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Caladrius (NASDAQ/CLBS)

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Neutral: Delays, Delays & Delays + Burning Cash

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Caladrius has fallen to \$0.90 from \$1.61 (2.15.21) when we wrote "Dam the Shareholders Full Speed Ahead", commenting on the highly dilutive capital raise. Revisiting the story, we see little progress. Caladrius reported 3Q21 results spending \$7M in the quarter, steadily whittling down its \$100M in cash balance but to what end? We note multiple delays across previously promoted programs such as CLI in Japan, now suspended.

Investment Highlights

HONDERA (CLBS12) – Suspended for CLI in Japan – This was planned as a small Phase 2 study, an interventional, open-label, proof-of-concept (POC) trial planned for two centers, but the company had problems finding patients, blaming COVID. Caladrius now says the program is suspended until a Japanese partner is identified. We remain skeptical and see this program as "dead."

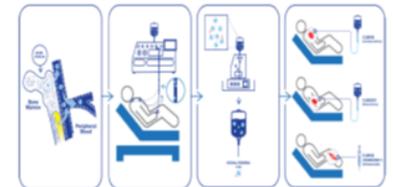
XOWNA (CLBS16) – Enrollment has Slowed: The product is currently being evaluated in a P2b study in patients with CMD and without obstructive coronary artery disease. Patient enrollment is behind schedule, so the company has been expanding the number of sites and modifying the study protocol. These protocol amendments were implemented in the latter part of the quarter. We see these as "red flags."

Management was Pushing the CD34+ cells as a COVID Play – This appears to have fizzled out. Is anyone surprised? **What's the Problem?** On just about every level, we find management's explanations across multiple programs as lacking. Management seems to lack an understanding of 1. the competitive environment. Multiple off-the-shelf, allogeneic companies are already treating COVID patients but on ventilators and potentially earlier, and recent failures of other cell therapies in COVID due to improved standard of care. 2. For example, in COVID, using cells to ameliorate the after-effects of ventilator therapy for COVID patients is a great idea, BUT a) harvesting cells from these patients is not ideal; b) how do you measure how effective your treatment is? For NORDA, we see a POC trial as a \$65M and multi-year investment. What size trial is needed to measure the effect versus standard of care? 3. Caladrius's autologous therapy is very late in the field.

Valuation. For Caladrius, we previously lowered our rating to Neutral from Buy (March 2020) and removed our price target. Our model uses our highest discount rate of 30% in our free cash flow to the Firm (FCFF), discounted EPS, and Sum of the Parts (SOP) models. Our models go out to 2029 and have been updated for the recent dilution. The company now has a negative enterprise value, but we believe that won't last as its likely management will now be on a spending spree. Spending on clinical trials that we feel go nowhere and or looking to make an acquisition. Our bottom-line concern is that Caladrius has, in our opinion, missed the window. Allogenic competitors are advancing now in heart failure, back pain, stroke, CLI, GvHD, and three companies are today treating COVID patients for ARDS

Risks to our thesis include the following: (1) commercial; (2) regulatory; (3) clinical; (4) manufacturing; (5) financial; (6) liability; and (7) intellectual property.

Current Price **\$0.90**
Price Target **NA**
Caladrius' CD34+ cell process is rapid/economical/scaled



DAY 0 to 1 CD34+ cell mobilization

DAY 1 Sample collection

DAY 2 ISOLATION

DAY 3 or 4 CD34+ cell infusion

- Drug induced mobilization eliminates need for surgical bone marrow aspiration
- No genetic manipulation or ex vivo expansion of cells
- Four days or less from donation to treatment

Source: Caladrius

Stock Data		
52-Week Range	\$0.82 -	\$4.89
Shares Outstanding (mil.)		59.8
Market Capitalization (mil.)		\$54
Enterprise Value (mil.)		\$17
Debt to Capital		3%
Book Value/Share		\$5.33
Price/Book		0.9
Average Three Months Trading Volume (K)		294
Insider Ownership		3.2%
Institutional Ownership		30.2%
Short interest (mil.)		1.8%
Dividend / Yield		\$0.00/0.0%

