

May 11, 2020



Fortress Biotech Reports Record First Quarter 2020 Financial Results and Recent Corporate Highlights

First quarter 2020 product revenue increased 95% year-over-year to \$11.9 million

NDA for IV tramadol accepted for review by FDA; assigned PDUFA date of October 10, 2020

Agreement executed with Columbia University to develop a broad platform technology to effectively deliver novel, proprietary oligonucleotides to bind and directly disable mutant DNA with an initial target of KRAS-driven cancers; platform is also being explored as a potential treatment for coronaviruses

NEW YORK, May 11, 2020 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (NASDAQ: FBIO) ("Fortress"), an innovative biopharmaceutical company, today announced financial results and recent corporate highlights for the first quarter ended March 31, 2020.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "The first quarter of 2020 was another record revenue quarter for Fortress Biotech. Revenue from our dermatology products marketed by our partner company, Journey Medical Corporation, increased 95% compared to the first quarter of 2019, demonstrating the strength of our commercial operations. We intend to acquire one to two new prescription products this year."

Dr. Rosenwald continued, "We also made significant progress across our robust pipeline of development-stage product candidates in the first quarter. Notably, IV tramadol was assigned a PDUFA date of October 10, 2020. If IV tramadol is approved by the FDA and Avenue Therapeutics is acquired, we would expect to realize approximately \$48 million, plus future contingent value rights. After a strong start to the year, we look forward to delivering key value-creating catalysts throughout the rest of 2020."

Recent Corporate Highlights¹:

Marketed Dermatology Products

- Our dermatology products are marketed by our partner company, Journey Medical Corporation.

- Our five marketed specialty dermatology products generated first quarter 2020 net revenues of \$11.9 million, compared to first quarter 2019 net revenues of \$6.1 million, representing growth of 95% year-over-year.
- We intend to acquire one to two new prescription products in 2020.

IV Tramadol

- In February 2020, the U.S. Food and Drug Administration ("FDA") accepted the submission of Avenue Therapeutics' New Drug Application ("NDA") for IV tramadol for review and assigned a Prescription Drug User Fee Act ("PDUFA") date of October 10, 2020. Pending a positive outcome resulting in FDA approval and other certain conditions being satisfied, a merger between Avenue and InvaGen will be completed shortly thereafter, which would result in a potential net distribution to Fortress of approximately \$48 million and future contingent value rights.
- In April 2020, Avenue announced that two e-posters highlighting efficacy and safety results from its Phase 3 program are available for online viewing from the cancelled Annual Regional Anesthesiology and Acute Pain Medicine Meeting hosted by the American Society of Regional Anesthesia and Pain Medicine ("ASRA").
 - o The e-poster (816) titled "Intravenous Tramadol is Effective in Management of Postoperative Pain Following Abdominoplasty: A 3-arm Randomized Controlled Trial" presents data from the Phase 3 abdominoplasty study and can be found [here](#).
 - o The e-poster (1001) titled "IV tramadol – A New Treatment Option for Management of Post-Operative Pain: A Safety Trial Including Various Types of Surgery" presents data from the Phase 3 safety study and can be found [here](#).
- IV Tramadol is currently in development at our partner company, Avenue Therapeutics, Inc.

CUTX-101

- In January 2020, the FDA granted Rare Pediatric Disease Designation to CUTX-101 for the treatment of Menkes disease.
- We intend to begin the rolling submission of the NDA for CUTX-101 to the FDA in the fourth quarter of 2020.
- CUTX-101 is currently in development at our partner company, Cyprium Therapeutics, Inc.

CAEL-101

- In March 2020, Caelum Biosciences, Inc. ("Caelum") began dosing patients in its Phase 2 dose selection clinical trial of CAEL-101, a light chain fibril-reactive monoclonal antibody for the treatment of AL amyloidosis.
- Caelum expects to begin its pivotal Phase 3 program in the second half of 2020.

