



OnKure Therapeutics Reports Third Quarter 2025 Financial Results and Provides a Business Update

November 6, 2025

- First patients dosed in triplet expansion arms of the PIKture-01 trial evaluating OKI-219 in combination with fulvestrant and ribociclib, and in combination with trastuzumab and tucatinib in patients with metastatic breast cancer
- Clinical data from OKI-219 PIKture-01 single agent and fulvestrant combination arms are maturing and is now expected to be reported together with initial data from the triplet expansion arms in the first quarter of 2026
- Significant progress in next-generation PI3K α pan-mutant inhibitor program; multiple candidates identified - announcement planned for the first quarter of 2026
- Expansion into Vascular Malformations - additional information to be provided in 2026

BOULDER, Colo., Nov. 06, 2025 (GLOBE NEWSWIRE) -- OnKure Therapeutics, Inc. (Nasdaq: OKUR), a clinical-stage biopharmaceutical company focused on developing novel precision medicines, today reported financial results for the third quarter ended September 30, 2025 and provided a business update.

"We have made steady progress advancing our lead clinical development program, OKI-219, and are committed to leading the advancement of selective PI3K α inhibitors for the treatment of patients with breast cancer and rare diseases. Based on its selectivity and safety profile, the differentiated value of OKI-219 is best demonstrated in early lines of therapy. This fact is at the heart of our clinical strategy. It is important to note that the single agent and fulvestrant dose ranging combination arms of our PIKture-01 trial have supported the expanded development of OKI-219 with the recent initiation of two triplet arms of the trial, including an evaluation of OKI-219 in combination with fulvestrant and ribociclib. We are at an exciting time in our company's history, and we look forward to sharing clinical data from several arms of our ongoing PIKture-01 trial of OKI-219 in the first quarter of 2026," said Nick Saccomano, Ph.D., President and Chief Executive Officer of OnKure.

"While the team has been hard at work advancing the development of OKI-219, we have also continued to fuel the future growth of OnKure, with important advancements in our next-generation PI3K α pan-mutant inhibitor program and the beginnings of an expansion program in vascular malformations. We look forward to offering additional details on these programs as our activities ramp up over the next several months."

Program Highlights

OKI-219

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 1 clinical trial for the treatment of patients with HR+ and HER2+ metastatic breast cancer.

- In August 2025, the Company announced that it had completed and closed enrollment in the monotherapy and fulvestrant combination dose escalation arms of the PIKture-01 trial. As of October 14, 2025, a total of 71 patients have been dosed across both arms: 37 in monotherapy and 34 in combination with fulvestrant. The last patient in the monotherapy arm was dosed in September 2025 and the last patient in the fulvestrant combination arm was dosed in July 2025. The Company expects to announce initial data from these two arms of the trial in the first quarter of 2026.
- In September 2025, the first patient was dosed in a triplet expansion arm of PIKture-01 evaluating OKI-219 in combination with fulvestrant and ribociclib in patients with PI3K α ^{H1047R} mutated, HR+ metastatic breast cancer. The 600 and 900 mg BID cohorts are enrolled. Initial data is expected in the first quarter of 2026.
- In October 2025, the first patient was dosed in a triplet expansion arm of PIKture-01 evaluating OKI-219 in combination with trastuzumab and tucatinib in patients with PI3K α ^{H1047R} mutated, HER2+ breast cancer. Initial data is expected in the first quarter of 2026.

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

OnKure has identified a series of next-generation PI3K α pan-mutant inhibitors. OnKure believes that to be truly "pan-mutant," a candidate should be highly selective against each of the most common PI3K α mutations (PI3K α ^{H1047X}, PI3K α ^{E542K}, and PI3K α ^{E545K}), with a favorable safety and tolerability profile that enables combinability with other agents.

- The Company is evaluating a series of PI3K α pan-mutant inhibitor development candidates shown preclinically to have an overall selectivity profile, combinability, and pharmaceutical attributes that the Company believes will produce best-in-class

pan-mutant PI3K α inhibitors.

