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 28, 2022

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** **(Address of Principal Executive Offices)**	**92121** **(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 February 28, 2022, Turning Point Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the fourth quarter and year ended December 31, 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 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 February 28, 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 thereunto duly authorized.

TURNING POINT THERAPEUTICS, INC.

Date: February 28, 2022

By: /s/ Annette North
Annette North
Executive Vice President and General Counsel

Exhibit 99.1

Contact:
Adam D. Levy, Ph.D., M.B.A.
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858-867-6366

TURNING POINT THERAPEUTICS REPORTS FOURTH-QUARTER AND FULL YEAR 2021 FINANCIAL RESULTS, PROVIDES OPERATIONAL UPDATES

- ***On Track for TRIDENT-1 ROS1+ NSCLC Topline Data Disclosure and Pre-NDA Meeting Anticipated 2Q 2022***
- ***Eighth Regulatory Designation Granted for Repotrectinib with Breakthrough Therapy Designation in China***
- ***Other Clinical and Preclinical Programs Continue to Advance***
- ***Cash, Cash Equivalents, and Marketable Securities of approximately $982 Million as of December 31, 2021, Expected to Fund Current Operations into Second Half of 2024***

SAN DIEGO, February 28, 2022 – 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 fourth quarter and year ended December 31, 2021, and provided operational updates.

“We are encouraged by the progress made during 2021 and into the first two months of 2022,” said Athena Countouriotis, M.D., President and CEO. “We look forward to sharing topline ORR and DOR data for our lead investigational therapy repotrectinib in patients with ROS1-positive NSCLC and completing a pre-NDA meeting with the FDA in the second quarter. Supported by our strong financial position, with approximately $1 billion in cash at the end of 2021, we continue to invest in our clinical programs and our research engine, while we also consider opportunities to bring in external innovation where there's a strategic fit.”

Fourth quarter and recent operational highlights include:

REPOTRECTINIB, ROS1/TRK INHIBITOR

- Remain on track to report topline blinded independent central review (BICR) data from all of the ROS1-positive non-small cell lung cancer (NSCLC) cohorts from TRIDENT-1 and discuss the BICR data with the FDA at a pre-NDA meeting, as well as share topline ORR and DOR BICR data prior to the pre-NDA meeting, in the second quarter of 2022.
- The Chinese Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) granted the company’s Greater China partner, Zai Lab, Breakthrough Therapy Designation for repotrectinib for the treatment of patients with ROS1-positive metastatic NSCLC who have not been treated with a ROS1 tyrosine kinase inhibitor (TKI).
- Strong enrollment progress in the Phase 2 registration enabling TRIDENT-1 study across all cohorts during the fourth quarter of 2021 with expansion cohort 4 (EXP-4 --

ROS1-positive advanced NSCLC population pretreated with one prior TKI without chemotherapy) now fully enrolled with the targeted 60 patients. Enrollment across all six cohorts of the study remains open and continues to progress steadily.

- Updated durability data from ROS1-positive TKI-naïve NSCLC patients in the Phase 1 portion of the TRIDENT-1 trial continues to demonstrate best-in-class potential. Among a total of 7 patients treated at or above the recommended Phase 2 dose (RP2D), 3 patients had a DOR of greater than 30 months, using blinded independent central review (BICR) assessments as of the data cut-off date of July 22, 2019 followed by physician assessments as of the data cut-off date of November 29, 2021. 4 out of 7 patients remained on treatment for greater than 3 years.
- Held a Type B meeting with the FDA to discuss potential next steps for repotrectinib in NTRK-positive TKI-pretreated advanced solid tumor patients treated within expansion cohort 6 (EXP-6) of the registrational TRIDENT-1 study.
    - The FDA guided that a pre-NDA meeting should be requested to discuss the topline BICR results from the Phase 2 TKI-pretreated EXP-6 and TKI-naïve EXP-5 patients, when responders have been followed for at least six months past onset of response.
    - The FDA noted that data from EXP-5 may be used to support the efficacy data for EXP-6, or potentially could be pooled with data from EXP-6 to support a broader indication.
    - The company plans to provide guidance on the timing of the pre-NDA meeting for repotrectinib in patients with NTRK-positive advanced solid tumors after completion of enrollment of the targeted 40 EXP-6 patients is achieved.