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

- In January 2020, we announced confirmation of the registration path for cosibelimab in metastatic cutaneous squamous cell carcinoma ("CSCC"). FDA feedback supports the plan to submit a BLA based on data from the ongoing Phase 1 clinical trial. Over one-third of enrollment is complete in the cohort of patients with metastatic CSCC. There is potential for cosibelimab to be differentiated both clinically and as a lower-cost

alternative to available anti-PD-1/L1 mAbs.

- In April 2020, we announced that the U.S. Patent and Trademark Office has issued a composition of matter patent for cosibelimab. U.S. Patent No. 10,590,199 specifically covers the antibody, cosibelimab, or a fragment thereof, providing protection through at least May 2038, exclusive of any additional patent-term extensions that might become available.
- We anticipate presenting additional cosibelimab data in the second half of 2020 and expect to complete enrollment of our registration-enabling Phase 1 clinical trial in CSCC in 2021.
- Cosibelimab is currently in development at our partner company, Checkpoint Therapeutics, Inc.

MB-107 (Lentiviral Gene Therapy for XSCID)

- In April 2020, we announced that the European Medicines Agency (“EMA”) granted Advanced Therapy Medicinal Product (“ATMP”) classification to MB-107, a lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency (“XSCID”), also known as bubble boy disease.
- In May 2020, Mustang Bio submitted an Investigational New Drug (“IND”) application with the FDA to initiate a multi-center Phase 2 clinical trial of MB-107 in newly diagnosed infants with XSCID who are under the age of two. The trial is expected to enroll 10 patients who, together with 15 patients enrolled in the current multicenter trial led by St. Jude Children’s Research Hospital, will be compared with 25 matched historical control patients who have undergone hematopoietic stem cell transplant (“HSCT”). The primary efficacy endpoint will be event-free survival. The initiation of this trial is currently on hold pending CMC clearance by the FDA. Mustang is targeting topline data from the trial in the second half of 2022.
- Mustang further expects to file an IND in the third quarter of 2020 for a registrational multi-center Phase 2 clinical trial of its lentiviral gene therapy in previously transplanted XSCID patients. This product will be designated MB-207. Mustang anticipates enrolling 20 patients and comparing them to matched historical control patients who have undergone a second HSCT. Mustang is targeting topline data for this trial in the second half of 2022.
- MB-107 is currently in development at our partner company, Mustang Bio, Inc.

MB-105 (PSCA-targeted CAR T cell therapy)

- In the ongoing Phase 1 trial at City of Hope with MB-105, a PSCA-directed CAR T administered systemically to patients with PSCA-positive castration resistant prostate cancer, the first patient to receive the therapy following a standard CAR T conditioning regimen experienced a significant reduction in his prostate-specific antigen (PSA) at day 28. This PSA response was associated with radiographic improvement of the patient’s metastatic disease.
- MB-105 is currently in development at our partner company, Mustang Bio, Inc.

MB-106 (CD20-targeted CAR T cell therapy)

- In February 2020, we announced that the first subject treated with the optimized MB-106 (CD20-targeted, autologous CAR T cell therapy) manufacturing process, developed in collaboration between Mustang Bio and the Fred Hutchinson Cancer

Research Center, achieved a complete response at the lowest starting dose in an ongoing Phase 1/2 clinical trial. The trial is evaluating the safety and efficacy of MB-106 in subjects with relapsed or refractory B-cell non-Hodgkin lymphomas.

- MB-106 is currently in development at our partner company, Mustang Bio, Inc.

