November 12, 2024

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

Biologics License Application for cosibelimab under review by U.S. FDA

PDUFA goal date of December 28, 2024

WALTHAM, Mass., Nov. 12, 2024 (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, 2024, and recent corporate updates.

“With the Prescription Drug User Fee Act (“PDUFA”) goal date set for next month, we await the decision by the U.S. Food and Drug Administration (“FDA”) on our Biologics License Application (“BLA”) resubmission for cosibelimab, our anti-programmed death ligand-1 (“PD-L1”) antibody,” said James Oliviero, President and Chief Executive Officer of Checkpoint. “The $9.2 million in cash proceeds received this month from the exercise of existing warrants has strengthened our balance sheet to extend beyond our PDUFA date and into 2025. We are now fully focused on preparing for the potential approval of cosibelimab and look forward to potentially offering oncologists a new, differentiated treatment option for patients with advanced cutaneous squamous cell carcinoma (“cSCC”).”

Recent Corporate Updates:

- In July 2024, Checkpoint announced that the FDA accepted for review the resubmission of its BLA for cosibelimab as a complete response to the complete response letter (“CRL”) issued in December 2023 and set a PDUFA goal date of December 28, 2024.
- Also in July 2024, Checkpoint announced a collaboration to explore the combined therapeutic potential of cosibelimab, its anti-PD-L1 antibody with dual mechanism of action, with GC Cell’s Immuncell-LC, an innovative autologous Cytokine Induced Killer T cell therapy composed of cytotoxic T lymphocytes and natural killer T cells.
- Also in July 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 $12.0 million.
- In September 2024, Checkpoint presented longer-term data from its pivotal trial of

cosibelimab in locally advanced and metastatic cSCC during the European Society for Medical Oncology ("ESMO") Congress 2024. Longer-term results for cosibelimab presented at the ESMO Congress demonstrate a deepening of response over time, with higher objective response and complete response rates than initially observed at the primary analyses. A copy of the ESMO poster can be found on the Publications page of Checkpoint's website.
- In November 2024, Checkpoint received $9.2 million in cash proceeds through the exercise of existing warrants.

Financial Results:

- **Cash Position**: As of September 30, 2024, Checkpoint's cash and cash equivalents totaled $4.7 million, compared to $5.0 million at June 30, 2024 and $4.9 million at December 31, 2023, a decrease of $0.3 million for the quarter and a decrease of $0.2 million, year-to-date. Subsequent to the end of the quarter, in November 2024, Checkpoint received $9.2 million in cash proceeds through the exercise of existing warrants.
- **R&D Expenses**: Research and development expenses for the third quarter of 2024 were $6.4 million, compared to $5.5 million for the third quarter of 2023, an increase of $0.9 million. Research and development expenses for the third quarter of 2024 included $0.5 million of non-cash stock expenses, compared to $0.3 million for the third quarter of 2023.
- **G&A Expenses**: General and administrative expenses for the third quarter of 2024 were $3.4 million, compared to $2.2 million for the third quarter of 2023, an increase of $1.2 million. General and administrative expenses for the third quarter of 2024 included $1.4 million of non-cash stock expenses, compared to $0.6 million for the third quarter of 2023.
- **Net Loss**: Net loss attributable to common stockholders for the third quarter of 2024 was $9.7 million, or $0.23 per share, compared to a net loss of $5.7 million, or $0.29 per share, in the third quarter of 2023. Net loss for the third quarter of 2024 included $1.9 million of non-cash stock expenses, compared to $0.9 million for the third quarter of 2023.

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 differentiated 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, 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 resubmission of our BLA for cosibelimab and review thereof, our belief that the BLA resubmission potentially addresses all the issues in the CRL, our belief about the comprehensive nature of our BLA resubmission and reaching alignment with the FDA on our cosibelimab BLA resubmission strategy, our ability to work with our third-party contract manufacturing organization ("CMO") and the FDA to adequately address the issues raised in the CRL and execute on a pathway forward for the potential marketing approval of cosibelimab, the adequacy of the responses to the inspection issues submitted to FDA by our third-party CMO, our projections of regulatory review timelines, the commercial potential of cosibelimab, if approved, and the potential differentiation of cosibelimab, including a potentially favorable safety profile as compared to the currently available anti-programmed death receptor-1 therapies and the dual mechanism of action of cosibelimab translating into potential enhanced efficacy. Factors that could cause our actual results to differ materially include the following: the risks and uncertainties associated with the regulatory review process; uncertainties regarding the timeline of FDA review of the resubmitted BLA; any inability to successfully work with the FDA to find a satisfactory solution to address any concerns in a timely manner or at all during the review process for the BLA, including any inability to provide the FDA with data, analysis or other information sufficient to support an approval of the BLA; our, and our third party CMO's, ability to adequately address the issues raised in the CRL; issues associated with any facility inspection or re-inspection of our third party CMO or otherwise during the review process for the BLA; the risk that our third-party CMO will not meet deadlines, and/or comply with applicable regulations; whether the FDA accepts the data and results as included in the BLA resubmission at levels consistent with the published results, or at all; our ability to execute a partnering or other relationship to enable the commercialization of cosibelimab, if approved, on acceptable terms, if at all; 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 Quarterly Report on Form 10-Q for the period ended June 30, 2024, and in our subsequent 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, 2024	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,703	$ 4,928
Prepaid expenses and other current assets	476	450
Total current assets	5,179	5,378
Total Assets	**$ 5,179**	**$ 5,378**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 15,635	$ 15,485
Accounts payable and accrued expenses - related party	2,009	2,815
Common stock warrant liabilities	125	125
Total current liabilities	17,769	18,425
Total Liabilities	**17,769**	**18,425**
Commitments and Contingencies		

Stockholders' Equity (Deficit)		
Common Stock ($0.0001 par value), 175,000,000 and 80,000,000 shares authorized as of September 30, 2024 and December 31, 2023, respectively		
Class A common shares, 700,000 shares issued and outstanding as of September 30, 2024 and December 31, 2023	-	-
Common shares, 45,095,500 and 27,042,035 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	5	3
Common stock issuable, 0 and 1,492,915 shares as of September 30, 2024 and December 31, 2023, respectively	-	3,419
Additional paid-in capital	329,078	297,864
Accumulated deficit	(341,673)	(314,333)
Total Stockholders' Equity (Deficit)	(12,590)	(13,047)
Total Liabilities and Stockholders' Equity (Deficit)	**$ 5,179**	**$ 5,378**

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,	
	2024	**2023**	**2024**	**2023**
Revenue - related party	$ -	$ 31	$ 41	$ 97
Operating expenses:				
Research and development	6,366	5,496	19,343	35,267
General and administrative	3,358	2,236	8,043	6,809
Total operating expenses	9,724	7,732	27,386	42,076
Loss from operations	(9,724)	(7,701)	(27,345)	(41,979)
Other income (expense)				
Interest income	2	7	9	81
Gain on common stock warrant liabilities	-	1,970	-	9,179
Foreign currency exchange loss	(3)	-	(4)	-
Total other income (expense)	(1)	1,977	5	9,260
Net Loss	**$ (9,725)**	**$ (5,724)**	**$ (27,340)**	**$ (32,719)**
Loss per Share:				
Basic and diluted net loss per common share outstanding	$ (0.23)	$ (0.29)	$ (0.73)	$ (2.07)
Basic and diluted weighted average number of common shares outstanding	43,151,861	19,988,079	37,556,863	15,842,693

Source: Checkpoint Therapeutics, Inc