March 18, 2019

Fortress Biotech Reports Fourth Quarter and Full-Year 2018 Financial Results and Recent Corporate Highlights

NEW YORK, March 18, 2019 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (NASDAQ: FBIO) ("Fortress"), an innovative biopharmaceutical company focused on identifying, in-licensing and developing high-potential marketed and development-stage drugs and drug candidates, today announced financial results and recent corporate highlights for the fourth quarter and full year ended December 31, 2018.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "Fortress achieved significant milestones in 2018 and early 2019, closing numerous business development transactions and developing high-quality partnerships with Alexion Pharmaceuticals and InvaGen Therapeutics (a subsidiary of Cipla Limited), which could provide our shareholders with long-term revenue streams. These contingent sale agreements have the potential for combined aggregate proceeds to shareholders of up to $680 million (excluding potential contingent value right ("CVR") amounts based on drug sales). Also in 2018, our seven marketed specialty dermatology products generated net revenue of $23.4 million and $3.8 million in net income. Additionally, Fortress and our development partners continued to efficiently advance more than 25 development-stage programs across seven therapeutic categories within a streamlined operating structure, allowing us to create value while mitigating risk for our shareholders."

Dr. Rosenwald continued, "2019 is positioned to be a successful year on the business development and partnership fronts. Our world-class business development team continues to identify and in-license high-potential marketed and development-stage assets to further expand our portfolio of product opportunities. We look forward to several important data readouts and the potential for our first New Drug Application ("NDA") filing later this year."

Financial Results[1]:

- As of December 31, 2018, Fortress' consolidated cash, cash equivalents, short-term investments (certificates of deposit) and restricted cash totaled $99.2 million, compared to $114.4 million as of September 30, 2018, and $147.0 million as of December 31, 2017, a decrease of $15.2 million for the fourth quarter and a decrease of $47.8 million year-to-date.
- Fortress' net revenue totaled $26.9 million as of December 31, 2018, compared to $17.2 million as of December 31, 2017, an increase of $9.7 million year-to-date.

- Research and development expenses were $83.3 million for the year ended December 31, 2018, of which $78.5 million was related to partner companies. This compares to $48.3 million for 2017, of which $40.6 million was related to partner companies. Non-cash, stock-based compensation expenses included in research and development were $5.3 million for the year ended December 31, 2018, compared to $4.0 million for 2017.
- Research and development expenses from license acquisitions totaled $4.1 million for the year ended December 31, 2018, compared to $4.2 million for 2017.
- General and administrative expenses were $53.4 million for the year ended December 31, 2018, of which $33.0 million was related to partner companies. This compares to $50.9 million for 2017, of which $31.4 million was related to partner companies. Non-cash, stock-based compensation expenses included in general and administrative expenses were $9.7 million for the year ended December 31, 2018, compared to $9.4 million for 2017.
- Net loss attributable to common stockholders was $84.1 million, or $1.94 per share, for the year ended December 31, 2018, compared to a net loss attributable to common stockholders of $66.9 million, or $1.61 per share, for 2017.

2018 and Recent Corporate Highlights[2]:

Marketed Dermatology Products

- In 2018, our seven marketed products generated net revenue of $23.4 million and $3.8 million in net income.
- In the fourth quarter of 2018, we launched Exelderm®, a cream and solution for fungal infections.
- Also in 2018, we signed a co-promotion agreement with Crown Laboratories to promote Triderm®, a topical corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses; Ala-quin®, a cream for mixed infections; and Ala-scalp®, a hydrocortisone lotion for corticosteroid-responsive dermatoses.
- Additionally, we anticipate launching at least one or two new prescription drugs in 2019.

