OnKure Therapeutics Reports First Quarter 2025 Financial Results and Business Highlights

May 6, 2025

-- Continued progress in the PIKture-01 trial; on track to report additional data in the second half of 2025, including mature single agent and initial combination data

-- Expansion of the Company's PI3K a franchise with the planned announcement of a pan-mutant selective development candidate in Q2 2025

-- $96.7M in cash and cash equivalents expected to be sufficient to fund operations through multiple anticipated milestones into Q4 2026

BOULDER, Colo., May 06, 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 quarter ended March 31, 2025, and provided business highlights.

"OnKure looks to define a new standard of performance for precision targeted agents. We designed OKI-219 and our ongoing PIKture-01 trial to set a high bar for achieving considerable selectivity in targeting oncogenic PI3Kα^{H1047R}. Late last year, we announced preliminary data that showed OKI-219 was well tolerated across all dose levels, allowing us to complete the dose escalation portion of the study up to 1500 mg BID. We anticipate presenting a mature clinical update in the second half of 2025 that could demonstrate a clear and meaningful benefit in treating this very challenging patient population. This exciting next step in our program would further solidify OnKure's place as a leader in developing PI3Ka inhibitors," said Nick Saccomano, Ph.D., President and Chief Executive Officer of OnKure.

"Building on the advancement of our initial candidate, our research and development team is advancing towards a second development candidate in the second quarter of 2025; a true pan-mutant inhibitor with a selectivity profile that augurs well for rendering all major PI3Ka mutants actionable."

Business Highlights and Upcoming Anticipated Milestones

- **PIKture-01 trial Part A Monotherapy** – The Company has completed dose escalating and closed enrollment in Part A with dose limiting toxicities observed in only one patient to date and at the highest dose level. OnKure expects to provide a mature clinical update in the second half of 2025.

  OnKure previously announced encouraging preliminary safety, tolerability, and pharmacokinetic ("PK") data from the part A single-agent arm of the PIKture-01 trial, with a data cut-off of October 28, 2024. These preliminary data showed OKI-219 was well tolerated across all dose levels, with no hyperglycemia, stomatitis, or rash observed. Additionally, only grade 1 treatment-related adverse events ("TRAEs") were reported with no dose interruptions, delays, reductions, or discontinuations reported for any adverse events.

- **PIKture-01 Part B Fulvestrant Combination** – OnKure is actively enrolling patients in Part B of the PIKture-01 trial, evaluating OKI-219 in combination with fulvestrant in patients with PI3Kα^{H1047R} mutated HR+/HER2- metastatic breast cancer. The Company is nearing the end of the dose escalation portion of Part B, with no dose limiting toxicities observed to date. OnKure expects to report initial combination data with fulvestrant in the second half of 2025. It is anticipated that the dose escalation portion of Part B will be completed at the time of the presentation.

- **Pan-mutant Program** – OnKure believes that to be truly "pan-mutant", a candidate should be highly selective against each of the most common PI3Ka mutations with a favorable safety and tolerability profile. OnKure is targeting approximately 10-fold selectivity against each of the most common mutations (PI3Kα^{H1047X}, PI3Kα^{E542K}, and PI3Kα^{E545K}) over wild type with its pan-mutant development candidate, which it expects to announce in the second quarter of 2025.

First Quarter 2025 Financial Results

Cash and cash equivalents were approximately $96.7 million as of March 31, 2025.

Research and development (R&D) expenses were $13.0 million for the first quarter of 2025, compared with $8.6 million for the first quarter of 2024. The increase in R&D expenses was primarily due to increases in personnel-related costs, including share-based compensation charges, clinical trial and outsourced manufacturing expenses, and outsourced research as OnKure seeks to advance multiple programs.

General and Administrative (G&A) expenses were $4.0 million for the first quarter of 2025, compared with $1.3 million for the first 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 legal expenses, board, consulting, and other professional service fees.

Net loss and net loss per share for the first quarter of 2025 were $15.9 million and $1.19 per share, compared with $9.5 million, and $30.37 per share, for the first 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 PI3Kα^{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, anticipated development candidate announcements and advancement of OnKure's discovery stage programs; and statements regarding OnKure's financial position, including its liquidity, cash runway and the sufficiency of its cash resources. 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, 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 Annual Report on Form 10-K filed with the SEC on March 10, 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)

	March 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 96,661	$ 110,761
Prepaid expenses and other current assets	1,511	2,242
Total current assets	98,172	113,003
Property and equipment, net	925	1,025
Operating lease right-of-use asset	676	770
Other assets	109	109
Total assets	$ 99,882	$ 114,907
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,344	$ 2,968
Accrued expenses	5,895	7,026
Operating lease liabilities, current portion	546	536
Total current liabilities	8,785	10,530
Long-term operating lease liabilities	409	549
Other long-term liabilities	40	—
Total liabilities	9,234	11,079
Commitments and contingencies		
Stockholders' equity:		
Common stock, Class A, $0.0001 par value; 200,000,000 shares authorized; 12,755,348 and 12,660,590 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	1	1
Common stock, Class B, $0.0001 par value; 10,000,000 shares authorized; 686,527 shares issued and outstanding at both March 31, 2025 and December 31, 2024	—	—
Additional paid-in capital	261,296	258,551
Accumulated deficit	(170,649)	(154,724)
Total stockholders' equity	90,648	103,828
Total liabilities and stockholders' equity	$ 99,882	$ 114,907

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

	Three Months Ended March 31,	
	2025	2024
Operating expenses:		
Research and development	$ 13,012	$ 8,566
General and administrative	3,988	1,265
Total operating expenses	17,000	9,831
Loss from operations	(17,000)	(9,831)
Other income:		
Interest income	1,075	295
Net loss and comprehensive loss	$ (15,925)	$ (9,536)

Net loss per share attributable to common stockholders:		
Basic and diluted	$ (1.19)	$ (30.37)
Weighted average shares outstanding:		
Basic and diluted	13,424,335	314,016