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Checkpoint Therapeutics Reports Fourth Quarter and Full-Year 2017 Financial Results and Recent Corporate Highlights

NEW YORK, March 15, 2018 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. ("Checkpoint") (NASDAQ:CKPT), a clinical-stage, immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers, today announced financial results and recent corporate highlights for the fourth quarter and full year ended December 31, 2017.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, "Checkpoint achieved significant financial and pipeline-related milestones in 2017. Most notably, our common stock began trading on The NASDAQ Capital Market in June 2017, and in October, we announced the dosing of the first patient in our Phase 1 trial of our anti-PD-L1 antibody, CK-301. In addition, the FDA granted Orphan Drug Designation to our third-generation EGFR inhibitor, CK-101, for the treatment of EGFR mutation-positive non-small cell lung cancer. As we enter 2018, we believe we are well-positioned to generate initial efficacy data from our clinical trials in support of our planned registration studies to commence in 2019."

Financial Results:

- **Cash Position:** As of December 31, 2017, Checkpoint's cash and cash equivalents totaled \$19.2 million, compared to \$35.1 million at December 31, 2016, a decrease of \$15.9 million. On a non-GAAP basis, pro-forma cash and cash equivalents as of December 31, 2017 (excluding first quarter 2018 operations) totaled approximately \$40.1 million, after giving effect to \$20.9 million of net proceeds from an underwritten public offering during March 2018.
- **R&D Expenses:** Research and development expenses for the year ended December 31, 2017 were \$19.1 million, compared to \$20.3 million for the year ended December 31, 2016, a decrease of \$1.2 million.
- **G&A Expenses:** General and administrative expenses for the year ended December 31, 2017 were \$5.4 million, compared to \$4.5 million for the year ended December 31, 2016, an increase of \$0.9 million.
- **Net Loss:** Net loss attributable to common stock holders for the year ended December 31, 2017 was \$22.7 million, or \$1.00 per share, compared to a net loss of \$22.5 million, or \$1.04 per share, for the year ended December 31, 2016.

2017 and Recent Corporate Highlights:

- In February 2017, the U.S. Patent and Trademark Office issued a composition of matter patent for CK-101, an oral, third-generation epidermal growth factor receptor (“EGFR”) inhibitor in development for the treatment of EGFR mutation-positive non-small cell lung cancer (“NSCLC”).
- In June 2017, Checkpoint’s common stock began trading on The NASDAQ Capital Market under the ticker symbol “CKPT.”
- In September 2017, Checkpoint announced that the U. S. Food and Drug Administration granted Orphan Drug Designation to CK-101 for the treatment of EGFR mutation-positive NSCLC.
- In October 2017, Checkpoint announced the dosing of the first patient in a Phase 1 clinical trial evaluating the safety and tolerability of CK-301, an anti-PD-L1 antibody, in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers.
- In March 2018, Checkpoint completed an underwritten public offering that raised net proceeds of \$20.9 million.

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. (“Checkpoint”) is a clinical-stage, immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. Checkpoint is currently evaluating its lead product candidate, CK-301, an anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in a Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers. Checkpoint plans to develop CK-301 as a treatment for patients with non-small cell lung cancer (“NSCLC”) and other solid tumors. In addition, Checkpoint is evaluating its small-molecule, targeted anti-cancer agent, CK-101, in the Phase 1 portion of a Phase 1/2 clinical trial for the treatment of patients with epidermal growth factor receptor (“EGFR”) mutation-positive NSCLC. Checkpoint’s pipeline also includes antibodies that target glucocorticoid-induced TNFR-related protein (“GITR”) and carbonic anhydrase IX (“CAIX”), in addition to oral, small-molecule, targeted anti-cancer agents that inhibit bromodomain and extra-terminal (“BET”) proteins and poly (ADP-ribose) polymerase (“PARP”). Checkpoint is a majority-controlled subsidiary of Fortress Biotech, Inc., and is headquartered in New York City. For more information, visit www.checkpointtx.com.

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress”) (NASDAQ:FBIO) is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress develops and commercializes products both within Fortress and through certain of its subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, Fortress leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. Fortress and the Fortress Companies may seek licensing arrangements, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs. For more information, visit www.fortressbiotech.com.

Forward-Looking Statements

This press release may contain “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. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. 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.

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

	December 31,	
	2017	2016
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 19,225	\$ 35,086
Prepaid expenses and other assets	1,857	71
Other receivables - related party	331	821
Total current assets	21,413	35,978

Total Assets	\$ 21,413	\$ 35,978
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 5,762	\$ 3,355
Accounts payable and accrued expenses - related party	610	318
Total current liabilities	6,372	3,673
Total Liabilities	6,372	3,673
Commitments and Contingencies		
Stockholders' Equity		
Common Stock (\$0.0001 par value), 50,000,000 shares authorized		
Class A common shares, 7,000,000 shares issued and outstanding as of December 31, 2017 and 2016	1	1
Common shares, 18,512,429 and 17,426,876 shares issued and outstanding as of December 31, 2017 and 2016, respectively	2	2
Common stock issuable, 591,836 and 721,699 shares as of December 31, 2017 and 2016, respectively	2,296	3,919
Additional paid-in capital	71,772	64,736
Accumulated deficit	(59,030)	(36,353)
Total Stockholders' Equity	15,041	32,305
Total Liabilities and Stockholders' Equity	\$ 21,413	\$ 35,978

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

	For the year ended December 31,		
	2017 (Unaudited)	2016	2015
Revenue - related party	\$ 1,725	\$ 2,570	\$ 590
Operating expenses:			
Research and development	19,081	20,267	11,323
General and administrative	5,419	4,467	2,488
Total operating expenses	24,500	24,734	13,811
Loss from operations	(22,775)	(22,164)	(13,221)
Other income (expense)			
Interest income	98	47	2
Interest expense and debt amortization	-	(344)	(235)
Change in fair value of warrant liabilities	-	-	(438)
Total other income (expense)	98	(297)	(671)
Net Loss	\$ (22,677)	\$ (22,461)	\$ (13,892)
Loss per Share:			
Basic and diluted net loss per common share outstanding	\$ (1.00)	\$ (1.04)	\$ (1.41)
Basic and diluted weighted average number of common shares outstanding	22,618,931	21,544,205	9,855,668



Source: Checkpoint Therapeutics, Inc