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): January 29, 2021

TURNING POINT THERAPEUTICS, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38871**	**46-3826166**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

10628 Science Center Drive, Suite 200, San Diego, CA	**92121**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (858) 926-5251

N/A
(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 (see General Instruction A.2. below):

☐ 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	**TPTX**	**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 8.01 Other Events.

On January 29, 2021, Turning Point Therapeutics, Inc. (the "Company") issued a press release providing program updates, including reporting updated interim data from the registrational Phase 2 TRIDENT-1 study of the Company's lead drug candidate repotrectinib, in patients with ROS1-positive, tyrosine kinase naïve, non-small cell lung cancer. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by Turning Point Therapeutics, Inc. on January 29, 2021.
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.

TURNING POINT THERAPEUTICS, INC.

Date: January 29, 2021

By: /s/ Annette North

Annette North
Executive Vice President and General Counsel

Exhibit 99.1

FOR IMMEDIATE RELEASE

Contact:
Jim Mazzola
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858-342-8272

TURNING POINT THERAPEUTICS REPORTS UPDATED INTERIM DATA FROM REGISTRATIONAL PHASE 2 TRIDENT-1 STUDY OF REPOTRECTINIB IN PATIENTS WITH ROS1-POSITIVE TKI-NAÏVE NON-SMALL CELL LUNG CANCER

- ***Phase 2 Confirmed Objective Response Rate is 93% (95% CI: 68-100); Pooled Phase 1/2 Confirmed Objective Response Rate is 91% (95% CI: 71-99)***
- ***Approximately 40 Patients with ROS1-Positive TKI-Naive Non-Small Lung Cancer Now Enrolled in Phase 1/2 TRIDENT-1 Study***
- ***Company Plans to Conduct Type B Meeting with Food and Drug Administration in 1H 2021 to Discuss Regulatory Path***

SAN DIEGO, Jan. 29, 2021 –Turning Point Therapeutics, Inc. (NASDAQ: TPTX), a precision oncology company developing next-generation therapies that target genetic drivers of cancer, announced updated interim findings from the ongoing TRIDENT-1 registrational study of lead drug candidate repotrectinib in patients with ROS1-positive TKI-naïve non-small cell lung cancer (NSCLC).

In a total of 15 patients enrolled in the Phase 2 portion of the TRIDENT-1 study, the preliminary efficacy analysis showed the confirmed objective response rate (ORR) by physician assessment was 93% (95% CI: 68-100) and in 22 patients pooled from the Phase 1 (dosed at or above the Phase 2 dose) and Phase 2 portions, the confirmed ORR was 91% (95% CI: 71-99).

The findings will be presented in a mini-oral presentation by Dr. Byoung Chul Cho, Division of Medical Oncology, Yonsei Cancer Center at Severance Hospital, Yonsei University College of Medicine, Seoul, Republic of Korea, at the International Association for the Study of Lung Cancer 2020 World Conference on Lung Cancer.

“These interim data confirm our belief that repotrectinib has the potential to be the best-in-class treatment for patients with ROS1-positive TKI-naïve advanced non-small cell lung cancer,” said Mohammad Hirmand, M.D., chief medical officer. “To date, we have enrolled approximately 40 ROS1-positive TKI-naïve patients in the Phase 1 and 2 portions of the TRIDENT-1 study dosed at or above the Phase 2 dose-- an encouraging increase in enrollment following our data update from last August—and we look forward to discussing next steps towards registration of repotrectinib in this patient population at a Type B meeting with the FDA anticipated in the first half of the year.”

Interim Update
Utilizing a Dec. 31, 2020 cutoff date, the TRIDENT-1 preliminary interim efficacy update includes 22 ROS1-positive TKI-naïve NSCLC patients pooled from the Phase 1 portion of the study (dosed at or above the Phase 2 dose) with patients from the Phase 2 portion who had at least two post-baseline scans. Responses for patients in the Phase 2 portion of the study were determined by physician assessment. The interim safety update includes a total of 185 patients from the Phase 1 and Phase 2 portions of the study utilizing an Oct. 30, 2020 cutoff date.

