



OnKure Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results

March 12, 2026

-- Data from the ongoing PIKture-01 trial is expected to be announced in March 2026; continued enrollment in breast cancer triplet combinations

-- Next-generation PI3K α pan-mutant inhibitor development candidate for HR+ metastatic breast cancer is expected to be announced in March 2026

-- Approximately \$59M in cash and cash equivalents at the end of Q4 2025

BOULDER, Colo., March 12, 2026 (GLOBE NEWSWIRE) -- OnKure Therapeutics, Inc. (Nasdaq: OKUR), a clinical-stage biopharmaceutical company focused on developing novel precision medicines, today reported financial results for the fourth quarter and full year ended December 31, 2025, and provided recent business highlights.

"We are pleased with the continued progress across our PI3K α -focused pipeline, including the steady execution of the PIKture-01 trial of OKI-219. We look forward to sharing updated data from this trial later this month," said Nicholas Saccomano, Ph.D., President and Chief Executive Officer of OnKure. "We are also excited to announce our next-generation pan-mutant inhibitor development candidate for HR+ metastatic breast cancer this month and provide additional information on our program in vascular malformations later this year. Overall, we believe our progress to date underscores the power of our mutation-selective approach to PI3K α inhibition and reinforces the momentum we are building as we work to deliver scientifically differentiated therapies to patients."

OKI-219 Program Highlights

OnKure's lead product candidate, OKI-219, is a highly selective PI3K α ^{H1047} mutant specific inhibitor. OKI-219 is being evaluated in the PIKture-01 phase 1a/1b clinical trial for the treatment of patients with HR+ and HER2+ metastatic breast cancer.

- Parts A and B – Enrollment in both the monotherapy and fulvestrant combination dose escalation arms of the PIKture-01 trial has been completed and closed. A total of 71 patients have been dosed across both arms: 38 in monotherapy and 33 in combination with fulvestrant. The Company expects to report updated safety, tolerability, and clinical activity data from Parts A and B in March 2026.
- Part E – The Company continues to enroll patients with PI3K α ^{H1047R} mutated, HR+ metastatic breast cancer in the triplet expansion arm evaluating OKI-219 in combination with fulvestrant and ribociclib. A total of 17 patients have been dosed with OKI-219 in combination with fulvestrant and ribociclib. The Company expects to report initial safety, tolerability, and clinical activity data from Part E in March 2026.
- Part C – The Company continues to enroll patients with PI3K α ^{H1047R} mutated, HER2+ breast cancer in the triplet expansion arm evaluating OKI-219 in combination with trastuzumab and tucatinib. The Company expects to report initial data from Part C in 2026.

Next-Generation PI3K α ^{PAN} Mutant Selective Program

OnKure expects to announce its next-generation PI3K α pan-mutant inhibitor candidate for HR+ metastatic breast cancer in March 2026.

Additionally, PI3K α mutations represent the most common driver alterations in key subtypes of vascular malformations, where activating PIK3CA variants lead to dysregulated signaling that promotes abnormal cell growth, proliferation, and survival. OnKure believes its differentiated portfolio of PI3K α inhibitors has significant potential to address a large and underserved patient population. The Company expects to provide additional details on its PI3K α pan-mutant program in 2026. This progression reflects the Company's strategic expansion into indications driven by PI3K α biology.

Financial Results

Cash and cash equivalents were approximately \$59.1 million as of December 31, 2025.

Research and development (R&D) expenses were \$10.7 million for the fourth quarter of 2025, compared to \$14.4 million for the

fourth quarter of 2024. The decrease of \$3.6 million was primarily driven by a decrease in consulting, outsourced R&D, clinical trial, and manufacturing related expenses in addition to lower personnel-related costs.

General and Administrative (G&A) expenses were \$3.4 million for the fourth quarter of 2025, compared to \$4.3 million for the fourth quarter of 2024. The decrease of \$0.9 million was primarily driven by a decrease in personnel-related costs and consulting and professional service expenses including audit, tax, insurance, board of director compensation, and other consulting expenses.

Net loss and net loss per share for the fourth quarter of 2025 were \$13.5 million, or \$0.99 per share, compared to \$17.4 million, or \$1.37 per share, for the fourth quarter of 2024.

About PIKture-01 Study

PIKture-01 is a global, multi-center, dose-escalation, first-in-human phase 1a/1b study designed to evaluate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PDx), and efficacy of OKI-219 as monotherapy and in combination with other anti-cancer drugs. Phase 1a (Part A) of the study is investigating escalating doses of OKI-219 monotherapy, and Phase 1b is currently investigating OKI-219 (at a tolerated dose determined in Part A) in combination with fulvestrant (Part B), trastuzumab and tucatinib (Part C), and ribociclib and fulvestrant (Part E). Participants will continue to receive study treatment until disease progression, intolerable toxicity, or other study treatment withdrawal criteria are met. Additional information about PIKture-01 may be found at www.ClinicalTrials.gov, using Identifier: NCT06239467.

