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 09, 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, Ste. 200 **San Diego, California**	**92121**
(Address of Principal Executive Offices)	**(Zip Code)**

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

(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	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 2.02 Results of Operations and Financial Condition.

On November 9, 2021, Turning Point Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the third quarter ended September 30, 2021 and providing a corporate update. A copy of this press release is furnished herewith as Exhibit 99.1.

The information contained in this Current Report on Form 8-K under this Item 2.02, and Exhibit 99.1 hereto are being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section and will not be incorporated by reference into any registration statement filed by the Company, under the Securities Act of 1933, as amended, unless specifically identified as being incorporated therein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Turning Point Therapeutics, Inc. on November 9, 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 thereunto duly authorized.

TURNING POINT THERAPEUTICS, INC.

Date: November 9, 2021

By: /s/ Annette North

Annette North

Executive Vice President and General Counsel

FOR IMMEDIATE RELEASE

Contact:
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858-867-6366

TURNING POINT THERAPEUTICS REPORTS THIRD-QUARTER FINANCIAL RESULTS, PROVIDES OPERATIONAL UPDATES

- ***Updated Preliminary Clinical Data Presented for Lead Drug Candidate Repotrectinib and Elzovantinib at the AACR-NCI-EORTC Conference***
- ***Multiple FDA Interactions Anticipated in Q4 2021 and 1H 2022 for Repotrectinib and Elzovantinib***
- ***Cash, Cash Equivalents, and Marketable Securities of $1.0 Billion Expected to Fund Current Operations into 2024***

SAN DIEGO, November 9, 2021 – Turning Point Therapeutics, Inc. (NASDAQ: TPTX), a precision oncology company developing next-generation therapies that target genetic drivers of cancer, today reported financial results for the third quarter ended September 30, 2021 and provided operational updates.

“We are encouraged by the progress made across our pipeline, including recent preliminary data presented for repotrectinib and elzovantinib at the AACR-NCI-EORTC meeting,” said Athena Countouriotis, M.D., president and CEO. “We look forward to multiple anticipated upcoming FDA interactions including a pre-NDA meeting for repotrectinib in ROS1-positive non-small cell lung cancer.”

Third quarter and recent highlights include:

REPOTRECTINIB, ROS1/TRK INHIBITOR

- Second Breakthrough Therapy Designation (BTD) granted by the U.S. Food and Drug Administration (FDA) for repotrectinib for the treatment of patients with advanced solid tumors that have an NTRK gene fusion who have progressed following treatment with one or two prior TRK tyrosine kinase inhibitors, with or without prior chemotherapy, and have no satisfactory alternative treatments. BTD is granted by the FDA to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition.

  The company anticipates discussing next steps towards registration of repotrectinib in patients with NTRK-positive TKI-pretreated advanced solid

tumors at a Type B meeting with the FDA in the fourth quarter of 2021.

- Progress in the Phase 2 TRIDENT-1 registrational study of repotrectinib, where the company reported early interim data at the AACR-NCI-EORTC conference. Utilizing an August 26, 2021 data cutoff for the updated Phase 2 dataset and a July 22, 2019 data cutoff for Phase 1, the preliminary efficacy analysis across multiple cohorts pooled from the Phase 1 and Phase 2 portions of the study demonstrated confirmed objective response rates (cORRs) of 39% in ROS1-positive NSCLC patients pretreated with one prior TKI and prior platinum-based chemotherapy (EXP2: n=23); 30% in ROS1-positive NSCLC patients pretreated with two prior TKIs without prior chemotherapy (EXP-3: n=10); 38% in ROS1-positive NSCLC patients pretreated with one prior TKI without prior chemotherapy (EXP-4: n=39); 41% in NTRK-positive TKI-naïve solid tumor patients (EXP-5: n=17); and 48% in NTRK-positive TKI-pretreated solid tumor patients (EXP-6: n=23). The cORRs in patients with solvent front mutations (SFMs) were 53% in ROS1-positive TKI-pretreated NSCLC patients with a G2032R SFM (n=15), and 62% in NTRK-positive TKI-pretreated solid tumor patients with NTRK SFMs (n=13). Phase 2 responses were determined by physician assessment, and Phase 1 responses were determined by blinded independent central review (BICR).