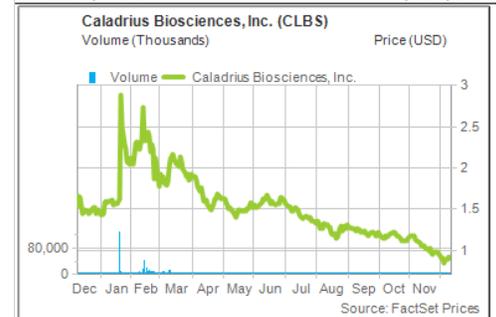


Exhibit 1. Income Statement

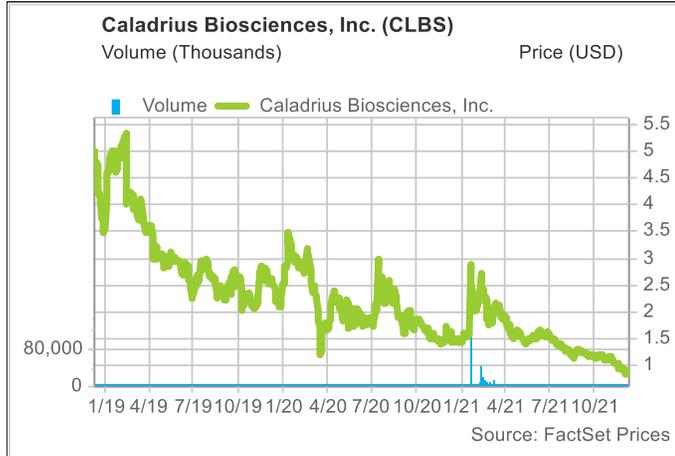
Caladrius Inc.: Income Statement (\$'000)																
YE December 31	2018A	2019A	2020E	1Q21A	2Q21A	3Q21A	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Product sales																
Cell Therapy - CLI Japan						-	-	-	-	1,929	3,859	5,673	7,413	9,082	8,901	8,724
Cell Therapy - CLI USA										-	-	-	-	-	-	-
Cell Therapy - CLI Europe										-	-	-	-	-	-	-
Cell Therapy - Coronary Microvascular Dysfunction USA										-	-	-	70,484	366,692	457,853	476,397
Cell Therapy - Coronary Microvascular Dysfunction Europe										-	-	-	48,914	101,790	158,869	275,507
Cell Therapy - Coronary Microvascular Dysfunction Japan										-	-	-	-	-	-	-
Cell Therapy - No Option Refractory Disabling Angina (NORDA) USA										-	-	-	9,171	28,629	59,576	61,989
Cell Therapy - No Option Refractory Disabling Angina (NORDA) Europe										-	-	-	3,151	6,493	10,033	17,227
Cell Therapy - No Option Refractory Disabling Angina (NORDA) Japan										-	-	-	-	-	-	-
Total Product Sales	-	-	-	-	-	-	-	-	-	1,929	3,859	5,673	139,133	512,686	695,233	839,843
Expenses																
Cost of Goods Sold - Products	-	-	-	-	-	-	-	-	-	637	1,158	1,815	43,131	153,806	201,617	235,156
% COGS (of product revenues)				35%	35%	35%	35%	#DIV/0!	#DIV/0!	33%	30%	32%	31%	30%	29%	28%
Research and Development	7,594	10,797	14,000	5,076	4,329	4,125	4,760	17,000	18,700	21,000	23,100	25,410	27,951	30,746	33,821	37,203
%R&D										1088%	599%	448%	377%	339%	380%	426%
General and Administrative	9,393	9,296	10,226	3,010	2,818	2,843	3,149	11,248	12,373	18,000	25,000	27,500	34,000	40,000	44,000	48,400
%SG&A										933%	648%	485%	459%	440%	494%	555%
Total expenses	16,987	20,093	20,482	8,086	7,147	6,968	7,909	30,110	31,073	39,637	49,258	54,725	105,082	224,552	279,438	320,759
Operating Income (Loss)	(16,987)	(20,093)	(20,482)	(8,086)	(7,147)	(6,968)	(7,909)	(30,110)	(31,073)	(37,707)	(45,399)	(49,053)	34,051	288,134	415,795	519,084
Other expense	824	740	143	23	47	41	41	152	799	799	799	799	799	799	799	799
Interest expense	(5)	(0)	(0)	(0)	(90)	(0)	(0)	(90)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Total other income	819	740	143	23	(43)	41	41	62	793	793	793	793	793	793	793	793
Pretax Income	(16,168)	(19,353)	(20,340)	(8,063)	(7,190)	(6,927)	(7,869)	(30,049)	(30,280)	(36,914)	(44,606)	(48,259)	34,844	288,927	416,588	519,878
Income Tax Benefit (Provision)	-	-	(10,872)		1,508			1,508				(4,826)	6,272	57,785	104,147	155,963
Tax Rate												10%	18%	20%	25%	30%
Less: Loss from continuing operations attributable to noncontrolling interests	(1)	(9)														
GAAP Net Income (loss)	(16,168)	(19,362)	(9,468)	(8,063)	(5,682)	(6,927)	(7,869)	(31,557)	(30,280)	(36,914)	(44,606)	(43,433)	28,572	231,142	312,441	363,915
GAAP-EPS	(1.67)	(1.87)	(0.45)	(0.19)	(0.10)	(0.12)	(0.13)	(0.53)	(0.51)	(0.61)	(0.74)	(0.80)	0.47	3.79	5.10	5.91
GAAP EPS (dil)	(1.67)	(1.88)	(0.40)	(0.19)	(0.10)	(0.12)	(0.07)	(0.47)	(0.25)	(0.30)	(0.36)	(0.35)	0.22	1.79	2.39	2.75
Wgtd Avg Shrs (Bas) - '000s	9,689	10,323	16,497	42,117	59,510	59,614	59,674	55,229	59,823	60,063	60,303	60,545	60,787	61,031	61,275	61,521
Wgtd Avg Shrs (Dil) - '000s	9,689	10,323	17,747	42,117	59,510	59,614	119,347	70,147	120,722	122,295	123,889	125,504	127,139	128,796	130,475	132,175

Source: Dawson James estimates, company reports

Important Disclosures:

Other Companies Mentioned in this Report:

Price Chart:



Price target and rating changes over the past three years:

- Initiated – Buy – February 27, 2019 – Price Target \$7.0
- Update – Buy – May 23, 2019 – Price Target \$7.0
- Update – Buy – June 4, 2019 – Price Target \$7.0
- Update – Buy – July 15, 2019 – Price Target \$7.0
- Update – Buy – August 12, 2019 – Price Target \$7.0
- Update – Buy – November 7, 2019 – Price Target \$7.0
- Update – Buy – November 18, 2019 – Price Target \$7.0
- Update – Buy – March 6, 2020 – Price Target \$7.0
- Rating Change – Neutral – March 18, 2020 Price Target NA
- Update – Neutral – November 6, 2020 Price Target NA
- Update – Neutral – November 19, 2020 Price Target NA
- Update – Neutral – February 15, 2021- Price Target NA
- Update – Neutral – December 10, 2021- Price Target NA

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- 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.

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Current as of... 1-Dec-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	24	67%	5	21%
Market Perform (Neutral)	12	33%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	5	14%

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