- 14 of 15 patients treated in the Phase 2 portion achieved a confirmed ORR of 93% (95% CI: 68-100). At the time of the data cut-off, the one non-responder remained on treatment and in stable disease with a 13% tumor reduction. In addition, one of the 14 patients in a partial response at the time of the data cutoff date has since achieved a confirmed complete response.

- Duration of response ranged from 1.3+ to 7.4+ months, and the duration of treatment ranged from 3.7+ to 10.9+ months with 14 of the 15 patients remaining on treatment. As of the cutoff date, one additional patient (not included in the confirmed ORR calculation) had an unconfirmed partial response and was on treatment awaiting a confirmatory scan. The company’s prior Phase 2 update with the data cutoff date of July 10, 2020 in 7 total patients, showed a confirmed ORR of 86% and a wider 95% confidence interval of 42 to 100.

- 20 of 22 patients pooled from Phase 1 and Phase 2 achieved a confirmed ORR of 91% (95% CI: 71-99). In the 7 patients from the Phase 1 portion dosed at or above the Phase 2 dose, duration of treatment ranged from 10.9 to 37.3 months with a median of 30.9 months, with four patients receiving treatment for longer than 30 months.

- Repotrectinib was generally well tolerated in 185 patients treated in the Phase 1 and Phase 2 portions of the study.

- Treatment-emergent adverse events (TEAE) found in greater than 15 percent of patients were dizziness (58%), dysgeusia (43%), constipation (32%), dyspnea (31%), fatigue (27%), paresthesia (25%), anemia (22%), nausea (20%), and muscular weakness (16%).

- There were four cases of Grade 3 dizziness (2%) and no cases of dizziness have led to treatment discontinuation. Dose modifications due to TEAEs were

infrequent, including 18% that led to dose reduction and 9% that led to drug discontinuation.

- The majority of treatment related AEs (TRAEs) were Grade 1 or 2 and there were no Grade 4 or Grade 5 TRAEs.

About Turning Point Therapeutics Inc.
Turning Point Therapeutics is a clinical-stage precision oncology company with a pipeline of internally discovered investigational drugs designed to address key limitations of existing cancer therapies. The company's lead drug candidate, repotrectinib, is a next-generation kinase inhibitor targeting the ROS1 and TRK oncogenic drivers of non-small cell lung cancer and advanced solid tumors. Repotrectinib, which is being studied in a registrational Phase 2 study in adults and a Phase 1/2 study in pediatric patients, has shown antitumor activity and durable responses among kinase inhibitor treatment-naïve and pre-treated patients. The company's pipeline of drug candidates also includes TPX-0022, targeting MET, CSF1R and SRC, which is being studied in a Phase 1 trial of patients with advanced or metastatic solid tumors harboring genetic alterations in *MET*; TPX-0046, targeting RET, which is being studied in a Phase 1/2 trial of patients with advanced or metastatic solid tumors harboring genetic alterations in *RET*; and TPX-0131, a next-generation ALK inhibitor currently pending IND submission. Turning Point's next-generation kinase inhibitors are designed to bind to their targets with greater precision and affinity than existing therapies, with a novel, compact structure that has demonstrated an ability to potentially overcome treatment resistance common with other kinase inhibitors. The company is driven to develop therapies that mark a turning point for patients in their cancer treatment. For more information, visit www.tptherapeutics.com.

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Forward Looking Statements
Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the efficacy, safety and therapeutic potential of repotrectinib, the results, conduct, progress and timing of the TRIDENT-1 clinical study, plans regarding future regulatory submissions, and the regulatory approval path for repotrectinib. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "plans", "will", "believes," "anticipates," "expects," "intends," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Turning Point Therapeutics' current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with Turning Point Therapeutics' business in general, risks and uncertainties related to the impact of the COVID-19 pandemic to Turning Point's business and the other risks described in Turning Point Therapeutics' filings with the SEC. All forward-looking statements contained in this press release

speak only as of the date on which they were made. Turning Point Therapeutics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.