OnKure Therapeutics Reports Third Quarter 2026 Financial Results and Provides Business Highlights

November 4, 2026

-- Announces PANORAMA, an OnKure-sponsored, large-scale, multiregional registry designed to characterize the natural disease course and treatment patterns of people living with vascular anomalies

-- Executing IND-enabling activities for next-generation PI3Kα pan-mutant-selective candidates OKI-345 in breast cancer and OKI-355 in vascular anomalies, with IND submissions planned for 1H 2027

BOULDER, Colo., Nov. 04, 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 third quarter ended September 30, 2026, and provided recent business highlights.

“We continue to advance the development of next-generation PI3Kα pan-mutant-selective inhibitors through our pipeline, including OKI-355 in vascular anomalies and OKI-345 in breast cancer. Both of our lead programs remain on track for IND submissions in the first half of 2027,” said Nicholas Saccomano, Ph.D., President and Chief Executive Officer of OnKure.

“People living with vascular anomalies remain underserved, and we believe OnKure has an opportunity to help shape the future of treatment for this community. Mutations in the PIK3CA gene drive a range of vascular malformations, providing a compelling rationale for our development of OKI-355, which is designed to provide broad coverage across these mutations. We are excited to build on that work with the introduction of PANORAMA, a large-scale observational registry designed to generate insights that may inform future research and treatment strategies. Together, these efforts reflect our commitment to addressing both the need for new therapies and the gaps in disease knowledge that can guide their development,” said Samuel Agresta, M.D., Chief Medical Officer of OnKure.

Vascular Anomalies

OnKure continues to advance its development of OKI-355, a next-generation PI3Kα pan-mutant-selective inhibitor candidate announced in March 2026 to lead its development pipeline in vascular anomalies. OKI-355 is 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. 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.

Expanding its commitment to the vascular anomalies community, the Company is also initiating PANORAMA, a large-scale, multiregional, longitudinal observational registry of people living with vascular anomalies. The registry will support retrospective and prospective analyses to characterize the natural disease course, treatment patterns, and associations between genetic variants and clinical characteristics. Genotyping will be offered to all participants and may support clinical diagnosis in regions where access to genetic testing is limited.

Breast Cancer

In breast cancer, OnKure continues to advance its development of OKI-345, a next-generation PI3Kα pan-mutant-selective inhibitor candidate selected in March 2026. OKI-345 is 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 regimens. OnKure plans to submit an IND application to the FDA for OKI-345 in the first half of 2027.

Financial Results

Cash position: As of September 30, 2026, the Company reported cash, cash equivalents, and marketable securities of $163.3 million, which is expected to provide cash runway into 2029.

Research and development (R&D) expenses: R&D expenses were $15.1 million for the third quarter of 2026, compared to $11.9 million for the third quarter of 2025. The increase was primarily driven by an increase in outsourced preclinical R&D expenses, manufacturing costs and consulting expenses.

General and Administrative (G&A) expenses: G&A expenses were $4.3 million for the third quarter of 2026, compared to $3.6 million for the third quarter of 2025. The increase was primarily driven by increases in personnel-related and consulting costs.

Net loss and net loss per share were $17.8 million, or $0.36 per share, for the third quarter of 2026, compared to $14.7 million, or $1.09 per share, for the third quarter of 2025.

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 important molecular target.

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, the PANORAMA registry, as well as OnKure's product candidates and programs, including OKI-355 and OKI-345; OnKure's ability to discover, develop and advance additional programs; expected milestones and the timing of such milestones, including 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 and Chief Medical Officer. In some cases, you can identify forward-looking statements by terminology such as "believe," "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 initiate, enroll and conduct the PANORAMA registry as planned and the risk that data generated by the registry may not yield useful insights or inform OnKure's development programs; 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 Annual Report on Form 10-K filed with the SEC on March 12, 2026, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2026 filed with the SEC on November 4, 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)

	September 30, 2026	December 31, 2025

Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 163,305	$ 59,050
Prepaid expenses and other current assets	2,288	1,789
Total current assets	165,593	60,839
Property and equipment, net	414	618
Operating lease, right-of-use asset	661	387
Other assets	409	273
Total assets	$ 167,077	$ 62,117
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses, and other current liabilities	$ 8,538	$ 5,372
Operating lease liabilities, current portion	251	549
Total current liabilities	8,789	5,921
Long-term liabilities	551	12
Total liabilities	9,340	5,933
Stockholders' equity	157,737	56,184
Total liabilities and stockholders' equity	$ 167,077	$ 62,117

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 15,064	$ 11,915	$ 39,382	$ 37,540
General and administrative	4,287	3,586	12,483	11,285
Total operating expenses	19,351	15,501	51,865	48,825
Loss from operations	(19,351)	(15,501)	(51,865)	(48,825)
Other income:				
Interest income	1,505	804	3,516	2,813
Interest and other expense	—	(2)	—	(2)
Total other income	1,505	802	3,516	2,811
Net loss	$ (17,846)	$ (14,699)	$ (48,349)	$ (46,014)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.36)	$ (1.09)	$ (1.27)	$ (3.41)
Weighted average shares outstanding:				
Basic and diluted	49,928,151	13,530,892	37,956,765	13,488,493