Kiniksa Pharmaceuticals International, plc](https://www.kiniksa.com) (Nasdaq: KNSA) (Kiniksa), a biopharmaceutical company developing and commercializing novel therapies for diseases with unmet need, with a focus on cardiovascular indications, today reported fourth quarter and full year 2024 financial results and recent portfolio execution.

"Strong commercial execution in 2024 resulted in 79% year-over-year ARCALYST sales growth to \$417.0 million. We believe substantial opportunity remains for ARCALYST, and expect 2025 sales of between \$560 and \$580 million," said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. "Today, we are excited to announce the development program for KPL-387, which we believe could expand the treatment options for recurrent pericarditis patients by enabling a single monthly subcutaneous injection in a liquid formulation. We have interacted with the FDA and plan to initiate a Phase 2/3 clinical trial of KPL-387 in recurrent pericarditis in mid-2025. In line with our prioritization of cardiovascular indications, we plan to discontinue the development of abiprubart in Sjögren's Disease. On behalf of our entire organization, I would like to thank the patients, caregivers, and investigators who contributed to our study."

Corporate Update

- Kiniksa continues to focus development on diseases with unmet need, prioritizing cardiovascular indications.
 - Kiniksa announced today the development of KPL-387 in recurrent pericarditis, with a target profile of monthly subcutaneous (SC) dosing. KPL-387 is a fully human immunoglobulin G2 (IgG2) monoclonal antibody that binds human interleukin-1 receptor 1 (IL-1R1), inhibiting the signaling of the cytokines interleukin-1 α (IL-1 α) and interleukin-1 β (IL-1 β).
 - Kiniksa announced today that it is advancing KPL-1161 towards clinical development with a target profile of quarterly SC dosing. KPL-1161 is an Fc-modified IgG2 monoclonal antibody that binds IL-1R1, inhibiting the signaling of the cytokines IL-1 α and IL-1 β .
 - Kiniksa announced today that it plans to discontinue abiprubart development in Sjögren's Disease. The company will explore strategic alternatives for the asset.
 - Kiniksa announced today that it has exercised its right to terminate its exclusive license agreement for mavrilimumab with MedImmune.

Portfolio Execution

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

- ARCALYST net product revenue was \$122.5 million and \$417.0 million for the fourth quarter and full year 2024, respectively.
- Since launch, more than 2,850 prescribers have written ARCALYST prescriptions for recurrent pericarditis.
- As of the end of the fourth quarter of 2024, average total duration of ARCALYST therapy in recurrent pericarditis was approximately 27 months.
- As of the end of the fourth quarter of 2024, approximately 13% of the target 14,000 multiple-recurrence patients were actively on ARCALYST treatment.

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

- Kiniksa is conducting a single ascending dose (SAD) and multiple ascending dose Phase 1 clinical trial of KPL-387 in healthy volunteers.
 - Topline data from the SAD portion of the Phase 1 trial support potential monthly SC dosing in recurrent pericarditis.
- Kiniksa has interacted with the U.S. Food and Drug Administration (FDA) and expects to initiate a Phase 2/3 clinical trial of

KPL-387 in recurrent pericarditis in mid-2025, with Phase 2 data expected in the second half of 2026.

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

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

Financial Results

- Total revenue for the fourth quarter of 2024 was \$122.5 million, compared to \$83.4 million for the fourth quarter of 2023. Total revenue for the full year 2024 was \$423.2 million, compared to \$270.3 million for the full year 2023.
 - Total revenue for the fourth quarter of 2024 did not include any license and collaboration revenue, compared to \$12.2 million for the fourth quarter of 2023.
 - Total revenue for the full year 2024 included \$6.2 million in license and collaboration revenue, compared to \$37.1 million for the full year 2023.
- Total operating expenses for the fourth quarter of 2024 were \$141.8 million, compared to \$83.3 million for the fourth quarter of 2023. Total operating expenses for the full year 2024 were \$468.9 million, compared to \$295.5 million for the full year 2023.
 - Total operating expenses for the fourth quarter of 2024 included \$48.2 million in collaboration expenses, which are driven by ARCALYST collaboration profitability, compared to \$16.9 million for the fourth quarter of 2023. Total operating expenses for the full year 2024 included \$128.3 million in collaboration expenses, compared to \$56.5 million for the full year 2023.
 - Total operating expenses for the fourth quarter of 2024 included \$8.3 million in non-cash, share-based compensation expense, compared to \$7.8 million for the fourth quarter of 2023. Total operating expenses for the full year 2024 included \$30.7 million in non-cash, share-based compensation expense, compared to \$27.1 million for the full year 2023.
- Net loss for the fourth quarter of 2024 was \$8.9 million, compared to a net income of \$25.2 million for the fourth quarter of 2023. Net loss for the full year 2024 was \$43.2 million, compared to net income of \$14.1 million for the full year 2023.
 - Net loss for the fourth quarter of 2024 included a tax benefit of \$8.1 million, compared to a tax benefit of \$22.8 million for the fourth quarter of 2023, both primarily due to the treatment of non-cash deferred tax assets.
 - Net loss for the full year 2024 included a tax expense of \$7.0 million, compared to a tax benefit of \$30.7 million for the full year 2023, both primarily due to the treatment of non-cash deferred tax assets.
- As of December 31, 2024, Kiniksa had \$243.6 million of cash, cash equivalents, and short-term investments and no debt, compared to \$206.4 million as of December 31, 2023.

