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

August 10, 2020

- ***Early Interim Data from Registrational Phase 2 TRIDENT-1 Study of Lead Drug Candidate Repotrectinib Anticipated in Third Quarter***
- ***Four Clinical Studies of Three Drug Candidates Ongoing; Early Interim TPX-0022 Data Anticipated in Fourth Quarter***
- ***Cash, Cash Equivalents, and Marketable Securities of $710 Million Expected to Fund Current Operations into 2023***

SAN DIEGO, Aug. 10, 2020 (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.

“We achieved many important milestones since our first quarter update in May, including advancing our pipeline of four drug candidates, sharing our preclinical combination data for repotrectinib in KRAS cancer models, raising gross proceeds of $374 million through our May stock offering, completing a strategic agreement with Zai Lab to develop repotrectinib in Greater China and strengthening our team with the hiring of our chief commercial officer, Andy Partridge,” said Athena Countouriotis, M.D., president and chief executive officer.

“Turning to the second half of 2020, we remain focused on advancing our pipeline, as we continue to navigate the COVID-19 pandemic and monitor its impact to our timelines. For the TRIDENT-1 Phase 2 registrational study of repotrectinib, site activations and enrollment have improved since our last update in May, and we are planning to report early interim data from the study in the third quarter. Our goal is to achieve full global site activation in the TRIDENT-1 study in early 2021.

“Overall, I am pleased with how our team has adapted and advanced our clinical development during these challenging times and I want to again thank the dedicated health care providers worldwide who continue to treat patients suffering from COVID-19.”

Second quarter and recent highlights include:

- Progress in the TRIDENT-1 Phase 2 registrational study of repotrectinib, where the company anticipates reporting early interim data in the third quarter. The preliminary efficacy and safety data by physician assessment are expected to be from 30 to 40 patients across multiple Phase 2 cohorts, including registrational and exploratory cohorts. The company’s goal is to achieve full site activation in the study in early 2021.
- Three additional trials ongoing, including the Phase 1/2 open-label study to assess repotrectinib in pediatric patients with ALK-, NTRK- or ROS1-positive advanced solid tumors; the Phase 1 study of TPX-0022, Turning Point’s MET/CSF1R/SRC inhibitor; and the Phase 1/2 study of TPX-0046, Turning Point’s RET/SRC inhibitor.
- Completing an exclusive license agreement with Zai Lab for the development and commercialization of repotrectinib in Greater China, which includes mainland China, Hong Kong, Macau and Taiwan. Under the terms of the agreement, Zai Lab obtained exclusive rights to develop and commercialize repotrectinib in Greater China and Turning Point Therapeutics will receive a $25 million upfront payment, with the potential to receive up to an additional $151 million in development, regulatory and sales-based milestone payments. Turning Point will also be eligible to receive mid-to-high teen royalties based on annual net sales of repotrectinib in Greater China.
- Appointing Andrew Partridge as executive vice president and chief commercial officer. Mr. Partridge has more than 20 years of global pharmaceutical sales and marketing experience leading more than 20 commercial launches across multiple indications, including oncology, hematology and rare diseases.

Second Quarter Financial Update

Operating expenses for the second quarter totaled $32.7 million compared to $18.5 million in the second quarter of 2019. Primary drivers of the year-over-year increase were investments made to develop repotrectinib, TPX-0022 and TPX-0046, as well as personnel expenses.

Excluding a one-time non-cash stock-based compensation charge in the first quarter of $31.4 million, non-GAAP operating expenses for the first half totaled $64 million compared to $32.5 million in the first half of 2019. Year-to-date net cash used in operating activities was $51.2 million.

Cash, cash equivalents and marketable securities at June 30 totaled $710.4 million, an increase of $329.6 million from Mar. 31 driven by proceeds from the company’s May stock offering. Turning Point Therapeutics projects its cash position funds current operations into 2023.

Upcoming Milestones
Key milestones anticipated into early 2021 include:

- Early interim data from approximately 30 to 40 patients across multiple TRIDENT-1 Phase 2 cohorts in the third quarter.
- Additional preclinical data highlighting the potential for repotrectinib to increase the effectiveness of KRAS-G12C inhibitors in the fourth quarter.
- Early interim data from initial patients treated with TPX-0022 in the fourth quarter.
- Submitting the IND for TPX-0131 by early 2021.
- Early interim data from initial patients treated with TPX-0046 in early 2021

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 and SRC, 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 in IND-enabling studies. 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.

Non-GAAP Financial Measures
In addition to the financial results that are provided in accordance with accounting principles generally accepted in the United States (GAAP), this press release also contains a non-GAAP financial measure. When preparing our supplemental non-GAAP financial results, the Company excluded certain GAAP items that management does not consider to be normal. In particular, the non-GAAP measure excludes non-cash stock-based compensation expense relating to a one-time charge of $31.4 million associated with previously disclosed modifications to the vesting of existing stock options, pursuant to the transition agreement with the company's scientific founder. This non-GAAP measure is provided as a complement to results provided in accordance with GAAP as management believes this non-GAAP financial measure is important in comparing current results with prior-period results. A reconciliation of the GAAP financial results to non-GAAP financial results is included in the attached financial information.

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' development programs and clinical trials including the Phase 2 TRIDENT-1 clinical study, the Phase 1/2 pediatric clinical study of repotrectinib, the Phase 1 clinical study of TPX-0022 and the Phase 1/2 clinical study of TPX-0046, plans regarding future clinical trials and regulatory submissions, the regulatory approval path for repotrectinib, the potential to receive milestone and royalty payments from Zai Lab, 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' 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, 2020	**December 31, 2019**
Balance Sheet Data:		
Cash, cash equivalents, and marketable securities	$ 710,430	$ 409,151
Working capital	707,427	400,915
Total assets	725,424	422,202
Accumulated deficit	(215,095)	(122,884)

Total stockholders' equity	710,827	404,351

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,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 24,154	$ 13,711	$ 46,923	$ 24,162
General and administrative	8,578	4,743	48,435	8,357
Total operating expenses	32,732	18,454	95,358	32,519
Loss from operations	(32,732)	(18,454)	(95,358)	(32,519)
Other income, net	1,239	1,312	3,147	1,830
Net loss	(31,493)	(17,142)	(92,211)	(30,689)
Unrealized gain on marketable securities, net of tax	1,063	345	747	345
Comprehensive loss	$ (30,430)	$ (16,797)	$ (91,464)	$ (30,344)
Net loss per share, basic and diluted	$ (0.82)	$ (0.70)	$ (2.47)	$ (2.19)
Weighted-average common shares outstanding, basic and diluted	38,603,236	24,479,767	37,261,296	14,004,957

TURNING POINT THERAPEUTICS, INC.
Reconciliation of GAAP to Non-GAAP Financial Results
(**In thousands**)
(**unaudited**)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
GAAP Loss from operations	$ (32,732)	$ (18,454)	$ (95,358)	$ (32,519)
Adjustments:				
Share-based compensation expense (1)	–	–	31,405	–
Non-GAAP Loss from operations	$ (32,732)	$ (18,454)	$ (63,953)	$ (32,519)

(1) During the first quarter of 2020, the Company recognized in non-cash stock-based compensation expense a one-time charge of $31.4 million associated with previously disclosed modifications to the vesting of existing stock options, pursuant to the transition agreement with the company's scientific founder.

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