March 28, 2024

Fortress Biotech Reports 2023 Financial Results and Recent Corporate Highlights

Record consolidated net revenue of $84.5 million for full-year 2023

Fortress may receive up to four regulatory decisions on NDAs and BLAs in the next 18 months

FDA accepted New Drug Application filing for DFD-29 to treat inflammatory lesions and erythema of rosacea in adults; PDUFA goal date of November 4, 2024

MIAMI, March 28, 2024 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (Nasdaq: FBIO) ("Fortress"), an innovative biopharmaceutical company focused on acquiring and advancing assets to enhance long-term value for shareholders through product revenue, equity holdings and dividend and royalty revenue, today announced financial results and recent corporate highlights for the full-year ended December 31, 2023.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "In 2023, we built a significant amount of momentum to position our Company to achieve multiple milestones in 2024. We also generated record consolidated net revenues of $84.5 million in 2023, the majority of which came from the sales and milestone payments from our dermatology and rare disease businesses."

Dr. Rosenwald continued, "We are pleased that the U.S. Food and Drug Administration ("FDA") accepted the New Drug Application ("NDA") filing for DFD-29 earlier this month and look forward to the Prescription Drug User Fee Act ("PDUFA") goal date of November 4, 2024. Across our portfolio, we could receive up to four NDA and Biologics License Application ("BLA") regulatory approvals over the next 18 months, while we continue to advance our 25 development stage programs in 2024."

2023 and Recent Corporate Highlights[1]:

Regulatory Milestones and Updates

- In January 2024, we submitted an NDA to the FDA seeking approval for DFD-29 (Minocycline Hydrochloride Modified Release Capsules, 40 mg) for the treatment of inflammatory lesions and erythema of rosacea in adults. In March 2024, the FDA accepted the NDA and has set a PDUFA goal date of November 4, 2024. If approved, DFD-29 has the potential to become the only oral, systemic therapy to address both

inflammatory lesions and erythema (redness) from rosacea, as demonstrated in clinical trials. DFD-29 is currently in development at our partner company, Journey Medical Corporation (Nasdaq: DERM) ("Journey Medical").

- We submitted a BLA to the FDA for cosibelimab, our investigational anti-PD-L1 antibody, as a treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or radiation, in January 2023. In December 2023, the FDA issued a complete response letter ("CRL") for the cosibelimab BLA. The CRL only cited findings that arose during a multi-sponsor inspection of a third-party contract manufacturing organization as approvability issues to address in a resubmission. The CRL did not state any concerns about the clinical data package, safety or labeling for the approvability of cosibelimab. We believe we can address the feedback in a resubmission to enable marketing approval in 2024. We also secured additional U.S. patent protection for cosibelimab through at least May 2038. Cosibelimab is currently in development at our partner company, Checkpoint Therapeutics, Inc. (Nasdaq: CKPT) ("Checkpoint").
- Based on its public statements, AstraZeneca plc ("AstraZeneca") has estimated that it expects the FDA to accept its BLA submission of CAEL-101 (anselamimab) to treat AL amyloidosis for review in 2025. In 2021, AstraZeneca acquired Caelum Biosciences, Inc. (founded by Fortress) for an upfront payment of approximately $150 million paid to Caelum shareholders, of which approximately $56.9 million was paid to Fortress. The agreement also provides for additional potential payments to Caelum shareholders, including approximately $148 million to Fortress, payable upon the achievement of regulatory and commercial milestones.
- In December 2023, we completed the asset transfer of CUTX-101 (copper histidinate for Menkes disease) to Sentynl, a wholly owned subsidiary of Zydus Lifesciences Ltd. The CUTX-101 rolling NDA submission is ongoing and is expected to be completed by Sentynl in 2024. Cyprium Therapeutics, Inc. ("Cyprium"), our subsidiary company that developed CUTX-101, will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.
- In October 2023, we announced that the FDA accepted our Investigational New Drug application to initiate a Phase 1 open-label, multicenter clinical trial to assess the safety, tolerability and efficacy of MB-109, a novel combination of MB-101 (IL13Rα2-targeted CAR-T cell therapy) and MB-108 (HSV-1 oncolytic virus), for the treatment of IL13Rα2+ recurrent GBM and high-grade astrocytoma. MB-109 is currently in development at our partner company, Mustang Bio, Inc. (Nasdaq: MBIO) ("Mustang Bio").

