UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 10, 2026

KALARIS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39409**	**83-1971007**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Kalaris Therapeutics, Inc.
400 Connell Drive, Suite 5500
Berkeley Heights, New Jersey 07922
(Address of principal executive offices, including zip code)

(650) 249-2727
(Registrant's telephone number, including area code)

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	KLRS	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 10, 2026, Kalaris Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended September 30, 2026. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Kalaris Therapeutics, Inc. on November 10, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KALARIS THERAPEUTICS, INC.

Date: November 10, 2026

By: /s/ Andrew Oxtoby
Name: Andrew Oxtoby
Title: Chief Executive Officer

Exhibit 99.1

Kalaris Reports Third Quarter 2026 Financial Results and Provides Business Update

Preliminary data from the ongoing Phase 1b/2 study of TH103 in nAMD is now expected in 2H 2027

Recently completed technology transfer from pilot to commercial-scale manufacturer with test batches meeting target specifications

$82.9 million in cash, cash equivalents and marketable securities as of September 30, 2026 now expected to fund operations into 2028

BERKELEY HEIGHTS, N.J., November 10, 2026 (GLOBE NEWSWIRE)—Kalaris Therapeutics, Inc. (Nasdaq: KLRS) ("Kalaris"), a clinical stage biopharmaceutical company dedicated to the development and commercialization of treatments for prevalent retinal diseases, today announced financial results for the third quarter ended September 30, 2026 and provided a business update.

Business Updates

- Kalaris continues to enroll a Phase 1b/2, multiple-ascending dose, dose-finding study evaluating up to four monthly loading doses of TH103 in patients with neovascular age-related macular degeneration (nAMD). The study aims to assess the safety and efficacy of repeat doses of TH103 in approximately 60-80 patients at different dose levels and to identify the optimal dose for potential Phase 3 development.
- In the third quarter, the pilot manufacturer for clinical supply of TH103 produced a batch that did not meet the applicable release specification for aggregation due to a batch-specific operational issue. A new batch of material is now expected in Q2 2027.
- As a result of this supply interruption, data from the Phase 1b/2 study is now expected in 2H 2027, which will include durability data from initial patient cohorts.
- Kalaris has now successfully completed the technology transfer from the pilot manufacturer to KBI Biopharma, the drug substance manufacturer selected to deliver the planned commercial-scale supply. Test batches achieved the target specifications required for Phase 3 clinical development.
- Potential initiation of a Phase 3 program is now expected in 2028, resulting in an extension of the anticipated cash runway into 2028 and beyond the preliminary Phase 1b/2 data readout.

"Kalaris made meaningful progress in the third quarter," said Andrew Oxtoby, Chief Executive Officer of Kalaris Therapeutics. "We continue to enroll and dose nAMD patients in the ongoing Phase 1b/2 study. In addition to progressing the clinical trial, we have successfully completed the tech transfer to a new commercial-scale manufacturer, with initial test batches achieving the target specifications. Given the paramount importance of ensuring critical quality attributes at the scale required for Phase 3 and commercial supply, this was a significant accomplishment in Q3 and strengthens our confidence in our future clinical supply."

Financial Results for the Third Quarter Ended September 30, 2026

Cash, Cash Equivalents and Marketable Securities: As of September 30, 2026, Kalaris had cash, cash equivalents and marketable securities of $82.9 million, compared with cash, cash equivalents and marketable securities of $118.0 million as of December 31, 2025. The decrease in cash, cash equivalents and marketable securities was primarily a result of cash used in operating activities during the period. Based on its current operating plans, Kalaris expects that its cash, cash equivalents and marketable securities as of September 30, 2026 will be sufficient to fund its operations into 2028.

Research and Development Expenses: Research and development expenses were $8.3 million for the quarter ended September 30, 2026, compared with $9.1 million for the quarter ended September 30, 2025. The decrease was primarily attributable to a decrease in manufacturing and process development activities, partially offset by an increase in contract research organization and other clinical expenses as Kalaris opened additional investigational sites and enrolled patients in its Phase 1b/2 clinical trial of TH103.

