Relay Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results and Outlines Anticipated 2026 Milestones

February 26, 2026

Initial Phase 1 data of zovegalisib in PIK3CA-driven vascular anomalies expected to be announced in first half of 2026

Breast cancer triplet data and frontline Phase 3 plans expected to be announced in 2026

Initial Phase 1/2 data of zovegalisib + fulvestrant at 400mg BID fed (Phase 3 dose) in CDK4/6-experienced patients to be presented at ESMO TAT on March 16, 2026

Approximately $555 million in cash, cash equivalents and investments at end of Q4 2025

CAMBRIDGE, Mass., Feb. 26, 2026 (GLOBE NEWSWIRE) -- Relay Therapeutics, Inc. (Nasdaq: RLAY), a clinical-stage, small molecule precision medicine company developing potentially life-changing therapies for patients living with cancer and genetic disease, today reported fourth quarter and full year 2025 financial results and 2026 guidance.

“Our focus on disciplined execution to date has strengthened the foundation of Relay, aligning our organization to support long-term success. In 2026, Relay is entering a pivotal period defined by multiple upcoming clinical milestones across our zovegalisib program, which recently received Breakthrough Therapy designation from the FDA,” said Sanjiv Patel, M.D., President and Chief Executive Officer of Relay Therapeutics. “We anticipate presenting Phase 1/2 breast cancer data at the upcoming ESMO TAT Congress, reporting initial data in PIK3CA-driven vascular anomalies, and providing updates on our breast cancer triplet data and frontline Phase 3 development plans. These milestones position us to deliver meaningful updates in areas with significant unmet need for patients, while continuing to build momentum toward potential commercialization.”

Anticipated 2026 Milestones

- Breast Cancer
  - Abstract accepted to European Society for Medical Oncology Targeted Anticancer Therapies (ESMO TAT) Congress 2026 for initial data from the Phase 1/2 ReDiscover trial of zovegalisib (RLY-2608) + fulvestrant at the Phase 3 dose
    - The abstract is focused on 57 patients treated at the recommended Phase 3 dose of 400mg twice daily (BID) fed that have HR+/HER2-, PI3Kα-mutated metastatic breast cancer and have previously been treated with a CDK4/6 inhibitor
    - Oral Proffered Paper Session: Dose optimization of zovegalisib, a novel PI3Kα inhibitor, in patients with PIK3CA-mutant HR+/HER2- advanced breast cancer: results from the first-in-human study to support the recommended Phase 3 dose
    - Location/Date/Time: Paris, France; Monday, March 16, 2026; 4:00 p.m. CET/11:00 a.m. ET
  - Triplet clinical data and frontline Phase 3 study design plan anticipated in 2026

- Vascular Anomalies
  - Initial clinical data disclosure from the Phase 1 ReInspire trial in PIK3CA-driven vascular anomalies planned for 1H 2026
    - The pediatric cohort in the trial recently opened ahead of schedule due to faster than expected enrollment and the company anticipates reporting on approximately 20 patients at time of disclosure

Zovegalisib 2025 Highlights

- Breast Cancer
  - Continued execution of the Phase 3 ReDiscover-2 trial of zovegalisib + fulvestrant in PI3Kα-mutated, CDK4/6 pre-treated, HR+/HER2- advanced breast cancer
  - Presented data from Phase 1/2 ReDiscover trial of zovegalisib + fulvestrant at the American Society of Clinical Oncology (ASCO) 2025 Annual Meeting and the 2025 San Antonio Breast Cancer Symposium (SABCS). SABCS summary with a data cut-off date of October 15, 2025:
    - The median progression free survival (PFS) was 10.3 months for all patients (n=52).
    - Among the total of 31 patients with measurable disease, objective response rate (ORR) was 39%. For second line (2L) patients, median PFS was 11.4 months and ORR was 47%. Median follow-up was 20.2 months.

