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Fortress Biotech Reports Second Quarter 2016 Financial Results and Recent Corporate Highlights

Quarter Milestones Include Commercialization of First Two Products

NEW YORK, Aug. 09, 2016 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (NASDAQ:FBIO) ("Fortress"), a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products, today announced its financial results and recent corporate highlights for the quarter ended June 30, 2016.

Dr. Lindsay A. Rosenwald, Chairman, President and CEO of Fortress, said, "During the second quarter of 2016, we attained several milestones, including the commercialization of our first two products from Journey Medical Corporation's ("Journey") dermatology franchise: Luxamend™ Wound Cream and Ceracade™ Skin Barrier Emulsion.

Our subsidiary Checkpoint Therapeutics, Inc. ("Checkpoint Therapeutics") also acquired an exclusive, worldwide license to BRD4-inhibiting (from the Bromodomain and Extra-Terminal motif ("BET") inhibitor class of anti-cancer proteins) compounds for solid tumors from Jubilant Biosys Limited ("Jubilant"). In addition, Checkpoint Therapeutics entered a sublicense agreement with TG Therapeutics, Inc., a related party ("TG Therapeutics"), to develop and commercialize the BRD4-inhibiting compounds for hematological malignancies, while Checkpoint Therapeutics retains the right to develop and commercialize these compounds for solid tumors. We believe clinical and corporate developments such as these will help position us to diversify our pipeline during the second half of 2016."

Financial Results:

- At June 30, 2016, Fortress' consolidated cash and cash equivalents totaled \$71.3 million compared to \$81.4 million at March 31, 2016 and \$98.2 million as of December 31, 2015, a decrease of \$10.1 million for the quarter, of which \$6.6 million relates to our subsidiaries, and \$26.9 million year-to-date, of which \$16.1 million relates to our subsidiaries. These totals exclude restricted cash of \$14.6 million.
- Total revenue for the second quarter of 2016 was \$2.2 million consisting of \$1.0 million of net product revenue from our subsidiary Journey and \$1.2 million of collaboration revenue from a related party, compared with no revenue reported during last year's second quarter. \$2.9 million in total revenue was reported for the first six months of 2016 consisting of \$1.4 million of net product sales from Journey and \$1.5 million of

collaboration revenue from a related party, compared with \$0.5 million of collaboration revenue from a related party reported for the first six months of 2015.

- Research and development expenses were \$6.3 million, of which \$4.0 million relates to our subsidiaries for the second quarter of 2016 and \$14.1 million, of which \$9.0 million relates to our subsidiaries for the first six months of 2016. This compares with \$2.4 million, of which \$1.1 million relates to our subsidiaries for the second quarter of 2015 and \$4.1 million, of which \$1.2 million relates to our subsidiaries for the first six months of 2015. Noncash stock-based compensation expense included in research and development for the second quarter of 2016 was \$1.1 million, compared to \$0.6 million for the second quarter of 2015, and \$2.4 million for the first six months of 2016, compared with \$0.9 million for the first six months of 2015.
- Research and development licenses acquired expenses were \$2.0 million for the second quarter of 2016 and \$2.1 million for the first six months of 2016, compared to \$1.5 million for the second quarter 2015 and \$9.0 million for the first six months of 2015.
- General and administrative expenses were \$8.6 million, of which \$3.7 million relates to our subsidiaries for the second quarter of 2016 and \$16.6 million, of which \$6.6 million relates to our subsidiaries for the first six months of 2016, compared to \$3.8 million, of which \$0.3 million relates to our subsidiaries for the second quarter of 2015 and \$7.3 million, of which \$1.6 million relates to our subsidiaries for the first six months of 2015. Noncash stock-based compensation expense included in general and administrative for the second quarter of 2016 was \$1.9 million, compared to \$1.3 million for the second quarter of 2015, and \$3.5 million for the first six months of 2016, compared with \$2.5 million for the first six months of 2015.
- Net loss was \$12.5 million, or \$0.31 per share, for the second quarter of 2016, compared to a net loss of \$6.2 million, or \$0.16 per share, for the second quarter of 2015. For the first six months of 2016, net loss was \$24.7 million or \$0.62 per share, compared with \$18.2 million or \$0.47 per share in the first six months of 2015.

