# 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): February 24, 2022

# RELAY THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

**Delaware** (State or Other Jurisdiction of Incorporation) 001-39385 (Commission File Number) 47-3923475 (IRS Employer Identification No.)

Relay Therapeutics, Inc.
399 Binney Street, 2<sup>nd</sup> Floor
Cambridge, Massachusetts 02139
(Address of principal executive offices, including zip code)

(617) 370-8837 (Registrant's telephone number, including area code)

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

	ck the appropriate box below if the Form 8-K filing is intended wing provisions:	ded to simultaneously satisfy th	e filing obligation of the registrant under any of the				
	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))						
Secu	ecurities registered pursuant to Section 12(b) of the Act:						
	Title of each class	Trading Symbol(s)	Name of each exchange on which registered				
Com	nmon Stock, \$0.001 par value per share	RLAY	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).							
	ter) or Rule 12b-2 of the Securities Exchange Act of 1934 (		ν-				
-	ter) or Rule 12b-2 of the Securities Exchange Act of 1934 ( $$ rging growth company $\Box$		<b>.</b>				
Eme		(§ 240.12b-2 of this chapter).  registrant has elected not to use	the extended transition period for complying with any new				

#### Item 2.02 Results of Operations and Financial Condition.

On February 24, 2022, Relay Therapeutics, Inc. announced its financial results for the quarter ended and year ended December 31, 2021. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Report on Form 8-K and 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 or the Exchange Act, except as expressly set forth by specific reference in such filing.

#### Item 9.01. Exhibits.

(d) Exhibits

99.1 Press release issued by Relay Therapeutics, Inc. on February 24, 2022, furnished herewith.

104 Cover Page Interactive Data File (embedded within Inline XBRL document).

#### **SIGNATURE**

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: February 24, 2022 By: /s/ Brian Ada

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



#### Relay Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Corporate Highlights

Announced RLY-4008 interim clinical data that suggest it is the first investigational therapy that selectively binds to FGFR2 and avoids offisoform toxicities in the treatment of patients with FGFR2-altered tumors

Shared preclinical data for RLY-2608, the first known allosteric, pan-mutant and isoform-selective PI3Kα inhibitor and dosed the first patient in a first-in-human trial

Continued to advance three additional oncology preclinical programs and two genetic disease preclinical programs, while expanding the capabilities of the Dynamo $^{\text{TM}}$  platform

Raised \$382 million in net proceeds from a follow-on financing in October 2021

\$958 million in cash, cash equivalents and investments at end of 2021 expected to fund operations into at least 2025

Cambridge, MA – February 24, 2022 – <u>Relay Therapeutics</u>, <u>Inc.</u>(Nasdaq: RLAY), a clinical-stage precision medicine company transforming the drug discovery process by combining leading-edge computational and experimental technologies, today reported fourth quarter and full year 2021 financial results and corporate highlights.

"2021 was the year that Relay Therapeutics showed clinical data for the first time, with the RLY-4008 disclosure supporting our belief that our approach of integrating experimental techniques and computational power can make the discovery of medicines more efficient and effective," said Sanjiv Patel, M.D., president and chief executive officer. "We also grew our team, continued to execute against our deep and broad precision medicine pipeline and pushed the boundaries of our Dynamo platform, through both internal innovation and the integration of an acquisition. We've entered 2022 with three clinical stage programs, a robust preclinical pipeline and a cash runway into at least 2025. We are excited to continue our efforts to achieve our goal of bringing life-changing therapies to patients."

#### 2021 Corporate Highlights

#### RLY-4008

- Presented preclinical data at the American Association for Cancer Research (AACR) Annual Meeting for RLY-4008, a highly selective irreversible and oral small molecule inhibitor of FGFR2
- Announced interim clinical data at the AACR-NCI-EORTC Molecular Targets Conference for RLY-4008 in a first-in-human trial in patients with FGFR2-altered cholangiocarcinoma, breast cancer and multiple other solid tumors

