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Fortress Biotech Recaps Corporate Highlights and Achievements in 2018

NEW YORK, Dec. 21, 2018 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (NASDAQ: FBIO) ("Fortress"), a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products, today recapped its corporate highlights and achievements in 2018.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "We have made significant progress in 2018. We continue to identify, in-license and develop high-potential clinical-stage assets. With over 25 programs in development across six large-market therapeutic areas, we have multiple shots on goal, which allows us to create value while mitigating risk for our shareholders. Our model is driven by a world-class business development team that is focused on leveraging its significant medical, clinical, technical and biopharmaceutical industry expertise to further expand our portfolio of product opportunities. Our robust pipeline is advanced by a streamlined operating structure that fosters efficient drug development. In 2018, we demonstrated success in developing high-quality partnerships, which could provide our shareholders with additional long-term revenue streams. We look forward to a productive 2019."

Accomplishments since launch of Fortress business model in January 2014:

- Established 9 development-stage Fortress Companies in areas including immuno-oncology, gene therapy, rare diseases, hematology and pain management
- Established Journey Medical Corporation, a specialty dermatology company with seven marketed products (Targadox®, Exelderm®, Ceracade®, Luxamend®, Triderm™, Ala-Quin®, and Ala-Scalp®) and a sales and marketing operation of more than 30 professionals
- In-licensed more than 25 development-stage programs across multiple therapeutic areas for Fortress and the Fortress Companies
- Established a 27,000 sq. foot cell processing facility at UMass Medicine Science Park in Worcester, Massachusetts, to manufacture Mustang Bio's CAR-T cell and gene therapies
- Established a business development / search and evaluate team with approximately 15 employees and have approximately 25 MDs / PhDs under the Fortress umbrella

2018 Fortress and Fortress Company Highlights:

Journey Medical Corporation

- We are delighted with the performance of Journey Medical Corporation this year. We anticipate it will generate net sales exceeding $20 million in 2018 and generate in excess of $5 million in positive cash flow. Additionally, we anticipate launching at least one or two new prescription drugs in 2019.

Avenue Therapeutics, Inc.

- In March 2018, Avenue received Notices of Allowance from the U.S. Patent and Trademark Office ("USPTO") for three patent applications covering methods of administration for IV tramadol. These patents were issued in the second quarter of 2018.
- In May 2018, Avenue announced that its 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 (SPID48) 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. Avenue initiated a second pivotal Phase 3 trial of IV tramadol in patients following abdominoplasty surgery this week.
- In November 2018, Avenue announced definitive agreements to be acquired by InvaGen Pharmaceuticals, Inc., USA ("InvaGen"), a subsidiary of Cipla Limited, a leading pharmaceutical company, with two closing stages, subject to shareholder approval and certain closing conditions. At the first stage closing, InvaGen will acquire, through the issuance by Avenue of new shares, shares representing a 33.3% stake in Avenue's capital stock on a fully diluted basis for $35 million at $6 per share. Following the second closing stage, InvaGen will acquire the remaining shares of Avenue's common stock, pursuant to a reverse triangular merger with Avenue remaining as the surviving entity, for up to $180 million in the aggregate. Based on current assumptions, such aggregate consideration is expected to represent approximately $13.92 per share. Post second stage closing, Avenue shareholders will receive Contingent Value Rights (CVRs).

Helocyte, Inc.

- The multicenter Phase 2 study of Triplex for CMV control in stem cell transplant recipients has concluded. We anticipate the full dataset will be presented at a conference in the first quarter of 2019.

Mustang Bio, Inc.

- In March 2018, Mustang announced that Sadik Kassim, Ph.D., was appointed Chief Scientific Officer, and Knut Niss, Ph.D., was named Chief Technology Officer.
- In May 2018, Mustang 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 Mustang's IL13Rα2-specific CAR T MB-101 in glioblastoma.
- In June 2018, Mustang opened a proprietary CAR T cell therapy manufacturing facility at UMass Medicine Science Park in Worcester, Mass. The facility will support the clinical development and commercialization of Mustang's CAR T product candidates and enable proprietary cell therapy research.