ONCOlogues (proprietary platform technology using PNA oligonucleotides)

- In May 2020, we entered into an exclusive worldwide licensing agreement with Columbia University to develop novel oligonucleotides for the treatment of genetically driven cancers. The proprietary platform produces oligomers, known as “ONCOlogues,” which are capable of binding gene sequences 1,000 times more effectively than complementary native DNA.
 - o ONCOlogues invade a DNA double helix and displace native mutated strands. This prevents the mRNA that antisense binds to from ever being created. It is higher upstream than an antisense approach as well as potentially more potent and broader in its utility.
- In addition, we are exploring the potential of the platform to treat novel coronaviruses, such as COVID-19.
- The “Suppression of KRAS-G12D and BRAF-V600E Oncogene Transcription with PNA Conjugates” data presentation from the European Society for Medical Oncology (ESMO) Congress in 2019 can be found [here](#).
- The ONCOlogues platform is currently in development at our partner company, Oncogenuity, Inc.

General Corporate

- In February 2020, we closed on a gross total of approximately \$14.4 million in an underwritten public offering of our 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock.
- In March 2020, our Board of Directors authorized the repurchase of up to \$5 million of Fortress’ 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock (Nasdaq: FBIOP).

Financial Results:

To assist our stockholders in understanding our company, we have prepared non-GAAP financial results for the three months ended March 31, 2020 and 2019. These results exclude the operations of our three public partner companies: Avenue Therapeutics, Inc., Checkpoint Therapeutics, Inc. and Mustang Bio, Inc., as well as any one-time, non-recurring, non-cash transactions, such as the gain of \$18.4 million we recorded in the first quarter of 2019 resulting from the de-consolidation of Caelum. 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, 2020, Fortress’ consolidated cash, cash equivalents and restricted cash totaled \$152.5 million, compared to \$153.4 million as of December 31, 2019, a decrease of \$0.9 million during the quarter.
- Fortress’ net revenue totaled \$12.9 million for the first quarter of 2020, which included \$11.9 million in net revenue generated from our marketed dermatology products. This

compares to net revenue totaling \$6.5 million for the first quarter of 2019, which included \$6.1 million in net revenue generated from our marketed dermatology products.

- On a GAAP basis, consolidated research and development expenses were \$14.9 million for the first quarter of 2020, compared to \$23.3 million for the first quarter of 2019. On a non-GAAP basis, research and development expenses were \$2.3 million for the first quarter of 2020, compared to \$1.6 million for first quarter of 2019.
- On a GAAP basis, consolidated research and development expenses from license acquisitions totaled \$0.3 million for the first quarter of 2020, compared to \$0.5 million for the first quarter of 2019.
- On a GAAP basis, consolidated general and administrative expenses were \$15.5 million for the first quarter of 2020, compared to \$13.5 million for the first quarter of 2019. On a non-GAAP basis, general and administrative expenses were \$11.6 million, of which \$5.6 million is attributed to Journey, for the first quarter of 2020, compared to \$8.5 million, of which \$3.9 million is attributed to Journey, for the first quarter of 2019.
- On a GAAP basis, consolidated net loss attributable to common stockholders was \$12.4 million, or \$0.19 per share, for the first quarter of 2020, compared to net income attributable to common stockholders of \$1.4 million, or \$0.03 per share for the first quarter of 2019, which includes the \$18.4 million gain due to the de-consolidation of Caelum.
- Fortress' non-GAAP loss attributable to common stockholders was \$4.2 million, or \$0.07 per share, for the first quarter of 2020, compared to Fortress' non-GAAP loss attributable to common stockholders of \$4.7 million, or \$0.07 per share, for the first quarter of 2019.

Use of Non-GAAP Measures:

In addition to the GAAP financial measures as presented in our Form 10-Q filed with the SEC on May 11, 2020, the Company, in this press release, has included certain non-GAAP measurements. The non-GAAP loss attributable to common stockholders is defined by the Company as GAAP net loss attributable to common stockholders, less net losses from our public partner companies: Avenue Therapeutics, Inc. (ATXI), Checkpoint Therapeutics, Inc. (CKPT) and Mustang Bio, Inc. (MBIO). 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, debt discount and depreciation.

