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Fortress Biotech Reports Second Quarter 2017 Financial Results and Recent Corporate Highlights

NEW YORK, Aug. 09, 2017 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (NASDAQ:FBIO) ("Fortress"), a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products, today announced financial results and recent corporate highlights for the second quarter ended June 30, 2017.

Dr. Lindsay A. Rosenwald, Fortress' Chairman, President and Chief Executive Officer, said, "Fortress and our Fortress subsidiaries achieved important corporate and clinical milestones during the second quarter of 2017. Avenue Therapeutics completed a \$38 million initial public offering, and is on track to initiate a Phase 3 clinical trial in the third quarter of IV tramadol in patients undergoing bunionectomy surgery. If approved, IV tramadol will be the only intravenous Schedule IV opioid for use in the United States. Avenue, along with Checkpoint Therapeutics, began trading their common shares on The NASDAQ Capital Market during the last week of June. In addition, Caelum Biosciences announced the dosing of the final patient in a Phase 1b clinical trial of its lead therapy, CAEL-101, in AL amyloidosis, with a data readout expected in the second half of 2017. Mustang Bio licensed three CAR T cell therapies from its research partner City of Hope, expanding its pipeline to five novel CAR T candidates."

Dr. Rosenwald continued, "Our strong business development engine continues to deliver on our goal of acquiring novel pharmaceutical and biotechnology products for development within Fortress and through our Fortress Companies. We look forward to continuing to execute on our business plan and reaching important milestones in the third quarter to add value for our shareholders."

Financial Results:

- As of June 30, 2017, Fortress' consolidated cash and cash equivalents totaled \$144.3 million, compared to \$134.0 million at March 31, 2017, and \$88.3 million at December 31, 2016, an increase of \$10.3 million for the quarter and \$56.0 million year-to-date. These totals as of June 30, 2017 exclude short-term investments of \$20.0 million, restricted cash of \$15.9 million and cash deposits with clearing organizations of \$1.0 million.
- Net revenue totaled \$50.7 million for the second quarter of 2017 and \$95.4 million for the first six months of 2017, compared to \$2.2 million for the second quarter of 2016

and \$2.9 million for the first six months of 2016. Net total revenue for the second quarter ended June 30, 2017 includes \$4.4 million of Fortress revenue and \$46.3 million of revenue from National Holdings Corporation (“National”), which Fortress acquired in September 2016, with no revenue attributable to National prior to the acquisition.

- Research and development expenses were \$11.7 million for the second quarter of 2017, of which \$10.0 million was related to Fortress Companies, and \$18.8 million for the first six months of 2017, of which \$15.8 million was related to Fortress Companies. This compares to \$6.3 million for the second quarter of 2016, of which \$4.0 million was related to Fortress Companies, and \$14.1 million for the first six months of 2016, of which \$9.0 million was related to Fortress Companies. Non-cash stock-based compensation expense included in research and development for the second quarter of 2017 was \$2.4 million, compared to \$1.1 million for the second quarter of 2016, and \$3.2 million for the first six months of 2017, compared to \$2.4 million for the first six months of 2016.
- Research and development expenses from license acquisitions totaled \$1.8 million for the second quarter of 2017 and \$3.1 million for the first six months of 2017, compared to \$2.0 million for the second quarter of 2016 and \$2.1 million for the first six months of 2016.
- General and administrative expenses were \$11.1 million for the second quarter of 2017, of which \$7.0 million was related to Fortress Companies, and \$21.4 million for the first six months of 2017, of which \$12.8 million was related to Fortress Companies. This compares to \$8.6 million for the second quarter of 2016, of which \$3.7 million was related to Fortress Companies, and \$16.6 million for the first six months of 2016, of which \$6.6 million was related to Fortress Companies. Non-cash stock-based compensation expenses included in general and administrative expenses were \$2.2 million for the second quarter of 2017, compared to \$1.9 million for the second quarter of 2016, and \$4.3 million for the first six months of 2017, compared to \$3.5 million for the first six months of 2016.
- National’s operating expenses totaled \$48.4 million for the second quarter of 2017 and \$91.5 million for the first six months of 2017, with no expenses attributable to National prior to Fortress’ acquisition of the company in September 2016.
- Net loss attributable to common stockholders was \$17.4 million, or \$0.43 per share, for the second quarter of 2017, compared to a net loss attributable to common stockholders of \$12.5 million, or \$0.31 per share, for the second quarter of 2016. For the first six months of 2017, net loss was \$29.3 million or \$0.73 per share, compared to \$24.7 million or \$0.62 per share in the first six months of 2016.