        - Efficacy was generally consistent across other subsets of patients. For patients who received prior SERD, median PFS was 11.4 months and ORR was 44% (7/16), and for patients who had a detectable *ESR1* mutation at baseline, median PFS was 8.8 months and ORR was 60% (6/10).
        - The overall tolerability profile remained consistent with mutant-selective PI3Kα inhibition, with treatment-related adverse events that were mostly low-grade, manageable and reversible.
    - Triplet cohorts of zovegalisib in combination with atirmociclib, ribociclib, or palbociclib are ongoing to inform frontline Phase 3 preferred regimen and plans
- Vascular Anomalies
    - Continued execution of Phase 1 RelInspire trial of zovegalisib in PIK3CA-driven vascular anomalies

Fourth Quarter and Full Year 2025 Financial Results

Cash, Cash Equivalents and Investments: As of December 31, 2025, cash, cash equivalents, and investments totaled $554.5 million compared to approximately $781.3 million as of December 31, 2024. The company expects its current cash, cash equivalents, and investments will be sufficient to fund its operating expenses and capital expenditure requirements into 2029.

Revenue: Revenue was $7.0 million for the fourth quarter of 2025, as compared to $0 for the fourth quarter of 2024. Revenue was $15.4 million for the full year 2025, as compared to $10.0 million for the full year 2024. The revenue recognized in the current year periods was under our Exclusive License Agreement with Elevar Therapeutics, Inc. The revenue recognized in the prior year periods was under our Collaboration and License Agreement with Genentech, Inc.

R&D Expenses: Research and development expenses were $55.4 million for the fourth quarter of 2025, as compared to $68.1 million for the fourth quarter of 2024. Research and development expenses were $261.4 million for the full year 2025, as compared to $319.1 million for the full year 2024. The decreases were primarily due to the series of strategic choices to streamline the research organization throughout 2024 and 2025, as well as decreases in costs incurred on continued development of lirafugratinib after execution of the Exclusive License Agreement with Elevar Therapeutics, Inc. in December 2024, offset by increases in costs related to the ReDiscover-2 trial and RelInspire trial.

G&A Expenses: General and administrative expenses were $12.2 million for the fourth quarter of 2025, as compared to $16.9 million for the fourth quarter of 2024. General and administrative expenses were $56.7 million for the full year 2025, as compared to $76.6 million for the full year 2024. The decreases were primarily due to decreases in stock compensation expense and other employee costs.

Net Loss: Net loss was $54.9 million for the fourth quarter of 2025, or a net loss per share of $0.32, as compared to a net loss of $76.0 million for the fourth quarter of 2024, or a net loss per share of $0.45. Net loss was $276.5 million for the full year 2025, or a net loss per share of $1.61, as compared to a net loss of $337.7 million for the full year 2024, or a net loss per share of $2.36.

About Zovegalisib

Zovegalisib is the lead program in Relay Therapeutics' efforts to discover and develop mutant selective inhibitors of PI3Kα, the most frequently mutated kinase in all cancers and all vascular anomalies. Zovegalisib has the potential, if approved, to address a significant portion of the approximately 140,000 patients with HR+/HER2- breast cancer with a PI3Kα mutation and the estimated 170,000 patients with vascular anomalies driven by a PI3Kα mutation per year in the United States, one of the largest patient populations for a precision medicine.

Traditionally, the development of PI3Kα inhibitors has focused on the active, or orthosteric, site. The therapeutic index of orthosteric inhibitors is limited by the lack of clinically meaningful selectivity for mutant versus wild-type (WT) PI3Kα and off-isoform activity. Toxicity related to inhibition of WT PI3Kα and other PI3K isoforms results in sub-optimal inhibition of mutant PI3Kα with reductions in dose intensity and frequent discontinuation. The Dynamo® platform enabled the discovery of zovegalisib, the first known allosteric, pan-mutant, and isoform-selective PI3Kα inhibitor, designed to overcome these limitations. Relay Therapeutics solved the full-length cryo-EM structure of PI3Kα, performed computational long time-scale molecular dynamic simulations to elucidate conformational differences between WT and mutant PI3Kα, and leveraged these insights to support the design of zovegalisib. Zovegalisib is currently being evaluated in multiple metastatic breast cancer studies and a first-in-human study designed to treat patients with PIK3CA (PI3Kα) mutation driven vascular anomalies. For more information on zovegalisib, please visit here.