IV Tramadol

- In May 2018, we announced that the first pivotal Phase 3 trial of IV tramadol achieved the primary endpoint of a statistically significant improvement in Sum of Pain Intensity Difference over 48 hours compared to placebo in patients with moderate to moderately severe postoperative pain following bunionectomy surgery. In addition, the trial met its key secondary endpoints and demonstrated a clear dose response.
- In November 2018, we announced definitive agreements regarding an equity investment and contingent acquisition by InvaGen, a subsidiary of Cipla Limited, a leading pharmaceutical company. The first stage of the transaction closed in February 2019, and InvaGen acquired 5,833,333 shares of Avenue Therapeutics' common stock at $6.00 per share for total gross consideration of $35.0 million, representing a 33.3% stake in Avenue's capital stock on a fully diluted basis.
- In December 2018, we announced that the first patient has been dosed in a pivotal Phase 3 clinical trial of IV tramadol for the management of moderate to moderately

severe pain in patients following abdominoplasty surgery. Topline data is expected to be available in mid-2019.
- IV Tramadol is currently in development at our partner, Avenue Therapeutics, Inc.

CAEL-101

- In January 2019, Caelum Biosciences, Inc. ("Caelum") signed a collaboration agreement with Alexion Pharmaceuticals, Inc. ("Alexion") to advance the development of CAEL-101. Under the terms of the agreement, Alexion acquired a minority equity interest in Caelum and an exclusive option to acquire the remaining equity in the company based on Phase 2 data for pre-negotiated economics. Alexion will make payments to Caelum totaling $60 million, including the purchase price for the equity and milestone-dependent development funding payments. The collaboration also provides for potential additional payments of up to $500 million, including the upfront, regulatory and commercial milestone payments, in the event Alexion exercises the acquisition option.
- In March 2018, a new analysis of data from the Phase 1b trial of CAEL-101 (mAb 11-1F4), a light chain fibril-reactive monoclonal antibody ("mAb") 11-1F4, for the treatment of relapsed or refractory amyloid light chain ("AL") amyloidosis was presented at the 16th International Symposium on Amyloidosis. The data demonstrated a correlation between a sustained decrease in N-terminal pro-brain natriuretic peptide (NT-proBNP) levels and an improvement in global longitudinal strain ("GLS") following CAEL-101 treatment in patients with cardiac AL amyloidosis.
- In June 2018, Caelum announced a complete analysis of cardiac data from a Phase 1b trial of CAEL-101 (mAb 11-1F4) for the treatment of relapsed or refractory AL amyloidosis demonstrating CAEL-101's potential to improve myocardial function as assessed by GLS and generate a sustained decrease in N-terminal pro-brain natriuretic peptide levels in AL amyloidosis patients experiencing cardiac involvement. Columbia University presented the data at the American Society of Echocardiography's 29th Annual Scientific Sessions.
- In December 2018, Caelum announced additional GLS data from the Phase 1b study of CAEL-101 in patients with cardiac AL amyloidosis, which further confirmed CAEL-101's efficiency improving GLS and NT-proBNP. The Company also announced imaging data from a preclinical study that demonstrate the potential of using radiolabeled CAEL-101 for real-time imaging of human amyloidosis in vivo. The data were presented during two oral sessions at the 60th American Society of Hematology ("ASH") Annual Meeting.

Triplex

- The multicenter Phase 2 study of Triplex for cytomegalovirus ("CMV") control in allogeneic stem cell transplant recipients has concluded, and its primary endpoint was met. We anticipate the full dataset will be presented at the 45th Annual Meeting of the European Society for Blood and Marrow Transplantation ("EBMT") being held in Frankfurt, Germany March 24-27, 2019.

MB-107 (XSCID Gene Therapy)

- In August 2018, we announced that we entered into an exclusive worldwide license agreement with St. Jude Children's Research Hospital for the development of a

potentially first-in-class *ex vivo* lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency (XSCID), also known as bubble boy disease. The therapy is currently being evaluated in a Phase 1/2 multicenter trial in infants under the age of two. This study is the world's first lentiviral gene therapy trial for infants with XSCID. The therapy is also being investigated in patients over the age of two in a second Phase 1/2 trial at the National Institutes of Health ("NIH"). We believe these may be registration trials.
- MB-107 (XSCID Gene Therapy) is currently in development at our partner, Mustang Bio, Inc.

