May 17, 2021

REPEAT -- Fortress Biotech Reports First Quarter 2021 Financial Results and Recent Corporate Highlights

Rolling NDA submission for CUTX-101 for the treatment of Menkes disease is expected to begin in the second half of 2021

On track to report top-line results from the registration-enabling study of cosibelimab in metastatic cutaneous squamous cell carcinoma by year-end 2021

Ended first quarter 2021 with $291.5 million in consolidated cash, cash equivalents and restricted cash

NEW YORK, May 17, 2021 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (NASDAQ: FBIO) ("Fortress"), an innovative biopharmaceutical company focused on acquiring, developing and commercializing or monetizing promising biopharmaceutical products and product candidates cost-effectively, today announced financial results and recent corporate highlights for the first quarter ended March 31, 2021.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "Fortress and our partner companies had an exciting start to the year, including the addition and commercial launch of two dermatology products, bringing our total number of marketed products to seven. Moreover, we continued to achieve significant milestones in the advancement of multiple key development programs. Notably, in February, our partner company, Cyprium Therapeutics ("Cyprium"), and Sentynl Therapeutics ("Sentynl"), a wholly owned subsidiary of the Zydus Group, signed a Development and Asset Purchase Agreement for CUTX-101 for the treatment of Menkes disease. This agreement, which included an $8 million upfront payment for the ongoing development of CUTX-101, in addition to regulatory and sales milestone payments plus royalties, allows us to potentially maximize the value of this important asset as Cyprium continues to advance CUTX-101 toward a rolling submission of a New Drug Application ("NDA") later this year."

Dr. Rosenwald continued, "Our portfolio continues to grow with more than 25 product candidates across our partner companies, including 17 clinical programs, of which four are pivotal programs. We expect to have a multitude of regulatory and clinical inflection points throughout the remainder of 2021, including the availability of clinical data from cosibelimab, CAEL-101 and MB-106. Importantly, our diversified business model is supported by a strong balance sheet, as we ended the first quarter with $291.5 million in consolidated cash, cash

equivalents and restricted cash. Our operational catalysts and financial strength have us well-positioned for success and we remain focused on creating long-term shareholder value."

Recent Corporate Highlights[1]:

Marketed Dermatology Products

- Our seven dermatology products are marketed by our partner company, Journey Medical Corporation ("Journey").
- Our products generated net revenues of $10.7 million for the first quarter of 2021, compared to first quarter 2020 net revenues of $11.9 million. While product demand increased in the first quarter of 2021 compared to the first quarter of 2020, the decrease in net revenue in the first quarter of 2021 is primarily attributable to increased coupon expense costs related to standard insurance deductible resets. We expect year-over-year annual revenue growth in 2021 to exceed the 28% growth Journey achieved in 2020.
- In April 2021, Journey acquired and recently launched its seventh prescription dermatology product, QBREXZA®.
- On April 1, 2021, Journey entered into an agreement with East West Bank ("EWB") in which EWB will provide a $7.5 million working capital line of credit.
- On March 31, 2021, Journey completed its first close in connection with its Cumulative Convertible Class A Preferred Stock Offering. In connection with the first close, Journey issued an aggregate of 501,480 Journey Preferred A shares at a price of $25.00 per share, and after deducting commissions, fees, and expenses, for a total of $11.2 million in net proceeds.
- We plan on launching one additional prescription product in the second half of this year.

CUTX-101 (Copper Histidinate for Menkes disease)

- In February 2021, our partner company, Cyprium, and Sentynl signed a Development and Asset Purchase Agreement for CUTX-101 for the treatment of Menkes disease. Under the terms of the agreement, Cyprium received $8 million upfront to fund the development of CUTX-101 and could receive up to $12 million in regulatory milestone payments through NDA approval, and is eligible to receive sales milestones plus royalties. Royalties start from mid-single digits, scaling up to 25% on sales exceeding $100 million annually. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101. Cyprium is responsible for the development of CUTX-101 through approval of the NDA by the FDA, and Sentynl will be responsible for commercialization of CUTX-101, as well as progressing newborn screening activities.
- We intend to begin the rolling submission of the NDA for CUTX-101 to the FDA in the second half of 2021.
- CUTX-101 is currently in development at our partner company, Cyprium Therapeutics, Inc.

