OnKure Therapeutics Reports First Quarter 2026 Financial Results

May 5, 2026

-- Announced nomination of OKI-355, a next-generation PI3Kα pan-mutant selective inhibitor candidate, in vascular anomalies

-- Initiated a discovery research program to expand the company's pipeline in vascular anomalies

-- Announced nomination of OKI-345, a next generation PI3Kα pan-mutant selective inhibitor candidate, in breast cancer

-- Closed $150 million private placement to advance next-generation PI3Kα pan-mutant programs into clinical development in 2027

-- $192 million cash and cash equivalents as of March 31, 2026, expected to fund operations into 2029

BOULDER, Colo., May 05, 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 first quarter ended March 31, 2026, and provided recent business highlights.

"During the first quarter, we sharpened our strategic focus on advancing our next generation PI3Kα pan-mutant selective inhibitor programs, which we believe represent the most compelling opportunity to deliver differentiated therapies across PI3Kα-driven diseases," said Nicholas Saccomano, Ph.D., President and Chief Executive Officer of OnKure. "Building on insights gained from our earlier clinical and translational work, we have advanced two highly selective pan-mutant development candidates that were purpose designed to achieve robust target coverage while avoiding class limiting toxicities. As we move forward with OKI-355 in vascular anomalies and OKI-345 in breast cancer, our focus is on translating the strengths of our chemistry platform and deep understanding of PI3Kα biology into programs with the potential to deliver meaningful, differentiated, and durable benefit to patients."

Vascular Anomalies

OnKure recently announced the selection of OKI-355, an advanced next-generation PI3Kα pan-mutant selective inhibitor candidate, to lead its development pipeline in vascular anomalies. OKI-355 has been designed to selectively inhibit mutant PI3Kα while sparing wildtype PI3Kα, potentially enabling a wider therapeutic index and avoidance of class-limiting toxicities. High and sustained target coverage across all hotspot PI3Kα mutations can support the potential for deep and durable responses in vascular anomalies. Additionally, the Company initiated a discovery research program to expand OnKure's pipeline in vascular anomalies.

OnKure plans to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for OKI-355 in the first half of 2027.

Breast Cancer

OnKure recently announced the selection of OKI-345, an advanced next-generation PI3Kα pan-mutant selective inhibitor candidate in breast cancer. Like OKI-355, OKI-345 has been designed to selectively inhibit mutant PI3Kα while sparing wildtype PI3Kα, potentially enabling a wider therapeutic index and avoidance of class-limiting toxicities. High and sustained target coverage across all hotspot PI3Kα mutations can support the potential for deep and durable responses in breast cancer, both as monotherapy and in combination. OnKure plans to submit an IND application to the FDA for OKI-345 in the first half of 2027.

Given the Company's strategic focus on advancing its next-generation PI3Kα pan-mutant inhibitors, OnKure is not planning to independently pursue further clinical development of OKI-219, a highly selective $PI3K\alpha^{H1047}$ mutant-specific inhibitor, at this time. The Company plans to report data from PIKture-01 by the end of 2026. Additional information about PIKture-01 may be found at www.ClinicalTrials.gov, using Identifier: NCT06239467.

Upcoming Conference

OnKure will participate as an exhibitor and sponsor in the International Society and Study of Vascular Anomalies (ISSVA) World Congress 2026 in Philadelphia, May 19-22, 2026.

Financial Results

Cash and cash equivalents were $192.1 million as of March 31, 2026, including proceeds from the oversubscribed $150 million private placement, which closed on March 31, 2026.

Research and development (R&D) expenses were $11.7 million for the first quarter of 2026, compared to $13.0 million for the first quarter of 2025. The decrease of $1.3 million was primarily driven by a decrease in outsourced R&D related expenses, partially offset by increased clinical trial costs.

General and Administrative (G&A) expenses were $3.9 million for the first quarter of 2026, compared to $4.0 million for the first quarter of 2025. The decrease of $0.1 million was primarily driven by a decrease in legal and filing service costs, partially offset by increased personnel-related costs.

Net loss and net loss per share were $15.2 million, or $1.11 per share, for the first quarter of 2026, compared to $15.9 million, or $1.19 per share, for the first quarter of 2025.

About the 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 for the treatment of HR+ and HER2+ advanced breast cancer. As of March 26, 2026, the PIKture-01 trial has completed enrollment in single-agent OKI-219 dose escalation (n=38) and OKI-219 + fulvestrant dose escalation (n=33). Phase 2 dose evaluation in the OKI-219 + tucatinib and trastuzumab triplet and the OKI-219 + ribociclib and fulvestrant triplets will be completed in 2026. Given the progress of the Company's PI3Kα pan-mutant inhibitors, OnKure is not planning to pursue further clinical development of OKI-219 independently at this time. 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 vascular anomalies and cancers that are underserved by available therapies. Using a structure and computational chemistry-driven drug design platform, OnKure is committed to improving clinical outcomes for patients by building a pipeline of small molecule drugs designed to selectively target specific mutations thought to be key drivers of vascular anomalies and cancer. OnKure aims to become a leader in targeting 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 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-355 and OKI-345; OnKure's ability to advance additional programs; expected milestones and the timing of such milestones, including additional data from, and completion of enrollment in, the PIKture-01 trial, and the submission of IND applications for OKI-355 and OKI-345; OnKure's expected cash runway; and statements by OnKure's President and Chief Executive Officer. In some cases, you can identify forward-looking statements by terminology such as "expect," "estimate," "intend," "may," "plan," "potentially," "will" or the negative of these terms or other similar expressions.

These forward-looking statements are based largely on OnKure's current expectations and projections about future events and trends that OnKure believes may affect its 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 OnKure's 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 SEC, including its Report on Form 10-Q filed with the SEC on May 5, 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 OnKure's management to predict all risk factors, nor can OnKure assess the impact of all factors on OnKure's 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 OnKure believes that the expectations reflected in the forward-looking statements are reasonable, OnKure cannot guarantee future results, levels of activity, performance or

achievements. Except as required by law, OnKure undertakes 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, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 192,106	$ 59,050
Prepaid expenses and other current assets	5,376	1,789
Total current assets	197,482	60,839
Property and equipment, net	519	618
Operating lease, right-of-use asset	288	387
Other assets	405	273
Total assets	$ 198,694	$ 62,117
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses, and other liabilities	$ 13,920	$ 5,372
Operating lease liabilities, current portion	409	549
Total current liabilities	14,329	5,921
Long-term liabilities	12	12
Total liabilities	14,341	5,933
Stockholders' equity	184,353	56,184
Total liabilities and stockholders' equity	$ 198,694	$ 62,117

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,	
	2026	2025
Operating expenses:		
Research and development	$ 11,707	$ 13,012
General and administrative	3,908	3,988
Total operating expenses	15,615	17,000
Loss from operations	(15,615)	(17,000)
Other income:		
Interest income	458	1,075
Net loss and comprehensive loss	$ (15,157)	$ (15,925)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (1.11)	$ (1.19)
Weighted average shares outstanding:		
Basic and diluted	13,674,577	13,424,335