The safety analysis from 301 treated patients from the pooled Phase 1 and Phase 2 portions of TRIDENT-1 across all cohorts demonstrated that repotrectinib was generally well tolerated, with the majority of treatment related adverse events reported as grade 1 or 2.

- The company anticipates reporting topline BICR data from all of the ROS1-positive NSCLC cohorts from TRIDENT-1 and discussing the BICR data with the FDA at a pre-NDA meeting, in the second quarter of 2022. The company plans to discuss available BICR data in at least 50 TKI-naïve and 50 TKI-pretreated patients with at least six months of follow-up for the majority of responders.

- Progress in the Phase 1/2 CARE study of repotrectinib in pediatric and young adult patients, where the company reported early data at the SIOP Congress. Utilizing an August 2, 2021 data cutoff, the company highlighted preliminary responses by physician assessment and a generally tolerable safety profile. Eight patients were evaluable for efficacy, including four TKI-naïve and four TKI-pretreated patients. Three TKI-naïve patients (two with NTRK fusion solid tumors and one with ROS1 fusion IMT) achieved confirmed responses, including 1 complete response.

ELZOVANTINIB (TPX-0022), MET/SRC/CSF1R INHIBITOR

- Progress in the Phase 1 SHIELD-1 study of elzovantinib, Turning Point's MET, SRC and CSF1R inhibitor, where updated preliminary data from the dose finding portion of the study reported at the AACR-NCI-EORTC conference highlighted clinical activity, including objective responses across multiple tumor types and a generally tolerable safety profile utilizing an August 23, 2021 data cutoff. Among 11 MET TKI-naïve NSCLC patients, four achieved confirmed responses for a cORR of 36% across all dose levels. Among nine MET TKI-naïve gastric/gastroesophageal junction (GC/GEJ) patients, three achieved confirmed

responses for a cORR of 33% across all dose levels. Elzovantinib was generally well tolerated, with the most frequently reported TEAE being dizziness (65%) of which 94% of reported cases were grade 1 or grade 2. Responses were determined by physician assessment.

- Completion of an End of Phase 1 Meeting with the FDA focused on next steps in NSCLC, where the design of the planned Phase 2 portion of the SHIELD-1 study and the recommended Phase 2 dose (RP2D) were discussed. The company proposed a RP2D of 40 mg QD to 40 mg BID at the meeting based on available data. The FDA recommended that the company explore an additional intermediate dose level using the QD titration to BID dosing strategy in at least six to 10 patients prior to starting the Phase 2 portion of the study.

  Patient screening at the intermediate dose level (60 mg QD to 60 mg BID) is ongoing and the company plans to enroll at least six to 10 patients at this dose level and provide data from this dose level to the FDA, with the intention of revising the SHIELD-1 study into a potentially registrational Phase 1/2 study and initiating the Phase 2 portion in 2022. The company also continues to enroll patients in the Phase 1 dose expansion portion of the study at 40 mg QD to 40 mg BID.

- FDA feedback on the development path for elzovantinib in gastric/gastroesophageal junction (GEJ) cancer is anticipated in the fourth quarter of 2021.

- The company announced a clinical collaboration with EQRx to evaluate elzovantinib in combination with aumolertinib, EQRx's drug candidate targeting EGFR, in patients with EGFR mutant MET-amplified advanced NSCLC. The company anticipates initiating the SHIELD-2 combination study of elzovantinib and aumolertinib in mid-2022, pending filing of an investigational new drug (IND) application by the FDA.

TPX-0046, RET INHIBITOR

- Progress in the ongoing dose-finding portion of the Phase 1/2 SWORD-1 study, where the company continues to evaluate multiple doses and schedules to further characterize the pharmacokinetics, safety, and efficacy profile before determining the RP2D.

TPX-0131, ALK INHIBITOR

- Ongoing patient dosing in the Phase 1/2 FORGE-1 study of TPX-0131 in locally advanced or metastatic TKI-pretreated ALK-positive NSCLC. The study endpoints include safety and tolerability, determination of the recommended Phase 2 dose, pharmacokinetics, and any early signals of efficacy.

