Turning Point Therapeutics Reports Second-Quarter Financial Results, Provides Operational Updates

August 9, 2021

- ***Phase 1/2 TRIDENT-1 Enrollment Reaches Approximately 300 Patients, Including More than 50 in the ROS1-Positive TKI-naïve NSCLC Cohort (EXP-1)***
- ***TPX-0022 Granted Fast Track Designation in MET Amplified Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction (GEJ) Adenocarcinoma after Prior Chemotherapy***
- ***SHIELD-1 Phase 1 Expansion Cohorts Initiated***
- ***TRIDENT-1, SHIELD-1 and CARE Studies Accepted for Clinical Data Presentations at Medical Conferences in October***
- ***Four Discovery Research Programs Ongoing with First 2 Development Candidates Targeted in 2H 2022; Goal to Achieve At Least 1 New IND Every Year Beginning in 2023***
- ***Cash, Cash Equivalents, and Marketable Securities of $1.1 Billion Expected to Fund Current Operations into 2024***

SAN DIEGO, Aug. 09, 2021 (GLOBE NEWSWIRE) -- Turning Point Therapeutics, Inc. (NASDAQ: TPTX), a precision oncology company developing next-generation therapies that target genetic drivers of cancer, today reported financial results and operational updates for the second quarter ended June 30, 2021.

“Our team made strong progress advancing our 4 clinical drug candidates in 5 ongoing clinical trials as well as our research programs with the first 2 development candidates targeted in the second half of 2022,” said Athena Countouriotis, M.D., president and CEO. “In our clinical programs, we are pleased with ongoing enrollment in our pivotal TRIDENT-1 study of repotrectinib. In addition, we recently initiated the Phase 1 expansion cohorts in our SHIELD-1 study of TPX-0022 and just last week were granted Fast Track designation for TPX-0022 in certain gastric cancer indications. We look forward to multiple data updates from our clinical studies at medical conferences during the fourth quarter.”

Second quarter and recent highlights include:

REPOTRECTINIB, ROS1/TRK Inhibitor

- Enrollment of approximately 300 patients in the Phase 1 and 2 portions of the TRIDENT-1 study, including more than 50 patients in the ROS1-positive TKI-naïve advanced non-small cell lung cancer (NSCLC) patient cohort (EXP-1). Enrollment in the EXP-1 cohort is ongoing to provide continued access to new patients.
- Acceptance of TRIDENT-1 clinical data for presentation at the 2021 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in October.
- Acceptance of initial clinical data from the ongoing Phase 1/2 CARE study in pediatric and young adult patients with advanced solid tumors harboring ALK, ROS1 or NTRK alterations for an oral presentation at the 53rd Congress of the International Society of Paediatric Oncology (SIOP) in October.
- First patients dosed in China in the TRIDENT-1 study as part of the company’s partnership with Zai Lab to develop repotrectinib in greater China. Achievement of the milestones resulted in revenue of $5 million to Turning Point under its collaboration agreement with Zai Lab.

TPX-0022, MET/ SRC/CSF1R Inhibitor

- Selection of the likely recommended Phase 2 dose (RP2D) in the ongoing Phase 1 SHIELD-1 study of TPX-0022, Turning Point’s MET, SRC and CSF1R inhibitor, and initiation of Phase 1 expansion cohorts. Subject to feedback from the U.S. Food and Drug Administration (FDA) at an end of Phase 1 meeting in the third quarter, including agreement on the RP2D, the company plans to revise the study into a potentially registrational Phase 1/2 and proceed into the Phase 2 portion.
- Acceptance of SHIELD-1 clinical data for presentation at the 2021 AACR-NCI-EORTC International Conference on

Molecular Targets and Cancer Therapeutics in October.

- Orphan Drug Designation granted by the FDA for the treatment of patients with gastric cancer, including gastroesophageal junction adenocarcinoma (GEJ).

- Fast Track Designation granted by the FDA for the treatment of patients with MET amplified advanced or metastatic gastric cancer or GEJ adenocarcinoma after prior chemotherapy.

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.

- Publication of preclinical data in the AACR Journal of Molecular Cancer Therapeutics showing TPX-0131 to be potent against a wide range of ALK resistant mutations, including G1202R, L1196M and multiple compound mutations.

Discovery

- Advancing 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.