- The Company plans to announce additional details in the first quarter of 2026.

Vascular Malformations Expansion

PI3K α mutations are the most common driver mutations for specific sub-types of vascular malformations. These mutations in the PI3KCA gene lead to overactivation of the pathway, which controls cell growth, proliferation, and survival.

- OnKure believes its portfolio of PI3K α inhibitors have great potential to serve patients in this large, underserved population. The Company plans to announce additional information on its vascular malformations program in 2026.

Financial Results

- **Cash and cash equivalents** were approximately \$70.3 million as of September 30, 2025. The Company believes its current cash and cash equivalents will be sufficient to fund its planned clinical activities and corporate operations into the fourth quarter of 2026.
- **Research and development (R&D) expenses** were \$11.9 million for the third quarter of 2025, compared with \$10.1 million for the third quarter of 2024. The increase in R&D expenses was primarily due to increased personnel-related costs, including share-based compensation charges.
- **General and Administrative (G&A) expenses** were \$3.6 million for the third quarter of 2025, compared with \$1.4 million for the third quarter of 2024. The increase in G&A expenses was primarily due to increased personnel-related costs, including share-based compensation charges, and increases in director compensation, consulting, filing fees, franchise taxes, and other professional service fees.
- **Net loss and net loss per share** for the third quarter of 2025 were \$14.7 million and \$1.09 per share, compared with \$11.6 million and \$36.55 per share for the third quarter of 2024.

About OnKure Therapeutics

OnKure Therapeutics, Inc. (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 diseases that are underserved by available therapies. Using a structure-based drug design platform, OnKure is building a pipeline of tumor-agnostic candidates that are designed to achieve optimal efficacy and tolerability. OnKure is currently developing OKI-219, a selective PI3K α ^{H1047R} inhibitor, as its lead program. OnKure aims to become a leader in targeting oncogenic or pathologically activated PI3K α and has multiple programs designed to enable best-in-class targeting of this key disease creating gene.

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 current and potential future product candidates and programs, including OKI-219 and the pan-mutant program; OnKure's ability to advance additional programs; OnKure's ability to advance and expected timing of additional programs in vascular malformations; expected milestones and timing of such milestones, including additional data for OKI-219 from the PIKture-01 trial and an anticipated development candidate announcement; and statements regarding OnKure's cash runway. In some cases, you can identify forward-looking statements by terminology such as "estimate", "intend", "expect", "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, timing of regulatory reviews and approvals, 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 Quarterly Report on Form 10-Q filed with the SEC on November 6, 2025 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.
Condensed Consolidated Balance Sheets
(in thousands, unaudited)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 70,331	\$ 110,761
Prepaid expenses and other current assets	1,195	2,242
Total current assets	71,526	113,003
Property and equipment, net	720	1,025
Operating lease, right-of-use asset	485	770
Other assets	104	109
Total assets	\$ 72,835	\$ 114,907
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses, and other liabilities	\$ 5,680	\$ 9,994
Operating lease liabilities, current portion	567	536
Total current liabilities	6,247	10,530
Long-term liabilities	160	549
Total liabilities	6,407	11,079
Stockholders' equity	66,428	103,828
Total liabilities and stockholders' equity	\$ 72,835	\$ 114,907

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	\$ 11,915	\$ 10,116	\$ 37,540	\$ 29,434
General and administrative	3,586	1,396	11,285	6,253
Total operating expenses	15,501	11,512	48,825	35,687
Loss from operations	(15,501)	(11,512)	(48,825)	(35,687)
Total other income and (expense), net	802	(44)	2,811	456
Net loss and comprehensive loss	\$ (14,699)	\$ (11,556)	\$ (46,014)	\$ (35,231)

Net loss per share, basic and diluted	\$	(1.09)	\$	(36.55)	\$	(3.41)	\$	(111.77)
Weighted average shares outstanding, basic and diluted		13,530,892		316,142		13,488,493		315,215