Recent Corporate Highlights:

Avenue Therapeutics

- Avenue completed an End-of-Phase 2 (“EOP2”) meeting with the FDA and, based on the outcome of the EOP2 meeting, Avenue anticipates that its Phase 3 program will consist of three studies: an efficacy and safety study in an orthopedic model, an efficacy and safety study in a soft tissue model, and an open label safety study.

Checkpoint Therapeutics

- In May 2016, Jubilant and Checkpoint Therapeutics announced the signing of an exclusive, worldwide license agreement under which Jubilant out-licensed to Checkpoint Therapeutics a family of patents covering compounds that inhibit BRD4, a member of the BET domain for cancer treatment. In connection with the license agreement with Jubilant, Checkpoint Therapeutics entered into a sublicense agreement with TG Therapeutics to develop and commercialize the licensed compounds for hematological malignancies, while Checkpoint Therapeutics retains the right to develop and commercialize these compounds for solid tumors.

Journey Medical Corporation

- In June 2016, sales began for Luxamend™ Wound Cream and Ceracade™ Skin Barrier Emulsion, the first two products in Journey's dermatology franchise. Both products were showcased at the 2016 American Academy of Dermatology (AAD) Summer Meeting in July 2016.
- In July 2016, Journey received FDA approval for the manufacturing of a product for the treatment of acne, for which it had entered into a license and supply agreement in 2015. Journey expects sales of this product to begin in the fourth quarter of 2016.

Mustang Bio, Inc.

- In April 2016, Mustang announced that two abstracts pertaining to MB-101 (IL13R α 2-specific CAR-T cells) for the treatment of glioblastoma were selected for presentation at the American Society of Gene and Cell Therapy's 19th Annual Meeting ("ASGCT"). Pre-clinical and preliminary Phase I data were presented at ASGCT.
- In May 2016, an oral presentation related to MB-101 (IL13R α 2-specific CAR-T cells) was presented by City of Hope investigators at the ASGCT at the Marriott Wardman Park Hotel in Washington, DC.

Fortress Biotech

- On June 10, 2016, CB Pharma Acquisition Corp ("CB Pharma") held an extraordinary general meeting of its shareholders. At such meeting, the shareholders approved each of the following items: (i) an amendment to the CB Pharma's Amended and Restated Memorandum and Articles of Association (the "Charter") to extend the date by which CB Pharma has to consummate a business combination from June 12, 2016 to December 12, 2016 (the "Extension"), (ii) an amendment to the Charter to allow the holders of the CB Pharma's ordinary shares issued in the initial public offering to elect to convert their shares into their pro rata portion of the funds held in trust, if the Extension is approved, and (iii) the change of CB Pharma's name from "CB Pharma Acquisition Corp." to "Origo Acquisition Corporation" ("Origo"). In connection with the meeting, Fortress transferred 1,050,000 of its CB Pharma ordinary shares to Origo, retaining a holding of 265,000 Origo shares.
- In May 2016, positive data from the Phase 1/2 study of CNDO-109-Activated Allogeneic Natural Killer (NK) Cells in patients with acute myeloid leukemia were presented in an oral session at the Innate Killer Summit 2016 in San Diego, CA.
- In July 2016 Fortress' stock was added to the Russell 2000® Index.