Recent Fortress Biotech and Fortress Company Highlights:

Fortress Biotech, Inc.

- In June 2017, Ms. Robyn Hunter was named Chief Financial Officer of Fortress. Lucy Lu, M.D., Fortress’ former Chief Financial Officer, was appointed President and Chief Executive Officer of Fortress subsidiary Avenue Therapeutics, Inc.
- As of June 30, 2017, Fortress raised a total of \$19.0 million in a Subordinated Note Financing; \$15.7 million of the \$19.0 million was raised in the second quarter of 2017. National Securities Corporation, a subsidiary of National, acted as the Placement Agent.

Avenue Therapeutics, Inc.

- In May 2017, Avenue received a Notice of Allowance from the U.S. Patent and Trademark Office (“USPTO”) for a new patent application (U.S. Application No. 15/163,111) titled “Intravenous Administration of Tramadol.” The patent application describes and claims a dosing regimen of intravenous (“IV”) 50 mg tramadol that provides certain pharmacokinetic parameters that are similar to those of 100 mg tramadol HCl administered orally every six hours at a steady state. Issuance of the patent (U.S. Patent No. 9,693,949) occurred in July 2017. This patent application falls under Avenue’s licensing agreement with Revogenex Ireland Ltd.
- On June 30, 2017, Avenue completed its initial public offering of 6,325,000 shares of common stock, at a public offering price of \$6.00 per share, for a total offering size of \$37,950,000, before deducting underwriting discounts and offering expenses. The shares sold include 825,000 that were subject to an underwriters’ overallotment option, which was exercised and closed concurrently with the closing of the initial public offering. Avenue’s common stock began trading on The NASDAQ Capital Market under the ticker symbol “ATXI.”
- Also in June 2017, Lucy Lu, M.D., was named President and Chief Executive Officer of Avenue, a position she held on an interim basis since the company’s inception.

Caelum Biosciences, Inc.

- In April 2017, the U.S. Department of Health & Human Services confirmed the transfer of two U.S. Food and Drug Administration (“FDA”) Orphan Drug Designations for CAEL-101 from Columbia University (“Columbia”) to Caelum. The designations cover use as a therapeutic agent for patients with AL amyloidosis and use as a radio-imaging agent in amyloidosis. Caelum in-licensed CAEL-101 from Columbia in January 2017.
- In May 2017, Columbia dosed the final patient in the Phase 1b trial of CAEL-101 in AL amyloidosis. As of July 2017, all patients completed treatment. Preliminary and full Phase 1b data are expected in the second half of 2017.
- Also in May 2017, Caelum entered a biopharmaceutical manufacturing agreement with Patheon N.V. for process development and current good manufacturing practices (cGMP) production to support Phase 2/3 studies of CAEL-101.
- In June 2017, Columbia filed a provisional patent application with the USPTO pertaining to CAEL-101 that, once converted into a U.S. non-provisional utility application, will provide composition of matter protection effective upon a grant of a U.S. patent. The legal protection offered by a granted U.S. patent will exceed any data exclusivity periods associated with Orphan Drug Designation and/or an original, branded-biologic product approved for marketing in the U.S. Just this month, Columbia filed a second provisional patent application with the USPTO to pursue additional method of treatment claims directed to surprising and positive outcomes observed from the Phase 1b trial of CAEL-101. If granted these new claims provide an additional layer of legal protection for the use of Caelum’s lead product candidate.