- The data suggest that RLY-4008 is the first investigational therapy designed to selectively bind to FGFR2 to avoid offisoform toxicities for the treatment of patients with FGFR2-altered tumors, with study investigators reporting robust inhibition of FGFR2 in the first 49 subjects that was not shown to be limited by off-target toxicities, including hyperphosphatemia and diarrhea
- o The interim clinical data included results from FGFR2-altered solid tumors, with approximately 80% of all patients treated achieving reductions in tumor size at the cut-off date of September 9, 2021
- o In pan-FGFRi treatment-naïve cholangiocarcinoma patients, RLY-4008 demonstrated tumor shrinkage in all six pan-FGFR treatment-naïve FGFR2 fusion positive cholangiocarcinoma patients, with three achieving confirmed partial responses, one of whom went on to surgery with curative intent
- o RLY-4008 also demonstrated encouraging early activity in gene amplifications and mutations, such as the first reported objective response for an FGFR inhibitor in a patient with FGFR2-mutated breast cancer, based on publicly available information
- Initiated expansion cohorts at 70 mg once daily in December 2021
- In January 2022, the FDA granted orphan drug designation to RLY-4008 for the treatment of cholangiocarcinoma

#### RLY-2608

- Presented preclinical data at the AACR-NCI-EORTC Molecular Targets Conference and 2021 San Antonio Breast Cancer Symposium for RLY-2608, the first known allosteric, pan-mutant and isoform-selective PI3Kα inhibitor in a novel allosteric pocket
  - o The data help support the clinical development of RLY-2608 both in single agent and combination clinical trials for patients with PIK3CA (PI3K $\alpha$ ) mutant tumors, including PI3K $\alpha$ -mutant, HR+/HER2- breast cancer
  - o The data indicate RLY-2608 synergizes with fulvestrant and the CDK4/6 inhibitor abemaciclib in cell viability assays in PIK3CAmut/ER+/HER2- cell lines
  - o Oral administration of RLY-2608 in combination with fulvestrant or abemaciclib led to improved efficacy compared to either agent alone in ER+/HER2- xenograft models representing the most commonly observed PIK3CA mutations in breast cancer (H1047R, E542K, E545K)
  - o The triple combination of all three agents resulted in deep regressions across all models, and additionally, the combination arms had similar tolerability to monotherapy arms
- Dosed the first patient in the dose escalation part of the RLY-2608 first-in-human trial in December 2021

#### Corporate Highlights

 Genentech initiated the cohort of RLY-1971/GDC-1971, an inhibitor of SHP2, in combination with GDC-6036, an inhibitor of KRAS G12C, in a Phase 1b trial in July 2021

- Extended leadership in integrating computational and experimental approaches, including by acquiring ZebiAI Therapeutics, Inc. and unlocking our ability to develop our machine learning powered DNA encoded library platform, REL-DEL (Relay DEL)
- Entered into a worldwide strategic collaboration with EQRx, Inc. to discover, develop and commercialize novel medicines
  against validated oncology targets, starting with one program and with the ability to mutually agree to add additional programs
  to the collaboration in the future
- Strengthened the executive team with multiple new appointments leveraging the experienced senior leaders from within Relay Therapeutics and greatly expanded the team through the addition of approximately 100 employees

#### 2022 Anticipated Milestones and Objectives

- Continue to enroll patients in the RLY-4008 expansion cohorts and provide a clinical data update in the second half of 2022
- Continue to enroll patients in the RLY-2608 first-in-human trial and gain experience in the clinic while also progressing against the rest of the preclinical  $PI3K\alpha$  mutant franchise
- Disclose an additional target in the first half of this year
- Genentech to continue driving the development and disclosures of RLY-1971/GDC-1971 in combination with GDC-6036 in the ongoing Phase 1b trial

#### Fourth Quarter and Full Year 2021 Financial Results

Cash, Cash Equivalents and Investments: As of December 31, 2021, cash, cash equivalents and investments totaled approximately \$958.1 million, compared to \$678.1 million as of December 31, 2020. The change in cash reflects the addition of \$382.2 million in net proceeds from Relay Therapeutics' public financing in October 2021. Relay Therapeutics expects its current cash, cash equivalents and investments will be sufficient to fund its current operating plan into at least 2025.

**R&D** Expenses: Research and development expenses were \$51.9 million for the fourth quarter of 2021, as compared to \$32.1 million for the fourth quarter of 2020. This increase was primarily due to \$4.2 million of increased employee related costs, \$7.9 million of increased outside and consulting expense and \$6.9 million of increased clinical trial and related costs. Research and development expenses were \$172.7 million for the full year 2021, as compared to \$99.9 million for the full year 2020. The increase was primarily due to \$30.0 million of increased employee related costs, including \$10.2 million of additional stock-based compensation expense, \$25.3 million of increased external R&D expenses and \$10.9 million of increased clinical trial expenses.