CK-301 (anti-PD-L1 antibody)

- In March 2018, we completed the dose escalation portion of the ongoing Phase 1 trial of CK-301, a fully human anti-PD-L1 antibody, in selected recurrent or metastatic cancers, and initiated the first dose expansion cohort, which is evaluating an 800 mg dose of CK-301 administered every two weeks.
- In January 2019, we announced that the ongoing multi-center clinical trial of anti-PD-L1 antibody CK-301 was expanded to enroll patients in three endometrial and colorectal cohorts intended to support requests for accelerated approval and Biologics License Application ("BLA") submissions to the FDA. The ongoing trial is also enrolling cohorts of patients with NSCLC and cutaneous squamous cell carcinoma.
- CK-301 (anti-PD-L1 antibody) is currently in development at our partner, Checkpoint Therapeutics, Inc.

CK-101 (third-generation EGFR inhibitor)

- In September 2018, we announced interim safety and efficacy data from our Phase 1/2 clinical trial of CK-101, a third-generation EGFR tyrosine kinase inhibitor ("TKI") being evaluated in advanced non-small cell lung cancer ("NSCLC"). The data were disclosed in an oral presentation at the International Association for the Study of Lung Cancer ("IASLC") 19th World Conference on Lung Cancer in Toronto. CK-101 was well tolerated across multiple dose groups. Durable anti-tumor activity was observed, particularly in treatment-naïve EGFR mutation-positive NSCLC patients.
- In March 2019, we announced two new patent issuances by the U.S. Patent and Trademark Office and the European Patent Office for CK-101. The patents cover CK-101 in the U.S. and Europe through at least August 2034, not including any potential patent term extensions.
- CK-101 (third-generation EGFR inhibitor) is currently in development at our partner, Checkpoint Therapeutics, Inc.

CUTX-101 and AAV-based gene therapy

- In July 2018, we announced that the FDA granted Fast Track Designation to CUTX-101 ("Copper Histidinate"), a product candidate for patients diagnosed with classic Menkes disease who have not demonstrated significant clinical progression. CUTX-101 is currently in a Phase 3 clinical trial.
- In September 2018, we announced the publication of preclinical data on adeno-associated virus (AAV)-based gene therapy combined with subcutaneous CUTX-101 for Menkes disease in *Molecular Therapy: Methods & Clinical Development*.

MB-102 (CD123 CAR T)

- In July 2018, we completed a pre-Investigational New Drug ("pre-IND") meeting with the U.S. Food and Drug Administration ("FDA") for MB-102 ("CD123 CAR T"). Based on the meeting, we expect to initiate a multicenter Phase 1/2 trial of MB-102 in acute myeloid leukemia ("AML"), blastic plasmacytoid dendritic cell neoplasm ("BPDCN") and high-risk myelodysplastic syndrome in the second half of 2019.
- In November 2018, we announced that additional safety and efficacy Phase 1 data evaluating MB-102 (CD123 CAR) in relapsed or refractory AML and BPDCN were presented in an oral session at the American Association for Cancer Research ("AACR") Special Conference on Tumor Immunology and Immunotherapy.
- In December 2018, the FDA granted Orphan Drug Designation to MB-102 (CD123 CAR T) for the treatment of BPDCN, a rare and incurable blood cancer. Historically the median survival for BPDCN has been less than 18 months.
- MB-102 (CD123 CAR T) is currently in development at our partner, Mustang Bio, Inc.

MB-101 (IL13Rα2-specific CAR T)

- In May 2018, we announced the publication of preclinical data in*JCI Insight* demonstrating that glioblastoma-targeted CD4+ CAR T cells mediate superior antitumor activity over CD8+ CAR T cells. The data, published by research partner City of Hope, will be applied in the ongoing Phase 1 trial of IL13Rα2-specific CAR T MB-101 in glioblastoma.
- MB-101 (IL13Rα2-specific CAR T) is currently in development at our partner, Mustang Bio, Inc.

Oncolytic Virus (C134)

- In February 2019, we announced that we partnered and entered into an exclusive worldwide license agreement with Nationwide Children's Hospital to develop an oncolytic virus (C134) for the treatment of glioblastoma multiforme. We intend to combine the oncolytic virus with MB-101 (IL13Rα2-specific CAR) to potentially enhance efficacy in treating glioblastoma multiforme.
- C134 (oncolytic virus) is currently in development at our partner, Mustang Bio, Inc.

