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Fortress Biotech (NASDAQ/FBIO)

September 29, 2021

BUY: \$64M payable to Fortress- AstraZeneca's Alexion

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AstraZeneca's Alexion has notified Caelum that regulatory hurdles (Hart-Scott-Rodino (HSR)) have been cleared paving the way for the acquisition of Caelum. Under terms of the agreement, upon closing of the acquisition, which is expected to take place on October 5, 2021, Alexion will purchase all of the outstanding shares of Caelum and will pay Caelum the agreed option exercise price of approximately \$150 million. Distributions will be made to all existing Caelum stockholders. The agreement also provides for additional potential payments to Caelum stockholders totaling up to \$350 million, payable upon the achievement of regulatory and commercial milestones. Fortress is eligible to receive approximately 43% of all proceeds from the transaction.

Investment Highlights

What is CAEL-101? It is a potentially first-in-class monoclonal antibody (mAb) designed to improve organ function by reducing or eliminating amyloid deposits in the tissues and organs of patients with AL amyloidosis. The antibody is designed to bind to misfolded light chain protein and amyloid and shows binding to both kappa and lambda subtypes. CAEL-101 has received Orphan Drug Designation from both the U.S. Food and Drug Administration and the European Commission as a potential therapy for patients with AL amyloidosis. Additionally, the U.S. FDA granted Fast Track Designation to CAEL-101 for AL amyloidosis in June 2021.

What is Amyloidosis? Amyloidosis is a rare systemic disorder caused by an abnormality of plasma cells in the bone marrow. Misfolded immunoglobulin light chains produced by plasma cells aggregate and form fibrils that deposit in tissues and organs. This deposition can cause widespread and progressive organ damage and high mortality rates, with death most frequently occurring as a result of cardiac failure. Approximately 20,000 people across the US, France, Germany, Italy, Spain and the UK live with AL amyloidosis classified as Mayo stage IIIa or IIIb disease.

What Stage of Development is CAEL-101 in Now? It is currently in a pivotal (Phase 3 "CARES" study with Alexion for amyloidosis. Recall that Caelum formed a collaboration with Alexion in 2019, which includes an option to acquire Caelum.

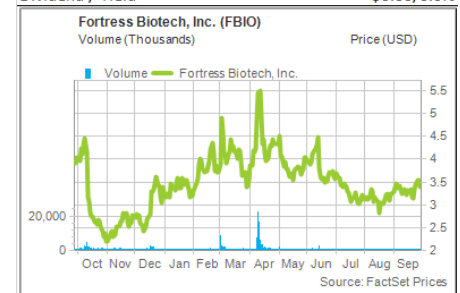
Other Fortress News: Journey Gets Hacked for \$9M. Fortress has learned that its subsidiary Journey Medical Corporation has been the victim of a business e-mail compromise cybersecurity incident affecting its accounts payable function that led to approximately \$9.5M in wire transfers being misdirected to apparently fraudulent accounts. Fortress is providing Journey with \$9.5M to ensure Journey's accounts payable operations continue to function smoothly.

Current Price	\$3.40
Price Target	\$24.00

	Commercial	Late Clinical	Early Clinical	Preliminary
Target #	OUTX-101	MB-102	ATYS-001 Gene Therapy	
Asset #	Covalimab	OK-101	AM-ATP7A Gene Therapy	
Target #	CAEL-101	MB-101	Anti-GITR	
Target #	IV Transferrin	MB-105	Anti-CDX	
Target #	MB-107	MB-103	OK-103	
Target # **	MB-207	MB-106	CEVA-102	
Target # ***	CEVA-101	MB-104	Contax	
		MB-105	KRAS G12D Oncologues	
		BAER-101	Multiple Other Oncologues	
		Triplex		
		Dobsonid		

Source: Fortress

Stock Data	
52-Week Range	\$2.12 - \$6.10
Shares Outstanding (mil.)	101.1
Market Capitalization (mil.)	\$344
Enterprise Value (mil.)	\$269
Debt to Capital	22%
Book Value/Share	\$1.03
Price/Book	3.0
Average Three Months Trading Volume (K)	441
Insider Ownership	24.2%
Institutional Ownership	25.6%
Short interest (mil.)	0.9%
Dividend / Yield	\$0.00/0.0%



