

Caladrius (NASDAQ/CLBS)

August 14, 2020

Neutral: More Red Flags ...CFO Departs, Timelines Get Delayed, Raises “Opportunistic Capital”

Caladrius announced the departure of the CFO, whom we have known for many years and with his departure it is a clear warning sign that the opportunity at the company has dimmed. The company reported a loss of \$4.3M in 2Q20 with no revenues, and none expected anytime soon. The company, as stated in their own press release, “opportunisticly” raised capital (and did so, in our opinion on very dilutive terms). The company continued to highlight what in our opinion is a non-sensical COVID play: a CD34 cell therapy for the after-effects associated with acute COVID therapy (ventilator). As we previously stated in our downgrade in May: “We spoke with management at length and conclude that the company lacks funds to develop its product for NORDA, and the Japan-CLI program is a reach at best. As for COVID, we find the plan makes no sense what-so-ever”. We conclude that recent advances by other allogeneic companies make Caladrius autologous CD34+ product expensive by comparison, plus harvesting from acute patients is, in our opinion, not practical, especially when combined with time required to process (manufacture) the cells. “In short, Caladrius has, in our opinion, missed its window to the market, is short of capital to finance the NORDA trial.”

Investment Highlights

Management is Pushing the CD34+ cells as a COVID Play – This Makes No Sense.

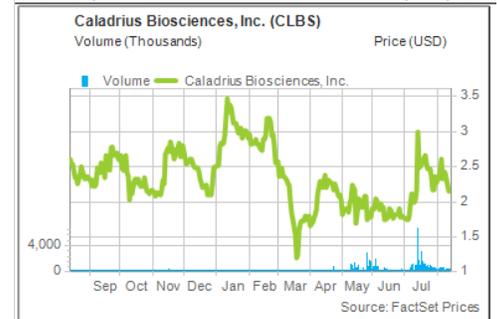
On just about every level, we found management’s explanation as lacking an understanding of 1—the competitive environment. Multiple off the shelf, allogeneic companies are already treating COVID patients but on ventilators and potentially earlier and later in the cycle. What’s critical to understand 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 say a Stroke trial, especially when the efficacy of the CD34 cells is totally unproven. 3. Caladrius autologous therapy is fourth or more, in the field.

What is the Status of the CLI Trial in Japan? CLBS12 – This is a small open-label trial, and just a handful of patients thus far have been treated. In the quarter’s press release, management cited 4 of 7 patients showed a positive outcome in the Buerger’s disease cohort. While we acknowledge the “Sakigake” designation, we are more skeptical that any product can be approved and commercially marketed based on a handful of patients. In addition, we see the timeline is now delayed, according to the company because of COVID delays, with data not expected until late 2021/22.

CLBS14 – No Option Refractory Angina (NORDA). The protocol is finalized for the confirmatory Phase 3 trial 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, and again, as we see allogeneic counterparts moving forward, we believe this product has missed its window to the market.

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Current Price	\$2.26		
Price Target	NA		
Estimates	F2018A	F2019A	F2020E
Expenses (\$000s)	\$ 16,987	\$ 20,093	\$ 21,431
1Q March	\$ 5,159	\$ 4,592	\$ 4,057
2Q June	\$ 4,269	\$ 5,346	\$ 4,292
3Q September	\$ 3,763	\$ 5,072	\$ 6,299
4Q December	\$ 3,796	\$ 5,083	\$ 6,783
	F2018A	F2019A	F2020E
EPS (diluted)	\$ (1.67)	\$ (1.87)	\$ (1.05)
1Q March	\$ (0.52)	\$ (0.44)	\$ (0.38)
2Q June	\$ (0.43)	\$ (0.49)	\$ (0.19)
3Q September	\$ (0.36)	\$ (0.47)	\$ (0.28)
4Q December	\$ (0.36)	\$ (0.47)	\$ (0.21)
EBITDA/Share	(\$1.67)	(\$0.47)	(\$0.21)
EV/EBITDA (x)	-	-1	-8
Stock Data			
52-Week Range	\$1.05	-	\$3.64
Shares Outstanding (mil.)	15.6		
Market Capitalization (mil.)	\$35		
Enterprise Value (mil.)	-\$2		
Debt to Capital	4%		
Book Value/Share	\$5.33		
Price/Book	1.3		
Average Three Months Trading Volume (K)	473		
Insider Ownership	9.0%		
Institutional Ownership	13.6%		
Short interest (mil.)	1.6%		
Dividend / Yield	\$0.00/0.0%		