Management believes 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, except for share and per share amounts)	For the three months ended March 31,	
	2020	2019
Net (loss) income attributable to common stockholders	\$ (12,370)	\$ 1,392
Net (loss) income attributable to common stockholders - Avenue ¹	(287)	(3,269)
Net (loss) income attributable to common stockholders - Checkpoint ²	(753)	(1,824)
Net (loss) income attributable to common stockholders - Mustang ³	(3,599)	(4,069)
Net (loss) income attributable to common stockholders - Caelum ⁴	-	18,384
Non-GAAP net loss attributable to common stockholders ^a	\$ (7,731)	\$ (7,830)
Stock based compensation	1,740	1,328
Non-cash interest	769	736
Amortization of licenses	355	234
Amortization of debt discount	488	622
Depreciation	154	193
Fortress non-GAAP loss attributable to common stockholders ^b	\$ (4,224)	\$ (4,717)
Net (loss) income per common share attributable to common stockholders - basic and diluted ⁵	\$ (0.19)	\$ 0.03
Non-GAAP net loss attributable to common stockholders ^a	\$ (0.12)	\$ (0.12)
Fortress non-GAAP loss per common share attributable to common stockholders - basic and diluted ^b	\$ (0.07)	\$ (0.07)
Weighted average common shares outstanding - basic and diluted ⁵	63,496,256	63,811,136

1. Avenue's net loss from their external SEC report for the three months ended March 31, 2020 and 2019 was \$1.2 million and \$11.3 million net of non-controlling interests of \$0.9 million and \$8.0 million, respectively.
2. Checkpoint's net loss from their external SEC report for the three months ended March 31, 2020 and 2019 was \$3.3 million net of non-controlling interests of \$2.4 million less quarterly Fortress MSA of \$0.1 million and \$5.9 million net of non-controlling interests of \$3.9 million less quarterly Fortress MSA of \$0.1 million, and \$9,000 financing stock fee, respectively.
3. Mustang's net loss from their external SEC report for the three months ended March 31, 2020 and 2019 was \$11.9 million net of non-controlling interests of \$8.0 million less quarterly Fortress MSA of \$0.1 million and financing stock fee of \$0.2 million and \$9.6 million net of non-controlling interests of \$5.4 million less quarterly Fortress MSA of \$0.1 million and no financing fee, respectively.
4. Caelum's one-time gain from de-consolidation recorded in January 2019.
5. Net income per share in Q1 of 2019 was calculated using basic weighted average common shares outstanding of 48,506,994.

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

For the three months ended March 31,

(\$ in thousands)

	2020	2019
Research and development	\$ 14,867	\$ 23,273
Less:		
Research and development Avenue	697	10,241
Research and development Checkpoint	2,635	4,581
Research and development Mustang ¹	9,252	6,898
Non-GAAP research and development costs	\$ 2,283	\$ 1,553
General and administrative	\$ 15,519	\$ 13,478
Less:		
General and administrative Avenue	577	1,119
General and administrative Checkpoint ²	1,553	1,569
General and administrative Mustang ³	1,768	2,281
Non-GAAP general and administrative costs	\$ 11,621	\$ 8,509

1. Excludes \$62,000 of Fortress MSA expense for the three months ended March 31, 2020 and 2019, respectively.
2. Excludes \$0.1 million of Fortress MSA expense for the three months ended March 31, 2020 and 2019, respectively. For the three months ended March 31, 2019 excludes \$9,000 of expense related to a financing stock fee to Fortress.
3. Excludes \$63,000 of Fortress MSA expense for the three months ended March 31, 2020 and 2019, respectively. For the three months ended March 31, 2020, excludes \$0.1 million of expense related to a financing stock fee to Fortress.