Checkpoint Therapeutics, Inc.

- In April 2017, Checkpoint presented preclinical data on CK-101, an epidermal growth factor receptor (“EGFR”) inhibitor, and CK-301, an anti-programmed cell death ligand-1 (“PD-L1”) antibody, in poster sessions at the American Association for Cancer Research (“AACR”) Annual Meeting.

- In June 2017, Checkpoint's common stock began trading on The NASDAQ Capital Market under the ticker symbol "CKPT."

Mustang Bio, Inc.

- In April 2017, Mustang appointed Manuel Litchman, M.D., as President and Chief Executive Officer, as well as a member of the Board of Directors.
- On May 31, 2017, Mustang entered into exclusive, worldwide licensing agreements with City of Hope ("COH") for the use of three CAR T therapies in the development of cancer treatments. The therapies covered under the agreements include: human epidermal growth factor receptor 2 ("HER2") CAR T technology ("HER2 Technology"), which will initially be applied in the treatment of glioblastoma multiforme; CS1-specific CAR T technology ("CS1 Technology") to be directed against multiple myeloma; and prostate stem cell antigen ("PSCA") CAR T technology ("PSCA Technology") to be used in the treatment of prostate, pancreatic, bladder and gastric cancers. All three technologies were developed in the laboratory of Stephen J. Forman, M.D., director of COH's T cell Immunotherapy Research Laboratory.

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 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, 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 price. 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; uncertainties relating to preclinical and clinical testing; risks relating to the timing of starting and completing clinical trials; 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.

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

	June 30, 2017	December 31, 2016
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 144,344	\$ 88,294
Accounts receivable	3,336	1,830
Short-term investment (certificate of deposit)	20,038	-
Cash deposits with clearing organizations	1,040	1,030
Receivables from broker-dealers and clearing organizations	2,813	3,357
Forgivable loans receivable	1,397	1,712
Securities owned, at fair value	3,406	2,357
Inventory	299	203
Other receivables - related party	1,605	1,790
Prepaid expenses and other current assets	11,902	9,061
Total current assets	190,180	109,634
Property and equipment, net	7,329	7,376
Restricted cash	15,860	15,860
Long-term investments, at fair value	903	1,414
Intangible asset - license	16,533	17,408
Goodwill	18,645	18,645
Other assets	396	394
Total assets	\$ 249,846	\$ 170,731
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 24,995	\$ 23,871
Accrued expense - related party	78	-
Accrued commissions and payroll payable	11,613	11,940
Deferred clearing and marketing credits	891	995
Securities sold, not yet purchased, at fair value	77	298
Interest payable	142	88
Interest payable - related party	326	77
Notes payable, short-term	3,007	1,000
Subsidiary convertible note, short-term, at fair value	3,211	1,031
Contingent consideration payable	630	424
Warrants issued in 2017 and issuable in 2016 - National	8,190	14,359
Contingently issuable liabilities	-	1,682
Derivative warrant liability	91	481
Other current liabilities	217	319
Total current liabilities	53,468	56,565
Notes payable, long-term (net of debt discount of \$4,723 and \$2,009 at June 30, 2017 and December 31, 2016, respectively)	39,274	22,528
Subsidiary convertible note, long-term, at fair value	1,462	3,656
Other long-term liabilities	5,026	5,014
Total liabilities	99,230	87,763
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, 2017 and December 31, 2016, respectively	-	-

