

Fortress Biotech (NASDAQ/FBIO)

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BUY: Avenue Therapeutics (ATXI), A Fortress Company, Announces Agreement with the FDA

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Avenue (ATXI-Not Rated) announced agreement with the FDA on key elements of the Phase 3 safety study, including the primary endpoint and statistical analysis approach, for intravenous (IV) tramadol, (for the treatment of acute post-operative pain) in a medically supervised setting. The agreed upon non-inferiority study is designed to assess the theoretical risk of opioid-induced respiratory depression related to opioid stacking on IV tramadol compared to IV morphine.

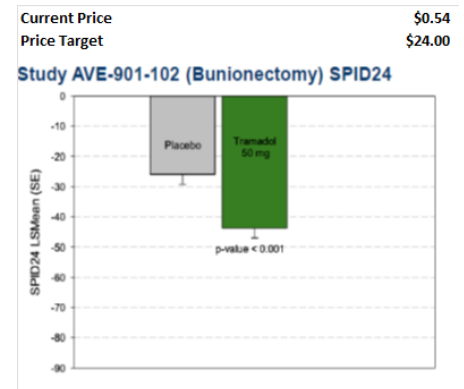
Investment Highlights

Study Design: The study plans to randomize post-bunionectomy patients to IV tramadol or IV morphine for pain relief administered during a 48-hour post-operative period. Of note, IV tramadol demonstrated safety and efficacy in this same surgical model in a Phase 3 efficacy trial. Patients will have access to IV hydromorphone, a Schedule II opioid, for rescue of breakthrough pain. The primary endpoint is a composite of elements indicative of respiratory depression. The goal is to begin the study this year.

What is Tramadol? Tramadol, which is also available under brand names such as Conzip and Ryzolt, like oxycodone are opioid medications used for pain relief. The main difference between tramadol and oxycodone is the difference in potency, or the amount of drug needed to produce its effects. Tramadol is a weak opioid with weaker opioid-like properties versus a potent opioid medication, such as oxycodone. Although both are controlled substances, meaning they have a potential for dependence and addiction, oxycodone has a higher risk of addiction and abuse. The FDA has classified oxycodone as a Schedule II controlled substance which is a high-risk classification for abuse and dependence compared to Schedule IV for tramadol.

Valuation: How to value Fortress? Fortress is a complex group of companies. Suffice to say; we model the contributions and Fortress holdings in many companies. Our valuation is based on an out-year 2030 share count. For each individual product, we make certain assumptions about the timing and probability of success and apply these assumptions to our model. We apply a probability of success in our therapeutic models. This ranges from as low as 30% to as high as 70% based on what we feel is the therapeutic risk that the product will advance. In addition to the success factor, we apply a 15% discount rate (r) in our Free Cash Flow to the Firm (FCFF), Discounted EPS (dEPS), and Sum of the Parts (SOP) models. We then average the result and round to the nearest whole number to derive our \$24.00 12-month price target.

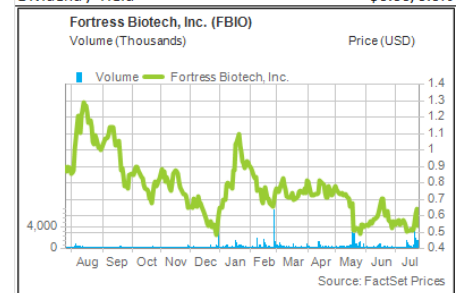
Risks to our thesis include the following: (1) commercial; (2) regulatory; (3) clinical; (4) financial; and (5) intellectual property. We review these and other risks in the Risk Analysis section of this report.



Source: Fortress

Stock Data

52-Week Range	\$0.48	-	\$1.33
Shares Outstanding (mil.)	134.3		
Market Capitalization (mil.)	\$72		
Enterprise Value (mil.)	-\$3		
Debt to Capital	103%		
Book Value/Share	\$1.03		
Price/Book	1.7		
Average Three Months Trading Volume (K)	198		
Insider Ownership	17.6%		
Institutional Ownership	12.3%		
Short interest (mil.)	0.5%		
Dividend / Yield	\$0.00/0.0%		



Risk Analysis

In addition to the typical risks associated with development-stage specialty pharmaceutical companies, potential risks specific to Fortress Biotech are as follows:

Financial risk. The company may need to raise capital in the marketplace in order to successfully push its products into the next phase, and there can be no assurances that the company will be able to successfully raise capital and/or do so on favorable terms.

Clinical and regulatory risk. Lead products must start and complete clinical trials. Trials may not produce results sufficient for regulatory approval.

Partnership risk. Fortress Biotech may seek partnerships for clinical development support and commercialization. We have no specific knowledge of any discussions with possible partners today, and there can be no assurances that the company will be able to secure a favorable partnership.