Valuation: How to value Fortress? As a reminder, Fortress, as the controlling entity, reports consolidated statements. Our valuation expenses are based on GAAP numbers, but we recognize this is conservative. If we substituted Non-GAAP projections, it would actually result in a higher valuation. There are multiple ways to value a "platform therapeutics company" such as Fortress that has a majority ownership in multiple public companies with the rights to royalties and milestones (such as monetization of a priority voucher), plus the company has its own internal products that are generating revenues and internal private companies that have their own therapeutic pipeline candidates. We choose to model the key products as they exist (inside and outside the company) and project them based on the ownership percentage to the Fortress income statement. We recognize that this is a "model." It is a method to forecast future value, i.e., reporting the revenues of outside companies based on the percentage ownership (not as a 100% consolidated entity), but we do show the consolidated expenses as they are currently reported by Fortress. We view our method as doubly conservative; that is, we cut the revenues but not the expenses. One might argue we need to assess each outside company, determine net income, and apply valuation metrics, based on the projected value of the external company. We leave that for "others" to do, as our purpose is to determine: is their upside to Fortress based on the value of the holding in the external companies, the product royalties, the annual stock dividend, and the internal companies and P&L metrics of Fortress itself? We conclude yes. In our model, we do separate and show our projected revenues, royalties, and milestones. We model external and internal products. We then assume R&D, SG&A based on the current consolidated numbers. We project the share count as well as revenues, expenses, and, ultimately, net income out to 2030. 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.

