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): May 25, 2023

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.)**
399 Binney 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 May 25, 2023, Relay Therapeutics, Inc. (the "Company") issued a press release announcing full dose escalation data from the Company's ReFocus trial for RLY-4008, an investigational, potent, selective and oral small molecule inhibitor of fibroblast growth factor receptor 2 ("FGFR2"), a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K. The Company plans to present this data at the 2023 American Society of Clinical Oncology Annual Meeting on June 4, 2023.

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 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release issued by Relay Therapeutics, Inc. on May 25, 2023, 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: May 25, 2023

By: /s/ Brian Adams
Brian Adams
Chief Legal Officer

Exhibit 99.1

Relay Therapeutics Announces Full Dose Escalation Data for RLY-4008

Data from FGFRi-naïve FGFR2-fusion CCA patients represent subset of September 2022 presentation and remain consistent with previously reported results

Cambridge, Mass. – May 25, 2023 – Relay Therapeutics, Inc. (Nasdaq: RLAY), a clinical-stage precision medicine company transforming the drug discovery process by combining leading-edge computational and experimental technologies, today announced complete first-in-human dose escalation data for RLY-4008, an investigational, potent, selective and oral small molecule inhibitor of fibroblast growth factor receptor 2 (FGFR2). These data, from the global Phase 1/2 ReFocus study in patients with FGFR2-altered cholangiocarcinoma (CCA) and multiple other solid tumors, will be presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting on June 4, 2023. The data being presented at ASCO are generally consistent with those previously reported at the European Society for Medical Oncology (ESMO) Congress in September 2022.

Key Data to be Presented at 2023 ASCO Annual Meeting

The data that will be presented at the ASCO Annual Meeting are from the dose escalation portion of the ReFocus study, with a cut-off date of January 30, 2023. The dose escalation portion of the study enrolled 116 patients with advanced, FGFR2-altered solid tumors, the majority of whom have CCA (n=91), and investigated 15 doses, ranging from 20mg to 100mg, across three dose schedules – once daily (QD), once daily intermittent and twice daily.

The ongoing dose expansion portion of the study includes pivotal and pivotal-supportive cohorts in CCA patients as well as three tumor-agnostic cohorts in patients with other tumor types (non-CCA). Data from the three non-CCA dose expansion cohorts will be presented in the second half of 2023.

Among the 91 CCA patients in the dose escalation portion of the study, 25 had FGFR2 fusions and had not previously received an FGFR inhibitor (FGFRi-naïve FGFR2-fusion CCA). This represents a subset of the interim data reported at ESMO in September 2022, which also included some patients from the ongoing dose expansion cohorts.

- Eleven of these patients were treated at or above the pivotal dose of 70mg QD
    - All 11 patients experienced radiographic tumor reductions
    - Eight of the 11 patients (including all 4 patients receiving the pivotal dose) had a partial response (73% overall response rate (ORR)), and an additional three patients experienced a best response of stable disease
    - The median duration of response (DoR) was 11.2 months
        - Maximum treatment duration is from a patient who remains on treatment at 27 months as of the data cut-off date of January 30, 2023
- Fourteen patients were treated at doses below the 70mg QD pivotal dose

- Twelve of 14 patients experienced radiographic tumor reductions
- Five patients experienced a partial response (36% ORR), and six patients experienced a best response of stable disease
- Median DoR was 5.6 months

The dose escalation portion of the study also included 50 CCA patients with FGFR2 fusions who were previously treated with a non-selective FGFR inhibitor.

- In patients treated at or above the pivotal dose of 70mg QD (n=14), the ORR was 21 percent, and in patients treated at doses below the 70mg QD pivotal dose (n=36), the ORR was 11 percent
- Multiple partial responses occurred in patients with detected V565 and/or N550 mutations

In addition, across all doses, there were early signs of activity in the 14 CCA patients with FGFR2 mutations.