About OnKure Therapeutics

OnKure Therapeutics (Nasdaq: OKUR) is a clinical-stage biopharmaceutical company focused on the discovery and development of best-in-class precision medicines that target biologically validated drivers of cancers and other diseases that are underserved by available therapies. Using a structure-based drug design platform, OnKure is building a pipeline of small molecule drugs designed to achieve optimal efficacy and tolerability by selectively targeting specific mutations shown to be key drivers of cancer and other diseases. OnKure is currently developing OKI-219, a highly selective PI3K α ^{H1047R} inhibitor, as its lead program. OnKure aims to become a leader in targeting oncogenic PI3K α and has multiple programs designed to enable best-in-class targeting of this key oncogene.

For more information about OnKure, visit us at www.onkure.com and follow us on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this press release, including statements regarding our future financial condition, results of operations, business strategy and plans, and objectives of management for future operations, as well as statements regarding industry trends, are forward-looking statements. Such forward-looking statements include, among other things, statements regarding the potential of, and expectations regarding, OnKure's product candidates and programs, including OKI-219 and the pan-mutant program; OnKure's ability to advance additional programs; the expected milestones and timing of such milestones, including additional data for OKI-219 from the PIKture-01 trial, the anticipated development candidate announcement and details on the pan-mutant program; statements regarding OnKure's financial position, including its liquidity, cash runway and the sufficiency of its cash resources; and statements by OnKure's President and Chief Executive Officer. In some cases, you can identify forward-looking statements by terminology such as "estimate," "intend," "may," "plan," "potentially" "will" or the negative of these terms or other similar expressions.

We based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things, OnKure's limited operating history; the significant net losses incurred since inception; the ability to raise additional capital to finance operations; the risk that actual uses of cash and cash equivalents differ from the assumptions underlying our expected cash runway; the ability to advance product candidates through preclinical and clinical development; the ability to obtain regulatory approval for, and ultimately commercialize, OnKure's product candidates; the outcome of preclinical testing and early clinical trials for OnKure's product candidates, including the ability of those trials to satisfy relevant governmental or regulatory requirements and the potential that the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials; OnKure's limited resources; the risk of adverse events, toxicities or other undesirable side effects; potential delays or difficulties in the enrollment or maintenance of patients in clinical trials; the decision to develop or seek strategic collaborations to develop OnKure's current or future product candidates in combination with other therapies and the cost of combination therapies; OnKure's limited experience in designing clinical trials and lack of experience in conducting clinical trials; the substantial competition OnKure faces in discovering, developing, or commercializing products; OnKure's ability to protect its intellectual property and proprietary technologies; developments relating to OnKure's competitors and its industry, including competing product candidates and therapies; reliance on third parties, contract manufacturers, and contract research organizations; legislative, regulatory, political and economic developments and general market conditions; and those risks described in the section entitled "Risk Factors" in documents that OnKure files from time to time with the Securities and Exchange Commission ("SEC"), including our Annual Report on Form 10-K filed with the SEC on March 12, 2026 and any subsequent filings with the SEC. These risks are not exhaustive. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. You should not rely upon

forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this press release.

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ONKURE THERAPEUTICS, INC.
Consolidated Condensed Balance Sheets
(In thousands, unaudited)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 59,050	\$ 110,761
Prepaid expenses and other current assets	1,789	2,242
Total current assets	60,839	113,003
Property and equipment, net	618	1,025
Operating lease, right-of-use asset	387	770
Other assets	273	109
Total assets	\$ 62,117	\$ 114,907
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses, and other liabilities	\$ 5,372	\$ 9,994
Operating lease liabilities, current portion	549	536
Total current liabilities	5,921	10,530
Long-term liabilities	12	549
Total liabilities	5,933	11,079
Stockholders' equity	56,184	103,828
Total liabilities and stockholders' equity	\$ 62,117	\$ 114,907

ONKURE THERAPEUTICS, INC.
Consolidated Condensed Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data, unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	\$ 10,720	\$ 14,361	\$ 48,260	\$ 43,795
General and administrative	3,405	4,338	14,690	10,591
Total operating expenses	14,125	18,699	62,950	54,386
Loss from operations	(14,125)	(18,699)	(62,950)	(54,386)
Total other income and (expense), net	622	1,257	3,433	1,713
Net loss and comprehensive loss	\$ (13,503)	\$ (17,442)	\$ (59,517)	\$ (52,673)
Net loss per share attributable to common stockholders:				
Basic and diluted	\$ (0.99)	\$ (1.37)	\$ (4.40)	\$ (15.28)
Weighted average shares outstanding:				

Basic and diluted

13,597,287

12,774,553

13,515,915

3,447,071