CAEL-101 (Light Chain Fibril-reactive Monoclonal Antibody for AL Amyloidosis)

- Caelum Biosciences, Inc. ("Caelum") has two on-going Phase 3 studies of CAEL-101

for AL amyloidosis.

- Caelum formed a collaboration with Alexion Pharmaceuticals, Inc. in 2019, which includes an option to acquire Caelum. AstraZeneca announced the execution of a definitive agreement to purchase Alexion Pharmaceuticals, Inc. In the event of the closing of such transaction, the timeline for a potential exercise of the option to purchase Caelum will be accelerated to six months following the date of acquisition closing.
- In May 2021, we announced that CAEL-101 clinical data were selected for two presentations at the European Hematology Association 2021 Virtual Congress ("EHA2021") taking place in June. The abstracts can be viewed online through the EHA2021 website: here and here.
- CAEL-101 is currently in development at Caelum Biosciences, Inc., a company founded by Fortress in 2017 and in which Fortress maintains a minority position.

Cosibelimab (formerly CK-301, an anti-PD-L1 antibody)

- The registration-enabling study in metastatic cutaneous squamous cell carcinoma is fully enrolled and we are on track to report top-line results by year-end. With a potentially favorable safety profile versus anti-PD-1 therapy and a plan to commercialize at a substantially lower price, we believe cosibelimab has the potential to be a market disruptive product in the $25 billion and growing PD-(L)1 class.
- A Phase 3 registration-enabling trial is planned to begin in first-line metastatic non-small cell lung cancer in mid-2021.
- Cosibelimab is currently in development at our partner company, Checkpoint Therapeutics, Inc. ("Checkpoint").

MB-107 and MB-207 (Lentiviral Gene Therapies for X-linked Severe Combined Immunodeficiency)

- In February 2021, we announced encouraging MB-107 and MB-207 clinical updates from our investigator-IND X-linked severe combined immunodeficiency ("XSCID") trials, as well as additional consistent safety and efficacy data. On January 28, 2021, the FDA removed a CMC hold on the MB-107 Phase 2 clinical trial Investigational New Drug ("IND") application after reviewing a comprehensive CMC package that was submitted in late December 2020. We expect to enroll the first patient in this pivotal multicenter trial in the second quarter of 2021 and we are targeting top-line data from the trial in the second half of 2022. We also expect to file an IND in the second quarter of 2021 for our pivotal multicenter Phase 2 clinical trial of MB-207.
- MB-107 and MB-207 are currently in development at our partner company, Mustang Bio, Inc. ("Mustang Bio").

MB-106 (CD20-targeted CAR T Cell Therapy)

- In May 2021, we announced that the FDA approved Mustang Bio's IND application to initiate a multicenter Phase 1/2 clinical trial investigating the safety and efficacy of MB-106, a CD20-targeted CAR T for relapsed or refractory B-cell non-Hodgkin lymphomas ("B-NHL") and chronic lymphocytic leukemia ("CLL").
- Also in May 2021, we announced that CD20-targeted CAR T data were selected for presentation at EHA2021 scheduled to take place in June. Dr. Mazyar Shadman of Fred Hutchinson Cancer Research Center will present updated interim data from the

ongoing Phase 1/2 clinical trial for B-NHL and CLL. A copy of the abstract can be viewed online through the EHA2021 website here.
- MB-106 is currently in development at our partner company, Mustang Bio.

Dotinurad (Urate Transporter (URAT1) Inhibitor)

- In May 2021, we announced an exclusive license agreement with Fuji Yakuhin Co. Ltd. to develop Dotinurad in North America and Europe. Dotinurad is a potential best-in-class urate transporter (URAT1) inhibitor for gout and possibly other hyperuricemic indications including chronic kidney disease and heart failure. Dotinurad (URECE® tablet) was approved in Japan in 2020 as a once-daily oral therapy for gout and hyperuricemia. Dotinurad was efficacious and well-tolerated in more than 500 Japanese patients treated for up to 58 weeks in Phase 3 clinical trials.
- Dotinurad is currently in development at our partner company, FBIO Acquisition Corp. VIII.

