

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

NEW YORK, Nov. 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 September 30, 2016.

Dr. Lindsay A. Rosenwald, Chairman, President and CEO of Fortress, said, "We recently launched our seventh Fortress Company, Cellvation, based on compelling science from The University of Texas Health Science Center at Houston in traumatic brain injury, an area of great unmet need, including two Phase 2 cell therapy programs. In addition, the clinical oncology pipeline of our Fortress Companies continues to grow, with the initiation of Checkpoint's Phase 1/2 study of its EGFR inhibitor CK-101. In September, Fortress, through its subsidiary FBIO Acquisition, Inc., closed its tender offer for shares of National Holdings Corporation. We believe that as Fortress and National leverage their synergies, growth opportunities will be created for both companies."

Financial Results:

- As of September 30, 2016, Fortress' consolidated cash and cash equivalents totaled \$82.5 million, compared to \$71.3 million as of June 30, 2016, and \$98.2 million as of December 31, 2015, an increase of \$11.2 million for the third quarter and a decrease of \$15.7 million year-to-date. These totals exclude restricted cash of \$15.9 million as of September 30, 2016.
- Total revenue for the third quarter of 2016 was \$1.0 million, consisting of \$0.43 million of net product revenue from Journey Medical Corporation ("JMC"), a Fortress Company, and \$0.55 million of collaboration revenue from a related party, compared to \$0.03 million in total revenue reported during the third quarter of 2015. Total revenue for the first nine months of 2016 was \$3.9 million, consisting of \$1.8 million in net product sales from JMC and \$2.1 million in collaboration revenue from a related party, compared to \$0.5 million in collaboration revenue from a related party reported for the first nine months of 2015.
- Research and development expenses were \$7.3 million for the third quarter of 2016, of which \$5.5 million was related to Fortress Companies, and \$21.4 million for the first nine months of 2016, of which \$15.8 million was related to Fortress Companies. This compares to \$9.1 million for the third quarter of 2015, of which \$4.9 million was related

- to Fortress Companies, and \$13.2 million for the first nine months of 2015, of which \$3.8 million was related to Fortress Companies. Noncash stock-based compensation expense included in research and development for the third quarter of 2016 was \$0.9 million, compared to \$4.3 million for the third quarter of 2015, and \$3.4 million for the first nine months of 2016, compared to \$5.2 million for the first nine months of 2015.
- Research and development expenses from licenses acquired were \$1.0 million for the third quarter of 2016 and \$3.1 million for the first nine months of 2016, compared to \$1.9 million for the third quarter of 2015 and \$10.9 million for the first nine months of 2015.
- General and administrative expenses were \$8.9 million for the third quarter of 2016, of which \$3.8 million was related to Fortress Companies, and \$25.4 million for the first nine months of 2016, of which \$11.5 million was related to Fortress Companies, compared to \$7.1 million for the third quarter of 2015, of which \$1.7 million was related to Fortress Companies, and \$14.4 million for the first nine months of 2015, of which \$3.3 million was related to Fortress Companies. Noncash stock-based compensation expense included in general and administrative expenses was \$2.0 million for the third quarter of 2016 and \$5.4 million for the first nine months of 2016, compared to \$4.2 million for the third quarter of 2015 and \$6.7 million for the first nine months of 2015.
- Net loss was \$13.0 million, or \$0.32 per share, for the third quarter of 2016, compared to a net loss of \$18.2 million, or \$0.46 per share, for the third quarter of 2015. For the first nine months of 2016, net loss was \$37.7 million, or \$0.94 per share, compared to \$36.4 million, or \$0.93 per share, for the first nine months of 2015.

Recent Fortress and Fortress Company Highlights:

Fortress Biotech, Inc.

• In September 2016, Fortress, through its subsidiary FBIO Acquisition, Inc., purchased approximately 56% of National Holdings Corporation (NASDAQ:NHLD) common stock, par value \$0.02 per share, at a purchase price of \$3.25 per share in cash, for an aggregate purchase price of approximately \$22.9 million.

Cellvation, Inc.

In October 2016, Cellvation entered into an agreement with The University of Texas
Health Science Center at Houston to secure exclusive worldwide rights to three
programs for TBI, including two Phase 2 cell therapies and a next-generation
bioreactor that enhances the anti-inflammatory potency of bone marrow-derived cells
without genetic manipulation.

Checkpoint Therapeutics, Inc.

• In August 2016, the U.S. Food and Drug Administration ("FDA") accepted an Investigational New Drug Application ("IND") for a Phase 1/2 clinical trial of Checkpoint's epidermal growth-factor receptor inhibitor ("EGFR") CK-101, and in September 2016, the first patient was dosed. The Phase 1 dose escalation portion of the study will evaluate the safety and tolerability of ascending doses of CK-101 in patients with advanced solid tumors to determine the maximum tolerated dose and/or recommended Phase 2 dose of CK-101. The Phase 2 portion of the study is planned to evaluate the safety and efficacy of the recommended Phase 2 dose of CK-101 in

patients with EGFR T790M mutation-positive non-small cell lung cancer.

Helocyte, Inc.