**G&A Expenses:** General and administrative expenses were \$15.5 million in each of the three-month periods ended December 31, 2021 and 2020. General and administrative expenses were \$57.4 million for the full year 2021, as compared to \$38.6 million for the full year 2020. The increase was primarily due to \$12.8 million of increased employee related costs, including \$6.3 million of additional stock-based compensation expense, and \$6.0 million of other general and administrative expenses.

**Net Income/Loss:** Net loss was \$67.5 million for the fourth quarter of 2021, as compared to net income of \$35.3 million for the fourth quarter of 2020. Net loss was \$363.9 million for the full year 2021, or a net loss per share of \$3.82, as compared to a net loss of \$52.4 million for the full year 2020, or a net loss per

share of \$5.40. The increase in net loss included one-time expenses of \$134.9 million in 2021 associated with the acquisition of ZebiAI Therapeutics, Inc.

#### **About Relay Therapeutics**

Relay Therapeutics (Nasdaq: RLAY) is a clinical-stage precision medicines company transforming the drug discovery process by combining leading-edge computational and experimental technologies with the goal of bringing life-changing therapies to patients. Relay Therapeutics is the first of a new breed of biotech created at the intersection of disparate technologies. Relay Therapeutics' 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 <u>follow us on Twitter</u>.

#### **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 updates on the clinical development of the programs across Relay Therapeutics' portfolio, including the timing of a clinical data update for RLY-4008, RLY-2608 and RLY-1971/GDC-1971, and the disclosure of an additional target; expected therapeutic benefits of its programs; whether preclinical or early clinical results of Relay Therapeutics' product candidates will be predictive of future clinical trials; ability to optimize the impact of collaborations on Relay Therapeutics' programs; expectations regarding Relay Therapeutics' use of capital, expenses, future accumulated deficit and other financial results during 2022 and in the future; and Relay Therapeutics' cash runway projection. 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 the ongoing COVID-19 pandemic 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 and future operations; the delay of any current or planned clinical trials or the development of Relay Therapeutics' drug candidates; the risk that the results of its clinical trials may not be predictive of future results in connection with future clinical trials; 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 or 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. Consolidated Statements of Operations and Comprehensive Loss (In thousands, except share and per share data)

	Year Ended December 31,				
		2021		2020	2019
Revenue:					
License and other revenue	\$	3,029	\$	82,654	\$ <u> </u>
Total revenue		3,029		82,654	<u> </u>
Operating expenses:					
Research and development expenses		172,650		99,862	70,306
In-process research and development expenses		123,000		_	_
Loss on initial consolidation of variable interest entity		11,855		_	_
Change in fair value of contingent consideration liability		2,836		_	
General and administrative expenses		57,386		38,588	13,742
Total operating expenses		367,727		138,450	84,048
Loss from operations		(364,698)		(55,796)	(84,048)
Other income (expense):					
Interest income		830		3,400	8,801
Other expense		(4)		(16)	 (58)
Total other income, net		826		3,384	8,743
Net loss	\$	(363,872)	\$	(52,412)	\$ (75,305)
Deemed dividend resulting from extinguishment upon modification of Series C preferred stock		_		(177,789)	_
Net loss attributable to common stockholders	\$	(363,872)	\$	(230,201)	\$ (75,305)
Net loss attributable to common stockholders per share, basic and diluted	\$	(3.82)	\$	(5.40)	\$ (21.82)
Weighted average shares of common stock, basic and diluted		95,136,719		42,619,582	3,450,500
Other comprehensive income (loss):					
Unrealized holding (loss) gain		(1,152)		(261)	 325
Total other comprehensive (loss) income		(1,152)		(261)	325
Total comprehensive loss	\$	(365,024)	\$	(52,673)	\$ (74,980)

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

	December 31, 2021	December 31, 2020
Cash, cash equivalents and investments	\$ 958,07	3 \$ 678,061
Working capital (1)	951,92	1 756,468
Total assets	1,008,44	3 799,829
Total liabilities	110,63	5 36,536
Total stockholders' equity	897,80	8 763,293
Restricted cash	2,57	8 878

<sup>(1)</sup> Working capital is defined as current assets less current liabilities.