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

NEW YORK, May 10, 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 its financial results and recent corporate highlights for the quarter ended March 31, 2017.

Dr. Lindsay A. Rosenwald, Fortress' Chairman, President and Chief Executive Officer, said, "Fortress had a strong start to 2017, with the launch of our subsidiaries Caelum Biosciences and Cyprium Therapeutics, which we believe strengthens our rare disease portfolio. Importantly, we announced a Cooperative Research and Development Agreement between Cyprium and the NICHD to advance the clinical development of Cyprium's Phase 3 candidate CUTX-101 in Menkes disease, a rare and devastating pediatric illness. We also reported that Caelum announced the dosing of the final patient in its Phase 1b study of CAEL-101 for the treatment of AL amyloidosis, a fatal orphan disease that affects organ function. In addition, our established subsidiaries continued to deliver on key milestones, including Mustang Bio raising a total of approximately \$95.0 million in private placement financings to support its CAR T pipeline. We look forward to the continued clinical advancement of our Fortress Companies, and are evaluating opportunities to expand our portfolio through compelling new indications and in-licensing opportunities."

Financial Results:

- As of March 31, 2017, Fortress' consolidated cash and cash equivalents totaled \$134.0 million compared to \$88.3 million at December 31, 2016, an increase of \$45.7 million for the quarter. These totals exclude restricted cash of \$15.9 million and cash deposits with clearing organizations of \$1.0 million.
- Net revenue totaled \$44.7 million for the first quarter of 2017, compared to \$0.7 million for the first quarter of 2016. Net total revenue as of March 31, 2017 includes \$2.8 million of Fortress revenue and \$41.9 million of revenue from National Holdings Corporation ("National"), which we acquired in September 2016, with no revenue attributable to National prior to the acquisition.
- Research and development expenses were \$7.1 million for the first quarter of 2017, of which \$6.0 million was related to Fortress Companies. This compares to \$7.7 million for the first quarter of 2016, of which \$6.0 million was related to Fortress Companies. Non-cash stock-based compensation expenses included in research and development

were \$0.8 million for the first quarter of 2017, and \$1.3 million for the first quarter of 2016.

- Research and development expenses from license acquisitions totaled \$1.3 million for the first quarter of 2017, compared to \$0.1 million for the first quarter of 2016.
- General and administrative expenses were \$10.3 million for the first quarter of 2017, of which \$7.1 million was related to Fortress Companies. This compares to \$7.9 million for the first quarter of 2016, of which \$4.0 million was related to Fortress Companies. Non-cash stock-based compensation expenses included in general and administrative expenses were \$2.1 million for the first quarter of 2017, and \$1.6 million for the first quarter of 2016.
- National's operating expenses totaled \$43.1 million for the first quarter of 2017, with no expenses attributable to National prior to our acquisition of the company in September 2016.
- Net loss attributable to common stockholders was \$12.0 million, or \$0.30 per share, for the first quarter of 2017, compared to a net loss attributable to common stockholders of \$12.2 million, or \$0.31 per share, for the first quarter of 2016.

Recent Fortress Biotech and Fortress Company Highlights:

Fortress Biotech, Inc.

- Fortress recently launched two new Fortress Companies: Caelum Biosciences to develop therapies for amyloid light chain ("AL") amyloidosis, and Cyprium Therapeutics to develop novel therapies for the treatment of Menkes disease and related copper metabolism disorders.

Avenue Therapeutics, Inc.

- In February 2017, two continuation patents covering methods of administration for intravenous tramadol for the treatment of acute pain were issued by the U.S. Patent and Trademark Office ("USPTO").

Caelum Biosciences, Inc.

- In January 2017, Michael Spector was appointed Chief Executive Officer and a member of the Board of Directors of Caelum.
- In January 2017, Caelum entered into an agreement with Columbia University ("Columbia") to secure exclusive worldwide license rights to CAEL-101, a chimeric fibril-reactive monoclonal antibody.
- 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 to Caelum. The designations cover use as a therapeutic agent for patients with AL amyloidosis and use as a radio-imaging agent in amyloidosis.
- In May 2017, Columbia dosed the final patient in the Phase 1b trial of CAEL-101. Preliminary Phase 1b data are expected mid-2017, with full data anticipated by the end of the year.

Checkpoint Therapeutics, Inc.

- In February 2017, the USPTO 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.
- In April 2017, preclinical data on CK-101 and anti-programmed cell death ligand-1 (“PD-L1”) antibody, CK-301, were presented in poster sessions at the American Association for Cancer Research Annual Meeting.

Cyprium Therapeutics, Inc.