IV Tramadol

- In October 2020, Avenue Therapeutics ("Avenue") announced that it had received a Complete Response Letter ("CRL") from the FDA regarding Avenue's NDA for IV tramadol. The FDA held a Type A meeting with Avenue in November 2020 to discuss the issues outlined in the CRL. On February 12, 2021, Avenue resubmitted its NDA to the FDA for IV tramadol. The NDA resubmission followed the receipt of the official minutes from Avenue's Type A meeting with the FDA. The NDA resubmission included revised language relating to the proposed product label and a report relating to terminal sterilization validation. On February 26, 2021, Avenue received an acknowledgment letter from the FDA stating that Avenue's resubmission of its NDA is a complete, class 1 response to the CRL, and a Prescription Drug User Free Act ("PDUFA") goal date was set for April 12, 2021. On April 13, 2021, Avenue announced that the FDA was still reviewing its NDA for IV tramadol and had not provided a decision regarding the NDA. As of May 1, 2021, Avenue had not received approval from the FDA for IV tramadol. Accordingly, under the Stock Purchase and Merger Agreement ("SPMA"), InvaGen retains an option to consummate the second stage closing until October 31, 2021 (after which Avenue can choose to terminate the SPMA), and also retains the option to terminate the SPMA.
- IV tramadol is currently in development at our partner company, Avenue.

General Corporate

- In February 2021, Fortress partner company, Aevitas Therapeutics, appointed Markus Peters, Ph.D., M.Sc., as Chief Executive Officer.

Financial Results:

To assist our stockholders in understanding our company, we have prepared non-GAAP financial results for the three months ended March 31, 2021 and 2020. These results exclude the operations of our three public partner companies: Avenue, Checkpoint, and Mustang Bio. The goal in providing these non-GAAP financial metrics is to highlight the financial results of Fortress' core operations, which are comprised of our commercial-stage business, our privately held development-stage entities, as well as our business

development and finance functions.

- As of March 31, 2021, Fortress' consolidated cash, cash equivalents and restricted cash totaled $291.5 million, compared to $235.0 million as of December 31, 2020, an increase of $56.5 million during the quarter.
- On a GAAP basis, Fortress' net revenue totaled $11.6 million for the first quarter of 2021, which included $10.7 million in net revenue generated from our marketed dermatology products. This compares to net revenue totaling $12.9 million for the first quarter of 2020, which included $11.9 million in net revenue generated from our marketed dermatology products.
- On a GAAP basis, consolidated research and development expenses including license acquisitions were $20.2 million for the first quarter of 2021, compared to $15.1 million for the first quarter of 2020. On a non-GAAP basis, research and development expenses including license acquisitions were $4.1 million for the first quarter of 2021, compared to $2.3 million for first quarter of 2020.
- On a GAAP basis, consolidated selling, general and administrative expenses were $17.5 million for the first quarter of 2021, compared to $15.5 million for the first quarter of 2020. On a non-GAAP basis, consolidated selling, general and administrative expenses were $13.0 million, of which $6.2 million is attributed to Journey, for the first quarter of 2021, compared to $11.6 million, of which $5.6 million is attributed to Journey, for the first quarter of 2020.
- On a GAAP basis, consolidated net loss attributable to common stockholders was $8.8 million, or $0.11 per share, for the first quarter of 2021, compared to consolidated net loss attributable to common stockholders of $12.4 million, or $0.19 per share for the first quarter of 2020.
- Fortress' non-GAAP loss attributable to common stockholders was $7.3 million, or $0.09 per share, for the first quarter of 2021, compared to Fortress' non-GAAP loss attributable to common stockholders of $4.2 million, or $0.07 per share, for the first quarter of 2020.

Use of Non-GAAP Measures:

In addition to the GAAP financial measures as presented in our Form 10-Q that will be filed with the Securities and Exchange Commission ("SEC") on May 17, 2021, the Company has, in this press release, included certain non-GAAP measurements. The non-GAAP net loss attributable to common stockholders is defined by the Company as GAAP net loss attributable to common stockholders, less net losses attributable to common stockholders from our public partner companies Avenue, Checkpoint and Mustang Bio. In addition, the Company has also provided a Fortress non-GAAP loss attributable to common stockholders which is a modified EBITDA calculation that starts with the non-GAAP loss attributable to common stockholders and removes stock-based compensation expense, non-cash interest expense, amortization of licenses and debt discount, changes in fair values of investment, changes in fair value of derivative liability, and depreciation expense.

