

Member FINRA/SIPC

Toll-Free: : 866-928-0928 ♦ www.DawsonJames.com ♦ 101 North Federal Highway - Suite 600 ♦ Boca Raton, FL 33432

## Caladrius (NASDAQ/CLBS)

December 10, 2021

### Neutral: Delays, Delays & Delays + Burning Cash

**Jason H. Kolbert**  
Senior HC Analyst  
jkolbert@dawsonjames.com

*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."

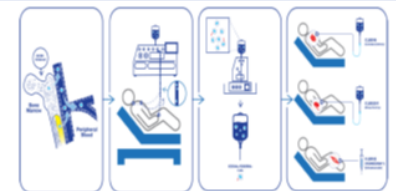
**XOWNA (CLBS16) – Enrollment has Slowed:** The product is currently being evaluated in a P2b study in patients with CMD and without obstructive coronary artery disease. Patient enrollment is behind schedule, so the company has been expanding the number of sites and modifying the study protocol. These 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. Allogeneic 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 -5 to 0 CD34+ cell mobilization

DAY 1 Sample collection

DAY 2 ISOLATION

DAY 3 or 4 CD34+ cell infusion

CD34+ cells are harvested from the same patient as administered to individual-specific

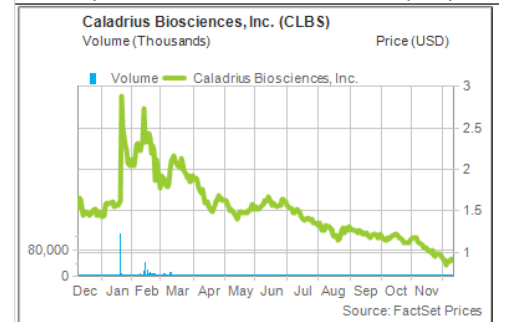
• Drug induced mobilization eliminates need for surgical bone marrow aspiration