Commercial Product Updates

- In September 2023, our partner company, Journey Medical, entered into an exclusive license agreement with Maruho Co., Ltd. ("Maruho"), a Japanese company specializing in dermatology as well as Journey Medical's exclusive licensing partner that developed and is commercializing Qbrexza® (Rapifort®) in Japan. Under the terms of a new license agreement, Journey Medical received a $19 million nonrefundable upfront payment and granted Maruho an exclusive license to develop and commercialize Qbrexza (glycopyrronium tosylate hydrate) for the treatment of hyperhidrosis in South Korea, Taiwan, Hong Kong, Macau, Thailand, Indonesia, Malaysia, Philippines, Singapore, Vietnam, Brunei, Cambodia, Myanmar and Laos (the "Territory"). Maruho is responsible for all development and commercialization costs for the program

throughout the Territory.

- Journey Medical's total net revenues for the year ended December 31, 2023, were $79.2 million, an increase of $5.5 million, or 7%, compared to total net revenues of $73.7 million for 2022.
- Journey Medical's total product net revenues were $59.7 million for the year ended December 31, 2023, compared to total product net revenues of $71.0 million for the year ended December 31, 2022.

General Corporate:

- Throughout 2023 and in January 2024, Fortress raised total gross proceeds of approximately $34.9 million in registered direct offerings priced at-the-market under Nasdaq rules and in a public offering.
- In October 2023, Fortress effected a 1-for-15 reverse stock split of its issued and outstanding common stock to bring the Company into compliance with Nasdaq's minimum bid price requirement for continued listing.
- In April 2023, we announced the execution of an asset purchase agreement for 4D Molecular Therapeutics ("4DMT") to acquire proprietary rights to our short-form human complement factor H asset for the treatment of complement-mediated diseases. Under the terms of the agreement, 4DMT will make cash payments totaling up to ~$140 million in potential late-stage development, regulatory and sales milestones. A range of single-digit royalties on net sales are also payable. Our short-form human complement factor H asset was in development at our subsidiary company, Aevitas Therapeutics, Inc. ("Aevitas"), prior to the asset purchase agreement with 4DMT.

Financial Results:

- As of December 31, 2023, Fortress' consolidated cash, cash equivalents and restricted cash totaled $83.4 million, compared to $74.7 million as of September 30, 2023, and $181.0 million as of December 31, 2022, an increase of $8.7 million for the fourth quarter and a decrease of $97.6 million for the full year.
- Fortress' consolidated cash, cash equivalents and restricted cash, totaling $83.4 million as of December 31, 2023, includes $42.2 million attributable to Fortress and private subsidiaries, $1.8 million attributable to Avenue, $4.9 million attributable to Checkpoint, $7.0 million attributable to Mustang Bio and $27.4 million attributable to Journey Medical.
- Subsequent to the end of the fourth quarter, in January 2024, Fortress raised approximately $11.0 million in gross proceeds in a registered direct offering, Checkpoint raised approximately $14.0 million in gross proceeds in a registered direct offering and Avenue raised approximately $5.0 million in gross proceeds from warrant exercise transactions.
- Fortress' consolidated net revenue totaled $84.5 million for the full year ended December 31, 2023, which included $59.7 million in net revenue generated from our marketed dermatology products. This compares to consolidated net revenue totaling $75.7 million for the full year ended 2022, which included $71.0 million in net revenue generated from our marketed dermatology products.
- Consolidated research and development expenses including license acquisitions totaled $106.1 million for the full year ended December 31, 2023, compared to $134.9 million for the full year ended December 31, 2022.

- Consolidated selling, general and administrative costs were $94.1 million for the full year ended December 31, 2023, compared to $113.7 million for the full year ended December 31, 2022.
- Consolidated net loss attributable to common stockholders was $(68.7) million, or $(8.47) per share, for the full year ended December 31, 2023, compared to net loss attributable to common stockholders of $(94.6) million, or $(15.97) per share for the full year ended December 31, 2022.

About Fortress Biotech

Fortress Biotech, Inc. ("Fortress") is an innovative biopharmaceutical company focused on acquiring and advancing assets to enhance long-term value for shareholders through product revenue, equity holdings and dividend and royalty revenue. 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 subsidiaries and at partners and subsidiaries 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 focused on leveraging its significant biopharmaceutical industry expertise and network 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 AstraZeneca, City of Hope, Fred Hutchinson Cancer Center, St. Jude Children's Research Hospital, Nationwide Children's Hospital and Sentynl. For more information, visit www.fortressbiotech.com.