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

- Patient enrollment continues in the SHIELD-1 study at 40 mg QD to 40 mg BID in Phase 1 dose expansion and in parallel elzovantinib is being studied at an intermediate dose level (60 mg QD to 60 mg BID) in Phase 1 dose escalation.
- FDA clearance of the Investigational New Drug (IND) Application for the combination of elzovantinib and aumolertinib in EGFR mutant MET-amplified NSCLC. The combination of elzovantinib and aumolertinib will be studied in the SHIELD-2 Phase 1b/2 trial in patients with EGFR mutant MET-amplified advanced NSCLC who have progressed following treatment with osimertinib.

TPX-0046, RET INHIBITOR

- Ongoing evaluation of 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 RP2D, pharmacokinetics, and any early signals of efficacy.

DISCOVERY

- Continued advancement of 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. The company is targeting nomination of two development candidates in the second half of 2022 with a goal to achieve at least one new IND per year beginning in 2023.

Upcoming Milestones

Key milestones anticipated in 2022 include:

Repotrectinib
- Provide topline BICR data from all the ROS1-positive NSCLC cohorts from TRIDENT-1 and discuss the BICR data with the FDA at a pre-NDA meeting in the second quarter of 2022
- Provide a clinical data update from the NTRK+ advanced solid tumor cohorts from TRIDENT-1 in the second half of 2022

Elzovantinib
- Initiate the Phase 1b/2 SHIELD-2 study of elzovantinib in combination with aumolertinib in mid-2022
- Initiate the Phase 2 portion of the SHIELD-1 study in the second half of 2022, pending FDA feedback on data from the intermediate dose level
- Provide a clinical data update from the Phase 1 SHIELD-1 study in the second half of 2022

TPX-0131
- Provide early interim data from initial patients treated in the dose-finding portion of the FORGE-1 study in the fourth quarter of 2022 or early 2023

Discovery
- Nominate 2 development candidates in the second half of 2022
- Provide details on the other 2 GTPase signaling discovery programs in the second half of 2022

Fourth Quarter and Full-Year 2021 Financial Results

- Revenue: Revenue of $30.8 million for the year was attributable to the company's licensing agreements with Zai Lab for repotrectinib and elzovantinib in Greater China.

- R&D Expenses: Research and development expenses were $58.2 million for the fourth quarter compared to $34.3 million for the fourth quarter of 2020, and $193.0 million for the year compared to $113.4 million for the year ended December 31, 2020. Primary drivers of the year-over-year increase were investments made to develop repotrectinib, elzovantinib, TPX-0046, TPX-0131, discovery efforts and personnel expenses.

- G&A Expenses: General and administrative expenses were $20.5 million for the fourth quarter compared to $13.7 million for the fourth quarter of 2020, and $75.9 million for the year compared to $73.4 million for the year ended December 31, 2020. G&A expenses in 2020 included a one-time non-cash stock-based compensation charge of $31.4 million associated with the modification of the vesting and expected term of the outstanding stock options pursuant to a transition agreement with our scientific founder.

- Net Loss: Net loss was $78.4 million for the fourth quarter compared to net loss of $47.4 million for the fourth quarter of 2020, and $236.6 million for the year compared to $157.3 million for the year ended December 31, 2020.

- Cash position: Cash, cash equivalents and marketable securities at December 31 totaled $981.6 million, reflecting a net decrease of $140.9 million from December 31, 2020. Turning Point projects its cash position is sufficient to fund current operations into the second half of 2024.

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 annual report on Form 10-K filed with the SEC on February 28, 2022. 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)

	December 31, 2021	December 31, 2020
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 981,582	$ 1,122,508
Working capital	945,373	1,106,287
Total assets	1,003,463	1,136,713
Accumulated deficit	(516,727)	(280,176)
Total stockholders' equity	$ 954,425	$ 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 December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenue	$ -	$ -	$ 30,829	$ 25,000
Operating expenses:				
Research and development	58,177	34,275	192,979	113,411
General and administrative	20,464	13,664	75,850	73,425
Total operating expenses	78,641	47,939	268,829	186,836
Loss from operations	(78,641)	(47,939)	(238,000)	(161,836)
Other income, net	192	563	1,449	4,544
Net loss	(78,449)	(47,376)	(236,551)	(157,292)
Unrealized loss on marketable securities	(1,258)	(203)	(1,483)	(62)
Comprehensive loss	$ (79,707)	$ (47,579)	$ (238,034)	$ (157,354)
Net loss per share, basic and diluted	$ (1.58)	$ (1.02)	$ (4.80)	$ (3.85)
Weighted-average common shares outstanding, basic and diluted	49,498,541	46,588,835	49,264,549	40,843,782