- On June 30, September 30 and October 31, 2016, Helocyte closed on additional sales
 of convertible promissory notes raising an aggregate of approximately \$4.0 million to
 date.
- In October 2016, Helocyte announced the online publication of data in*Blood* from the Phase 1 trial of Triplex vaccine for control of cytomegalovirus (CMV) in allogeneic hematopoietic stem cell transplant (HSCT) and solid organ transplant (SOT) recipients. In the Phase 1 study, Triplex was found to be safe, well-tolerated and highly immunogenic when administered to healthy volunteers at multiple dose levels. These data supported the initiation of an ongoing Phase 2 trial evaluating Triplex in patients undergoing allogeneic HSCT.

Journey Medical Corporation (JMC)

- In July 2016, JMC received FDA approval to manufacture Targadox™ for the treatment of severe acne. Sales commenced in October 2016.
- Also in July 2016, JMC products Luxamend Wound Cream and Ceracade™ Skin Emulsion were showcased at the 2016 American Academy of Dermatology (AAD) Summer Meeting in Boston.

Mustang Bio, Inc.

 On September 30 and October 25, 2016, Mustang Bio closed on private placements of Units, comprised of shares of its common stock and warrants, raising an aggregate of approximately \$19.5 million, less offering expenses. Units were sold at \$65,000 each. National Securities Corporation acted as sole placement agent in the private placements.

About Fortress Biotech

Fortress Biotech, Inc. ("Fortress") 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. Additionally, Fortress recently acquired a controlling interest in National Holdings Corporation (NASDAQ:NHLD), a diversified independent brokerage company (together with its subsidiaries, "NHLD"). 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 licensings, 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 include: 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)

	September 30, 2016 (Unaudited)		December 31, 2015	
ASSETS	•	•		
Current assets				
Cash and cash equivalents	\$	82,537	\$	98,182
Accounts receivable		5,007		-
Cash deposits with clearing organizations		1,030		-
Receivables from broker-dealers and clearing organizations		1,607		-
Securities owned, at fair value		2,178		-
Inventory		123		-
Other receivables - related party		1,545		156
Prepaid expenses and other current assets		4,556		1,599
Total current assets		98,583	· <u> </u>	99,937
Property and equipment, net		6,957		309
Restricted cash		15,859		14,586
Long-term investments, at fair value		685		2,485
Intangible assets, net		1,550		1,250
Goodwill		21,739		-
Other assets		48		43
Total assets	\$	145,421	\$	118,610
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities				
Accounts payable and accrued expenses	\$	21,831	\$	10,438
Accrued commissions and payroll payable		14,029		-
Deferred clearing and marketing credits		1,007		-
Interest payable		68		27
Derivative warrant liability		951		114
Other current liabilities		707		
Total current liabilities		38,593		10,579

Notes payable, long-term (net of debt discount of \$2,764 and \$835 at September 30, 2016 and		
December 31, 2015, respectively)	24,373	23,174
Subsidiary convertible note, at fair value	3,031	-
Other long-term liabilities	4,583	584
Total liabilities	70,580	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 September 30, 2016 and December 31, 2015, respectively	_	_
Common Stock, \$.001 par value, 100,000,000 shares authorized, 48,875,087 and 47,147,032 shares issued and		
outstanding as of September 30, 2016 and December 31, 2015, respectively	49	47
Additional paid-in-capital	264,397	246,955
Accumulated deficit	(227,820)	(190,156)
Total stockholders' equity attributed to the Company	36,626	56,846
Non-controlling interests	38,215	27,427
Total stockholders' equity	74,841	84,273
Total liabilities and stockholders' equity	\$ 145,421	\$ 118,610

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

	For the Three I Septem		For the Nine Months Ended September 30,			
	2016	2016 2015		2015		
Revenue			·			
Product revenue, net	\$ 429	\$ -	\$ 1,793	\$ -		
Revenue - from a related party	546	25	2,072	525		
Total revenue	975	25	3,865	525		
Cost of goods sold - product revenue	41	-	365	-		
Gross margin	934	25	3,500	525		
Operating expenses						
Research and development	7,316	9,073	21,416	13,172		
Research and development - licenses acquired	1,000	1,895	3,143	10,882		
General and administrative	8,864	7,129	25,414	14,376		
Total operating expenses	17,180	18,097	49,973	38,430		
Loss from operations	(16,246)	(18,072)	(46,473)	(37,905)		
Other income (expenses)						
Interest income	89	39	241	195		
Interest expense and financing fees	(689)	(350)	(1,838)	(1,033)		
Change in fair value of derivative liabilities	(16)	-	(105)	-		
Change in fair value of subsidiary convertible note	(13)	-	(13)	-		
Change in fair value of investments	(81)	(1,472)	(1,800)	(65)		
Total other expenses	(710)	(1,783)	(3,515)	(903)		
Net loss	(16,956)	(19,855)	(49,988)	(38,808)		

Less: net loss attributable to non-controlling interests	3,975		1,694		12,324		2,416	
Net loss attributable to common stockholders	\$	(12,981)	\$	(18,161)	\$	(37,664	\$	(36,392)
Basic and diluted net loss per common share	\$	(0.32)	\$	(0.46_)	\$	(0.94)	\$	(0.93)
Weighted average common shares outstanding-basic and diluted	40,128,475		39,412,056 39,888		9,885,685	3	9,038,522	

Contact:

Lucy Lu, MD, Executive Vice President & Chief Financial Officer Fortress Biotech, Inc. 781-652-4500 ir@fortressbiotech.com

Media Relations:

Laura Bagby 6 Degrees 312-448-8098 lbagby@6degreespr.com



Source: Fortress Biotech, Inc.