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

August 12, 2025

-- PIKture-01, a phase 1 clinical trial assessing OKI-219 in patients with advanced solid tumors, including breast cancer, is on track for single agent and fulvestrant combination data in Q4 2025

-- Initiated a new expansion arm of PIKture-01 to evaluate OKI-219 in combination with fulvestrant and ribociclib in HR+ metastatic breast cancer

-- Initiated a new expansion arm of PIKture-01 to evaluate OKI-219 in combination with trastuzumab and tucatinib in HER2+ metastatic breast cancer

-- Cash position of $83.4M expected to provide cash runway into Q4 2026

BOULDER, Colo., Aug. 12, 2025 (GLOBE NEWSWIRE) -- OnKure Therapeutics, Inc. (Nasdaq: OKUR), a clinical-stage biopharmaceutical company focused on developing novel precision medicines in oncology, today reported financial results for the second quarter ended June 30, 2025 and provided a business update.

“We are encouraged by the continued progress in the development of our lead asset, OKI-219, as we have completed the enrollment of the single agent and the fulvestrant combination arms and have initiated two new triplet arms. Given the clinical performance of OKI-219 to date, we are eager to move broad and deep in both HR+ and HER2+ breast cancer with OKI-219,” said Nick Saccomano, Ph.D., President and Chief Executive Officer of OnKure.

“We believe OKI-219 has the potential to become an important medicine in the first-line hormone receptor positive setting and have initiated an arm to evaluate OKI-219 in combination with fulvestrant and ribociclib in PI3Kα^{H1047R} mutated, metastatic HR+ breast cancer. We also see an opportunity for OKI-219 in HER2+ breast cancer and have initiated an arm to evaluate OKI-219 in combination with trastuzumab and tucatinib. We look forward to sharing OKI-219 monotherapy and fulvestrant combination data as well as announcing the expansion of our PI3Kα franchise with the nomination of a pan-mutant selective PI3Kα inhibitor later this year.”

PI3Kα Portfolio Progress

- **PIKture-01 Monotherapy and Fulvestrant Combination** – The Company has completed and closed enrollment in both the monotherapy and fulvestrant combination dose escalation arms in the PIKture-01 trial. As of August 5, 2025, the Company dosed a total of 70 patients across both arms: 36 in monotherapy and 34 in combination with fulvestrant. OnKure expects to report data from both arms in the fourth quarter of 2025.

- **PIKture-01 Ribociclib Triplet Combination** – The Company recently initiated the evaluation of OKI-219 in combination with fulvestrant and ribociclib in patients with PI3Kα^{H1047R} mutated, HR+ metastatic breast cancer. The initial phase of this arm of the PIKture-01 trial will evaluate the safety of escalating doses of OKI-219 administered as part of a triplet combination, leveraging data from the completed single agent and fulvestrant doublet arms. Expansion of the ribociclib triplet arm will be determined after this run-in phase.

- **PIKture-01 Tucatinib Triplet Combination** – The Company recently initiated the evaluation of OKI-219 in combination with trastuzumab and tucatinib in patients with PI3Kα^{H1047R} mutated, HER2+ breast cancer. The initial phase of this arm of the PIKture-01 trial will evaluate the safety of escalating doses of OKI-219 administered as part of a triplet combination. Expansion of the tucatinib triplet combination arm will be determined after this run-in phase.

- **Pan-mutant Selective Program** – OnKure believes that to be truly “pan-mutant,” a candidate should be highly selective against each of the most common PI3Kα mutations, with a favorable safety and tolerability profile. OnKure is targeting approximately 10-fold selectivity over PI3Kα wild type against each of the most common mutations (PI3Kα^{H1047X}, PI3Kα^{E542K}, and PI3Kα^{E545K}). The Company has identified a series of promising third-generation PI3Kα compounds with an overall selectivity profile that the Company believes will produce a best-in-class pan-mutant inhibitor. OnKure plans to announce the nomination of a development candidate by the end of 2025.

Upcoming Investor Conferences

OnKure’s President and Chief Executive Officer, Nicholas Saccomano, Ph.D., will participate in a fireside chat at the upcoming

Cantor Global Healthcare investor conference taking place in New York on September 3, 2025, at 3:20 P.M.ET. A live audio webcast can be accessed under “News & Events” on the Investor section of OnKure’s website at onkure.com. Following the event, a replay will be available for at least 90 days.

Second Quarter 2025 Financial Results

- **Cash and cash equivalents** were approximately $83.4 million as of June 30, 2025.
- **Research and development (R&D) expenses** were $12.6 million for the second quarter of 2025, compared with $10.8 million for the second quarter of 2024. The increase in R&D expenses was primarily due to increased clinical trial, outsourced manufacturing, and research expenses.
- **General and Administrative (G&A) expenses** were $3.7 million for the second quarter of 2025, compared with $3.6 million for the second 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, and other professional service fees. These increases were partially offset by a decrease in legal expenses during 2025.
- **Net loss and net loss per share** for the second quarter of 2025 were $15.4 million and $1.14 per share, compared with $14.1 million and $44.82 per share for the second 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 cancers 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 $PI3K\alpha^{H1047R}$ inhibitor, as its lead program. OnKure aims to become a leader in targeting oncogenic PI3Kα 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 current and potential future product candidates and programs, including OKI-219 and the pan-mutant program; OnKure’s ability to advance additional programs; 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 August 12, 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)

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 83,374	$ 110,761
Prepaid expenses and other current assets	1,178	2,242
Total current assets	84,552	113,003
Property and equipment, net	821	1,025
Operating lease, right-of-use asset	581	770
Other assets	116	109
Total assets	$ 86,070	$ 114,907
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses, and other liabilities	$ 7,041	$ 9,994
Operating lease liabilities, current portion	556	536
Total current liabilities	7,597	10,530
Long-term liabilities	307	549
Total liabilities	7,904	11,079
Stockholders' equity	78,166	103,828
Total liabilities and stockholders' equity	$ 86,070	$ 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 12,613	$ 10,752	$ 25,625	$ 19,318
General and administrative	3,711	3,591	7,699	4,857
Total operating expenses	16,324	14,343	33,324	24,175
Loss from operations	(16,324)	(14,343)	(33,324)	(24,175)
Total other income and (expense), net	934	204	2,009	500
Net loss and comprehensive loss	$ (15,390)	$ (14,139)	$ (31,315)	$ (23,675)
Net loss per share, basic and diluted	$ (1.14)	$ (44.82)	$ (2.33)	$ (75.22)
Weighted average shares outstanding, basic and diluted	13,509,080	315,478	13,466,942	314,747