Common stock, \$.001 par value, 100,000,000 shares authorized, 50,463,245 and 48,932,023 shares issued and outstanding as of June 30, 2017 and December 31, 2016, respectively	50	49
Common stock issuable, 45,818 and 0 shares as of June 30, 2017 and December 31, 2016, respectively	189	-
Additional paid-in-capital	346,630	283,697
Accumulated deficit	(274,598)	(245,251)
Total stockholders' equity attributed to the Company	<u>72,271</u>	<u>38,495</u>
Non-controlling interests	78,345	44,473
Total stockholders' equity	<u>150,616</u>	<u>82,968</u>
Total liabilities and stockholders' equity	<u>\$ 249,846</u>	<u>\$ 170,731</u>

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,	
	2017	2016	2017	2016
Revenue				
Fortress				
Product revenue, net	\$ 4,054	\$ 981	\$ 6,139	\$ 1,364
Revenue - from a related party	350	1,249	1,043	1,526
Net Fortress revenue	<u>4,404</u>	<u>2,230</u>	<u>7,182</u>	<u>2,890</u>
National				
Commissions	23,993	-	48,499	-
Net dealer inventory gains	2,366	-	4,877	-
Investment banking	10,592	-	17,653	-
Investment advisory	3,490	-	6,875	-
Interest and dividends	675	-	1,391	-
Transfer fees and clearing services	1,687	-	4,185	-
Tax preparation and accounting	3,144	-	4,000	-
Other	346	-	717	-
Total National revenue	<u>46,293</u>	<u>-</u>	<u>88,197</u>	<u>-</u>
Net revenue	<u>50,697</u>	<u>2,230</u>	<u>95,379</u>	<u>2,890</u>
Operating expenses				
Fortress				
Cost of goods sold - product revenue	878	324	1,347	324
Research and development	11,683	6,347	18,793	14,100
Research and development – licenses acquired	1,800	2,060	3,094	2,143
General and administrative	11,134	8,635	21,386	16,550
Total Fortress operating expenses	<u>25,495</u>	<u>17,366</u>	<u>44,620</u>	<u>33,117</u>
National				
Commissions, compensation and fees	41,762	-	79,020	-
Clearing fees	618	-	1,356	-
Communications	682	-	1,404	-
Occupancy	936	-	1,944	-
Licenses and registration	427	-	832	-
Professional fees	991	-	2,254	-
Interest	4	-	8	-
Depreciation and amortization	500	-	1,006	-
Other administrative expenses	2,475	-	3,705	-
Total National operating expenses	<u>48,395</u>	<u>-</u>	<u>91,529</u>	<u>-</u>
Total operating expenses	<u>73,890</u>	<u>17,366</u>	<u>136,149</u>	<u>33,117</u>

Loss from operations	<u>(23,193)</u>	<u>(15,136)</u>	<u>(40,770)</u>	<u>(30,227)</u>
Other income (expenses)				
Interest income	190	77	326	152
Interest expense and financing fee	(1,380)	(529)	(2,078)	(1,149)
Change in fair value of derivative liabilities	1,452	-	5,794	(89)
Change in fair value of subsidiary convertible note	(188)	-	(285)	-
Change in fair value of investments	157	(801)	(511)	(1,719)
Other income	13	-	13	-
Total other income (expenses)	<u>244</u>	<u>(1,253)</u>	<u>3,259</u>	<u>(2,805)</u>
Net loss	<u>(22,949)</u>	<u>(16,389)</u>	<u>(37,511)</u>	<u>(33,032)</u>
Less: net loss attributable to non-controlling interests	<u>(5,584)</u>	<u>(3,911)</u>	<u>(8,164)</u>	<u>(8,349)</u>
Net loss attributable to common stockholders	<u>\$ (17,365)</u>	<u>\$ (12,478)</u>	<u>\$ (29,347)</u>	<u>\$ (24,683)</u>
Basic and diluted net loss per common share	<u>\$ (0.43)</u>	<u>\$ (0.31)</u>	<u>\$ (0.73)</u>	<u>\$ (0.62)</u>
Weighted average common shares outstanding—basic and diluted	<u>40,551,844</u>	<u>39,867,724</u>	<u>40,457,524</u>	<u>39,762,956</u>

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