November 8, 2022

Checkpoint Therapeutics Reports Third Quarter 2022 Financial Results and Recent Corporate Highlights

Successful completion of pre-BLA meetings in July

Biologics license application ("BLA") for both metastatic and locally advanced cutaneous squamous cell carcinoma indications expected to be submitted by January 2023

WALTHAM, Mass., Nov. 08, 2022 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced financial results for the third quarter ended September 30, 2022, and recent corporate highlights.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, "In the third quarter of 2022, we successfully completed two pre-Biologics License Application ("BLA") meetings with the U.S. Food and Drug Administration ("FDA"). Importantly, we continue to achieve significant progress toward our planned submission of a BLA by January of next year, which will include both the metastatic and locally advanced cutaneous squamous cell carcinoma ("cSCC") indications. We believe cosibelimab, with its differentiated two-fold mechanism of action, has the potential to be the first anti-PD-L1 antibody approved for advanced cSCC, which is the second most frequently diagnosed skin cancer, and provide physicians worldwide with an important new treatment option in the fight against this common and possibly deadly cancer. Our planned BLA submission will represent a significant milestone both for us as a company and for patients seeking treatment for cSCC."

"The reverse stock split recently approved by shareholders and planned for December is a proactive measure that we are confident will improve long-term liquidity and better position us for success by providing the opportunity for our stock to trade in a price range more attractive to a broader array of institutional investors. This increased visibility with institutional investors is critical as we continue our transition from a development-stage company to a fully integrated commercial organization to support the potential launch of cosibelimab."

Recent Corporate Highlights:

- In July 2022, Checkpoint successfully completed two pre-BLA meetings with the FDA (chemistry, manufacturing and controls [CMC] and clinical/non-clinical). Based upon favorable interactions with the agency, the planned BLA submission will include both the metastatic and locally advanced cutaneous squamous cell carcinoma indications. Checkpoint also reached agreement with the FDA on all key aspects discussed with regard to the content of the upcoming BLA submission.

- In November 2022, holders of a majority of the voting power of the capital stock of Checkpoint approved a 1-for-10 reverse stock split of the company's common stock. Checkpoint expects its common shares will begin trading on a split-adjusted basis on the Nasdaq Capital Market in December 2022. The Board of Directors determined the 1-for-10 ratio to be appropriate in order to improve the marketability and liquidity of Checkpoint's common stock and to remain in compliance with all of Nasdaq's continued listing requirements.

Financial Results:

- **Cash Position**: As of September 30, 2022, Checkpoint's cash and cash equivalents totaled $20.5 million, compared to $30.9 million at June 30, 2022 and $54.7 million at December 31, 2021, a decrease of $10.4 million for the quarter and a decrease of $34.2 million for the first nine months of 2022.
- **R&D Expenses**: Research and development expenses for the third quarter of 2022 were $8.9 million, compared to $9.4 million for the third quarter of 2021, a decrease of $0.5 million. Research and development expenses for the third quarter of 2022 included $0.3 million of non-cash stock expenses, compared to $0.2 million for the third quarter of 2021.
- **G&A Expenses**: General and administrative expenses for the third quarter of 2022 were $1.8 million, compared to $1.9 million for the third quarter of 2021, a decrease of $0.1 million. General and administrative expenses for the third quarter of 2022 included $0.5 million of non-cash stock expenses, compared to $0.6 million for the third quarter of 2021.
- **Net Loss**: Net loss attributable to common stockholders for the third quarter of 2022 was $10.6 million, or $0.12 per share, compared to a net loss of $11.3 million, or $0.14 per share, in the third quarter of 2021. Net loss for the third quarters of 2022 and 2021 both included $0.8 million of non-cash stock expenses.