General and Administrative Expenses: General and administrative expenses were $3.5 million for the quarter ended September 30, 2026, compared with $3.6 million for the quarter ended September 30, 2025. The decrease was primarily attributable to a decrease in professional services, consulting and other general and administrative expenses, partially offset by an increase in personnel-related costs.

Net Loss: For the quarter ended September 30, 2026, net loss was $11.0 million compared with a net loss of $11.9 million for the quarter ended September 30, 2025. The total number of shares of common stock outstanding as of September 30, 2026 was 23,804,981.

About TH103

TH103 is an investigational dual-targeting biologic with the potential to be best-in class for neovascular and exudative retinal diseases. TH103 was engineered by VEGF scientific discoverer Dr. Napoleone Ferrara to achieve extended intraocular retention with enhanced VEGF inhibition through optimized binding to VEGF receptor 1 ligands and concurrent heparan sulfate proteoglycan (HSPG) anchoring. It is a fully humanized, recombinant fusion protein designed for intravitreal delivery, with potential applications as a treatment for exudative and/or neovascular retinal diseases, such as neovascular Age-related Macular Degeneration (nAMD), diabetic eye disease and retinal vein occlusion. TH103 is currently being investigated in a Phase 1b/2 clinical trial in patients with nAMD.

About Kalaris

Kalaris Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development and commercialization of treatments for prevalent retinal diseases. Founded by renowned scientist Dr. Napoleone Ferrara, whose pioneering research led to the development of anti-VEGF therapy, the company is committed to advancing novel therapeutic approaches for patients with sight-threatening retinal conditions with major unmet medical needs.

For more information, visit www.kalaristx.com.

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, future financial position, plans and objectives of management of Kalaris, the therapeutic potential of TH103 for neovascular age-related macular degeneration and other exudative and neovascular retinal diseases, the anticipated timeline for reporting data from the ongoing Phase 1b/2 clinical trial of TH103 and initiating Phase 3 clinical trials, plans to advance TH103 into Phase 3 clinical trials and to develop TH103 for additional indications, Kalaris’ expectations regarding the anticipated timeline for obtaining a new batch of TH103 for use in its Phase 1b/2 clinical trial, Kalaris’ expectations regarding the ability of its new commercial-scale drug substance manufacturer to supply sufficient TH103 drug substance meeting the quality standards and applicable regulatory requirements for clinical development 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. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: risks associated with the clinical development and regulatory approval of TH103, including potential delays in the completion of clinical trials; expectations regarding the therapeutic benefits, clinical potential and clinical development of TH103; the timing of and Kalaris’ ability to enroll patients in clinical trials; whether results from preclinical studies and initial data from early clinical trials will be predictive of the final results of the clinical trials or future trials; dependence on third parties for the development and manufacture of TH103 and their ability to supply sufficient TH103 drug substance meeting the quality standards and applicable regulatory requirements for clinical development; 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; the risk of involvement in current and future litigation; and such other factors as are set forth in Kalaris’ public filings with the Securities and Exchange Commission, 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. 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses				
Research and development	$ 8,344	$ 9,126	$ 24,934	$ 23,596
General and administrative	3,467	3,615	11,096	11,755
Total operating expenses	11,811	12,741	36,030	35,351
Loss from operations	(11,811)	(12,741)	(36,030)	(35,351)
Total other income, net	785	847	2,633	1,911
Net loss	$ (11,026)	$ (11,894)	$ (33,397)	$ (33,440)
Net loss per share, basic and diluted	$ (0.46)	$ (0.64)	$ (1.40)	$ (2.41)
Weighted-average shares outstanding, basic and diluted	23,804,981	18,701,708	23,775,600	13,872,369

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

	September 30, 2026	December 31, 2025
Assets		
Current assets		
Cash, cash equivalents and marketable securities	$ 82,856	$ 117,982
Other current assets	2,320	827
Total current assets	85,176	118,809
Other assets	3,827	2,927
Total assets	$ 89,003	$ 121,736
Liabilities and stockholders' equity		
Current liabilities	$ 8,514	$ 9,714
Long-term liabilities	33,087	33,208
Total liabilities	41,601	42,922
Total stockholders' equity	47,402	78,814
Total liabilities and stockholders' equity	$ 89,003	$ 121,736