May 10, 2024

Checkpoint Therapeutics Reports First Quarter 2024 Financial Results and Recent Corporate Updates

WALTHAM, Mass., May 10, 2024 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (Nasdaq: CKPT), a clinical-stage immunotherapy and targeted oncology company, today announced financial results for the first quarter ended March 31, 2024, and recent corporate updates.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, "Over the past few months, we have worked closely with our third-party contract manufacturing organization ("CMO") for cosibelimab to resolve their inspection deficiencies noted in the complete response letter ("CRL") we received from the U.S. Food and Drug Administration ("FDA") last December. Recently, our CMO submitted to FDA their response to the inspection deficiencies, which we believe could allow for the resubmission of our biologics license application ("BLA"). We plan to meet with the FDA shortly, at which time we will seek to reach alignment for a potential mid-year BLA resubmission."

Recent Corporate Updates:

- Checkpoint submitted a BLA to the FDA in January 2023 seeking approval of cosibelimab as a potential new treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC") who are not candidates for curative surgery or curative radiation, and the FDA accepted the BLA for filing in March 2023. In December 2023, the FDA issued a CRL for the cosibelimab BLA. The CRL only cited findings that arose during a multi-sponsor inspection of Checkpoint's third-party CMO as approvability issues to address in a BLA resubmission. The CRL did not state any concerns about the clinical data package, safety, or labeling for the approvability of cosibelimab. Checkpoint intends to seek to address the feedback in a potential BLA resubmission, which is currently targeted for mid-year.
- In January 2024, Checkpoint completed a registered direct offering priced At-the-Market under Nasdaq rules and a concurrent private placement of warrants to purchase Checkpoint common stock, for total gross proceeds of approximately $14.0 million.
- In March 2024, Checkpoint announced the appointment of life sciences executive, Amit Sharma, M.D., FACP, FASN, FNKF, currently Vice President of Clinical Development and Therapeutic Head for Nephrology and Hematology at Alexion, AstraZeneca Rare Disease, as a non-executive director to Checkpoint's Board of Directors.

Financial Results:

- **Cash Position**: As of March 31, 2024, Checkpoint's cash and cash equivalents totaled $11.2 million, compared to $4.9 million at December 31, 2023, an increase of $6.3 million.
- **R&D Expenses**: Research and development expenses for the first quarter of 2024 were $8.5 million, compared to $15.8 million for the first quarter of 2023, a decrease of $7.3 million. Research and development expenses for the first quarter of 2024 included $0.5 million of non-cash stock expenses, compared to $0.4 million for the first quarter of 2023.
- **G&A Expenses**: General and administrative expenses for the first quarter of 2024 were $2.5 million, compared to $2.3 million for the first quarter of 2023, an increase of $0.2 million. General and administrative expenses for the first quarter of 2024 included $0.6 million of non-cash stock expenses, compared to $0.7 million for the first quarter of 2023.
- **Net Loss**: Net loss attributable to common stockholders for the first quarter of 2024 was $10.9 million, or $0.33 per share, compared to a net loss of $10.5 million, or $0.89 per share, in the first quarter of 2023. Net loss for the first quarter of 2024 and 2023 both included $1.1 million of non-cash stock expenses.

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. 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, as a potential new treatment for patients with selected recurrent or metastatic cancers, including metastatic and locally advanced cSCC. Checkpoint is also 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 regarding our ability to work with our third-party CMO and the U.S. FDA to adequately address the issues raised in the CRL and execute on a pathway forward for the potential approval of cosibelimab for the treatment of patients with metastatic or locally advanced cSCC who are not candidates for curative surgery or radiation, the adequacy of the responses to the inspection issues submitted to FDA by our CMO to allow a BLA resubmission, and our projections of resubmission and regulatory review timelines, statements related to our ability to shorten our launch timeline in anticipation of a potential approval, and statements relating to the potential differentiation of cosibelimab, including a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies and the two-fold mechanism of action of cosibelimab translating into potential enhanced

efficacy. Factors that could cause our actual results to differ materially include the following: 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; unfavorable market or other economic conditions; 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, 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)

	March 31, 2024	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 11,241	$ 4,928
Prepaid expenses and other current assets	734	450
Total current assets	11,975	5,378
Total Assets	**$ 11,975**	**$ 5,378**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 19,159	$ 15,485
Accounts payable and accrued expenses - related party	2,941	2,815
Common stock warrant liabilities	125	125
Total current liabilities	22,225	18,425
Total Liabilities	**22,225**	**18,425**
Commitments and Contingencies		
Stockholders' Equity (Deficit)		
Common Stock ($0.0001 par value), 80,000,000 shares authorized as of March 31, 2024 and December 31, 2023		
Class A common shares, 700,000 shares issued and outstanding as of March 31, 2024 and December 31, 2023	-	-
Common shares, 34,986,279 and 27,042,035 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	4	3
Common stock issuable, 1,492,915 shares as of March 31, 2024 and December 31, 2023	3,419	3,419
Additional paid-in capital	311,605	297,864
Accumulated deficit	(325,278)	(314,333)
Total Stockholders' Equity (Deficit)	(10,250)	(13,047)
Total Liabilities and Stockholders' Equity (Deficit)	**$ 11,975**	**$ 5,378**

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

	For the three months ended March 31,	
	2024	2023
Revenue - related party	$ -	$ 35
Operating expenses:		
Research and development	8,497	15,826
General and administrative	2,451	2,292
Total operating expenses	10,948	18,118
Loss from operations	(10,948)	(18,083)
Other income:		
Interest income	4	43

Gain on common stock warrant liabilities		-		7,566
Foreign currency exchange loss		(1)		-
Total other income		3		7,609
Net Loss	**$**	**(10,945)**	**$**	**(10,474)**
Loss per Share:				
Basic and diluted net loss per common share outstanding	$	(0.33)	$	(0.89)
Basic and diluted weighted average number of common shares outstanding		33,930,977		11,749,139

Source: Checkpoint Therapeutics, Inc