Commercial risk. There are no assurances that the company will be able to secure favorable pricing, commercially launch products, and achieve significant market share to become profitable.

Legal and intellectual property risk. The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and or that the company may infringe on third parties' patents.

Exhibit 1. Income Statement

	2019A	2020A	2021A	2022A	1Q23A	2Q23E	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Probability Revenue Forecast: ('000)																
Avenue Therapeutics: IV Tramadol end use sales			\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Percent Owned by Fortress	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%
Revenues Attributed back to Fortress																
Mustang Bio - Bubble Boy (MB-107)			\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 73,125	\$ 101,250	\$ 150,938	\$ 268,125	\$ 255,938	\$ 230,625	\$ 195,000
Percent Owned by Fortress	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Revenues Attributed back to Fortress	0	0							21,938	30,375	45,281	80,438	76,781	69,188	58,500	
Cyprium - CUTX-101 - Menkes Disease			\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 22,500	\$ 67,500	\$ 112,500	\$ 112,500	\$ 112,500	\$ 112,500
Percent Owned by Fortress	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%
Revenues Attributed back to Fortress	1	1	1							20,025	60,075	100,125	100,125	100,125	100,125	100,125
Checkpoint (Cosibelimab PD-L1)			\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 94,112	\$ 282,336	\$ 376,448	\$ 470,559	\$ 564,671	\$ 658,783
Percent Owned by Fortress	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%
Revenues Attributed back to Fortress	-	-	-	-	-	-	-	-	-	-	30,116	90,347	120,463	150,579	180,695	210,811
CK-101 end use sales			\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 271,206	\$ 542,413	\$ 813,619	\$ 867,861	\$ 922,102	\$ 976,343
Percent Owned by Fortress	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%
Revenues Attributed back to Fortress	-	-	-	-	-	-	-	-	-	86,786	173,572	260,358	277,715	295,073	312,430	
Journey Medical Corporation (Dermatology)	34,921	44,531	63,134	65,246	11,089	18,660	17,225	24,797	71,771	78,948	86,842	95,527	105,079	115,587	127,146	139,861
Percent Owned by Fortress	100%	100%	100%	47%	47%	47%	47%	47%	47%	47%	47%	47%	47%	47%	47%	47%
Revenues Attributed back to Fortress	34,921	44,531	63,134	30,666	5,212	8,770	8,096	11,654	33,732	37,105	40,816	44,898	49,387	54,326	59,759	65,734
Other Revenue Back to Fortress	1,708	1,068	5,656	4,254	1,076	1,123	1,170	1,310	4,679	5,147	5,662	6,228	6,851	7,536	8,290	9,119
Fortress Revenues	36,629	45,599	68,791	70,995	12,165	9,893	9,266	12,965	44,289	64,190	213,780	420,402	617,622	667,063	713,128	756,719
Avenue Therapeutic (IV Tramadol) Royalties (4.5% on sales > \$325M)																
Associate Milestones			\$ -													
Mustang Bio - Bubble Boy (MB-107) Prob. Adj. Royalties - 4.5%				\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 3,290.63	\$ 4,556	\$ 6,792	\$ 12,066	\$ 11,517	\$ 10,378	\$ 8,775
Associate Milestones																
Cyprium - CUTX-101 Menke's Disease - Prob. Adj. Royalties - 4.5%				\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 5,625	\$ 16,875	\$ 28,125	\$ 28,125	\$ 28,125	\$ 28,125
Associate Milestones										\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000
Checkpoint (Cosibelimab PD-L1) - Prob. Adj. Royalties - 4.5%				\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 4,235	\$ 12,705	\$ 16,940	\$ 21,175
Associate Milestones																
Checkpoint (CK-101 - TKI) - Prob. Adj. Royalties -25%				\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 12,204	\$ 24,409	\$ 36,613	\$ 39,054	\$ 41,495	\$ 43,935
Associate Milestones			\$ 2,400		\$ -	\$ -	\$ -	\$ -	\$ -	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000
