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Caladrius (NASDAQ/CLBS)

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Neutral: Is the Autologous Model Flawed? Yes

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Caladrius continues to spend cash on their CD34+ autologous cell therapy for a host of regenerative conditions. We see no sensitivity to dilution by management and believe the company, which had \$95M in cash at year's end, is likely to raise capital if the opportunity arises. Fundamentally, we remain skeptical about the advantages of an autologous model in the regenerative medicine space. All of the current data suggests that allogeneic models (aka: off-the-shelf ready product, like pills in a bottle) are equally viable (and may be superior in terms of potency) with a time advantage (immediately "off the shelf" available) and significant cost advantages. We believe Caladrius is spending to deliver a flawed product that will be a third or fourth to the market.

Investment Highlights

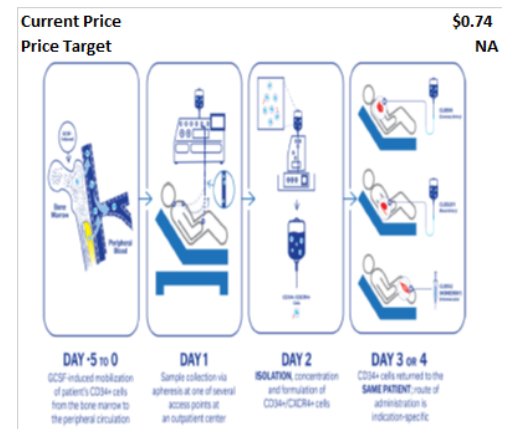
HONDERA – Remains Suspended for CLI in Japan – This was planned as a small Phase 2 study, an interventional, open-label, proof-of-concept (POC) trial planned for two centers, but the company had problems finding patients, blaming COVID. Caladrius now says the program is suspended until a Japanese partner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

XOWNA – Enrollment has Slowed now extends to 2023 and beyond: 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."

No Mention of the CD34+ cells as a COVID Play that Management has been Pushing – This appears to have fizzled out. 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. 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 recent dilution.

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



Source: Caladrius

Stock Data		
52-Week Range	\$0.63 -	\$2.07
Shares Outstanding (mil.)		59.8
Market Capitalization (mil.)		\$44
Enterprise Value (mil.)		\$7
Debt to Capital		3%
Book Value/Share		\$5.33
Price/Book		0.9
Average Three Months Trading Volume (K)		434
Insider Ownership		3.5%
Institutional Ownership		16.2%
Short interest (mil.)		1.2%
Dividend / Yield		\$0.00/0.0%

