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RATING CHANGE REPORT

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Caladrius (NASDAQ/CLBS)

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Neutral: COVID-19; Red Flag on the Play

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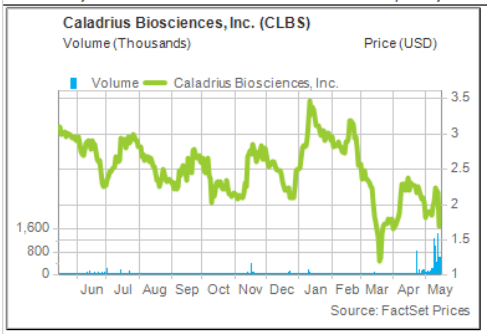
Caladrius announced 1Q20 results, raised $5M of capital, and reviewed their plan to develop a CD34 cell therapy for the after-effects associated with acute COVID therapy (ventilator). We spoke with management at length and conclude that the company lacks funds to develop its product for NORDA, and the Japan-CLI program is a reach at best. As for COVID, we find the plan makes no sense what-so-ever. We conclude that the lack of capital and 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, and may now see a downward spiral driven by multiple dilutive financing rounds. We lower our rating from Buy to Neutral and remove our price target.

Current Price	**$1.83**
Price Target	**NA**

Estimates	F2018A	F2019A	F2020E
Expenses ($000s)	$ 16,987	$ 20,093	$ 22,953
1Q March	$ 5,159	$ 4,592	$ 4,057
2Q June	$ 4,269	$ 5,346	$ 5,814
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)	$ (1.50)
1Q March	$ (0.52)	$ (0.44)	$ (0.38)
2Q June	$ (0.43)	$ (0.49)	$ (0.41)
3Q September	$ (0.36)	$ (0.47)	$ (0.44)
4Q December	$ (0.36)	$ (0.47)	$ (0.28)
EBITDA/Share	($1.67)	($0.47)	($0.28)
EV/EBITDA (x)	-	-8	-49
Stock Data			
52-Week Range	$1.05	-	$3.64
Shares Outstanding (mil.)			12.8
Market Capitalization (mil.)			$23
Enterprise Value (mil.)			-$13
Debt to Capital			6%
Book Value/Share			$5.33
Price/Book			1.3
Average Three Months Trading Volume (K)			4
Insider Ownership			3.4%
Institutional Ownership			12.5%
Short interest (mil.)			0.1%
Dividend / Yield			$0.00/0.0%



Investment Highlights

Retribution? No. We may not agree with management's decision to raise capital recently, $5M with 2.1M shares and over 1M warrants, but ending 1Q20 with $21M in cash ($34M today) is positive. Our concern is that the most promising Caladrius program, the NORDA trial, is estimated by management at $65M plus. Our model has Caladrius burning $23M this year w/o the trial. In other words, the company is likely to "have-to" raise more capital. Given the recent terms (last $5M raise) and the performance following the raise, (stock is down sharply), we feel we have no choice but to step to the sidelines and lower our rating to Neutral and remove our price target, as we feel more raises are likely and at progressively lower values.

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 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 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.

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 ($65 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 allogenic counterparts moving forward, we believe this product has missed its window to the market.

CLBS16 – The ESCaPE Trial Background. 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 expects to initiate a Phase 2b study in the fall.

Valuation. For Caladrius, we have 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

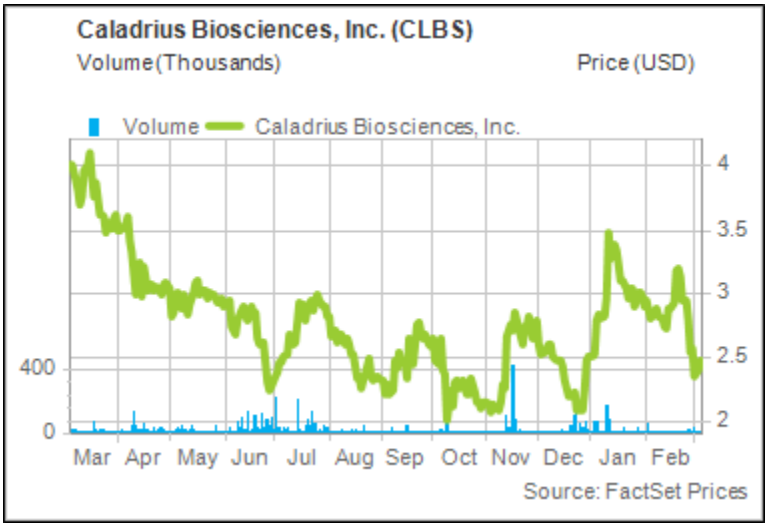
Caldrius Inc.: Income Statement ($000)																				
YE December 31	2018A	2019A	1Q20A	2Q20E	3Q20E	4Q20E	2020E	1Q21E	2Q21E	3Q21E	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Product sales																				
Cell Therapy - CLI Japan								1,318	1,376	1,433	1,605	5,732	9,648	15,436	27,010	34,036	44,478	47,226	48,066	48,854
Cell Therapy - CLI USA													-	-	-	17,242	21,986	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	3,360	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	2,454	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	5,814	6,299	6,783	22,953	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)	(5,814)	(6,299)	(6,783)	(22,953)	(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	194	214	214	692	178	194	214	214	799	799	799	799	799	799	799	799	799
Interest expense	(5)	(0)		(2)	(0)	(0)	(2)	(3)	(2)	(0)	(0)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Total other income	819	740	71	192	214	214	690	174	192	214	214	793	793	793	793	793	793	793	793	793
Pretax Income	(16,168)	(19,353)	(3,986)	(5,622)	(6,085)	(6,570)	(22,263)	(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)																	
GAAP Net Income (loss)	(16,168)	(19,362)	(3,990)	(5,622)	(6,085)	(6,570)	(22,263)	(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)	(0.44)	(0.48)	(0.37)	(1.66)	(0.14)	(0.15)	(0.16)	(0.18)	(0.63)	(0.63)	(0.42)	1.11	4.13	6.04	8.87	11.37	13.15
GAAP EPS (dil)	(1.67)	(1.88)	(0.38)	(0.41)	(0.44)	(0.28)	(1.43)	(0.08)	(0.09)	(0.10)	(0.10)	(0.37)	(0.37)	(0.24)	0.64	2.13	3.41	4.96	6.31	7.23
Wgtd Avg Shrs (Bas) - '000s	9,689	10,323	10,623	12,796	12,808	17,821	13,512	37,839	37,877	37,915	37,953	37,896	38,048	38,200	38,353	38,507	38,661	38,816	38,971	39,127
Wgtd Avg Shrs (Dil) - '000s	9,689	10,323	10,623	13,834	13,847	23,861	15,541	64,100	64,164	64,228	64,292	64,196	65,033	65,880	66,739	67,609	68,490	69,383	70,287	71,203

Source: Dawson James estimates

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

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Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	88%	3	14%
Market Perform (Neutral)	3	13%	1	33%
Market Underperform (Sell)	0	0%	0	0%
Total	24	100%	4	17%

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