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Toll-Free: 561-391-5555 ♦ www.DawsonJames.com ♦ 101 North Federal Highway - Suite 600 ♦ Boca Raton, FL 33432

Caladrius (NASDAQ/CLBS)

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Neutral: Dam the Shareholders, Full Speed Ahead

Jason H. Kolbert

Head of Healthcare Research

646-465-6891

jkolbert@dawsonjames.com

We expected that Caladrius would raise capital, and it didn't disappoint, with a \$25M raise in January. Still, we were surprised, actually shocked, to see that this \$75M market capitalized company raised \$65M just a few weeks later. The share count has now grown from 10M shares in January 2020 to 85M (our estimate), a year later. Shareholders have now been diluted almost 10x in the last year. OK, but for what purpose? Caladrius is now likely to push forward with its personalized, expensive autologous CD 34+ stem cell therapy and do so without the technology founder who resigned from the company. While regenerative medicine has a role to play, we do not support Caladrius's autologous model. This model harvests patients' cells in a long and expensive process, multiples more so than allogenic models, which likely will have the same efficacy but off the shelf availability and at a much lower COGS.

Investment Highlights

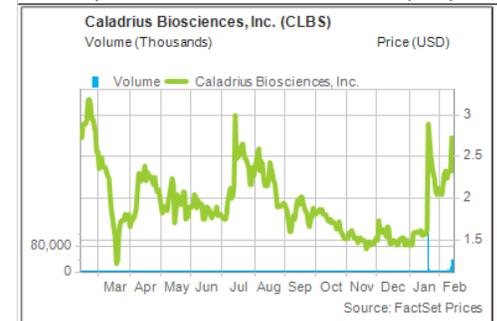
We Assume that CLBS14 – No Option Refractory Angina (NORDA) moves forward on Caladrius's dollar. Management previously discussed the protocol for a prospective, randomized, double-blind, ~400 total subject trial with a primary endpoint of total exercise time at the six-month follow-up visit. Considering resources needed (\$65M to \$70M), the trial has been delayed, but with capital now raised, we assume the company will move this program forward. Recall that business development has not found any willing partners thus far. Again, as we see allogenic counterparts moving forward, **we believe this product has missed its window to the market.**

Management has been Pushing the CD34+ cells as a COVID Play – This Makes No Sense to Us. On just about every level, we found management's explanation as lacking 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 there have been recent failures of other cell therapies in COVID due to improved standard of care. 2. 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? If the NORDA trial is \$65M what size trial is needed to measure post-acute ventilator recovery? It seems magnitudes more complex than, for example, a stroke trial, especially when the efficacy of the CD34 cells is unproven. 3. Caladrius's autologous therapy is very late in the field.

What is the Status of the CLI Trial in Japan? CLBS, now called Honedra – This is a small open-label trial, and just a handful of patients thus far have been treated. Management cites COVID as causing the delay, but given the fact that this is a tiny seven-patient trial, we find the explanation as making no sense. Some data is expected this year. We see this data as going nowhere as the trial is too small to produce definitive results.

CLBS16 – Management pushed the timeline back – This small Phase 2 study is an interventional, open-label, proof-of-concept (POC) trial planned for two centers. The study is small, with just twenty patients diagnosed with Coronary Microvascular Dysfunction (CMD). Patients are to receive CLBS16 via a routine intracoronary infusion. The endpoints (beyond safety) include the changes from baseline to six months

Current Price	\$1.61		
Price Target	NA		
Estimates	F2018A	F2019A	F2020E
Expenses (\$000s)	\$ 16,987	\$ 20,093	\$ 20,482
1Q March	\$ 5,159	\$ 4,592	\$ 4,057
2Q June	\$ 4,269	\$ 5,346	\$ 4,292
3Q September	\$ 3,763	\$ 5,072	\$ 5,350
4Q December	\$ 3,796	\$ 5,083	\$ 6,783
	F2018A	F2019A	F2020E
EPS (diluted)	\$ (1.67)	\$ (1.87)	\$ (0.40)
1Q March	\$ (0.52)	\$ (0.44)	\$ (0.38)
2Q June	\$ (0.43)	\$ (0.49)	\$ 0.50
3Q September	\$ (0.36)	\$ (0.47)	\$ (0.29)
4Q December	\$ (0.36)	\$ (0.47)	\$ (0.24)
EBITDA/Share	(\$1.67)	(\$0.47)	(\$0.24)
EV/EBITDA (x)	-	10	69
Stock Data			
52-Week Range	\$1.05	-	\$4.89
Shares Outstanding (mil.)			33.0
Market Capitalization (mil.)			\$53
Enterprise Value (mil.)			\$16
Debt to Capital			3%
Book Value/Share			\$5.33
Price/Book			1.3
Average Three Months Trading Volume (K)			114
Insider Ownership			5.8%
Institutional Ownership			9.5%
Short interest (mil.)			8.9%
Dividend / Yield			\$0.00/0.0%



Please find Important Disclosures beginning on Page 4.

for coronary flow reserve, or Coronary Flow Reserve (CFR, a direct measure of microvascular function), endothelial-dependent microvascular function, time to angina, and other cardiovascular metrics.

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 it's likely management will now be on a spending spree, possibly on clinical trials that we think will likely 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

Risk Analysis

Clinical and regulatory risk. Caladrius is currently in several Phase 2/3 clinical trials with its CD34 cell therapy product. There is no assurance that the product will be approved for any additional indications and even if approved, will be reimbursed by insurance or successfully commercialized.

Commercial risk. The focus of the company is on successfully developing its products and eventually bringing them to the market. It is important to note that the market opportunity in ischemic disease is large. However, we have no assurances that the company will be able to achieve a critical level of market share to become profitable in any of the planned indications.

