# **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

	Therapeutics, I me of Registrant as Specified in Its Char	
Delaware (State or Other Jurisdiction of Incorporation)	001-38997 (Commission File Number)	47-3313701 (IRS Employer Identification No.)
561 Eccles Avenue South San Francisco, CA (Address of Principal Executive Offices)		94080 (Zip Code)
(Regis	(650) 489-9000 strant's Telephone Number, Including Area Code)	
. 0	Not Applicable ame or Former Address, if Changed Since Last Rep	ourt)
Check the appropriate box below if the Form 8-K filing is following provisions (see General Instructions A.2. below  Written communications pursuant to Rule 425 under Soliciting material pursuant to Rule 14a-12 under the Pre-commencement communications pursuant to Rule Pre-commence	r the Securities Act (17 CFR 230.425) he Exchange Act (17 CFR 240.14a-12) he 14d-2(b) under the Exchange Act (17 CF	FR 240.14d-2(b))
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, \$0.0001 par value per share	RAPT	Nasdaq Global Market
Indicate by check mark whether the registrant is an emerg chapter) or Rule 12b-2 of the Securities Exchange Act of		of the Securities Act of 1933 (§230.405 of this
Emerging growth company ⊠		
If an emerging growth company, indicate by check mark in the work revised financial accounting standards provided put		

## Item 8.01. Other Events

On December 8, 2022, RAPT Therapeutics, Inc. ("RAPT" or the "Company") issued a press release presenting an update from its Phase 1/2 clinical trial for FLX175 as monotherapy and in combination with pembrolizumab in patients with advanced cancer. A copy of the press release is filed as Exhibit 99.1 hereto and is incorporated by reference herein.

### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description	
99.1	Press Release titled "RAPT Therapeutics Presents Update from its Phase 1/2 Clinical Trial for FLX175 as Monotherapy and in Combination	
	with Pembrolizumab in Patients with Advanced Cancer" dated December 8, 2022.	
104	Cover Page Interactive Data File (embedded within the 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.

Dated: December 12, 2022 RAPT Therapeutics, Inc.

By: /s/ Rodney Young

Rodney Young Chief Financial Officer



# RAPT Therapeutics Presents Update from its Phase 1/2 Clinical Trial for FLX475 as Monotherapy and in Combination with Pembrolizumab in Patients with Advanced Cancer

#### Data Presented at ESMO Immuno-Oncology Congress

**SOUTH SAN FRANCISCO, Calif. – December 8, 2022** – RAPT Therapeutics, Inc. (Nasdaq: RAPT), a clinical-stage, immunology-based biopharmaceutical company focused on discovering, developing and commercializing oral small molecule therapies for patients with significant unmet needs in inflammatory diseases and oncology, today reported a poster presentation at the ESMO IO Congress covering data from its ongoing Phase 1/2 clinical trial of FLX475 as monotherapy and in combination with pembrolizumab in patients with advanced cancer (NCT03674567).

The data showed a confirmed overall response rate of 31% (4/13 patients) in Stage 1 of a Phase 2 expansion cohort of patients with checkpoint-naïve NSCLC, including two responses which are ongoing for over one year. Of the 13 patients treated with 100 mg once-daily FLX475 and a standard regimen of pembrolizumab, eight patients had PD-L1 positive tumors (TPS  $\geq$ 1%), including two with PD-L1 high tumors (TPS  $\geq$ 50%), four patients had PD-L1 negative tumors (TPS  $\leq$ 1%) and one patient's PD-L1 status was unknown. The confirmed response rate in the PD-L1 positive tumors was 38% (3/8 patients) and in the PD-L1 negative tumors was 25% (1/4 patients). None of the four responders were PD-L1 high. Most of the patients enrolled in this NSCLC cohort had been previously treated with 1-3 or more prior therapies for advanced disease (10/13 patients).

In a separate Phase 2 expansion cohort of six patients with EBV+ NK/T cell lymphoma treated with FLX475 monotherapy, there were four responses, with two durable complete metabolic responses (CMR), one unconfirmed CMR and one unconfirmed partial metabolic response.

The safety profile for FLX475 was favorable, consistent with that previously seen in healthy volunteers, and there was no evidence of increased severity or frequency of adverse events in combination therapy compared to either FLX475 or pembrolizumab monotherapy.

"These data further support the antitumor activity for FLX475 with clear demonstration as a monotherapy and encouraging activity in a combination regimen with checkpoint inhibition," said Brian Wong, M.D., Ph.D., President and Chief Executive Officer of RAPT Therapeutics. "These data meet our criteria for continued development and based on the promising activity of FLX475 with pembrolizumab in checkpoint-naïve NSCLC patients, we have moved this indication to Stage 2 and are enrolling additional patients into the cohort.

#### **About FLX475**

FLX475 is a small molecule CCR4 antagonist designed to block the migration of regulatory T cells ( $T_{reg}$ ) specifically into tumors, but not healthy tissues.  $T_{reg}$  represent a dominant pathway for downregulating the immune response, generally correlate with poor clinical outcomes, and may limit the effectiveness of currently available therapies such as checkpoint inhibitors. RAPT is developing FLX475 in "charged" tumors, which represent cancer types the company believes are most likely to respond to FLX475, where a large quantity of  $T_{reg}$  cells are likely to be the cause of immune suppression within the tumor. FLX475 may restore naturally occurring antitumor immunity alone and may synergize with a variety of both conventional and immune-based therapies, such as radiation, chemotherapy, checkpoint inhibitors, immune stimulators, cancer vaccines, and adoptive T cell therapy.

#### About RAPT Therapeutics, Inc.

RAPT Therapeutics is a clinical stage immunology-based biopharmaceutical company focused on discovering, developing and commercializing oral small molecule therapies for patients with significant unmet needs in inflammatory diseases and oncology. Utilizing its proprietary discovery and development engine, the Company is developing highly selective small molecules designed to modulate the critical immune drivers underlying these diseases. RAPT has discovered and advanced two unique drug candidates, RPT193 and FLX475, each targeting C-C motif chemokine receptor 4 (CCR4), for the treatment of inflammation and cancer, respectively. The Company is also pursuing a range of targets that are in the discovery stage of development.

#### Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipate," "could," "expect," "look forward," "target," "will" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These statements relate to future events and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future performances or achievements expressed or implied by the forward-looking statements. Each of these statements is based only on current information, assumptions and expectations that are inherently subject to change and involve a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements about the therapeutic potential of our product candidates, clinical development progress and results from the ongoing Phase 1/2 study of FLX475. Many factors may cause differences between current expectations and actual results, including unexpected or unfavorable safety or efficacy data observed during clinical studies, preliminary data and trends may not be predictive of future data or results, may not demonstrate safety or efficacy or lead to regulatory approval, clinical trial site activation or enrollment rates that are lower than expected, unanticipated or greater than anticipated impacts or delays due to the COVID-19 pandemic (along with the effects of the war in Ukraine, inflation, rising interest rates and other economic uncertainty), changes in expected

or existing competition, changes in the regulatory environment, the uncertainties and timing of the regulatory approval process and the sufficiency of RAPT's cash resources. Detailed information regarding risk factors that may cause actual results to differ materially from the results expressed or implied by statements in this press release may be found in RAPT's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, filed with the Securities and Exchange Commission on November 10, 2022 and subsequent filings made by RAPT with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof. RAPT disclaims any obligation to update these forward-looking statements, except as required by law.

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