• 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**

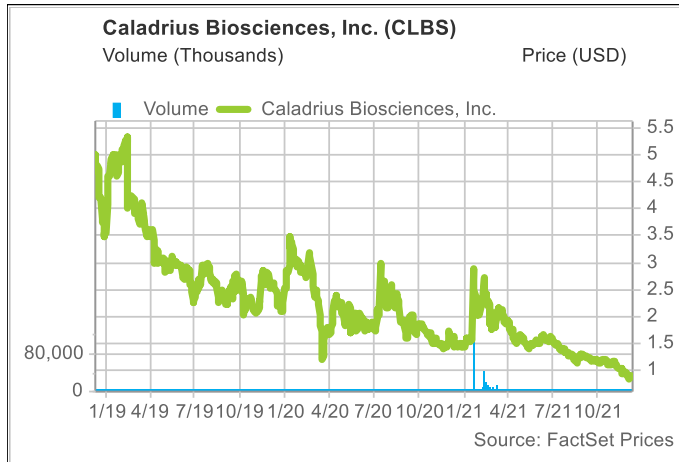
Caladrius Inc.: Income Statement (\$'000)																
YE December 31	2018A	2019A	2020E	1Q21A	2Q21A	3Q21A	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
<b>Product sales</b>																
Cell Therapy - CLI Japan						-	-	-	-	1,929	3,859	5,673	7,413	9,082	8,901	8,724
Cell Therapy - 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																
<b>Total Product Sales</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>1,929</b>	<b>3,859</b>	<b>5,673</b>	<b>139,133</b>	<b>512,686</b>	<b>695,233</b>	<b>839,843</b>
<b>Expenses</b>																
Cost of Goods Sold - Products	-	-	-	-	-	-	-	-	-	637	1,158	1,815	43,131	153,806	201,617	235,156
<b>% COGS (of product revenues)</b>				<b>35%</b>	<b>35%</b>	<b>35%</b>	<b>35%</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>33%</b>	<b>30%</b>	<b>32%</b>	<b>31%</b>	<b>30%</b>	<b>29%</b>	<b>28%</b>
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
<b>%R&amp;D</b>										<b>1088%</b>	<b>599%</b>	<b>448%</b>	<b>377%</b>	<b>339%</b>	<b>380%</b>	<b>426%</b>
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
<b>%SG&amp;A</b>										<b>933%</b>	<b>648%</b>	<b>485%</b>	<b>459%</b>	<b>440%</b>	<b>494%</b>	<b>555%</b>
<b>Total expenses</b>	<b>16,987</b>	<b>20,093</b>	<b>20,482</b>	<b>8,086</b>	<b>7,147</b>	<b>6,968</b>	<b>7,909</b>	<b>30,110</b>	<b>31,073</b>	<b>39,637</b>	<b>49,258</b>	<b>54,725</b>	<b>105,082</b>	<b>224,552</b>	<b>279,438</b>	<b>320,759</b>
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)
<b>Total other income</b>	<b>819</b>	<b>740</b>	<b>143</b>	<b>23</b>	<b>(43)</b>	<b>41</b>	<b>41</b>	<b>62</b>	<b>793</b>	<b>793</b>	<b>793</b>	<b>793</b>	<b>793</b>	<b>793</b>	<b>793</b>	<b>793</b>
<b>Pretax Income</b>	<b>(16,168)</b>	<b>(19,353)</b>	<b>(20,340)</b>	<b>(8,063)</b>	<b>(7,190)</b>	<b>(6,927)</b>	<b>(7,869)</b>	<b>(30,049)</b>	<b>(30,280)</b>	<b>(36,914)</b>	<b>(44,606)</b>	<b>(48,259)</b>	<b>34,844</b>	<b>288,927</b>	<b>416,588</b>	<b>519,878</b>
Income Tax Benefit (Provision)	-	-	(10,872)		1,508			1,508				(4,826)	6,272	57,785	104,147	155,963
<b>Tax Rate</b>												<b>10%</b>	<b>18%</b>	<b>20%</b>	<b>25%</b>	<b>30%</b>
Less: Loss from continuing operations attributable to noncontrolling interests	(1)	(9)														
<b>GAAP Net Income (loss)</b>	<b>(16,168)</b>	<b>(19,362)</b>	<b>(9,468)</b>	<b>(8,063)</b>	<b>(5,682)</b>	<b>(6,927)</b>	<b>(7,869)</b>	<b>(31,557)</b>	<b>(30,280)</b>	<b>(36,914)</b>	<b>(44,606)</b>	<b>(43,433)</b>	<b>28,572</b>	<b>231,142</b>	<b>312,441</b>	<b>363,915</b>
<b>GAAP-EPS</b>	<b>(1.67)</b>	<b>(1.87)</b>	<b>(0.45)</b>	<b>(0.19)</b>	<b>(0.10)</b>	<b>(0.12)</b>	<b>(0.13)</b>	<b>(0.53)</b>	<b>(0.51)</b>	<b>(0.61)</b>	<b>(0.74)</b>	<b>(0.80)</b>	<b>0.47</b>	<b>3.79</b>	<b>5.10</b>	<b>5.91</b>
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

Dawson James Securities, Inc. (the "Firm") is a member of the Financial Industry Regulatory Authority ("FINRA") and the Securities Investor Protection Corporation ("SIPC").

The Firm does not make a market in the securities of the subject company(s). The Firm has NOT engaged in investment banking relationships with CLBS in the prior twelve months, as a manager or co-manager of a public offering and has NOT received compensation resulting from those relationships. The Firm may seek compensation for investment banking services in the future from the subject company(s). The Firm has NOT received other compensation from the subject company(s) in the last 12 months for services unrelated to managing or co-managing of a public offering.

Neither the research analyst(s) whose name appears on this report nor any member of his (their) household is an officer, director or advisory board member of these companies. The Firm and/or its directors and employees may own securities of the company(s) in this report and may increase or decrease holdings in the future. As of November 30, 2021, the Firm as a whole did not beneficially own 1% or more of any class of common equity securities of the subject company(s) of this report. The Firm, its officers, directors, analysts, or employees may affect transactions in and have long or short positions in the securities (or options or warrants related to those securities) of the company(s) subject to this report. The Firm may affect transactions as principal or agent in those securities.

Analysts receive no direct compensation in connection with the Firm's investment banking business. All Firm employees, including the analyst(s) responsible for preparing this report, may be eligible to receive non-product or service-specific monetary bonus compensation that is based upon various factors, including total revenues of the Firm and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

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.

The securities of the company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.

**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... 1-Dec-21

	<b>Company Coverage</b>		<b>Investment Banking</b>	
<b>Ratings Distribution</b>	# 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%

**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 components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.