Exhibit 1. Income Statement

	2019A	2020A	1Q21A	2Q21A	3Q21E	4Q21E	2021E	1Q22E	2Q22E	3Q22E	4Q22E	2022E	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%	32%	32%	32%	32%
Revenues Attributed back to Fortress	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Mustang Bio - Bubble Boy (MB-107)																				
Percent Owned by Fortress	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Revenues Attributed back to Fortress	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Cyprum - CUTX-101 - Menkes Disease																				
Percent Owned by Fortress	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%
Revenues Attributed back to Fortress	1	1	0	0	0	0	1	4,606	5,407	4,406	5,607	20,025	60,075	100,125	140,175	160,200	160,200	160,200	160,200	160,200
CheckPoint (Cosibelimab PD-L1)																				
Percent Owned by Fortress	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%
Revenues Attributed back to Fortress	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CK-101 end use sales																				
Percent Owned by Fortress	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%	32%
Revenues Attributed back to Fortress	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Journey Medical Corporation (Dermatology)																				
Percent Owned by Fortress	34,921	44,531	10,719	15,288	15,000	15,000	53,437	12,536	14,171	13,081	14,716	54,506	59,956	65,952	72,547	79,802	87,782	96,560	106,216	116,837
Percent Owned by Fortress	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Revenues Attributed back to Fortress	34,921	44,531	10,719	15,288	15,000	15,000	56,007	12,536	14,171	13,081	14,716	54,506	59,956	65,952	72,547	79,802	87,782	96,560	106,216	116,837
Other Revenue Back to Fortress	1,708	1,068	868	155	150	150	1,323	230	240	250	280	1,000	1,100	1,210	1,331	1,464	1,611	1,772	1,949	2,144
Fortress Revenues	36,629	45,599	11,587	15,443	15,150	15,150	57,331	23,194	26,653	23,306	27,691	100,843	271,499	447,756	566,102	654,970	728,851	776,826	822,601	867,109
Avenue Therapeutic (IV Tramadol) Royalties (4.5% on sales > \$325M)																				
Associate Milestones							\$ -													
Mustang Bio - Bubble Boy (MB-107) Prob. Adj. Royalties - 4.5%								\$ 873	\$ 1,025	\$ 835	\$ 1,063	\$ 3,797	\$ 8,100	\$ 11,517.19	\$ 12,530	\$ 12,023	\$ 14,766	\$ 13,500	\$ 11,770	\$ 9,703
Associate Milestones																				
Cyprum - CUTX-101 Menke's Disease - Prob. Adj. Royalties - 4.5%								\$ 311	\$ 365	\$ 297	\$ 378	\$ 1,350	\$ 11,475	\$ 28,125	\$ 39,375	\$ 45,000	\$ 45,000	\$ 45,000	\$ 45,000	\$ 45,000
Associate Milestones								\$ 2,300	\$ 2,700	\$ 2,200	\$ 2,800	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000
CheckPoint (Cosibelimab PD-L1) - Prob. Adj. Royalties - 4.5%								\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 1,348	\$ 4,235	\$ 8,470	\$ 12,705	\$ 16,940	\$ 21,175
Associate Milestones																				
CheckPoint (CK-101 - TKI) - Prob. Adj. Royalties -25%													\$ 12,204	\$ 24,409	\$ 29,290	\$ 34,172	\$ 36,613	\$ 39,054	\$ 41,495	\$ 43,935
Associate Milestones							\$ 2,400					\$ 9,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000	\$ 50,000
Total Royalties & Milestones	-	-	11,587	17,843	15,150	15,150	59,731	3,484	13,090	3,332	4,241	24,147	91,779	124,051	142,542	155,430	149,849	120,259	125,205	129,814
Expenses:																				
Fortress																				
Costs of Goods Sold (Journey Medical)	10,532	14,594	3,908	7,484	3,000	3,000	17,392	2,507	2,834	2,616	2,943	10,901	11,991	13,190	14,509	15,960	17,556	19,312	21,243	23,367
%COGS	29%	33%	20%	49%	20%	20%	33%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Research and Development (Consolidated)	75,236	64,108	20,154	22,831	17,501	18,175	67,313	16,256	16,963	18,377	19,083	70,679	74,213	77,924	81,820	85,911	90,206	94,717	99,453	104,425
Fortress		2,780																		
Avenue		2,866																		
Checkpoint		11,735																		
Mustang		39,475																		
Other**		1,606																		
Research and Development- licenses acquired	6,090	1,920		11,003	3,120	3,240	12,000	3,680	3,840	4,160	4,320	16,000	16,800	17,640	18,522	19,448	20,421	21,442	22,514	23,639
General and Administrative (Consolidated)	55,590	61,166	17,542	19,382	14,350	11,116	62,389	15,909	16,546	14,637	16,546	63,637	64,910	66,208	67,532	68,883	70,261	71,666	73,099	74,561
Fortress		23,341																		
Avenue		2347																		
Checkpoint		6518																		
Journey Medical Corp. (SG&A)		25,659																		
Mustang		6810																		
Other**		1,184																		
Total Operating expenses	147,448	142,146	41,604	60,700	37,971	35,530	159,095	38,353	40,183	39,789	42,892	161,217	167,914	174,962	182,383	190,202	198,444	207,136	216,308	225,993
Total Operating expenses (Adjusted)		69,164																		
Operating Income (Loss)	110,819	(96,546)	(30,017)	(42,857)	(7,670)	(5,230)	(85,774)	(11,675)	(441)	(13,151)	(10,960)	(36,227)	195,365	396,845	526,261	620,199	680,256	689,949	731,497	770,930
Operating Income (Loss) adjusted		(23,565)																		
Interest income (expense), net	2,559	2,687	227	146	734	762	2,821	681	711	770	800	2,962	3,110	3,266	3,429	3,601	3,781	3,970	4,168	4,377
Interest expense and financing fee	(11,849)	(12,441)	(2,189)	(2,760)	(3,397)	(3,527)	(13,064)	(3,155)	(3,292)	(3,566)	(3,704)	(13,717)	(14,403)	(15,123)	(15,879)	(16,673)	(17,506)	(18,382)	(19,301)	(20,266)
Change in FV of derivative liability							30,918													
Change in FV of subsidiary convertible note	(27)	533																		
Change in FV of investments	18,476																			
Gain on deconsolidation of Caelum	9,159	(10,369)	3,951	18,466	(2,663)	(2,765)	20,676	(2,473)	(2,581)	(2,796)	(2,904)	(10,754)	(11,292)	(11,857)	(12,449)	(13,072)	(14,412)	(15,132)	(15,889)	
Pre-tax Income (loss from continuing operations)	(101,660)	(130,480)	(26,066)	(24,391)	(10,333)	(7,995)	(65,098)	(14,149)	(3,022)	(15,948)	(13,864)	(46,982)	184,073	346,489	436,740	497,844	533,224	533,674	551,601	566,281
Income Tax Benefit (Provision)														38,499	77,072	109,283	133,306	141,863	164,764	188,760
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	10%	15%	18%	20%	21%	23%	25%
GAAP Net Income (Loss)	(101,660)	(130,480)	(26,066)	(24,391)	(10,333)	(7,995)	(65,098)	(14,149)	(3,022)	(15,948)	(13,864)	(46,982)	184,073	346,489	436,740	497,844	533,224	533,674	551,601	566,281
Adjusted (Non-GAAP) Loss		(35,842)																		
Less: net loss attributable to non-controlling interests	61,700	55,264	17,244	20,856	15,087	15,667	58,027	12,946	13,509	14,634	15,197	56,286	52,909	49,735	46,751	43,946	41,309	38,830	36,500	34,310
Net Income (loss) attributable to common stockholders	(39,960)	(63,560)	(8,822)	(9,535)	4,754	7,672	89	(1,203)	(10,487)	(1,313)	1,333	9,305	236,982	396,224	483,491	541,789	574,533	572,504	588,102	600,591
GAAP-EPS	(0.73)	(0.76)	(0.11)	(0.04)	0.06	0.08	0.00	(0.01)	0.13	(0.02)	0.02	0.11	2.90	4.83	5.87	6.56	6.92	6.87	7.03	7.15
GAAP-EPS (Dil)	(0.60)	(0.76)	(0.11)	(0.04)	0.06	0.09	0.00	(0.01)	0.13	(0.02)	0.02	0.11	2.90	4.83	5.87	6.56	6.92	6.87	7.03	7.15
Adjusted Non-GAAP EPS (DIL)		(0.50)																		
Wtd Avg Shrs (Bas) - '000s	54,711	71,077	80,852	80,963	81,044	81,125	80,996	81,206	81,287	81,369	81,450	81,328	81,654	81,981	82,309	82,639	82,970	83,303	83,636	83,971
Wtd Avg Shrs (Dil) - '000s	65,502	71,077	80,852	80,963	81,044	81,125	80,996	81,206	81,287	81,369	81,450	81,328	81,654	81,981	82,309	82,639	82,970	83,303	83,636	83,971