MB-103 (HER2-specific CAR T)

- In October 2018, we announced that a first-of-its-kind Phase 1 clinical trial evaluating the safety and effectiveness of intraventricular delivery of CAR T cells to the brains of patients with HER2-positive breast cancer with brain metastases was initiated at City of Hope; the first patient was dosed in December 2018. In addition, we announced that City of Hope dosed the first patient in a Phase 1 clinical trial of HER2-specific CAR T cells in treating recurrent or refractory grade III-IV glioma. The trial is evaluating the side effects and best dose of HER2-specific CAR T cells in treating patients with grade III-IV glioma that has come back or does not respond to treatment.
- MB-103 (HER2-specific CAR T) is currently in development at our partner, Mustang Bio, Inc.

CK-103 (BET Inhibitor)

- In April 2018, preclinical data was presented on our BET inhibitor, CK-103, at the AACR Annual Meeting. CK-103 demonstrated combinatorial effects in an *in vivo* model with anti-PD-1 antibodies, which may support the development of CK-103 as an anti-cancer agent alone and in combination with CK-301.
- CK-103 (BET Inhibitor) is currently in development at our partner, Checkpoint Therapeutics, Inc.

CNDO-109

- In June 2018, data from a Phase 1 trial evaluating CNDO-109-activated allogeneic natural killer ("NK") cells in AML patients were published in the journal *Biology of Blood and Marrow Transplantation*. The data demonstrated that CNDO-109-activated NK cells are safe, well tolerated and may be capable of extending complete remissions in high-risk AML patients.

AVTS-001 (AAV Gene Therapy)

- In January 2018, we entered into a sponsored research agreement with the laboratory of Guangping Gao, Ph.D., at the University of Massachusetts Medical School to evaluate construct optimization for our AAV gene therapy treatment for complement-mediated diseases, including dry age-related macular degeneration, paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome.
- In August 2018, we announced that we entered into a sponsored research agreement with the laboratory of Wenchao Song, Ph.D., at the University of Pennsylvania to evaluate our AAV gene therapy technology in the university's proprietary animal models of complement-mediated diseases.

About Fortress Biotech

Fortress Biotech, Inc. ("Fortress") is an innovative biopharmaceutical company focused on identifying, in-licensing and developing high-potential marketed and development-stage drugs and drug candidates. The company has over 25 programs in development at Fortress, at its majority-owned and majority-controlled partners and at partners it founded and in which it holds significant minority ownership positions. Such product candidates span six large-market therapeutic areas, including oncology, rare diseases and gene therapy, which allow it to create value while mitigating risk for shareholders. Fortress advances its diversified pipeline through a streamlined operating structure that fosters efficient drug development. The Fortress model is driven by a world-class business development team that is focused on leveraging its significant biopharmaceutical industry expertise to further expand the company's portfolio of product opportunities. Fortress has established partnerships with some of the world's leading academic research institutions and biopharmaceutical companies to maximize each opportunity to its full potential, including Alexion Pharmaceuticals, Inc., City of Hope, Fred Hutchinson Cancer Research Center, InvaGen Pharmaceuticals, Inc. (a subsidiary of Cipla Limited), St. Jude Children's Research Hospital and UCL Business PLC. 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. As used below and throughout this press release, the words "we", "us" and "our" may refer to Fortress individually or together with one or more partner companies, as

dictated by context. 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 may be required by law.

Company Contacts:
Jaclyn Jaffe and William Begien
Fortress Biotech, Inc.
(781) 652-4500
ir@fortressbiotech.com

Investor Relations Contact:
Daniel Ferry
LifeSci Advisors, LLC
(617) 535-7746
daniel@lifesciadvisors.com

Media Relations Contact:
Tony Plohoros
6 Degrees
(908) 940-0135
tplohoros@6degreespr.com

[1] Financial results do not include National Holdings Corporation ("National"), as Fortress sold all of its remaining shares in National in February 2019 for an aggregate purchase price totaling approximately $22.9 million. The National segment results have been classified as discontinued operations in the accompanying Consolidated Balance Sheets and Consolidated Statements of Operations.

