

Caladrius (NASDAQ/CLBS)

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Neutral: Caladrius – Drunk with Cash (\$73M) but What Happens When Shareholders Wake Up? Hangover. We Remain Neutral

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Caladrius announced the 2nd Quarter, spending \$6.6M and closing the period with \$73M in cash. Management is now pushing its plans to acquire Cend Therapeutics and rename newco Lisata Therapeutics (LSTA). Recall that Caladrius proposes to give away half of the company to Cend Shareholders (three employees) and agreed to fund (\$10M) operations at Cend until the deal closes (as an investment in the company). As we previously stated: “We have known for a while that Caladrius had to do something...As we have believed, Caladrius's business model around autologous cell therapy is flawed and likely never to be commercialized”. The pivot is to become an early-stage cancer company now. We do not see the intrinsic value claimed in Cend Therapeutics by Caladrius management which seems more interested in perpetuating their own interests than those of the shareholders. We remain neutral.

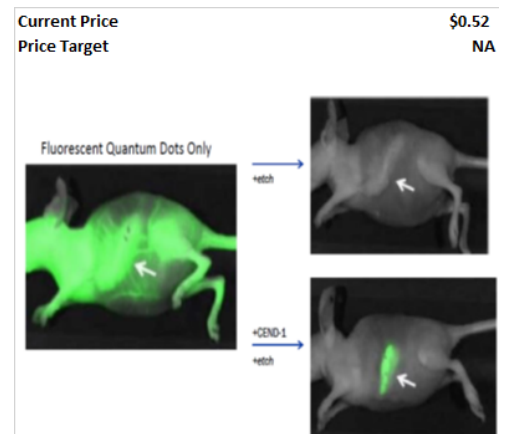
Investment Highlights

Reports the Quarter: Management spends \$3.2M in R&D and another \$3.4M on SG&A, reporting a total loss of \$6.6M. We are not optimistic about the outcome of talks in Japan for HONDERA (CLI/Buerger's disease). We see the P2b study of XOWNA for CMD as a bridge to nowhere. The effect (if any) is likely small, and the autologous business model is just not competitive. Ditto for CLBS201 in CKD. So what do you do when your company is focused on autologous cell therapy – regenerative medicine when the effect size is small and the business model flawed? You pivot and acquire an asset. Caladrius is doing just that with the proposed acquisition of Cend.

Cend's lead product is CEND-1. It is a cyclic peptide that targets tumors by binding to alpha-v "av" integrins, selectively expressed on tumor vascular endothelium and not on normal healthy vasculature. According to the company, AV integrins are expressed in Cancer-associated fibroblasts, a component of tumor stroma, and on tumor cells themselves; intratumoral immunosuppressive cells, which contribute to an immunotherapy-refractory or "cold" tumor microenvironment evident in pancreatic and other cancers. Our understanding is that the company plans to pursue first-line metastatic pancreatic ductal adenocarcinoma (PDAC). The current n=29-patient data set for CEND-1 combined with Gemcitabine and Nab-Paclitaxel showed some hints of efficacy. It sounds like the plan is to expand this trial in Australia. We expect time and money (years & millions) will be needed before proof of concept is demonstrated. **One could argue that such a program is outside the capacity of a micro-cap company.**

Our Conclusion is Unchanged: It's early days for CEND-1. We see a highly complex mechanism of action that will need to be validated in a complex background of cancer immunotherapy. We have not yet updated our model for CEND-1 and the additional associated expenses; however, our back-of-the-envelope calculations suggest this program does not move the needle. We maintain our highest discount rate of 30% in our free cash flow to the Firm (FCFF), discounted EPS, and Sum of the Parts (SOP) models.