CLBS16 – Trial Timeline gets bushed back. The Phase 2 study is an interventional, open-label, proof-of-concept (POC) trial conducted at two centers (Cedars-Sinai in Los Angeles, CA, and the Mayo Clinic in Rochester, MN). The study is in N=20 patients diagnosed with CMD. Patients received 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. **Management updated the timeline from fall to late 2020.**

Valuation. For Caladrius, we previously lowered our rating to Neutral from Buy 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 party's patents.

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

Exhibit 1. Income Statement

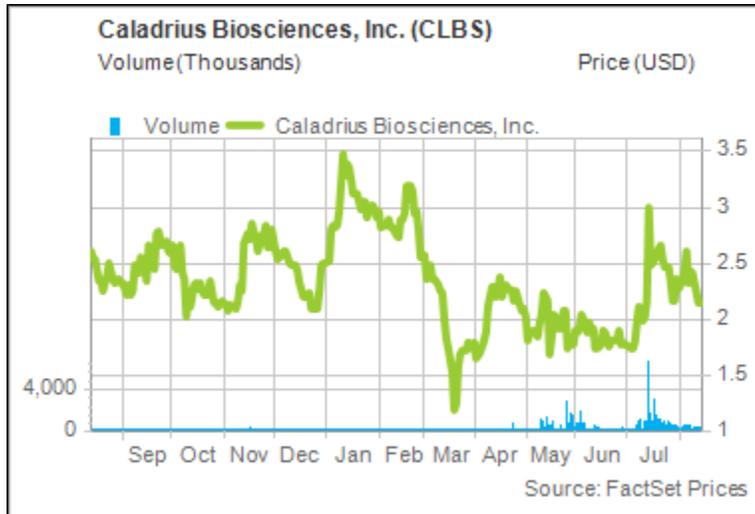
Caladrius Inc.: Income Statement (\$'000)																					
YE December 31	2018A	2019A	1Q20A	2Q20A	3Q20E	4Q20E	2020E	1Q21E	2Q21E	3Q21E	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	
Product sales																					
Cell Therapy - CLI Japan								1,318	1,376	1,433	1,605	5,732	9,648	15,436	27,010	34,036	44,478	47,226	48,066	48,854	
Cell Therapy - CLI USA													-	-	-	17,242	21,966	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	3,640	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	2,659	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	6,299	6,783	21,431	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)	(6,299)	(6,783)	(21,431)	(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	214	214	521	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	214	214	520	174	192	214	214	793	793	793	793	793	793	793	793	793	
Pretax Income	(16,168)	(19,353)	(3,986)	(4,270)	(6,085)	(6,570)	(20,911)	(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)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	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)																	
GAAP Net Income (loss)	(16,168)	(19,362)	(3,990)	(4,266)	(6,085)	(6,570)	(20,911)	(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)	(0.32)	(0.46)	(0.36)	(1.52)	(0.14)	(0.15)	(0.16)	(0.17)	(0.62)	(0.62)	(0.42)	1.10	4.09	5.99	8.79	11.27	13.03	
GAAP EPS (dil)	(1.67)	(1.88)	(0.38)	(0.19)	(0.28)	(0.21)	(0.96)	(0.07)	(0.08)	(0.09)	(0.09)	(0.33)	(0.33)	(0.22)	0.57	1.88	3.02	4.40	5.59	6.40	
Wgtd Avg Shrs (Bas) - '000s	9,689	10,323	10,623	13,151	13,164	18,177	13,779	38,195	38,234	38,272	38,310	38,253	38,406	38,560	38,714	38,869	39,025	39,182	39,338	39,496	
Wgtd Avg Shrs (Dil) - '000s	9,689	10,323	10,623	22,000	22,022	32,044	21,672	72,364	72,437	72,509	72,582	72,473	73,418	74,374	75,344	76,326	77,321	78,328	79,349	80,383	

Source: Dawson James estimates, company reports

Companies mentioned in this report:

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
 Rating Change – Neutral – August 14, 2020

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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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	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	23	85%	4	17%
Market Perform (Neutral)	4	15%	1	25%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	5	19%

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