- In March 2017, Lung Yam, M.D., Ph.D., was appointed Chief Executive Officer and a member of the Board of Directors of Cyprium.
- In March 2017, Cyprium entered into a Cooperative Research and Development Agreement (“CRADA”) with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (“NICHD”), part of the National Institutes of Health (“NIH”), to advance the clinical development of Phase 3 candidate CUTX-101 (Copper Histidinate injection) for the treatment of Menkes disease.
- Also effective in March 2017, Cyprium and the NICHD entered into a worldwide, exclusive license agreement to develop and commercialize the adeno-associated virus (“AAV”)-based gene therapy AAV-ATP7A to deliver working copies of the copper transporter that is defective in Menkes patients. AAV-ATP7A will be used in combination with CUTX-101.

Mustang Bio, Inc.

- From October 2016 to March 2017, Mustang closed on a total of approximately \$95.0 million in private placement financings, prior to fees and expenses.
- 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.

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 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, 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)
(Unaudited)

	March 31, 2017	December 31, 2016
ASSETS		
Current assets		
Cash and cash equivalents	\$ 134,037	\$ 88,294
Accounts receivable	1,368	1,830
Cash deposits with clearing organizations	1,030	1,030
Receivables from broker-dealers and clearing organizations	2,858	3,357
Forgivable loans receivable	1,528	1,712
Securities owned, at fair value	1,206	2,357
Inventory	204	203
Other receivables - related party	1,034	1,790
Prepaid expenses and other current assets	8,542	9,061
Total current assets	151,807	109,634
Property and equipment, net	7,386	7,376
Restricted cash	15,860	15,860
Long-term investments, at fair value	746	1,414
Intangible assets	17,077	17,408
Goodwill	18,645	18,645
Other assets	390	394
Total assets	\$ 211,911	\$ 170,731
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 24,864	\$ 23,871
Accrued commissions and payroll payable	10,190	11,940
Contingent consideration payable	623	424
Deferred clearing and marketing credits	943	995
Securities sold, not yet purchased, at fair value	1	298
Warrants issuable - National	10,096	14,359
Interest payable	89	88
Interest payable - related party	96	77
Notes payable, short-term	2,105	1,000
Subsidiary convertible note, short-term, at fair value	3,147	1,031
Contingently issuable liabilities	-	1,682
Derivative warrant liability	402	481
Other current liabilities	244	319

Total current liabilities	52,800	56,565
Notes payable, long-term (net of debt discount of \$2,549 and \$2,009 at March 31, 2017 and December 31, 2016, respectively)	26,137	22,528
Subsidiary convertible note, long-term, at fair value	1,637	3,656
Other long-term liabilities	5,020	5,014
Total liabilities	85,594	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 March 31, 2017 and December 31, 2016, respectively	-	-
Common Stock, \$.001 par value, 100,000,000 shares authorized, 50,319,919 and 48,932,023 shares issued and outstanding as of March 31, 2017 and December 31, 2016, respectively	50	49
Additional paid-in-capital	304,929	283,697
Accumulated deficit	(257,233)	(245,251)
Total stockholders' equity attributed to the Company	47,746	38,495
Non-controlling interests	78,571	44,473
Total stockholders' equity	126,317	82,968
Total liabilities and stockholders' equity	\$ 211,911	\$ 170,731

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

	For the Three Months Ended March 31,	
	2017	2016
Revenue		
Fortress		
Product revenue, net	\$ 2,085	\$ 383
Revenue - from a related party	693	277
Net Fortress revenue	2,778	660
National		
Commissions	24,506	-
Net dealer inventory gains	2,511	-
Investment banking	7,061	-
Investment advisory	3,385	-
Interest and dividends	716	-
Transfer fees and clearing services	2,498	-
Tax preparation and accounting	856	-
Other	371	-
Total National revenue	41,904	-
Net revenue	44,682	660
Operating expenses		
Fortress		
Cost of goods sold - product revenue	469	-
Research and development	7,110	7,736
Research and development – licenses acquired	1,294	83
General and administrative	10,252	7,932
Total Fortress operating expenses	19,125	15,751
National		
Commissions, compensation and fees	37,258	-

Clearing fees	738	-
Communications	722	-
Occupancy	1,008	-
Licenses and registration	405	-
Professional fees	1,263	-
Interest	4	-
Depreciation and amortization	506	-
Other administrative expenses	1,230	-
Total National operating expenses	<u>43,134</u>	<u>-</u>
Total operating expenses	<u>62,259</u>	<u>15,751</u>
Loss from operations	(17,577)	(15,091)
Other income (expenses)		
Interest income	136	75
Interest expense and financing fee	(698)	(620)
Change in fair value of derivative liabilities	4,342	(89)
Change in fair value of subsidiary convertible note	(97)	-
Change in fair value of investments	(668)	(918)
Total other income (expenses)	<u>3,015</u>	<u>(1,552)</u>
Net loss	(14,562)	(16,643)
Net loss attributable to non-controlling interests	(2,580)	(4,438)
Net loss attributable to common stockholders	<u>\$ (11,982)</u>	<u>\$ (12,205)</u>
Basic and diluted net loss per common share	<u>\$ (0.30)</u>	<u>\$ (0.31)</u>
Weighted average common shares outstanding—basic and diluted	<u>40,357,711</u>	<u>39,658,188</u>

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