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



Source: Braun et al., Nature Mater 2014

Stock Data		
52-Week Range	\$0.40 -	\$1.34
Shares Outstanding (mil.)		60.6
Market Capitalization (mil.)		\$31
Enterprise Value (mil.)		-\$5
Debt to Capital		5%
Book Value/Share		\$5.33
Price/Book		0.5
Average Three Months Trading Volume (K)		182
Insider Ownership		3.3%
Institutional Ownership		14.4%
Short interest (mil.)		0.9%
Dividend / Yield		\$0.00/0.0%

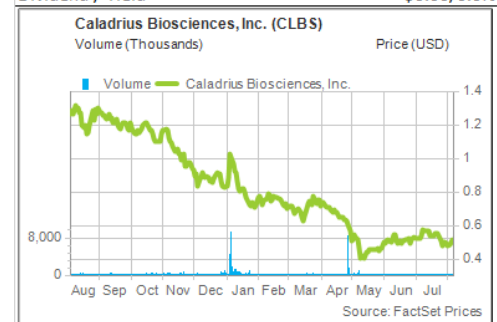


Exhibit 1. Income Statement

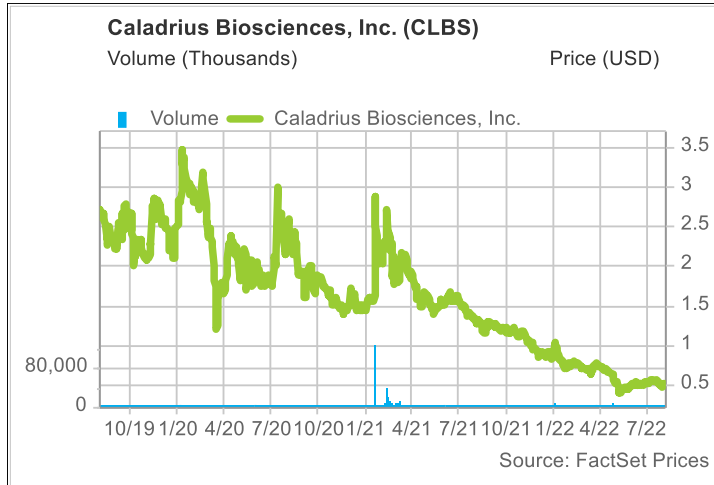
Caladrius Inc.: Income Statement (\$'000)	2018A	2019A	2020E	2021A	1Q22A	2Q22A	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
YE December 31																
Product sales																
Cell Therapy - CLI Japan					-	-	-	-	-	-	-	-	1,853	3,633	5,341	6,979
Cell Therapy - CLI USA					-	-	-	-	-	-	-	-	-	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	3,278	3,239	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	3,342	3,481	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	6,620	6,720	8,308	8,947	30,596	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)	(6,620)	(6,720)	(8,308)	(8,947)	(30,596)	(39,000)	(48,100)	(52,910)	(60,672)	(41,036)	(12,319)	43,736
Other expense	824	740	132	151	63	94	214	214	585	799	799	799	799	799	799	799
Interest expense	(5)	(0)	(75)	(148)	(148)	(0)	(0)	(0)	(148)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Total other income	819	740	132	76	(85)	94	214	214	436	793	793	793	793	793	793	793
Pretax Income	(16,168)	(19,353)	(19,013)	(28,974)	(6,705)	(6,626)	(8,095)	(8,734)	(30,160)	(38,207)	(47,307)	(52,117)	(59,879)	(40,243)	(11,525)	44,530
Income Tax Benefit (Provision)	-	-	(10,872)	(1,508)	(2,479)	-	-	-	(2,479)	-	-	(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)	(4,226)	(6,626)	(8,095)	(8,734)	(27,681)	(38,207)	(47,307)	(46,905)	(49,101)	(32,194)	(8,644)	31,171
GAAP-EPS	(1.67)	(1.87)	(0.53)	(0.50)	(0.07)	(0.11)	(0.13)	(0.14)	(0.46)	(0.63)	(0.77)	(0.85)	(0.80)	(0.52)	(0.14)	0.50
GAAP EPS (dil)	(1.67)	(1.88)	(0.53)	(0.50)	(0.03)	(0.05)	(0.07)	(0.07)	(0.23)	(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	60,560	60,533	60,594	60,654	60,585	60,806	61,050	61,294	61,540	61,786	62,034	62,282
Wgtd Avg Shrs (Dil) - '000s	9,689	10,323	15,540	55,313	121,120	121,241	121,362	121,484	121,302	122,883	124,484	126,107	127,750	129,415	131,102	132,811

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
- Update – Neutral – April 27, 2022- Price Target NA
- Update – Neutral – August 5, 2022- 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-Aug-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	30	68%	4	13%
Market Perform (Neutral)	13	30%	0	0%
Market Underperform (Sell)	1	2%	0	0%
Total	44	100%	4	9%

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