Management believes use of these non-GAAP measures provide meaningful supplemental information regarding the Company's performance because (i) it allows for greater transparency with respect to key measures used by management in its financial and operational decision-making, (ii) it excludes the impact of non-cash or, when specified, non-recurring items that are not directly attributable to the Company's core operating

performance and that may obscure trends in the Company's core operating performance, and (iii) it is used by institutional investors and the analyst community to help analyze the Company's results. However, non-GAAP loss attributable to common stockholders and any other non-GAAP financial measures should be considered as a supplement to, and not as a substitute for, or superior to, the corresponding measures calculated in accordance with GAAP. Further, non-GAAP financial measures used by the Company and the manner in which they are calculated may differ from the non-GAAP financial measures or the calculations of the same non-GAAP financial measures used by other companies, including the Company's competitors.

The tables below provide a reconciliation from GAAP to non-GAAP measures:

($ in thousands)	For the three months ended March 31, 2021	2020
Net income (loss) attributable to common stockholders	$ (8,822)	$ (12,370)
Net (Loss) income attributable to common stockholders - Avenue[1]	(225)	(287)
Net (Loss) income attributable to common stockholders - Checkpoint[2]	(1,158)	(753)
Net (Loss) income attributable to common stockholders - Mustang[3]	(2,917)	(3,599)
Non-GAAP net loss attributable to common stockholders	$ (4,522)	$ (7,731)
Stock based compensation	1,889	1,740
Non-cash interest	210	769
Amortization of licenses	584	355
Amortization of debt discount	309	488
Depreciation	141	154
Increase in fair value of investment[4]	(5,913)	-
Fortress non-GAAP loss attributable to common stockholders	$ (7,302)	$ (4,224)
Per common share - basic and diluted:		
Net income (loss) attributable to common stockholders (GAAP)	$ (0.11)	$ (0.19)
Non-GAAP net loss attributable to common stockholders	$ (0.06)	$ (0.12)
Fortress non-GAAP loss attributable to common stockholders	$ (0.09)	$ (0.07)
Weighted average common shares outstanding - basic and diluted	80,851,671	63,496,256

1. Avenue net loss from their external SEC report for the three months ended March 31, 2021 and 2020 of $1.0 million and $1.2 million, respectively, net of non-controlling interest of $0.8 million and $0.9 million, respectively.

2. Checkpoint net loss from their external SEC report of $6.5 million net of non-controlling interest of $4.6 million, MSA fee to Fortress of $0.1 million and financing fee to Fortress of $0.6 million for the quarter ended March 31, 2021; and net loss of $3.3 million net of non-controlling interest of $2.4 million, less MSA fee to Fortress of $0.1 million for the quarter ended March 31, 2020.

3. Mustang net loss from their external SEC report of $14.8 million net of non-controlling interest of $10.7 million, MSA fee to Fortress of $0.1 million and financing fee to Fortress of $1.2 million for the quarter ended March 31, 2021; and net loss of $11.9 million net of non-controlling interest of $8.0 million, MSA fee to Fortress of $0.1 million and financing fee to Fortress of $0.1 million for the quarter ended March 31, 2020.

4. Increase in fair value of investment in Caelum Biosciences for the quarter ended March 31, 2021.

Reconciliation to non-GAAP research and development and general and administrative costs:

	For the quarter ended March 31,	
($ in thousands)	**2021**	**2020**
Research and development[1]	**$ 20,154**	**$ 15,117**
Less:		
Research and development Avenue	258	697
Research and development Checkpoint	4,213	2,635
Research and development Mustang [2]	11,556	9,502
Non-GAAP research and development costs	**$ 4,127**	**$ 2,283**
Selling, general and administrative	**$ 17,542**	**$ 15,519**
Less:		
General and administrative Avenue	743	577
General and administrative Checkpoint [3]	1,615	1,553
General and administrative Mustang [4]	2,210	1,768
Non-GAAP selling, general and administrative costs	**$ 12,974**	**$ 11,621**

1. Includes Research and development expense and Research and development - licenses acquired expense for the quarter ended March 31, 2021 and 2020, respectively.

2. Excludes $0.1 million for Fortress MSA for the quarter ended March 31, 2021; excludes $0.1 million for Fortress MSA for the quarter ended March 31, 2020.

3. Excludes $0.1 million of Fortress MSA expense and $0.6 million Fortress financing fee for the quarter ended March 31, 2021; and $0.1 million of Fortress MSA expense for the quarter ended March 31, 2020.