Second Quarter Financial Results

- Revenue: Revenue of $5.2 million recognized during the quarter was driven primarily by milestones earned from Zai Lab (Shanghai) Co. Ltd. under the company’s license agreement for repotrectinib in Greater China. Revenue for the first half of 2021 totaled $30.4 million.

- R&D Expenses: Research and development expenses were $44.7 million in the quarter, compared to $24.2 million in the second quarter of 2020. The $20.5 million increase was primarily driven by the year-over-year increase in investments to develop repotrectinib, TPX-0022, TPX-0046 and TPX-0131, discovery efforts and personnel expenses. R&D expenses for the first half of 2021 totaled $85.9 million.

- G&A Expenses: General and administrative expenses were $17.2 million compared to $8.6 million in the second quarter of 2020, primarily related to higher personnel expenses from an increase in head count and professional services. G&A expenses for the first half of 2021 totaled $37.2 million.

- Net Income/Loss: Net loss was $56.3 million compared to a net loss of $31.5 million for the second quarter of 2020. Net loss for the first half of 2021 was $91.8 million.

- Cash position: Cash, cash equivalents and marketable securities at June 30, 2021 totaled approximately $1.1 billion. Net cash used during the first half of 2021 was $44.7 million. Turning Point projects its cash position funds current operations into 2024.

Upcoming Milestones
Key milestones anticipated in the second half of 2021 include:

Repotrectinib

- Initiate the first cohort of a multi-arm Phase 1b/2 TRIDENT-2 combination study in patients with *KRAS* mutant *G12D* advanced solid tumors in the third quarter

- Provide a clinical data update by physician assessment from multiple ROS1 and NTRK patient cohorts of the Phase 2 TRIDENT-1 study at the AACR-NCI-EORTC conference in October

- Report initial clinical data from the ongoing Phase 1/2 CARE study in pediatric and young adult patients in an oral

presentation at the 53rd SIOP Congress in October

TPX-0022

- Provide a clinical data update across multiple tumor types and MET genetic alterations from the Phase 1 dose finding portion of the SHIELD-1 study at the AACR-NCI-EORTC conference in October
- Initiate the Phase 2 portion of the SHIELD-1 study, pending FDA feedback, in the fourth quarter
- Initiate the Phase 1b/2 SHIELD-2 study of TPX-0022 in combination with an epidermal growth factor receptor (EGFR) targeted therapy in the fourth quarter

Webcast, Conference Call, Upcoming Investor Conferences
Turning Point will webcast its Quarterly Update Conference Call today, Aug. 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 4029189. A replay will be available through the "Investors" section of www.tptherapeutics.com.

Dr. Countouriotis will also participate in a targeted oncology panel discussion at the 2021 Wedbush Pacgrow Virtual Healthcare Conference on Aug. 10 at 10:55 a.m. ET, and a “fireside chat” question-and-answer session at the 41st Annual Canaccord Genuity Growth Conference on Aug. 11 at 4 p.m. ET. Both sessions will be accessible 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 pretreated 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, 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. 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.

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 Turning Point Therapeutics’ drug candidates, repotrectinib, TPX-0022, 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. 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’ Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 and other 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.

TURNING POINT THERAPEUTICS, INC.
Balance Sheet Data
(**In thousands**)
(**unaudited**)

	June 30, 2021	December 31, 2020
Balance Sheet Data:		
Cash, cash equivalents, and marketable securities	$ 1,077,806	$ 1,122,508
Working capital	1,059,525	1,106,287
Total assets	1,102,920	1,136,713
Accumulated deficit	(371,953)	(280,176)
Total stockholders' equity	$ 1,067,507	$ 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 June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenue	$ 5,164	$ -	$ 30,369	$ -
Operating expenses:				
Research and development	44,650	24,154	85,913	46,923
General and administrative	17,171	8,578	37,162	48,435
Total operating expenses	61,821	32,732	123,075	95,358
Loss from operations	(56,657)	(32,732)	(92,706)	(95,358)
Other income, net	384	1,239	929	3,147
Net loss	(56,273)	(31,493)	(91,777)	(92,211)
Unrealized gain / (loss) on marketable securities, net of tax	(22)	1,063	(208)	747
Comprehensive loss	$ (56,295)	$ (30,430)	$ (91,985)	$ (91,464)
Net loss per share, basic and diluted	$ (1.14)	$ (0.82)	$ (1.87)	$ (2.47)
Weighted-average common shares outstanding, basic and diluted	49,204,425	38,603,236	49,063,298	37,261,296

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