- Also in June 2018, Mustang was added to the Russell 2000®, 3000® and Microcap® Indexes.
- In July 2018, Mustang completed a pre-Investigational New Drug ("pre-IND") meeting with the FDA for MB-102 ("CD123 CAR T"). Based on the meeting, Mustang expects to initiate a Phase 1/2 trial in the first half of 2019 of MB-102 in acute myeloid leukemia, blastic plasmacytoid dendritic cell neoplasm and high-risk myelodysplastic syndrome.
- In August 2018, Mustang announced that it entered into an exclusive worldwide license agreement with St. Jude for the development of a potentially first-in-class *ex vivo* lentiviral gene therapy for the treatment of X-SCID, 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 X-SCID. 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"). The company believes these may be registration trials.
- In October 2018, Mustang appointed Martina A. Sersch, M.D., Ph.D., as Chief Medical Officer.
- Also in October 2018, Mustang 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 has been initiated at City of Hope. In addition, Mustang announced that City of Hope has 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 will evaluate 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.
- In November 2018, Mustang announced that additional safety and efficacy Phase 1 data evaluating MB-102 (CD123 CAR) in relapsed or refractory acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN) were presented in an oral session at the AACR Special Conference on Tumor Immunology and Immunotherapy.
- In December 2018, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to MB-102 (CD123 CAR T) for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN), a rare and incurable blood cancer with a median survival of less than 18 months and no standard of care.

Checkpoint Therapeutics, Inc.

- In March 2018, Checkpoint completed an underwritten public offering that raised net proceeds of $20.8 million.
- Also in March 2018, Checkpoint 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 April 2018, preclinical data was presented on Checkpoint's BET inhibitor, CK-103, at the American Association for Cancer Research (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 Checkpoint's anti-PD-L1 antibody CK-301.
- In September 2018, Checkpoint announced positive interim safety and efficacy data from its Phase 1/2 clinical trial of CK-101, a third-generation EGFR tyrosine kinase

inhibitor ("TKI") being evaluated in advanced NSCLC. The data were presented 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 and safe. Durable anti-tumor activity was observed, particularly in treatment-naïve EGFR mutation-positive NSCLC patients.
- In October 2018, Checkpoint appointed Christian Béchon to its Board of Directors.
- Checkpoint anticipates potentially initiating pivotal clinical trials in 2019 for CK-101 and CK-301.

Cyprium Therapeutics, Inc.

- In July 2018, Cyprium 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, Cyprium announced the publication of preclinical data on AAV-based gene therapy combined with subcutaneous CUTX-101 for Menkes disease in *Molecular Therapy: Methods & Clinical Development*.

Caelum Biosciences, Inc.

- In March 2018, a new analysis of data from the Phase 1b trial of Caelum's CAEL-101 (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 amyloid light chain ("AL") amyloidosis demonstrating CAEL-101's potential to improve myocardial function as assessed by global longitudinal strain and generate a sustained decrease in N-terminal pro-brain natriuretic peptide levels in AL amyloidosis patients experiencing cardiac involvement. The data were presented by Columbia University at the American Society of Echocardiography 29th Annual Scientific Sessions.
- In December 2018, Caelum announced additional global longitudinal strain ("GLS") data from the Phase 1b study of CAEL-101, a light chain fibril-reactive monoclonal antibody ("mAb") 11-1F4, in patients with cardiac amyloid light chain ("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.

Fortress Biotech, Inc.

- In June 2018, data from a Phase 1 trial evaluating Fortress' CNDO-109-activated allogeneic natural killer (NK) cells in acute myeloid leukemia (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.

- In November 2018, Fortress entered into an agreement to sell its 56.1 percent majority stake of National Holdings Corporation, to NHC Holdings, LLC, a wholly-owned subsidiary of B. Riley Financial, Inc. Under the terms of the agreement, 24.0 percent of National was sold in an initial closing on November 16 at $3.25 per share. We anticipate the remaining 32.1 percent stake to be sold at the same per-share price in the first quarter of 2019, for an aggregate purchase price totaling approximately $22.9 million.

Aevitas Therapeutics, Inc.

- In January 2018, Aevitas 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 Aevitas' AAV gene therapy treatment for complement-mediated diseases, including dry AMD, PNH and aHUS.
- In August 2018, Aevitas announced that it entered into a sponsored research agreement with the laboratory of Wenchao Song, Ph.D., at the University of Pennsylvania to evaluate Aevitas' adeno-associated virus ("AAV") gene therapy technology in the university's proprietary animal models of complement-mediated diseases.

About Fortress Biotech

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 may be required by law.

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