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. ("Checkpoint") is a clinical-stage immunotherapy and targeted oncology company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. Checkpoint is evaluating its lead antibody product candidate, cosibelimab, a potential best-in-class anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in an ongoing global, open-label, multicohort Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including ongoing cohorts in locally advanced and metastatic cutaneous squamous cell carcinoma ("cSCC") intended to support one or more applications for marketing approval. Following positive topline and interim results in metastatic and locally advanced cSCC, respectively, Checkpoint intends to submit a Biologics License Application for these indications later this year. Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, olafertinib (formerly CK-101), a third-generation epidermal growth factor receptor ("EGFR") inhibitor, as a potential new treatment for patients with EGFR mutation-positive non-small cell lung cancer. Checkpoint is headquartered in Waltham, MA and was founded by Fortress Biotech, Inc. (Nasdaq: FBIO). For more information, visit www.checkpointtx.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A

of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended, that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements relating to the potential differentiation of cosibelimab, including a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies, the two-fold mechanism of action of cosibelimab translating into potential enhanced efficacy, projections of publication and regulatory submission timelines, and our planned price disruptive strategy generating substantial market share for cosibelimab in the U.S. Factors that could cause our actual results to differ materially include the following: our ability to successfully deliver the complete dataset from the clinical trial and complete a BLA submission on schedule as planned; the risk that topline and interim data remains subject to audit and verification procedures that may result in the final data being materially different from the topline or interim data we previously published; the risk that safety issues or trends will be observed in the clinical trial when the full safety dataset is available and analyzed; the risk that a positive primary endpoint does not translate to all, or any, secondary endpoints being met; risks that regulatory authorities will not accept an application for approval of cosibelimab based on data from the Phase 1 clinical trial; the risk that the clinical results from the Phase 1 clinical trial will not support regulatory approval of cosibelimab to treat cSCC or, if approved, that cosibelimab will not be commercially successful; risks related to our chemistry, manufacturing and controls and contract manufacturing relationships; risks related to our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks related to our need for substantial additional funds; other uncertainties inherent in research and development; our dependence on third-party suppliers; government regulation; patent and intellectual property matters; competition; and our ability to achieve the milestones we project, including the risk that the evolving and unpredictable Russia/Ukraine conflict and COVID-19 pandemic delay achievement of those milestones. Further discussion about these and other risks and uncertainties can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, and in our other filings with the U.S. Securities and Exchange Commission. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this press release should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

Any forward-looking statements set forth in this press release speak only as of the date of this press release. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law. This press release and prior releases are available at www.checkpointtx.com. The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

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CHECKPOINT THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and per share amounts)
(Unaudited)

	September 30, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 20,478	$ 54,735
Prepaid expenses and other current assets	1,094	976
Other receivables - related party	48	17
Total current assets	21,620	55,728
Total Assets	**$ 21,620**	**$ 55,728**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 21,844	$ 24,919
Accounts payable and accrued expenses - related party	1,111	1,063
Total current liabilities	22,955	25,982
Total Liabilities	**22,955**	**25,982**
Commitments and Contingencies		
Stockholders' (Deficit) Equity		
Common Stock ($0.0001 par value), 135,000,000 shares authorized as of September 30, 2022 and December 31, 2021		
Class A common shares, 7,000,000 shares issued and outstanding as of September 30, 2022 and December 31, 2021	1	1
Common shares, 85,844,320 and 77,574,405 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	9	8

Common stock issuable, 0 and 2,121,422 shares as of September 30, 2022 and December 31, 2021, respectively	-	6,598
Additional paid-in capital	240,119	223,001
Accumulated deficit	(241,464)	(199,862)
Total stockholders' (deficit) equity	(1,335)	29,746
Total Liabilities and Stockholders' (Deficit) Equity	**$ 21,620**	**$ 55,728**

CHECKPOINT THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(Unaudited)

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue - related party	$ 48	$ 29	$ 118	$ 252
Operating expenses:				
Research and development	8,866	9,384	35,589	20,795
General and administrative	1,846	1,923	6,218	6,410
Total operating expenses	10,712	11,307	41,807	27,205
Loss from operations	(10,664)	(11,278)	(41,689)	(26,953)
Other income				
Interest income	52	13	87	39
Total other income	52	13	87	39
Net Loss	**$ (10,612)**	**$ (11,265)**	**$ (41,602)**	**$ (26,914)**
Loss per Share:				
Basic and diluted net loss per common share outstanding	$ (0.12)	$ (0.14)	$ (0.48)	$ (0.36)
Basic and diluted weighted average number of common shares outstanding	88,567,497	78,530,952	87,055,290	74,805,868

Checkpoint Therapeutics

Source: Checkpoint Therapeutics, Inc