4. Excludes $0.1 million of Fortress MSA expense and $1.2 million Fortress financing fee for the quarter ended March 31, 2021; and $0.1 million of Fortress MSA expense and $0.1 million Fortress financing fee for the quarter ended March 31, 2020.

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress”) is an innovative biopharmaceutical company that was ranked in Deloitte’s 2019 and 2020 Technology Fast 500™, annual rankings of the fastest-growing North American companies in the technology, media, telecommunications, life sciences and energy tech sectors, based on percentages of fiscal year revenue growth over three-year periods. Fortress is focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has seven marketed prescription pharmaceutical products and 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 areas, including oncology, rare diseases and gene therapy, which allow it to create value 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., AstraZeneca, City of Hope, Fred Hutchinson Cancer Research Center, St. Jude Children’s Research Hospital and Nationwide Children’s Hospital. 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; risks relating to the COVID-19 outbreak and its potential impact on our employees’ and consultants’ ability to complete work in a timely manner and on our ability to obtain additional financing on favorable terms or at all; 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, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply

to a given piece of information in one part of this press release should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

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

	March 31, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 289,897	$ 233,351
Accounts receivable, net	19,439	19,349
Inventory	2,291	1,404
Other receivables - related party	849	744
Prepaid expenses and other current assets	5,517	6,723
Total current assets	317,993	261,571
Property and equipment, net	12,291	11,923
Operating lease right-of-use asset, net	20,072	20,487
Restricted cash	1,645	1,645
Long-term investment, at fair value	23,479	17,566
Intangible asset, net	14,442	14,629
Other assets	1,121	1,013
Total assets	**$ 391,043**	**$ 328,834**

LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 39,181	$ 40,674
Deferred revenue	7,200	—
Income taxes payable	136	136
Operating lease liabilities, short-term	1,840	1,849
Partner company note payable, short-term	5,463	5,300
Total current liabilities	53,820	47,959
Notes payable, long-term (net of debt discount of $8,014 and $8,323 at March 31, 2021 and December 31, 2020, respectively)	51,986	51,677
Operating lease liabilities, long-term	22,447	22,891
Partner company note payable, long-term	5,613	7,359
Partner company convertible preferred shares	10,687	—
Partner company derivative warrant liability	362	—
Other long-term liabilities	1,903	1,949
Total liabilities	**146,818**	**131,835**
Commitments and contingencies		
Stockholders' equity		
Cumulative redeemable perpetual preferred stock, $.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively, liquidation value of $25.00 per share	3	3
Common stock, $.001 par value, 150,000,000 shares authorized, 97,263,054 and 94,877,492 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	97	95
Additional paid-in-capital	597,384	583,000
Accumulated deficit	(491,582)	(482,760)
Total stockholders' equity attributed to the Company	105,902	100,338
Non-controlling interests	138,323	96,661
Total stockholders' equity	244,225	196,999
Total liabilities and stockholders' equity	**$ 391,043**	**$ 328,834**

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

	Three Months Ended March 31,	
	2021	**2020**
Revenue		
Product revenue, net	$ 10,719	$ 11,946
Collaboration revenue	800	—
Revenue - related party	68	972
Net revenue	11,587	12,918
Operating expenses		
Cost of goods sold - product revenue	3,908	3,810
Research and development	20,028	14,867
Research and development - licenses acquired	126	250
Selling, general and administrative	17,542	15,519
Total operating expenses	41,604	34,446
Loss from operations	(30,017)	(21,528)
Other income (expense)		
Interest income	227	627
Interest expense and financing fee	(2,189)	(3,125)
Change in fair value of investments	5,913	—
Change in fair value of derivative liability	—	(42)
Total other income (expense)	3,951	(2,540)
Net loss	**(26,066)**	**(24,068)**
Less: net loss attributable to non-controlling interests	17,244	11,698
Net loss attributable to common stockholders	**$ (8,822)**	**$ (12,370)**
Net loss per common share - basic and diluted	$ (0.32)	$ (0.38)
Net loss per common share attributable to non - controlling interests - basic and diluted	$ (0.21)	$ (0.18)
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.11)	$ (0.19)
Weighted average common shares outstanding - basic and diluted	80,851,671	63,496,256

[1] 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.

Source: Fortress Biotech, Inc.