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress”) is an innovative biopharmaceutical company that was recently ranked number 10 in Deloitte’s 2019 Technology Fast 500™, an annual ranking of the fastest-growing North American companies in the technology, media, telecommunications, life sciences and energy tech sectors, based on percentage of fiscal year revenue growth over a three-year period. Fortress is focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has five 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 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., AstraZeneca, City of Hope, Fred Hutchinson Cancer Research Center, InvaGen Pharmaceuticals Inc. (a subsidiary of Cipla Limited), 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. 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)

March 31,

December 31,

	2020	2019
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 135,943	\$ 136,858
Accounts receivable (net of allowance for doubtful accounts of \$0 and \$100 at March 31, 2020 and December 31, 2019, respectively)	15,810	13,539
Inventory	769	857
Other receivables - related party	1,753	865
Prepaid expenses and other current assets	4,526	4,133
Total current assets	158,801	156,252
Property and equipment, net	12,785	12,433
Operating lease right-of-use asset, net	21,076	21,480
Restricted cash	16,574	16,574
Long-term investment, at fair value	11,148	11,148
Intangible asset, net	7,022	7,377
Other assets	1,353	1,158
Total assets	\$ 228,759	\$ 226,422
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 34,200	\$ 35,451
Accounts payable and accrued expenses - related party	13	-
Interest payable	1,081	1,042
Interest payable - related party	53	92
Notes payable, short-term (net of debt discount of \$0 at March 31, 2020 and December 31, 2019)	14,522	7,220
Operating lease liabilities - short-term	1,794	1,784
Derivative warrant liability	69	27
Total current liabilities	51,732	45,616
Notes payable, long-term (net of debt discount of \$4,354 and \$5,086 at March 31, 2020 and December 31, 2019, respectively)	70,866	77,436
Operating lease liabilities - long-term	23,647	23,712
Other long-term liabilities	7,229	7,126
Total liabilities	153,474	153,890
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 2,059,917 and 1,341,167 shares issued as of March 31, 2020 and December 31, 2019, respectively; 2,054,917 and 1,341,167 shares outstanding as of March 31, 2020 and December 31, 2019, respectively; liquidation value of \$25.00 per share	2	1
Common stock, \$.001 par value, 100,000,000 shares authorized, 78,572,169 and 74,027,425 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	79	74
Common stock issuable, 489,095 and 251,337 shares as of March 31, 2020 and December 31, 2019, respectively	661	500
Treasury stock	(70)	-
Additional paid-in-capital	485,160	461,874
Accumulated deficit	(448,604)	(436,234)
Total stockholders' equity attributed to the Company	37,228	26,215
Non-controlling interests	38,057	46,317
Total stockholders' equity	75,285	72,532
Total liabilities and stockholders' equity	\$ 228,759	\$ 226,422

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

	Three Months Ended March 31,	
	2020	2019
Revenue		
Product revenue, net	\$ 11,946	\$ 6,125
Revenue - related party	972	352
Net revenue	<u>12,918</u>	<u>6,477</u>
Operating expenses		
Cost of goods sold - product revenue	3,810	1,884
Research and development	14,867	23,273
Research and development – licenses acquired	250	450
General and administrative	15,519	13,478
Total operating expenses	<u>34,446</u>	<u>39,085</u>
Loss from operations	(21,528)	(32,608)
Other income (expense)		
Interest income	627	438
Interest expense and financing fee	(3,125)	(2,469)
Change in fair value of derivative liability	(42)	-
Gain on deconsolidation of Caelum	-	18,384
Total other (expense) income	<u>(2,540)</u>	<u>16,353</u>
Net loss	<u>(24,068)</u>	<u>(16,255)</u>
Less: net loss attributable to non-controlling interests	11,698	17,647
Net (loss) income attributable to common stockholders	<u>\$ (12,370)</u>	<u>\$ 1,392</u>
Net loss per common share - basic	\$ (0.38)	\$ (0.34)
Net loss per common share - diluted	\$ (0.38)	\$ (0.25)
Net (loss) income per common share attributable to common stockholders - basic	\$ (0.19)	\$ 0.03
Net (loss) income per common share attributable to common stockholders - diluted	\$ (0.19)	\$ 0.02
Weighted average common shares outstanding - basic	63,496,256	48,506,994
Weighted average common shares outstanding - diluted	63,496,256	63,811,136

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.