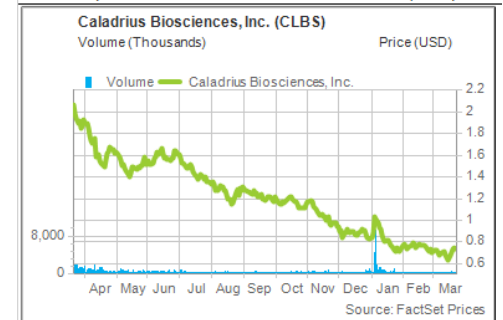


Exhibit 1. Income Statement

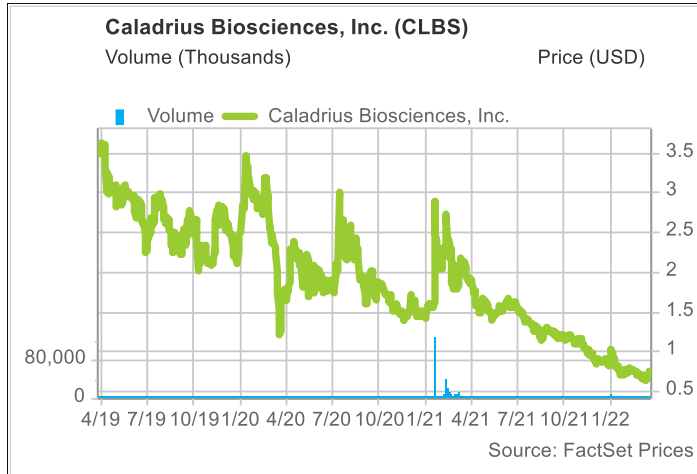
Caladrius Inc.: Income Statement (\$'000)	2018A	2019A	2020E	2021A	1Q22E	2Q22E	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
YE December 31																
Product sales																
Cell Therapy - CLI Japan					-	-	-	-	-	-	-	-	1,853	3,633	5,341	6,979
Cell Therapy - CLI USA					-	-	-	-	-	-	-	-	-	22,428	27,454	32,674
Cell Therapy - CLI Europe					-	-	-	-	-	-	-	-	-	-	-	15,683
Cell Therapy - Coronary Microvascular Dysfunction USA					-	-	-	-	-	-	-	-	-	-	25,436	52,933
Cell Therapy - Coronary Microvascular Dysfunction Europe					-	-	-	-	-	-	-	-	-	-	-	18,367
Cell Therapy - Coronary Microvascular Dysfunction Japan					-	-	-	-	-	-	-	-	-	9,425	19,614	30,612
Cell Therapy - No Option Refractory Disabling Angina (NORDA) USA					-	-	-	-	-	-	-	-	-	3,181	6,620	10,332
Cell Therapy - No Option Refractory Disabling Angina (NORDA) Europe					-	-	-	-	-	-	-	-	-	3,246	6,689	10,336
Cell Therapy - No Option Refractory Disabling Angina (NORDA) Japan					-	-	-	-	-	-	-	-	-	530	1,103	1,722
Total Product Sales													1,853	42,443	92,256	179,638
Expenses																
Cost of Goods Sold - Products					-	-	-	-	-	-	-	-	575	12,733	26,754	50,299
% COGS (of product revenues)					34%	34%	34%	34%	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	31%	30%	29%	28%
Research and Development	7,594	10,797	9,253	17,680	4,279	4,668	5,056	5,445	19,448	21,000	23,100	25,410	27,951	30,746	33,821	37,203
%R&D					#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	1508%	846%	633%	533%
General and Administrative	9,393	9,296	9,892	11,370	2,752	3,002	3,252	3,502	12,507	18,000	25,000	27,500	34,000	40,000	44,000	48,400
%SG&A					#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	1835%	1101%	824%	693%
Total expenses	16,987	20,093	19,145	29,050	7,030	7,669	8,308	8,947	31,955	39,000	48,100	52,910	62,526	83,479	104,575	135,901
Operating Income (Loss)	(16,987)	(20,093)	(19,145)	(29,050)	(7,030)	(7,669)	(8,308)	(8,947)	(31,955)	(39,000)	(48,100)	(52,910)	(60,672)	(41,036)	(12,319)	43,736
Other expense	824	740	132	151	178	194	214	214	799	799	799	799	799	799	799	799
Interest expense	(5)	(0)	(75)	(75)	(3)	(2)	(0)	(0)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Total other income	819	740	132	76	174	192	214	214	793	793	793	793	793	793	793	793
Pretax Income	(16,168)	(19,353)	(19,013)	(28,974)	(6,856)	(7,477)	(8,095)	(8,734)	(31,162)	(38,207)	(47,307)	(52,117)	(59,879)	(40,243)	(11,525)	44,530
Income Tax Benefit (Provision)	-	-	(10,872)	(1,508)	-	-	-	-	-	-	-	(5,212)	(10,778)	(8,049)	(2,881)	13,359
Tax Rate												10%	18%	20%	25%	30%
Less: Loss from continuing operations attributable to noncontrolling interests	(1)	(9)	(9)													
GAAP Net Income (loss)	(16,168)	(19,362)	(8,150)	(27,466)	(6,856)	(7,477)	(8,095)	(8,734)	(31,162)	(38,207)	(47,307)	(46,905)	(49,101)	(32,194)	(8,644)	31,171
GAAP-EPS	(1.67)	(1.87)	(0.53)	(0.50)	(0.11)	(0.12)	(0.13)	(0.14)	(0.51)	(0.62)	(0.76)	(0.84)	(0.79)	(0.51)	(0.14)	0.49
GAAP EPS (dil)	(1.67)	(1.88)	(0.53)	(0.50)	(0.06)	(0.06)	(0.07)	(0.07)	(0.25)	(0.31)	(0.38)	(0.37)	(0.38)	(0.25)	(0.07)	0.23
Wgtd Avg Shrs (Bas) - '000s	9,689	10,323	15,540	55,313	61,290	61,351	61,412	61,474	61,382	61,628	61,875	62,122	62,371	62,621	62,872	63,124
Wgtd Avg Shrs (Dil) - '000s	9,689	10,323	15,540	55,313	122,580	122,702	122,825	122,948	122,764	124,363	125,984	127,626	129,290	130,975	132,682	134,411

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
 Update – Neutral – March 23, 2022- Price Target NA

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Current as of... 15-Mar-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	31	74%	4	13%
Market Perform (Neutral)	11	26%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	42	100%	4	10%

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