About Fortress Biotech

Fortress Biotech, Inc. ("Fortress") is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress plans to develop and commercialize products both within Fortress and through subsidiary companies, also known as Fortress Companies. Fortress intends to leverage its biopharmaceutical business expertise and drug development capabilities to help the Fortress Companies achieve their goals. Additionally, Fortress intends to provide funding and management services to each of the Fortress Companies and, from time to time, Fortress and the Fortress Companies will seek licensing, 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. Such statements include, but are not limited to, any statements relating to our growth strategy, potential acquisitions, 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 price. Factors that could cause actual results to differ materially from those currently anticipated are: risks related to our growth strategy; our ability to continue to commercialize products; our ability to identify, acquire, close and integrate product candidates and companies successfully and on a timely basis; our need for substantial additional funds; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; 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; government regulation; patent and intellectual property matters; competition; and 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.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(\$ in thousands except for share and per share amounts)

	June 30, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current assets		
Cash and cash equivalents	\$ 71,336	\$ 98,182
Accounts receivable	967	-
Inventory	100	-
Other receivables - related party	2,570	156
Prepaid expenses and other current assets	1,579	1,599
Total current assets	76,552	99,937
Property and equipment, net	4,535	309
Restricted cash	14,586	14,586
Long-term investments, at fair value	766	2,485
Intangible asset - license	1,579	1,250
Other assets	44	43
Total assets	\$ 98,062	\$ 118,610
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 5,126	\$ 1,868
Accrued expenses	8,883	8,570

Interest payable	26	27
Derivative liabilities	302	114
Total current liabilities	14,337	10,579

Notes payable, long-term (net of debt discount of \$412 and \$835 at June 30, 2016 and December 31, 2015, respectively)	20,805	23,174
Convertible note, at fair value	1,000	-
Other long-term liabilities	3,706	584
Total liabilities	39,848	34,337

Commitments and contingencies

Stockholders' equity

Convertible Preferred stock, \$.001 par value, 129,767 Series C shares authorized, 0 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively	-	-
Common Stock, \$.001 par value, 100,000,000 shares authorized, 48,668,630 and 47,147,032 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively	49	47
Additional paid-in-capital	250,127	246,955
Accumulated deficit	(214,839)	(190,156)
Total stockholders' equity attributed to the Company	35,337	56,846
Non-controlling interests	22,877	27,427
	58,214	84,273
Total stockholders' equity		
Total liabilities and stockholders' equity	\$ 98,062	\$ 118,610

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(\$ in thousands except for share and per share amounts)
(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2016	2015	2016	2015
Product revenue, net	\$ 981	\$ -	\$ 1,364	\$ -
Revenue - from a related party	1,249	-	1,526	500
Total revenue	2,230	-	2,890	500
Cost of goods sold - product revenue	324	-	324	-
Gross margin	1,906	-	2,566	500
Operating expenses				
Research and development	6,347	2,411	14,100	4,066
Research and development – licenses acquired	2,060	1,548	2,143	8,987
General and administrative	8,635	3,803	16,550	7,280
Total operating expenses	17,042	7,762	32,793	20,333
	(15,136)	(7,762)	(30,227)	(19,833)
Loss from operations				
Other income (expenses)				
Interest income	77	74	152	156
Interest expense and financing fee	(529)	(352)	(1,149)	(683)
Change in fair value of derivative liabilities	-	-	(89)	-
Change in fair value of investments	(801)	1,622	(1,719)	1,407
Total other income (expenses)	(1,253)	1,344	(2,805)	880
Net loss	(16,389)	(6,418)	(33,032)	(18,953)
Less: net loss attributable to non-controlling interests	3,911	243	8,349	722

Net loss attributable to common stockholders	<u><u>\$ (12,478)</u></u>	<u><u>\$ (6,175)</u></u>	<u><u>\$ (24,683)</u></u>	<u><u>\$ (18,231)</u></u>
Basic and diluted net loss per common share	<u><u>\$ (0.31)</u></u>	<u><u>\$ (0.16)</u></u>	<u><u>\$ (0.62)</u></u>	<u><u>\$ (0.47)</u></u>
Weighted average common shares outstanding— basic and diluted	<u><u>39,867,724</u></u>	<u><u>39,119,606</u></u>	<u><u>39,762,956</u></u>	<u><u>38,848,660</u></u>

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Source: Fortress Biotech, Inc.