Financial Guidance

- Kiniksa expects 2025 ARCALYST net product revenue of between \$560 million and \$580 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, February 25, 2025, to discuss fourth quarter and full year 2024 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 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 the treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older. ARCALYST is also approved by the FDA for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 years and older, and the maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing 10 kg or more. The FDA granted Orphan Drug Exclusivity to ARCALYST upon its approval for recurrent pericarditis in 2021. 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 IgG2 monoclonal antibody that binds 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 enabling dosing with a single monthly SC injection in a liquid formulation.

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 IND-enabling development activities for KPL-1161.

About Abiprubart

Abiprubart is an investigational humanized monoclonal antibody that binds to CD40 and is designed to inhibit the 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 co-stimulatory interaction is an attractive approach to addressing multiple autoimmune disease pathologies.

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 belief that substantial opportunity remains for ARCALYST and our expectation that ARCALYST 2025 net product revenue will be between \$560 million and \$580 million; our plan to initiate a Phase 2/3 clinical trial of KPL-387 in recurrent pericarditis in mid-2025, with Phase 2 data expected in the second half of 2026; our plan to discontinue abiprubart development in Sjögren’s Disease and explore strategic alternatives for the asset; our expectation that our current operating plan will remain cash flow positive on an annual basis; our plan to focus development on diseases with unmet need, prioritizing cardiovascular indications; our belief that KPL-387 could expand the treatment options for recurrent pericarditis patients by enabling a single monthly SC injection in a liquid formulation; our target profile of monthly and quarterly dosing for KPL-387 and KPL-1161, respectively; 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; 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.

Every Second Counts!®

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

	Three Months Ended December 31,		Years Ended December 31,	
	2024	2023	2024	2023
Revenue:				
Product revenue, net	\$ 122,536	\$ 71,220	\$ 417,029	\$ 233,176
License and collaboration revenue	—	12,175	6,210	37,083
Total revenue	<u>122,536</u>	<u>83,395</u>	<u>423,239</u>	<u>270,259</u>
Costs and operating expenses:				
Cost of goods sold	17,896	9,584	60,910	33,407
Collaboration expenses	48,189	16,939	128,311	56,524
Research and development	35,215	20,052	111,623	76,097
Selling, general and administrative	40,535	36,739	168,011	129,427
Total operating expenses	<u>141,835</u>	<u>83,314</u>	<u>468,855</u>	<u>295,455</u>
Income (loss) from operations	(19,299)	81	(45,616)	(25,196)
Other income	2,320	2,369	9,464	8,544
Income (loss) before income taxes	(16,979)	2,450	(36,152)	(16,652)
Benefit (provision) for income taxes	8,091	22,787	(7,041)	30,736
Net income (loss)	<u>\$ (8,888)</u>	<u>\$ 25,237</u>	<u>\$ (43,193)</u>	<u>\$ 14,084</u>
Net income (loss) per share attributable to ordinary shareholders—basic	\$ (0.12)	\$ 0.36	\$ (0.60)	\$ 0.20
Net income (loss) per share attributable to ordinary shareholders—diluted	<u>\$ (0.12)</u>	<u>\$ 0.35</u>	<u>\$ (0.60)</u>	<u>\$ 0.20</u>
Weighted average ordinary shares outstanding—basic	72,319,129	70,371,601	71,424,159	70,058,952
Weighted average ordinary shares outstanding—diluted	<u>72,319,129</u>	<u>72,660,171</u>	<u>71,424,159</u>	<u>71,922,915</u>

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

	As of	
	December 31, 2024	December 31, 2023
Cash, cash equivalents, and short-term investments	\$ 243,627	\$ 206,371
Working capital	231,178	212,631

Total assets	580,553	526,332
Accumulated deficit	(521,143)	(477,950)
Total shareholders' equity	438,436	438,839