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): March 16, 2026

RELAY THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39385**	**47-3923475**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
60 Hampshire Street Cambridge, Massachusetts		**02139**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 370-8837

(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, par value $0.001 per share	RLAY	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 7.01 Regulation FD Disclosure.

On March 16, 2026, Relay Therapeutics, Inc. (the "Company") issued a press release announcing the data from the Phase 1/2 ReDiscover trial of zovegalisib (RLY-2608) in combination with fulvestrant at the recommended Phase 3 dose of 400mg twice daily ("BID") taken with food (fed) in patients with PI3Kα-mutated, HR+/HER2- metastatic breast cancer, a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On March 16, 2026, the Company announced data from the Phase 1/2 ReDiscover trial of zovegalisib in combination with fulvestrant at the 400mg BID fed dose, which is the recommended Phase 3 dose, at the European Society for Medical Oncology Targeted Anticancer Therapies Congress 2026.

Zovegalisib is currently being evaluated in the ReDiscover trial, an ongoing first-in-human study designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of zovegalisib in combination with fulvestrant and in combination with fulvestrant and CDK inhibitors in patients with PI3Kα-mutated, HR+/HER2- metastatic breast cancer.

As of the January 13, 2026 data cut-off date (the "Data Cut-off Date"), 60 patients had received the 400mg BID fed regimen. The efficacy population consisted of 57 patients who did not have a PTEN or AKT co-mutation, consistent with the planned pivotal population. All patients had previously received a CDK4/6 inhibitor and at least one prior endocrine therapy in the advanced setting.

Pharmacokinetic analyses demonstrated that the 400mg BID fed regimen achieved exposures comparable to the previously evaluated 600mg BID fasted dose, with mean concentrations approaching IC90 in majority of patients and nearly all patients maintaining exposure above the IC80 throughout the dosing interval.

As of the Data Cut-off Date, among the 57 efficacy-evaluable patients at the 400mg BID fed dose:

- Median follow-up was 12.0 months
- Median progression-free survival ("PFS") was 11.1 months (95% confidence interval: 7.3–13.0 months)
  - Median PFS was 11.2 months in patients with kinase mutations (n=33) and 11.0 months in patients with non-kinase mutations (n=24)
- Among 35 patients with measurable disease, confirmed objective response rate ("ORR") was 43% (15/35) and in second line only patients the ORR was 52% (11/21)

Zovegalisib in combination with fulvestrant at the 400mg BID fed dose was generally well tolerated in the 60 treated patients as of the Data Cut-off Date. The overall tolerability profile consisted primarily of low-grade, manageable and reversible treatment-related adverse events ("TRAEs").

- Safety profile consistent with previously disclosed 600mg BID fasted data
- Majority of hyperglycemia events were Grade 1; no Grade 4-5 hyperglycemia observed
  - In the limited cases of Grade 2/3 hyperglycemia, the vast majority occurred in patients that were pre-diabetic at baseline
- Only four patients discontinued due to TRAEs

Cautionary Note Regarding Forward Looking Statements

This Current Report on Form 8-K and certain materials furnished or filed herewith contain 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 the Company's strategy, business plans and focus; the progress and timing of the clinical development of the programs across the Company's portfolio; 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, as well as the clinical data for zovegalisib; the interactions with regulatory authorities and any related approvals; and the potential commercialization and market opportunity for zovegalisib. 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 Current Report on Form 8-K and certain materials furnished or filed herewith 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 Current Report on Form 8-K and certain materials furnished or filed herewith, 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 the Company 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 the Company's control; the delay or pause of any current or planned clinical trials or the development of the Company's 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; the Company's 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 the Company's 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 the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company 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.

Item 9.01 Financial Statements and Exhibits.

99.1	Press Release issued by Relay Therapeutics, Inc. on March 16, 2026, furnished herewith.
104	Cover Page Interactive Data File (embedded within 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.

Relay Therapeutics, Inc.