- Nine patients experienced radiographic tumor reductions and four patients experienced a partial response (29% ORR)

The safety analysis from the complete dose escalation portion of the study was generally consistent with the analysis from the 2022 ESMO data disclosure, which also included patients treated at the 70mg QD dose in the expansion cohorts:

- Most treatment-related adverse events were expected FGFR2 on-target, low-grade, monitorable, generally manageable and largely reversible
- There were no observed Grade 4 or 5 adverse events
- Off-target toxicities of hyperphosphatemia and diarrhea continued to be clinically insignificant

The ASCO presentation will be available on the Relay Therapeutics website under Publications: https://relaytx.com/publications/ after it is presented on June 4, 2023.

Key Upcoming RLY-4008 Milestones

- Complete enrollment of pivotal cohort (FGFRi-naïve FGFR2-fusion CCA patients) in the second half of 2023
- Initial data from non-CCA expansion cohorts in the second half of 2023

About RLY-4008

RLY-4008 is a potent, selective and oral small molecule inhibitor of FGFR2, a receptor tyrosine kinase that is frequently altered in certain cancers. FGFR2 is one of four members of the FGFR family, a set of closely related proteins with highly similar protein sequences and properties. Preclinically, RLY-4008 demonstrated FGFR2-dependent killing in cancer cell lines and induced regression in in vivo models, while minimal inhibition of other targets was observed, including other members of the FGFR family. In addition, RLY-4008 demonstrated strong activity against known clinical on-target resistance mutations in cellular and in vivo preclinical models. RLY-4008 is currently being evaluated in ReFocus, a Phase 1/2

study in patients with advanced or metastatic FGFR2-altered solid tumors with a single arm, potentially registration-enabling cohort for FGFRi-naïve FGFR2-fusion CCA.

ReFocus Background

RLY-4008 is currently being evaluated in the global ReFocus Phase 1/2 study in patients with FGFR2-altered CCA and multiple other solid tumors, including a single arm, potentially registration-enabling cohort for FGFRi-naïve FGFR2-fusion CCA. The Phase 1 dose escalation portion of the study has been completed, and 70mg QD has been selected as the registrational dose. The expansion cohorts were initiated in December 2021 and now consist of seven different cohorts based on FGFR2 alteration and tumor type. Of the seven cohorts, the potential pivotal cohort consists of approximately 100 previously treated, FGFRi-naïve FGFR2-fusion CCA patients. To learn more about the ReFocus study, please visit here.

About Relay Therapeutics

Relay Therapeutics is a clinical-stage precision medicine company transforming the drug discovery process by combining leading-edge computational and experimental technologies with the goal of bringing life-changing therapies to patients. As the first of a new breed of biotech created at the intersection of complementary techniques and technologies, Relay Therapeutics aims to push the boundaries of what's possible in drug discovery. Its 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. Relay Therapeutics' initial focus is on enhancing small molecule therapeutic discovery in targeted oncology and genetic disease indications. For more information, please visit www.relaytx.com or follow us on Twitter.

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 the potential therapeutic effects and anticipated clinical benefits of RLY-4008, including potential efficacy and tolerability; whether initial clinical results of RLY-4008 will be predictive of final results in future clinical trials; Relay Therapeutics' strategy, business plans and focus; the progress and timing of updates on the clinical development of and enrollment for the programs across Relay Therapeutics' portfolio, including RLY-4008; and expected therapeutic benefits of its programs; and Relay Therapeutics' expectations relating to its current and future interactions with the U.S. Food and Drug Administration, including its belief regarding a potential pivotal cohort. 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 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, or public health epidemics or outbreaks

of an infectious disease, such as COVID-19, 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; the delay of any current or planned clinical trials or the development of Relay Therapeutics' drug candidates; the risk that the preliminary results of its preclinical or clinical trials, including ReFocus, may not be predictive of future or final results in connection with future clinical trials of its product candidates; 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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