Total Royalties & Milestones			72,666	4,748	12,429	-	-	-	12,429	63,291	82,386	108,076	126,039	101,401	106,938	112,011
Expenses:																
Fortress																
Costs of Goods Sold (Journey Medical)	10,532	14,594	32,084	30,775	6,449	-	-	-	6,449	-	-	-	-	-	-	-
%COGS	29%	33%	51%	47%	0%	0%	0%	0%	9%	0%	0%	0%	0%	0%	0%	0%
Research and Development (Consolidated)	75,236	64,108	113,240	134,199	35,276	33,818	36,636	38,045	140,909	147,954	155,352	163,120	171,276	179,839	188,831	198,273
Fortress		2,780														
Avenue		2,866														
Checkpoint		11,735														
Mustang		39,475														
Journey																
Other**		1,606														
Research and Development-licenses acquired	6,090	1,820	15,625	677	4,230	171	185	192	711	746	784	823	864	907	953	1,000
General and Administrative (Consolidated)	55,590	61,166	86,843	113,656	25,341	30,142	26,664	33,783	115,929	118,248	120,613	123,025	125,485	127,995	130,555	133,166
Fortress		23,341														
Avenue		2,347														
Checkpoint		6,518														
Journey Medical Corp. (SG&A)		25,659														
Mustang		6,810														
Journey																
Other**		1,184	9540													
Total Operating expenses	147,448	142,146	257,332	279,307	71,296	64,130	63,485	72,020	263,998	266,948	276,748	286,968	297,625	308,742	320,339	332,439
Total Operating expenses (Adjusted)		69,164														
Operating Income (Loss)	110,819	(96,546)	(188,541)	(203,564)	(58,867)	(54,237)	(54,219)	(59,056)	(226,379)	(139,468)	19,417	241,510	446,036	459,722	499,727	536,290
Operating Income (Loss) adjusted	-	(23,565)														
Interest income (expense), net	2,559	2,687	649	1,398	1,036	352	382	396	1,468	1,541	1,618	1,699	1,784	1,873	1,967	2,065
Interest expense and financing fee	(11,849)	(12,441)	(15,308)	(13,642)	(4,296)	(3,438)	(3,724)	(3,868)	(14,324)	(15,040)	(15,792)	(16,582)	(17,411)	(18,282)	(19,196)	(20,155)
Change in FV of derivative liability		(1,147)	39,294	(47)												
Change in FV of subsidiary convertible note			(447)		6,678											
Change in FV of investments	(27)	533			351											
Gain on deconsolidation of Caelum	18,476															
Total Other Income	9,159	(10,369)	24,188	(9,900)	3,722	(3,085)	(3,343)	(3,471)	(12,856)	(13,499)	(14,174)	(14,883)	(15,627)	(16,408)	(17,229)	(18,050)
Pretax Income (Loss) from continuing operations	(101,660)	(130,480)	(164,826)	(213,913)	(55,145)	(57,322)	(57,502)	(62,527)	(230,235)	(137,670)	4,457	185,834	344,327	350,218	371,524	388,650
Income Tax Benefit (Provision)			(447)	449						(15,297)	786	40,793	86,082	93,096	110,975	129,550
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	10%	15%	18%	20%	21%	23%	25%
GAAP Net Income (Loss)	(101,660)	(130,480)	(164,826)	(213,913)	(55,145)	(57,322)	(57,502)	(62,527)	(230,235)	(137,670)	4,457	185,834	344,327	350,218	371,524	388,650
Adjusted (Non-GAAP) Loss		(35,842)														
Less: net loss attributable to non-controlling interests	61,700	55,264	100,123	127,338	33,608	28,727	31,121	32,318	119,698	112,516	105,765	99,419	93,454	87,847	82,576	77,621
Net Income (Loss) attributable to common stockholders	(39,960)	(53,560)	(64,703)	(86,575)	(21,537)	(28,595)	(26,440)	(30,208)	(110,731)	(25,154)	110,221	285,253	437,781	438,065	454,100	466,271
GAAP EPS	(0.73)	(0.72)	(0.79)	(0.97)	(0.21)	(0.28)	(0.26)	(0.30)	(1.05)	(0.25)	1.07	2.76	4.22	4.21	4.34	4.44
GAAP-EPS (Dil)	(0.60)	(0.76)	(0.79)	(0.97)	(0.21)	(0.28)	(0.26)	(0.30)	(1.05)	(0.25)	1.07	2.76	4.22	4.21	4.34	4.44
Adjusted Non-GAAP EPS (Dil)		(0.50)														
Wgtd Avg Shrs (Bas) - '000s	54,711	71,077	81,700	88,875	101,886	101,988	102,090	102,192	102,039	102,447	102,858	103,270	103,683	104,099	104,516	104,935
Wgtd Avg Shrs (Dil) - '000s	65,502	71,077	81,700	88,875	101,886	101,988	102,090	102,192	102,039	102,447	102,858	103,270	103,683	104,099	104,516	104,935