Date: March 16, 2026

By: /s/ Soo-Yeun Lim
Soo-Yeun Lim
General Counsel

Exhibit 99.1

Relay Therapeutics Announces Data from Zovegalisib + Fulvestrant at the Phase 3 Dose of 400mg BID Fed at ESMO Targeted Anticancer Therapies Congress 2026

400mg BID fed is the dose used in the ongoing Phase 3 ReDiscover-2 trial, which initiated mid-2025

11.1-month median PFS in heavily pre-treated patients with PI3Kα-mutated, HR+/HER2- metastatic breast cancer

Efficacy in patients with kinase and non-kinase domain mutations is similar, with median PFS of 11.2 and 11.0 months, respectively

Safety and tolerability data are consistent with 600mg BID fasted data

Zovegalisib has received FDA Breakthrough Therapy designation for the Phase 3 ReDiscover-2 trial population

Cambridge, Mass. – March 16, 2026 – 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 announced data from the Phase 1/2 ReDiscover trial of zovegalisib (RLY-2608) + fulvestrant at the recommended Phase 3 dose of 400mg twice daily (BID) taken with food (fed) in patients with PI3Kα-mutated, HR+/HER2- metastatic breast cancer. The data are being presented at the European Society for Medical Oncology (ESMO) Targeted Anticancer Therapies (TAT) Congress 2026 in Paris, France.

“As supported by the data presented, the 400mg BID fed regimen maintains robust efficacy with a safety profile consistent with mutant-selective PI3Kα inhibition,” said Don Bergstrom, M.D., Ph.D., President of R&D at Relay Therapeutics. “These results further support our decision to advance this regimen into the ongoing Phase 3 ReDiscover-2 trial and reinforce our confidence in selectively targeting PI3Kα mutations as a potentially differentiated approach for CDK4/6-experienced patients.”

Phase 1/2 ReDiscover Trial – Zovegalisib 400mg Fed Cohort Data Consistent with 600mg Fasted Data
Zovegalisib is currently being evaluated in ReDiscover, an ongoing first-in-human study designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of zovegalisib in combination with fulvestrant and in combination with fulvestrant and CDK inhibitors in patients with PI3Kα-mutated, HR+/HER2- metastatic breast cancer.

As of the January 13, 2026 data cut-off date, 60 patients had received the 400mg BID fed regimen. The efficacy population consisted of 57 patients who did not have a PTEN or AKT co-mutation, consistent with the planned pivotal population. All patients had previously received a CDK4/6 inhibitor and at least one prior endocrine therapy in the advanced setting.

Pharmacokinetics of Both Doses are Similar
Pharmacokinetic analyses demonstrate that the 400mg BID fed regimen achieves exposures comparable to the previously evaluated 600mg BID fasted dose, with mean concentrations approaching IC90 in majority of patients and nearly all patients maintaining exposure above the IC80 throughout the dosing interval.

Efficacy Consistent with 600mg BID Fasted
As of the January 13, 2026 data cut-off date, among the 57 efficacy-evaluable patients at the 400mg BID fed dose, which is the recommended Phase 3 dose (RP3D):

- Median follow-up was 12.0 months
- Median progression-free survival (PFS) was 11.1 months (95% CI: 7.3–13.0)
    - Median PFS was 11.2 months in patients with kinase mutations (n=33) and 11.0 months in patients with non-kinase mutations (n=24)
- Among 35 patients with measurable disease, confirmed objective response rate (ORR) was 43% (15/35) and in second line only patients the ORR was 52% (11/21)

Maintained Favorable and Differentiated Tolerability Profile
Zovegalisib + fulvestrant at the 400mg BID fed dose was generally well tolerated in the 60 treated patients as of the January 13, 2026 data cut-off. The overall tolerability profile consisted primarily of low-grade, manageable and reversible treatment-related adverse events (TRAEs).

- Safety profile consistent with previously disclosed 600mg BID fasted data
- Majority of hyperglycemia events were Grade 1; no Grade 4-5 hyperglycemia observed
    - In the limited cases of Grade 2/3 hyperglycemia, the vast majority occurred in patients that were pre-diabetic at baseline
- Only four patients discontinued due to TRAEs

The data presentation from the ESMO TAT Congress 2026 is available on the Relay Therapeutics website in the “Publications/Presentations” section through the following link: https://relaytx.com/publications.

ReDiscover-2 – Ongoing Phase 3 Trial
The Phase 3 ReDiscover-2 trial (NCT06982521) is evaluating zovegalisib 400mg BID administered in combination with fulvestrant versus capivasertib + fulvestrant in patients with PI3Kα-mutated, HR+/HER2- advanced breast cancer who have progressed on prior CDK4/6 inhibitor therapy. The study initiated in mid-2025 and is enrolling globally.

Zovegalisib + fulvestrant has received FDA Breakthrough Therapy designation for the Phase 3 ReDiscover-2 trial population.

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.

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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.

Contact:
Pete Rahmer
prahmer@relaytx.com

Media:
Dan Budwick
1AB
973-271-6085
dan@1abmedia.com