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): November 03, 2023

RAPT Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38997**	**47-3313701**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

561 Eccles Avenue **South San Francisco, California** **(Address of Principal Executive Offices)**	**94080** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (650) 489-9000

Not Applicable
(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, $0.0001 par value per share	RAPT	The Nasdaq Stock Market LLC

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 November 3, 2023, RAPT Therapeutics, Inc. (the "Company") issued a press release announcing clinical data from its ongoing Phase 2 trial of FLX475 (tivumecirnon) in patients with advanced non-small cell lung cancer (NSCLC) who had no prior checkpoint inhibitor therapy. A copy of this press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On November 3, 2023, the Company presented clinical data from its ongoing Phase 2 trial of FLX475 in patients with advanced NSCLC who had no prior checkpoint inhibitor therapy at the Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting in San Diego, California.

The trial evaluated FLX475, an oral small molecule C-C motif chemokine receptor 4 (CCR4) antagonist designed to block the migration of regulatory T cells, in combination with the checkpoint inhibitor pembrolizumab. In this cohort of NSCLC patients, there were 36 patients evaluable for efficacy, of which 20 were PD-L1 positive (TPS ≥1%). In this PD-L1 positive subset of patients, the combination of FLX475 and pembrolizumab showed a 40% (8/20) confirmed objective response rate (ORR). In addition, the median progression-free survival (PFS) for the 20 patients was 6.3 months as of the data cutoff date of October 6, 2023, with several patients continuing on study.

Phase 2 Data Summary in CPI-naïve NSCLC Patients (n=20)

PD-L1 Status	**(n)**	**Confirmed ORR**
Positive (TPS ≥1%)	8/20	40%
Low (TPS 1-49%)	6/16	38%
High (TPS ≥50%)	2/4	50%

At the time of data cutoff, among the PD-L1 positive patients, there was one additional response awaiting confirmation.

The combination of FLX475 and pembrolizumab was well tolerated in this Phase 2 NSCLC cohort. FLX475 has now been dosed in more than 300 patients with various advanced cancers and has been generally well tolerated, and the combination with pembrolizumab has had no signal of increased immune-related toxicity over that expected with pembrolizumab alone.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Exhibit Description**
99.1	Press Release titled "RAPT Therapeutics Announces Positive Data from Phase 2 Trial of FLX475.
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 thereunto duly authorized.

RAPT Therapeutics, Inc.

Date: November 3, 2023

By: /s/ Rodney Young
Rodney Young
Chief Financial Officer

RAPT Therapeutics Announces Positive Data, Including Objective Response Rates and Progression-Free Survival, from its Phase 2 Trial of FLX475 in Combination with a Checkpoint Inhibitor in Patients with Advanced NSCLC

-Confirmed objective response rate (ORR) of 40% in PD-L1 positive patients (TPS ≥1%) with no prior checkpoint inhibitor therapy (CPI)

-Median progression-free survival (PFS) of 6.3 months in PD-L1 positive patients at time of data cut off

- Confirmed ORR of 50% in patients with PD-L1 high expression (TPS ≥50%) and 38% in patients with PD-L1 low expression (TPS 1-49%)

- *Median progression-free survival (PFS) over 6 months at time of data cut off*
- *RAPT to host webcast conference call today at 10.00 am PT*

SOUTH SAN FRANCISCO, Calif. – November 3, 2023 – RAPT Therapeutics, Inc. (Nasdaq: RAPT), a clinical-stage, immunology-based therapeutics company focused on discovering, developing and commercializing oral small molecule therapies for patients with significant unmet needs in inflammatory diseases and oncology, today announced safety and efficacy data from its Phase 2 trial of FLX475 (tivumecirnon) in patients with advanced non-small cell lung cancer (NSCLC) who had no prior checkpoint inhibitor therapy. The In these PD-L1 positive patients, the combination of FLX475 and pembrolizumab showed a 40% (8/20) confirmed ORR and a median PFS of 6.3 months as of the data cut off date, with seven patients continuing on study. For comparison, historical pembrolizumab monotherapy activity in checkpoint inhibitor-naïve and previously-treated NSCLC patients showed a confirmed ORR of 18% and a median PFS of 4.0 months. The confirmed ORR for the combination of FLX475 and pembrolizumab in PD-L1 low and high subsets were 38% (6/16) and 50% (2/4), respectively. For comparison, the ORR for pembrolizumab monotherapy in the PD-L1 low and high subsets has been previously reported as 10% and 30%, respectively.

The data were presented today in a poster at the Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting being held in San Diego. The presenting author was Julie Brahmer, M.D., Co-director of the Upper Aerodigestive Department and Professor of Oncology, Johns Hopkins University.

“We are excited by the response rates and PFS data for FLX475 in combination with a checkpoint inhibitor in this cohort of NSCLC patients. The data from this cohort, which will continue to mature

and potentially improve, met our criteria to advance development of FLX475," said Brian Wong, M.D., Ph.D., President and Chief Executive Officer of RAPT. "We are particularly intrigued to see differentiating efficacy in patients with cool (PD-L1 low) tumors, which are typically poorly responsive to checkpoint inhibitors and checkpoint inhibitor combinations, such as those with anti-TIGIT antibodies. Along with RPT193, we now have two internally discovered compounds that have demonstrated clinical proof of concept in large, commercially attractive indications."

Phase 2 Data Summary in CPI-naïve NSCLC Patients (n=20)

PD-L1 Status	Confirmed Responses(n)	Confirmed ORR
Positive (TPS ≥1%)	8/20	40%
Low (TPS 1-49%)	6/16	38%
High (TPS ≥50%)	2/4	50%

At the time of data cut off, there was one additional response awaiting among the PD-L1 low patients confirmation.

The combination of FLX475 and pembrolizumab was well tolerated in this Phase 2 NSCLC cohort. The most common treatment-emergent adverse event deemed related to study treatment was QT prolongation that was asymptomatic and reversible. FLX475 has now been dosed in more than 300 patients with various advanced cancers and has been generally well tolerated, and the combination with pembrolizumab has not increased immune-related toxicity beyond that expected with pembrolizumab alone.

In previous disclosures, FLX475 showed durable objective responses as monotherapy in an EBV+ lymphoma, as well as in combination with pembrolizumab in EBV+ gastric cancer.

Webcast Conference Call Information
RAPT will host a webcast conference call today, November 3, 2023 at 10:00 a.m. PT. To join the conference call via phone and participate in the live Q&A session, please pre-register online here
to receive a telephone number and unique passcode required to enter the call. The live webcast and audio archive of the presentation may be accessed on the RAPT Therapeutics website at https://investors.rapt.com/events-and-presentations.

About FLX475
FLX475 (tivumecirnon) 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. 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 therapeutics 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 (zelnecirnon) and FLX475 (tivumecirnon), 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,” “plan,” “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 FLX475, plans to advance clinical development of FLX475 and RPT193, plans to seek a partner to accelerate development of FLX475 and other statements that are not historical fact. Many factors may cause differences between current expectations and actual results, including unexpected 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 by the FDA or other regulatory agencies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, the uncertainties and timing of the regulatory approval process, the timing and results of unexpected litigation or other disputes, 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 Form 10-Q for the quarter ended June 30, 2023 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.

Investor Contact:
Sylvia Wheeler
swheeler@wheelhouselsa.com

Media Contact:
Aljanae Reynolds
areynolds@wheelhouselsa.com