Source: Company reports and Dawson James

** Includes the following partner companies: Aevitas, Cellvation, Cyprium, Helocyte and Tamid (a Fortress partner company that discontinued development and terminated the related licenses and clinical trial agreements with the University of North Carolina at Chapel Hill for all three of its preclinical product candidates).

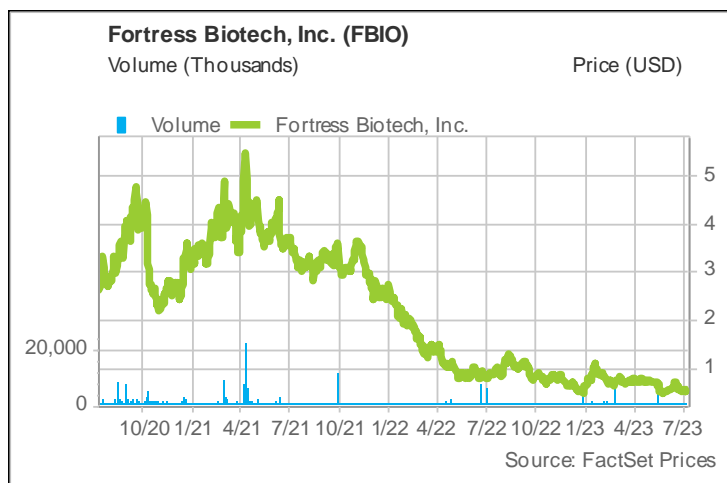
Source: Dawson James estimates and company reports

Companies that may be mentioned in this report, working with Fortress and/or part of valuation discussion:

- Alexion (ALXN/NASDAQ)-Not covered.
- Astra Zeneca (AZN/NASDAQ) – Not Covered
- InvaGen Pharmaceuticals – (Private).
- St. Jude Children’s Research Hospital (Private).
- Mustang Bio (MBIO/NASDAQ) – Not covered.
- Checkpoint Therapeutics (CKPT/NASDAQ) – Not covered.
- Avenue Therapeutics (ATXI/ NASDAQ) – Not covered.
- Caelum Biosciences (Private).
- Journey Medical Corporation (DERM).
- Cyprium Therapeutics (Private).
- Fuji Yakuhin (subsidiary of Fuji-Japan – Not Covered)
- Dr. Reddy’s Laboratories Ltd. (RDY-Not Covered)

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:

- Initiated – Buy August 26, 2019, Price Target \$19.00
- Update – Buy September 17, 2019, Price Target \$19.00
- Update – Buy November 4, 2019, Price Target \$19.00
- Update – Buy December 11, 2019, Price Target \$19.00
- Update – Buy December 23, 2019, Price Target \$19.00
- Update – Buy January 15, 2020, Price Target \$19.00
- Update – Buy February 14, 2020, Price Target \$19.00
- Update – Buy February 20, 2020, Price Target \$19.00
- Update – Buy March 30, 2020, Price Target \$19.00
- Update – Buy May 14, 2020, Price Target \$19.00
- Update – Buy July 31, 2020, Price Target \$19.00
- Update – Buy September 8, 2020, Price Target \$19.00
- Price Target Change – Buy October 12, 2020, Price Target \$15.00
- Update – Buy October 20, 2020, Price Target \$15.00
- Price Target Change – Buy November 10, 2020, Price Target \$16.00
- Update – Buy December 14, 2020, Price Target \$16.00
- Update – Buy February 2, 2021, Price Target \$16.00

Price Target Change – Buy February 17, 2021, Price Target \$21.00
Price Target Change – Buy February 24, 2021, Price Target \$22.00
Price Target Change – Buy April 7, 2021, Price Target \$24.00
Update – Buy April 13, 2021, Price Target \$24.00
Update – Buy May 10, 2021, Price Target \$24.00
Update – Buy May 20, 2021, Price Target \$24.00
Update – Buy June 11, 2021, Price Target \$24.00
Update – Buy June 15, 2021, Price Target \$24.00
Update – Buy August 17, 2021, Price Target \$24.00
Update – Buy September 29, 2021, Price Target \$24.00
Update – Buy October 26, 2021, Price Target \$24.00
Update – Buy November 19, 2021, Price Target \$24.00
Update – Buy February 17, 2022, Price Target \$24.00
Update – Buy March 28, 2022, Price Target \$24.00
Update – Buy May 17, 2022, Price Target \$24.00
Update – Buy August 11, 2022, Price Target \$24.00
Update – Buy October 7, 2022, Price Target \$24.00
Update – Buy January 25, 2023, Price Target \$24.00
Update – Buy April 12, 2023, Price Target \$24.00
Update – Buy July 3, 2023, Price Target \$24.00
Update – Buy July 12, 2023, Price Target \$24.00
Update – Buy July 26, 2023, Price Target \$24.00

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Information about valuation methods and risks can be found in the “VALUATION” and “RISK ANALYSIS” sections of this report.

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Rating Definitions:

- 1) **Buy:** the analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** the analyst believes the price of the stock is fairly valued for the next 12-18

- months;
- 3) **Sell:** the analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies, followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Current as of 17-Jul-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	25	69%	2	5.50%
Market Perform (Neutral)	11	31%	2	5.50%
Market Underperform (Sell)	0	0%	0	0.00%
Total	36	100%	4	11.00%

Analyst Certification:

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