Source: Company reports and Dawson James

** Includes the following partner companies: Aevitas, Cellvation, Cyprum, Helocyte and Tarnid (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).

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.

Companies 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).

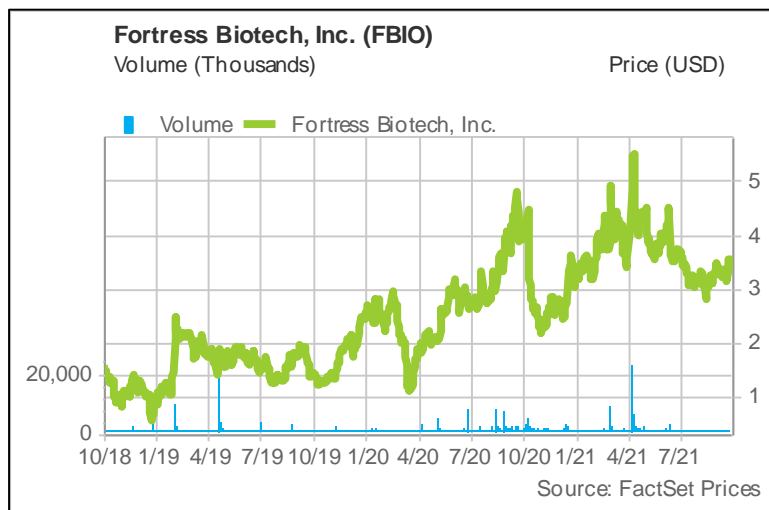
Journey Medical Corporation (internal Fortress company).

Cyprium Therapeutics (Private).

Fuji Yakuhin (subsidiary of Fuji-Japan – 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

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Although the statements in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice.

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... 27-Aug-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	26	72%	4	15%
Market Perform (Neutral)	10	28%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	4	11%

Analyst Certification:

The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his (their) personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) all Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service-specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of

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