Forward-Looking Statements

Statements in this press release that are not descriptions of historical facts are "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. The words "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "might," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology are generally intended to identify forward-looking statements. These 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, financing and strategic agreements and relationships; our need for substantial additional funds and uncertainties relating to financings; our ability to identify, acquire, close and integrate product candidates successfully and on a timely basis; our ability to attract, integrate and retain key personnel; the early stage of products under development; the results of research and development activities; uncertainties relating to preclinical and clinical testing; our ability to obtain regulatory approval for products under development; our ability to successfully commercialize products for which we receive regulatory approval; our ability to secure and maintain third-party manufacturing, marketing and distribution of our and our partner companies' products and product candidates; 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
Consolidated Balance Sheets
($ in thousands except for share and per share amounts)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 80,927	$ 178,266
Accounts receivable, net	15,222	28,208
Inventory	10,206	14,159
Other receivables - related party	167	138
Prepaid expenses and other current assets	10,500	9,661
Total current assets	117,022	230,432
Property, plant and equipment, net	6,505	13,020
Operating lease right-of-use asset, net	16,990	19,991
Restricted cash	2,438	2,688
Intangible asset, net	20,287	27,197
Other assets	4,284	973
Total assets	**$ 167,526**	**$ 294,301**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued expenses	$ 73,562	$ 97,446
Income taxes payable	843	722
Common stock warrant liabilities	886	13,869
Operating lease liabilities, short-term	2,523	2,447
Partner company convertible preferred shares, short-term, net	3,931	2,052
Partner company line of credit	—	2,948
Partner company installment payments - licenses, short-term, net	3,000	7,235
Other short-term liabilities	163	996
Total current liabilities	84,908	127,715
Notes payable, long-term, net	60,856	91,730

Operating lease liabilities, long-term	18,282	21,572
Partner company installment payments - licenses, long-term, net	—	1,412
Other long-term liabilities	1,893	1,847
Total liabilities	**165,939**	**244,276**
Commitments and contingencies		
Stockholders' equity (deficit)		
Cumulative redeemable perpetual preferred stock, $0.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 15,093,053 and 7,366,283 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	15	7
Additional paid-in-capital	717,396	675,944
Accumulated deficit	(694,870)	(634,233)
Total stockholders' equity attributed to the Company	22,544	41,721
Non-controlling interests	(20,957)	8,304
Total stockholders' equity (deficit)	1,587	50,025
Total liabilities and stockholders' equity (deficit)	**$ 167,526**	**$ 294,301**

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

	Year Ended December 31, 2023	2022
Revenue		
Product revenue, net	$ 59,662	$ 70,995
Collaboration revenue	5,229	1,882
Revenue - related party	103	192
Other revenue	19,519	2,674
Net revenue	84,513	75,743
Operating expenses		
Cost of goods sold - product revenue	26,660	30,775
Research and development	101,747	134,199
Research and development - licenses acquired	4,324	677
Selling, general and administrative	94,124	113,656
Total operating expenses	226,855	279,307
Loss from operations	(142,342)	(203,564)
Other income (expense)		
Interest income	3,003	1,398
Interest expense and financing fee	(15,315)	(13,642)
Change in fair value of warrant liabilities	4,424	1,129
Other income (expense)	(3,403)	1,215
Total other income (expense)	(11,291)	(9,900)
Loss before income tax expense	(153,633)	(213,464)
Income tax expense	521	449
Net loss	**(154,154)**	**(213,913)**
Net loss attributable to non-controlling interests	93,517	127,338
Net loss attributable to Fortress	**(60,637)**	**$ (86,575)**
Preferred A dividends declared and paid	(8,032)	(8,032)
Net loss attributable to common stockholders	**$ (68,669)**	**(94,607)**

Net loss per common share attributable to common stockholders - basic and diluted	$ (8.47)	$ (15.97)
Weighted average common shares outstanding - basic and diluted	8,110,906	5,924,967

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[1] The development programs depicted in this press release include product candidates in development at Fortress, at Fortress' private subsidiaries (referred to herein as "subsidiaries"), at Fortress' public subsidiaries (referred to herein as "partner companies") and at entities with whom one of the foregoing parties has a significant business relationship, such as an exclusive license or an ongoing product-related payment obligation (such entities referred to herein as "partners"). The words "we", "us" and "our" may refer to Fortress individually, to one or more of our subsidiaries and/or partner companies, or to all such entities as a group, as dictated by context.

Source: Fortress Biotech, Inc.