About Relay Therapeutics

Relay Therapeutics (Nasdaq: RLAY) is a clinical-stage, small molecule precision medicine company developing potentially life-changing therapies for patients living with cancer and genetic disease. Relay's Dynamo® platform integrates an array of leading-edge computational and experimental approaches designed to drug protein targets that have previously been intractable or inadequately addressed. The company's lead clinical asset, zovegalisib, is the first pan-mutant selective PI3Kα inhibitor to enter clinical development and is currently in a Phase 3 clinical trial (ReDiscover-2) in HR+/HER2- metastatic breast cancer. Zovegalisib is also being investigated in a group of genetic disease indications called PI3Kα-driven vascular anomalies. Relay's pipeline also includes programs for NRAS-driven solid tumors and Fabry disease. For more information, please visit www.relaytx.com or follow us on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding Relay Therapeutics' strategy, business plans and focus; the progress and timing of the clinical development of the programs across Relay Therapeutics' portfolio; the timing of clinical data readouts for zovegalisib; the expected therapeutic benefits and potential efficacy and tolerability of zovegalisib, both as a monotherapy and in combination with other agents, and its other programs; the clinical data for zovegalisib; the interactions with regulatory authorities and any related approvals; the potential commercialization and market opportunity for zovegalisib; and the cash runway projection and the expectations regarding Relay Therapeutics' use of capital and expenses. The words "may," "might," "will," "could," "would," "should," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" and similar words or expressions, or the negative thereof, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: the impact of global economic uncertainty, geopolitical instability and conflicts, or public health epidemics or outbreaks of an infectious disease on countries or regions in which Relay Therapeutics has operations or does business, as well as on the timing and anticipated results of its clinical trials, strategy, future operations and profitability; significant political, trade or regulatory developments, such as tariffs, beyond Relay Therapeutics' control; the delay or pause of any current or planned clinical trials or the development of Relay Therapeutics' drug candidates; the risk that the preliminary or interim results of its preclinical or clinical trials may not be predictive of future or final results in connection with future clinical trials of its product candidates and that interim and early clinical data may change as more patient data become available and are subject to audit and verification procedures; Relay Therapeutics' ability to successfully demonstrate the safety and efficacy of its drug candidates; the timing and outcome of its planned interactions with regulatory authorities; and obtaining, maintaining and protecting its intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Relay Therapeutics' most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Relay Therapeutics' views only as of today and should not be relied upon as representing its views as of any subsequent date. Relay Therapeutics explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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Relay Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	3 Months Ended December 31,		12 Months Ended December 31,	
	2025	2024	2025	2024
Revenue:				
License and other revenue	$ 7,000	$ —	$ 15,355	$ 10,007
Total revenue	7,000	—	15,355	10,007
Operating expenses:				
Research and development expenses	$ 55,415	$ 68,075	$ 261,383	$ 319,089
Change in fair value of contingent consideration liability	—	—	—	(13,206)
General and administrative expenses	12,215	16,904	56,710	76,592
Total operating expenses	67,630	84,979	318,093	382,475
Loss from operations	(60,630)	(84,979)	(302,738)	(372,468)
Other income:				
Interest income	5,710	8,974	27,035	34,746
Other income (expense)	31	1	(776)	14
Total other income, net	5,741	8,975	26,259	34,760
Net loss	$ (54,889)	$ (76,004)	$ (276,479)	$ (337,708)
Net loss per share, basic and diluted	$ (0.32)	$ (0.45)	$ (1.61)	$ (2.36)
Weighted average shares of common stock, basic and diluted	173,404,585	167,337,579	171,586,558	142,867,844
Other comprehensive income (loss):				
Unrealized holding gain (loss)	240	(3,500)	1,724	(795)
Total other comprehensive income (loss)	240	(3,500)	1,724	(795)
Total comprehensive loss	$ (54,649)	$ (79,504)	$ (274,755)	$ (338,503)

Relay Therapeutics, Inc.
Selected Condensed Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	December 31, 2025	December 31, 2024

Cash, cash equivalents and investments	$	554,518	$	781,323
Working capital (1)		552,701		758,475
Total assets		621,331		871,296
Total liabilities		54,271		93,504
Total stockholders' equity		567,060		777,792
Restricted cash		1,336		2,119

(1) Working capital is defined as current assets less current liabilities.