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): September 07, 2022

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 September 7, 2022, a late breaking abstract providing interim clinical data from Relay Therapeutics, Inc.'s (the "Company") ReFocus trial for RLY-4008, a potent, selective and oral small molecule inhibitor of fibroblast growth factor receptor 2 ("FGFR2"), was published on the European Society for Medical Oncology's ("ESMO") website. The abstract has been selected for an oral presentation at the upcoming ESMO Congress 2022, being held both virtually and in Paris, France, from September 9-13, 2022 (the "ESMO Congress"), on September 11, 2022. A copy of the abstract is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The Company plans to issue a press release to announce the results of the interim clinical data presented at the ESMO Congress on September 11, 2022 and intends to host a conference call and live webcast on September 12, 2022 at 8:00 am E.T.

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, as amended (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.

99.1	Abstract: Efficacy of RLY-4008, a highly selective FGFR2 inhibitor in patients (pts) with a FGFR2-fusion or rearrangement (f/r), FGFR inhibitor (FGFRi)-naïve cholangiocarcinoma (CCA): ReFocus trial
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 thereunto duly authorized.

RELAY THERAPEUTICS, INC.

Date: September 8, 2022

By: /s/ Brian Adams
Brian Adams, J.D.
Chief Legal Officer

Efficacy of RLY-4008, a highly selective FGFR2 inhibitor in patients (pts) with a FGFR2-fusion or rearrangement (f/r), FGFR inhibitor (FGFRi)-naïve cholangiocarcinoma (CCA): ReFocus trial

Antoine Hollebecque[1], Mitesh J. Borad[2], Lipika Goyal[3], Alison M. Schram[4], Joon Oh Park[5], Philippe Cassier[6], Suneel Kamath[7], David Tai[8], Efrat Dotan[9], Richard Kim[10], Vaibhav Sahai[11] Do-Youn Oh[12], Chih-Yi Andy Liao[13], Michael Millward[14], Desamparados Roda Perez[15], Charles Ferté[16], Rick Blakesley[16], Beni B. Wolf[16], Vivek Subbiah[17], Robin Kate Kelley [18]

[1]Institut Gustave Roussy, Paris, France; [2] Mayo Cancer Center, Scottsdale, USA; [3]Massachusetts General Hospital, Boston, USA; [4]Memorial Sloan Kettering Cancer Center, New York, USA; [5]Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea; [6]Centre Léon Berard, Lyon, France; [7]The Cleveland Clinic Taussig Cancer Institute, Cleveland, USA; [8]National Cancer Centre Singapore, Singapore; [9]Fox Chase Cancer Center, Philadelphia, USA; [10]H. Lee Moffitt Cancer Center & Research Institute, Tampa, USA; [11]The University of Michigan, Ann Arbor, USA; [12]Seoul National University Hospital, Seoul, Republic of Korea; [13]The University of Chicago, Chicago, USA; [14]Linear Clinical Research & University of Western Australia, Nedlands, Australia; [15]Hospital Clínico Universitario de Valencia, Spain; [16]Relay Therapeutics, Cambridge, USA; [17]The University of Texas MD Anderson Cancer Center, Houston, USA; [18]UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, CA, USA

Background

Previous, nonselective FGFRi have validated FGFR2 f/r as a target in CCA by achieving an objective response rate (ORR) of ~20-40% with duration of response (DOR) ~5-9 months. However, off-target toxicity and emergence of polyclonal FGFR2 resistance limit their efficacy. RLY-4008 is the first highly selective, potent FGFR2 inhibitor designed to target both driver alterations and FGFR resistance mutations. Here we present the initial efficacy of RLY-4008 in pts with a FGFR2 f/r, FGFRi-naïve CCA.

Methods

ReFocus (RLY-4008-101), a Phase 1/2 study (NCT04526106), enrolled pts with advanced solid tumors who received RLY-4008 orally (20-200 mg QD or BID). FGFR2 f/r status was determined by local testing. Key objectives were investigator-assessed ORR per RECIST v1.1, DOR, and safety. Safety was analyzed in all dosed pts and efficacy in pts with FGFR2 f/r, FGFRi-naïve CCA with measurable disease and an opportunity for ≥2 tumor assessments to confirm response.

Results

As of 01AUG22, 38 pts with FGFR2 f/r, FGFRi naïve CCA were efficacy evaluable. Most pts received the recommended phase 2 dose (RP2D); most (68%) remain on treatment with median duration of 6 months (<0.1 - 18.5 months). Potent efficacy was observed across all doses, particularly at the RP2D with an ORR of 88% (Table). One pt treated at the RP2D had a near-complete response and subsequent tumor resection with curative intent. DOR is not yet mature, with majority of responses ongoing. Across all doses (N=195), the most common treatment-related AEs (TRAEs) were low-grade stomatitis (48%), PPE (46%), and dry mouth (31%). No grade 4/5 TRAEs were observed.

	RP2D (70 mg QD) N=17	All dose levels N=38
ORR, n (% [95% CI])	15 (88.2 [63.6 - 98.5])	24 (63.2 [46.0 - 78.2])
Confirmed ORR, n (% [95% CI])	14 (82.4 [56.6 - 96.2])	22 (57.9 [40.8 - 73.7])
Response ongoing, n/N (%)	15/15 (100.0)	19/24 (79.2)
Disease control rate, n (%)	17 (100.0)	36 (94.7)
Remain on treatment, n (%)	15 (88.2)	26 (68.4)

Conclusions

RLY-4008 is a promising next-generation inhibitor with potential to transform the treatment of FGFR2 f/r, FGFRi- naïve CCA. Pivotal testing continues in ReFocus.