DISCOVERY

- Continued advancement of four internal discovery programs targeting aberrant GTPase signaling known to drive genomically defined cancers with significant unmet medical need. The most advanced programs target KRAS G12D and the p21 activated kinase, or "PAK" family. Turning Point is targeting 2 development

candidates in the second half of 2022 with a goal to achieve at least one new IND per year beginning in 2023.

Third Quarter Financial Results

- R&D Expenses: Research and development expenses were $48.9 million in the quarter, compared to $32.2 million in the third quarter of 2020. The $16.7 million increase was primarily driven by the year-over-year increase in investments to develop repotrectinib, elzovantinib, TPX-0046 and TPX-0131, discovery efforts and personnel expenses.

- G&A Expenses: General and administrative expenses were $18.2 million compared to $11.3 million in the third quarter of 2020. This increase was primarily due to higher personnel expenses from an increase in head count and professional fees, including those associated with launch readiness.

- Net Income/Loss: Net loss was $66.3 million compared to a net loss of $17.7 million for the third quarter of 2020. The net loss in the third quarter of 2020 was partially offset by the $25 million recorded as a result of the upfront payment from Zai Lab under the company's license agreement for repotrectinib in Greater China.

- Cash Position: Cash, cash equivalents and marketable securities at September 30, 2021 totaled approximately $1.0 billion, reflecting a net decrease of $86.5 million in the first three quarters of 2021. Turning Point projects its cash position funds current operations into 2024.

Webcast and Conference Call

Turning Point will webcast its Quarterly Update Conference Call today, November 9 at 4:30 p.m. ET/1:30 p.m. PT. Dr. Countouriotis will host the call, which will be accessible through the "Investors" section of tptherapeutics.com or by dialing (877) 388-2118 (in the United States) or (470) 495-9489 (outside the U.S.) using conference ID 3118428. A replay will be available through the "Investors" section of www.tptherapeutics.com.

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 elzovantinib, 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, which is being studied in a Phase 1/2 trial of previously treated patients with ALK-positive advanced or metastatic non-small cell lung cancer. 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.

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. Words such as “plans”, “will”, “believes,” “anticipates,” “expects,” “intends,” “goal,” “potential” and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include statements regarding, among other things, the efficacy, safety and therapeutic potential of Turning Point Therapeutics’ drug candidates, repotrectinib, elzovantinib, TPX-0046 and TPX-0131, the results, conduct, progress and timing of Turning Point Therapeutics’ research and development programs and clinical trials, plans regarding future data presentations, clinical trials, regulatory meetings and regulatory submissions, the regulatory approval path for repotrectinib, and the strength of Turning Point Therapeutics’ balance sheet and the adequacy of cash on hand. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such 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 Therapeutics’ business and the other risks described in Turning Point Therapeutics’ filings with the Securities and Exchange Commission (SEC), including its quarterly report on Form 10-Q filed with the SEC on November 9, 2021. 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.

TURNING POINT THERAPEUTICS, INC.

Balance Sheet Data

(**In thousands**)
(**unaudited**)

	September 30, 2021	December 31, 2020
Balance Sheet Data:		
Cash, cash equivalents, and marketable securities	$ 1,036,014	$ 1,122,508
Working capital	1,008,388	1,106,287
Total assets	1,058,985	1,136,713
Accumulated deficit	(438,278)	(280,176)
Total stockholders' equity	$ 1,017,337	$ 1,109,898

TURNING POINT THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	$ 460	$ 25,000	$ 30,829	$ 25,000
Operating expenses:				
Research and development	48,889	32,213	134,802	79,136
General and administrative	18,224	11,326	55,386	59,761
Total operating expenses	67,113	43,539	190,188	138,897
Loss from operations	(66,653)	(18,539)	(159,359)	(113,897)
Other income, net	328	834	1,257	3,981
Net loss	(66,325)	(17,705)	(158,102)	(109,916)
Unrealized (loss) / gain on marketable securities, net of tax	(18)	(606)	(225)	141
Comprehensive loss	$ (66,343)	$ (18,311)	$ (158,327)	$ (109,775)
Net loss per share, basic and diluted	$ (1.34)	$ (0.42)	$ (3.21)	$ (2.82)
Weighted-average common shares outstanding, basic and diluted	49,426,496	42,185,824	49,185,693	38,914,789