[2] Includes product candidates in development at Fortress, majority-owned and controlled partners and partners in which Fortress holds significant minority ownership positions. As used herein, the words "we", "us" and "our" may refer to Fortress individually or together with our affiliates and partners, as dictated by context.

FORTRESS BIOTECH, INC. AND SUBSIDIARIES

Consolidated Balance Sheets
($ in thousands except for share and per share amounts)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets		
Cash and cash equivalents	$ 65,508	$ 94,952
Accounts receivable	5,498	7,758
Short-term investments (certificates of deposit)	17,604	36,002
Inventory	678	171
Other receivables - related party	2,095	618
Prepaid expenses and other current assets	6,735	5,732
Current assets held for sale	13,089	37,948
Total current assets	111,207	183,181
Property and equipment, net	12,019	7,116
Restricted cash	16,074	16,006
Long-term investments, at fair value	-	1,390
Intangible asset	1,417	883
Other assets	276	258
Noncurrent assets held for sale	-	37,116
Total assets	**$ 140,993**	**$ 245,950**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 34,067	$ 27,412
Accounts payable and accrued expenses - related party	149	222
Interest payable	1,232	315
Interest payable - related party	97	669
Notes payable, short-term – related party (net of debt discount of $336 and $973 at December 31, 2018 and December 31, 2017, respectively)	9,164	8,528
Partner company convertible note, short-term, at fair value	9,914	4,700
Derivative warrant liability	991	309
Current liabilities held for sale	-	29,283
Total current liabilities	55,614	71,438
Notes payable, long-term (net of debt discount of $4,567 and $4,072 at December 31, 2018 and December 31, 2017, respectively)	60,425	39,212
Partner company convertible note, long-term, at fair value	-	10,059
Other long-term liabilities	5,211	4,739
Total liabilities	**121,250**	**125,448**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 1,000,000 shares issued and outstanding as of December 31, 2018 and December 31, 2017; liquidation value of $25.00 per share	1	1
Common stock, $.001 par value, 100,000,000 shares authorized, 57,845,447 and 50,991,285 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively	58	51
Common stock issuable, 744,322 and 158,015 shares as of December 31, 2018 and December 31, 2017, respectively	659	500
Additional paid-in-capital	397,408	364,148
Accumulated deficit	(396,274)	(312,127)
Total stockholders' equity attributed to the Company	1,852	52,573
Non-controlling interests	17,891	67,929
Total stockholders' equity	19,743	120,502
Total liabilities and stockholders' equity	**$ 140,993**	**$ 245,950**

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

	For the Years Ended December 31,	
	2018	**2017**
Revenue		
Product revenue, net	$ 23,376	$ 15,520
Revenue – from a related party	3,506	1,725
Net revenue	26,882	17,245
Operating expenses		
Cost of goods sold – product revenue	6,125	3,658
Research and development	83,333	48,322
Research and development – licenses acquired	4,050	4,164
General and administrative	53,371	50,897
Total operating expenses	146,879	107,041
Loss from operations	(119,997)	(89,796)
Other income (expenses)		
Interest income	1,104	819
Interest expense and financing fee	(10,340)	(7,687)
Change in fair value of derivative liabilities	(682)	(368)
Change in fair value of subsidiary convertible note	437	(457)
Change in fair value of investments	(1,390)	226
Other income (loss)	68	(250)
Total other expenses	(10,803)	(7,717)
Loss from continuing operations	(130,800)	(97,513)
Discontinued operations:		
Gain from disposal of National	2,333	-
Loss from discontinued operations, net of tax	(13,469)	(2,323)
Total loss from discontinued operations	(11,136)	(2,323)
Net loss	**(141,936)**	**(99,836)**
Less: net loss attributable to non-controlling interests	57,789	32,960
Net loss attributable to common stockholders	**$ (84,147)**	**$ (66,876)**
Loss from continuing operations per common share – basic and diluted	$ (3.01)	$ (2.34)
Loss from discontinued operations per common share – basic and diluted	$ (0.26)	$ (0.06)
Net loss per common share attributable to common stockholders – basic and diluted	$ (1.94)	$ (1.61)
Weighted average common shares outstanding – basic and diluted	43,461,978	41,658,733

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Source: Fortress Biotech, Inc.