Kalaris Reports First Quarter 2025 Financial Results and Provides Business Highlights

May 14, 2025

Actively enrolling nAMD patients in a Phase 1 trial of TH103, a novel, differentiated anti-VEGF agent engineered to potentially provide longer-lasting and increased anti-VEGF activity to treat neovascular and exudative diseases of the retina; initial clinical data is expected in Q4 2025

Cash and cash equivalents of $101M as of March 31, 2025, expected to fund operations into Q4 2026

PALO ALTO, Calif., May 14, 2025 (GLOBE NEWSWIRE) -- Kalaris Therapeutics, Inc. (Nasdaq: KLRS) ("Kalaris"), a clinical-stage biopharmaceutical company dedicated to the development and commercialization of treatments for prevalent diseases of the retina, today announced financial results for the first quarter ended March 31, 2025 and provided a business update.

"We are excited by our progress in 2025," said Andrew Oxtoby, Chief Executive Officer of Kalaris. "We recently completed our merger with Allovir, and our Phase 1 trial investigating TH103 for nAMD is well underway. TH103 was engineered by VEGF pioneer, Napoleone Ferrara, MD, to address the limitations of current nAMD therapies and has demonstrated both potent anti-VEGF activity and sustained ocular residence time in preclinical studies. TH103 has the potential to provide longer-lasting and increased anti-VEGF activity to treat neovascular and exudative diseases of the retina. We look forward to reporting the initial clinical data from our Phase 1 trial in the fourth quarter of this year."

Business Highlights

- Kalaris is currently enrolling a Phase 1, single ascending dose trial to assess the safety, pharmacokinetics, and preliminary treatment effect of TH103 in nAMD patients. Initial clinical data is expected in the fourth quarter of 2025.
- As previously announced, Kalaris completed its merger with AlloVir in March 2025.
- As recently announced, Kalaris therapeutics had expanded its Board of Directors with the appointment of Leone Patterson as a director and Chair of the Audit Committee.

Financial Results for the First Quarter Ended March 31, 2025

Cash and Cash Equivalents: As of March 31, 2025, Kalaris had cash and cash equivalents of $101.0 million, compared with cash and cash equivalents of $1.6 million as of December 31, 2024. The increase in cash and cash equivalents was primarily a result of the completion of its merger with AlloVir.

Research and Development Expenses: Research and development expenses were $6.0 million for the quarter ended March 31, 2025, compared with $2.0 million for the quarter ended March 31, 2024. The increase quarter-over-quarter was primarily attributable to an increase in costs related to the outsourcing of manufacturing and clinical-related costs as Kalaris initiated its Phase 1 clinical trial in June 2024.

General and Administrative Expenses: General and administrative expenses were $4.3 million for the quarter ended March 31, 2025, compared with $0.6 million for the quarter ended March 31, 2024. The increase quarter-over-quarter was primarily attributable to a one-time charge for AlloVir's directors and officers' liability insurance and an increase in legal, accounting, and professional fees associated with operating as a public company.

Net Loss: For the quarter ended March 31, 2025, net loss was $10.2 million or $2.52 per share, compared with a net loss of $3.4 million or $2.60 per share for the quarter ended March 31, 2024. The total number of shares of common stock outstanding as of March 31, 2025 was 18,702,418.

About Kalaris

Kalaris is a clinical-stage biopharmaceutical company dedicated to the development and commercialization of treatments for prevalent retinal diseases. The company is focused on development of TH103, a novel, differentiated anti-VEGF investigational therapy. Developed by Dr. Napoleone Ferrara, TH103 is a fully humanized, recombinant fusion protein that acts against VEGF as a decoy receptor and has been specifically engineered for potentially improved VEGF inhibition and longer retention in the retina. TH103 is currently being evaluated in an ongoing, Phase 1 clinical trial for the treatment of neovascular Age-related Macular Degeneration (nAMD), with plans to develop TH103 for additional neovascular and exudative diseases of the retina such as Diabetic Macular Edema (DME), and Retinal Vein Occlusion (RVO).

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risk and uncertainties. All statements, other than statements of historical fact, contained in this press release, including statements regarding the strategy, future operations, prospects, plans and objectives of management of Kalaris, including the therapeutic potential of TH103, the anticipated timeline for reporting initial clinical data from the Phase 1 trial of TH103 in nAMD, and the sufficiency of Kalaris' cash resources for the period anticipated, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are based on current expectations and beliefs of the management of Kalaris as well as assumptions made by, and information currently available to, the management of Kalaris and are subject to risks and uncertainties. There can be no assurance that future developments affecting Kalaris will be those that it has anticipated. Forward-looking statements include, but are not limited to, statements concerning the following: the future operations of Kalaris, including research and development activities; the nature, strategy and focus of Kalaris; the development and commercial potential and potential benefits of any product candidate of Kalaris, including expectations around intellectual property protection; anticipated clinical drug development activities and related timelines, including the expected timing for announcement of data and other clinical results; the uncertainties associated with Kalaris' product candidate, as well as risks associated with the clinical development and regulatory approval of its product candidate, including potential delays in the completion of clinical trials; expectations regarding the therapeutic benefits, clinical potential and clinical development of TH103; risks related to the inability of Kalaris to obtain sufficient additional capital to continue to advance its product candidate; uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; risks related to the failure to realize any value from any product candidates being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; the ability to obtain, maintain, and protect intellectual property rights related to product candidates; changes in regulatory requirements and government incentives; Kalaris' competitive position and expectations regarding developments and projections relating to its competitors and any competing therapies that are or become available; potential adverse reactions or changes to business relationships resulting from the completion of the merger with AlloVir, Inc.; risks associated with the possible failure to realize, or that it may take longer to realize than expected, certain anticipated benefits of the merger, including with respect to future financial and operating results; the risk of involvement in current and future litigation, including securities class action litigation, that could divert the attention of the management of Kalaris, harm Kalaris' business and for which Kalaris may not have sufficient insurance coverage to cover all costs and damages; and such other factors as are set forth in Kalaris' public filings with the SEC, including, but not limited to, those described under the heading "Risk Factors". Kalaris may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on its forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements Kalaris makes. The forward-looking statements contained in this press release are made as of the date of this press release, and Kalaris does not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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Kalaris Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(unaudited, in thousands, except share and per share data)

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses		
Research and development	$ 6,030	$ 1,961
General and administrative	4,324	602
Total operating expenses	10,354	2,563
Loss from operations	(10,354)	(2,563)
Total other income (expense), net	158	(844)
Net loss	$ (10,196)	$ (3,407)
Net loss per share, basic and diluted	$ (2.52)	$ (2.60)

Weighted-average shares outstanding, basic and diluted	4,053,140	1,312,552

Kalaris Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(unaudited, in thousands)

	March 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 100,965	$ 1,639
Other current assets	1,217	967
Total current assets	102,182	2,606
Other assets	910	3,556
Total assets	$ 103,092	$ 6,162
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities	7,142	24,703
Long-term liabilities	32,076	32,076
Total liabilities	39,218	56,779
Redeemable convertible preferred stock	—	45,999
Total stockholders' equity (deficit)	63,874	(96,616)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 103,092	$ 6,162