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Caladrius (NASDAQ/CLBS)

November 19, 2020

Neutral: Technology Founder Leaves as Caladrius Shows a Downward Spiral

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Renowned cardiologist Dr. Douglas Losordo, who is the technology founder and pioneer of the CD34+ cell-technology that Caladrius is based upon has “resigned” from the company. Dr. Losordo’s departure follows that of the CFO who also resigned this year. Hmmm. Look for Caladrius to make an acquisition and shift its strategy away from the current focus of a CD34 cell (COVID – Post ARDS), which we believe makes no sense, CLI in Japan (too small a trial), and CLBS-NORDA, which lacks funds, to proceed with a low probability of success. We also note the recent failure of Brainstorm’s (BCLI – Neutral Rated), autologous therapy for ALS to demonstrate significance in its pivotal trial.

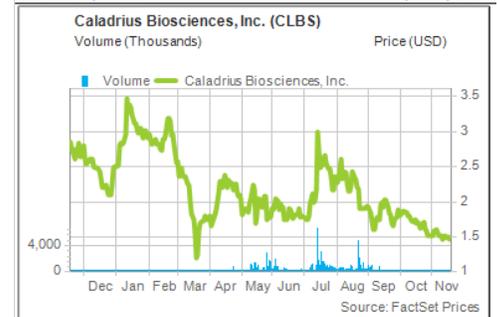
Investment Highlights

Management is Pushing the CD34+ cells as a COVID Play – This Makes No Sense. 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 later in the cycle. What’s critical to understand is that these companies are evaluating the therapies with metrics like time on a ventilator in patients now. 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 and Caladrius can’t afford that, 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 totally unproven. 3. Caladrius’s autologous therapy is fourth or more 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. No data is expected until at best late next year or early 2021. We see this data as going nowhere as the trial is too small to produce definitive results.

CLBS14 – No Option Refractory Angina (NORDA). The protocol is finalized for the confirmatory Phase 3 trial in NORDA of CLBS14. The protocol defines 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 is not planned to start until funding is secured. Business development has not found any willing partners thus far, and again, as we see allogenic counterparts moving forward, **we believe this product has missed its window to the market.**

Current Price				\$1.46
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)	-	-5	-36	
Stock Data				
52-Week Range	\$1.05	-	\$3.64	
Shares Outstanding (mil.)				19.4
Market Capitalization (mil.)				\$28
Enterprise Value (mil.)				-\$9
Debt to Capital				5%
Book Value/Share				\$5.33
Price/Book				1.3
Average Three Months Trading Volume (K)				306
Insider Ownership				8.0%
Institutional Ownership				13.8%
Short interest (mil.)				1.3%
Dividend / Yield				\$0.00/0.0%



CLBS16 – Management pushed the timeline back – The first patient by year-end? 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 CMD. Patients are to receive CLBS16 via a routine intracoronary infusion. The endpoints (beyond safety) include the changes from baseline to six months for coronary flow reserve, or 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 include projected dilution; however, as the stock moves lower, our dilution numbers may be too low. In effect, a downward spiral may have now been triggered. The price of the stock will ultimately be driven near term by factors such as business development (a partnership for NORDA trial), which we now think is unlikely, news flow, early trial data, and cyclic concerns of financings (dilution). 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 their products and eventually bringing them to the market. It is important to note that the market opportunity in ischemic disease is large. However, we can make 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 of the company 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	1Q20A	2Q20A	3Q20A	4Q20E	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	1,499	1,818	3,029	3,920	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	2,558	2,474	2,321	2,863	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	4,057	4,292	5,350	6,783	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)	(4,057)	(4,292)	(5,350)	(6,783)	(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	71	22	25	25	143	178	194	214	214	799	799	799	799	799	799	799	799	799
Interest expense	(5)	(0)			(0)	(0)	(0)	(3)	(2)	(0)	(0)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Total other income	819	740	71	22	25	25	143	174	192	214	214	793	793	793	793	793	793	793	793	793
Pretax Income	(16,168)	(19,353)	(3,986)	(4,270)	(5,325)	(6,758)	(20,340)	(5,183)	(5,693)	(6,200)	(6,653)	(23,729)	(23,912)	(16,113)	42,722	159,886	284,986	430,591	591,074	735,258
Income Tax Benefit (Provision)	-	-		(10,872)			(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)	(4)	4	2															
GAAP Net Income (loss)	(16,168)	(19,362)	(3,990)	6,598	(5,327)	(6,758)	(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)	(0.38)	0.50	(0.29)	(0.29)	(0.45)	(0.12)	(0.13)	(0.14)	(0.15)	(0.54)	(0.54)	(0.37)	0.97	3.58	5.24	7.69	9.86	11.40
GAAP EPS (dil)	(1.67)	(1.87)	(0.38)	0.50	(0.29)	(0.24)	(0.40)	(0.08)	(0.08)	(0.09)	(0.10)	(0.34)	(0.34)	(0.23)	0.60	1.98	3.17	4.62	5.87	6.72
Wgt'd Avg Shrs (Bas) - '000s	9,689	10,323	10,623	13,151	18,597	23,616	16,497	43,639	43,683	43,727	43,770	43,705	43,880	44,056	44,232	44,409	44,587	44,766	44,945	45,125
Wgt'd Avg Shrs (Dil) - '000s	9,689	10,323	10,623	13,151	18,597	28,616	17,747	68,902	68,971	69,040	69,109	69,005	69,905	70,816	71,739	72,674	73,621	74,580	75,552	76,537

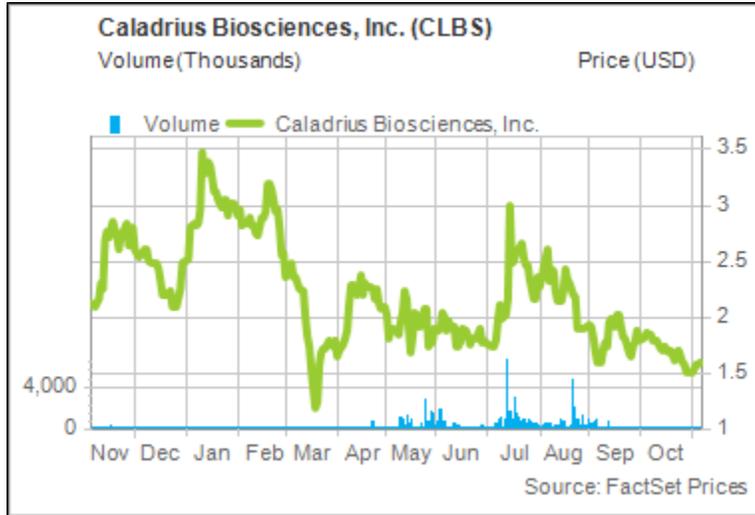
Source: Dawson James estimates, company reports

Important Disclosures:

Other Companies Mentioned in this Report:

Brainstorm (BCLI) - Neutral rated

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 NA
- Update – Neutral – November 6, 2020 NA
- Update – Neutral – November 19, 2020 NA

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- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
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	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	78%	4	19%
Market Perform (Neutral)	6	22%	1	17%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	5	19%

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