Employee risk. Caladrius has recently revamped the central components of the company, including senior management. Caladrius's success will depend, to a great extent, upon the experience, abilities and continued services of its senior officers, sales staff, and key scientific personnel.

Financial risk. The company may need to raise capital in the marketplace, and there can be no assurances that the company will be able to successfully raise capital and do so on favorable terms.

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 the company may infringe on third parties' patents.

Reimbursement and insurance payment risk. Insurance payment for products may be an additional hurdle for adoption.

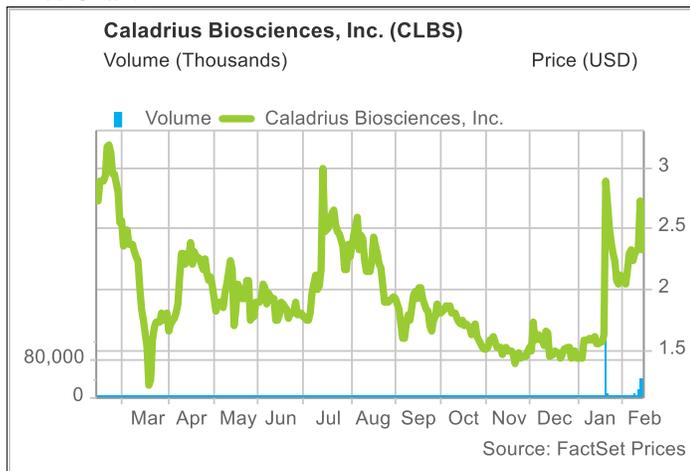
Exhibit 1. Income Statement

Caladrius Inc.: Income Statement (\$'000)																
YE December 31	2018A	2019A	2020E	1Q21E	2Q21E	3Q21E	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Product sales																
Cell Therapy - CLI Japan				1,318	1,376	1,433	1,605	5,732	9,648	15,436	27,010	34,036	44,478	47,226	48,066	48,854
Cell Therapy - CLI USA								-	-	-	-	17,242	21,986	44,856	68,636	93,354
Cell Therapy - CLI Europe								-	-	-	-	-	22,162	45,214	69,185	94,101
Cell Therapy - Coronary Microvascular Dysfunction USA								-	-	-	65,103	203,220	281,935	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								-	8,041	16,733	26,117	36,233	47,125	58,841	61,224	
Cell Therapy - No Option Refractory Disabling Angina (NORDA) USA								-	8,142	16,943	26,443	36,686	47,714	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								-	1,357	2,824	4,407	6,114	7,952	9,929	10,332	
Total Product Sales	-	-	-	1,318	1,376	1,433	1,605	5,732	9,648	23,477	108,846	280,615	501,658	715,062	940,988	1,138,983
Expenses																
Cost of Goods Sold - Products	-	-	-	461	481	502	562	2,006	3,280	10,882	38,584	99,669	155,514	214,519	272,887	318,915
% COGS (of product revenues)				35%	35%	35%	35%	35%	34%	46%	35%	36%	31%	30%	29%	28%
Research and Development	7,594	10,797	14,000	3,740	4,080	4,420	4,760	17,000	18,700	21,000	23,100	25,410	27,951	30,746	33,821	37,203
%R&D										136%	86%	75%	63%	65%	70%	76%
General and Administrative	9,393	9,296	10,226	2,475	2,700	2,925	3,149	11,248	12,373	18,000	25,000	27,500	34,000	40,000	44,000	48,400
%SG&A										117%	93%	81%	76%	85%	92%	99%
Total expenses	16,987	20,093	20,482	6,676	7,261	7,846	8,471	30,254	34,353	49,882	86,684	152,579	217,465	285,265	350,707	404,518
Operating Income (Loss)	(16,987)	(20,093)	(20,482)	(5,358)	(5,885)	(6,413)	(6,866)	(24,523)	(24,705)	(16,907)	41,929	158,886	284,193	429,798	590,281	734,465
Other expense	824	740	143	178	194	214	214	799	799	799	799	799	799	799	799	799
Interest expense	(5)	(0)	(0)	(3)	(2)	(0)	(0)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Total other income	819	740	143	174	192	214	214	793	793	793	793	793	793	793	793	793
Pretax Income	(16,168)	(19,353)	(20,340)	(5,183)	(5,693)	(6,200)	(6,653)	(23,729)	(23,912)	(16,113)	42,722	159,680	284,986	430,591	591,074	735,258
Income Tax Benefit (Provision)	-	-	(10,872)	-	-	-	-	-	-	-	-	15,968	51,298	86,118	147,769	220,578
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)	(5,183)	(5,693)	(6,200)	(6,653)	(23,729)	(23,912)	(16,113)	42,722	143,712	233,689	344,473	443,306	514,681
GAAP-EPS	(1.67)	(1.87)	(0.45)	(0.08)	(0.09)	(0.10)	(0.11)	(0.39)	(0.39)	(0.26)	0.69	2.56	3.75	5.50	7.05	8.15
GAAP EPS (dil)	(1.67)	(1.88)	(0.53)	(0.06)	(0.07)	(0.07)	(0.08)	(0.28)	(0.28)	(0.18)	0.48	1.60	2.57	3.74	4.76	5.45
Wgtd Avg Shrs (Bas) - '000s	9,689	10,323	16,497	61,045	61,106	61,167	61,229	61,137	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	17,747	85,011	85,096	85,181	85,266	85,138	86,248	87,372	88,511	89,664	90,833	92,017	93,216	94,431

Source: Dawson James estimates, company reports

Important Disclosures:

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 16, 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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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	72%	6	29%
Market Perform (Neutral)	8	28%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	29	100%	6	21%

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