

## Caladrius (NASDAQ/CLBS)

July 15, 2019

### BUY: Advanced Therapy Classification Received

Caladrius announced that the European Medicines Agency has granted Advanced Therapy Medicinal Product classification for CLBS12, for the treatment of critical limb ischemia. This news follows last month's announcement that the Phase 2 ESCaPE-CMD Trial for Coronary Microvascular Dysfunction is enrolled.

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### Investment Highlights

The European Medicines Agency (EMA) has granted Advanced Therapy Medicinal Product (ATMP) classification for CLBS12, for the treatment of critical limb ischemia. We note that the therapy received a similar designation in Japan, "SAKIGAKE" which makes the product eligible for early conditional approval based on the on-going clinical trial in Japan.

**ESCaPE Trial Enrollment is Complete. Data in six months.** This 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.

**Early Data Looks Good.** Caladrius discussed the preliminary results from the first 30% of the patients to complete the six-month follow-up on their recent earnings call. "Results were highly promising with evidence that improved CFR is associated with symptomatic improvement".

**Catalysts and Cash.** Caladrius ended 1Q19 with \$38M in cash versus a burn rate of \$4.4M in the quarter. We combine this with data coming around two key programs, Coronary Microvascular Dysfunction – CMD and Critical Limb Ischemia (CLI) and we see an opportunity on good data for the company to commercialize its CD34 cell therapy product line.

**Valuation.** For Caladrius as an early stage biotechnology company with no revenues, we use 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 ten years to 2029, and we project dilutions. Caladrius currently has just under 10 million shares outstanding. We assume by 2029 a fully diluted share count of 73M shares. We triangulate FCFF, discounted EPS (2022), and sum-of-the-parts models. We then average and equally weight each model to derive an NPV, which is rounded to the nearest whole number to set our target price. Investors should recognize that this modeling exercise, which models forward for ten years, while projected based on the current data and estimates, is limited in its ability to predict a 12-month target. The price of the stock will ultimately be driven near term by factors such as news flow, early trial data, and cyclic concerns of financings (dilution).

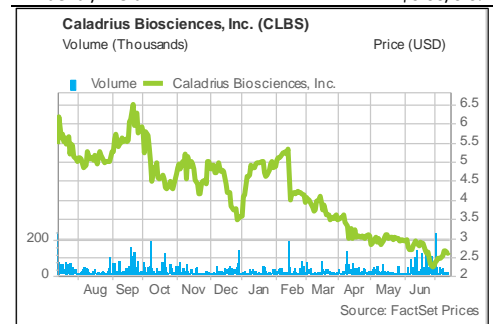
**Current Price** \$2.63  
**Price Target** \$7.00

Estimates	F2018A	F2019E	F2020E
<b>Expenses (\$000s)</b>	\$ 16,987	\$ 19,167	\$ 25,366
1Q March	\$ 5,159	\$ 4,592	\$ 5,580
2Q June	\$ 4,269	\$ 4,485	\$ 6,088
3Q September	\$ 3,763	\$ 4,858	\$ 6,595
4Q December	\$ 3,796	\$ 5,232	\$ 7,102

	F2018A	F2019E	F2020E
<b>EPS (diluted)</b>	\$ (1.67)	\$ (1.18)	\$ (0.54)
1Q March	\$ (0.52)	\$ (0.44)	\$ (0.12)
2Q June	\$ (0.43)	\$ (0.43)	\$ (0.13)
3Q September	\$ (0.36)	\$ (0.15)	\$ (0.14)
4Q December	\$ (0.36)	\$ (0.17)	\$ (0.15)

<b>EBITDA/Share</b>	(\$1.67)	(\$0.17)	(\$0.15)
<b>EV/EBITDA (x)</b>	-	-9	-95

Stock Data			
<b>52-Week Range</b>	\$2.16	-	\$6.83
<b>Shares Outstanding (mil.)</b>	10.4		
<b>Market Capitalization (mil.)</b>	\$27		
<b>Enterprise Value (mil.)</b>	-\$14		
<b>Debt to Capital</b>	6%		
<b>Book Value/Share</b>	\$5.33		
<b>Price/Book</b>	0.9		
<b>Average Three Months Trading Volume (K)</b>	32		
<b>Insider Ownership</b>	10.7%		
<b>Institutional Ownership</b>	17.8%		
<b>Short interest (mil.)</b>	0.4%		
<b>Dividend / Yield</b>	\$0.00/0.0%		



## 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**

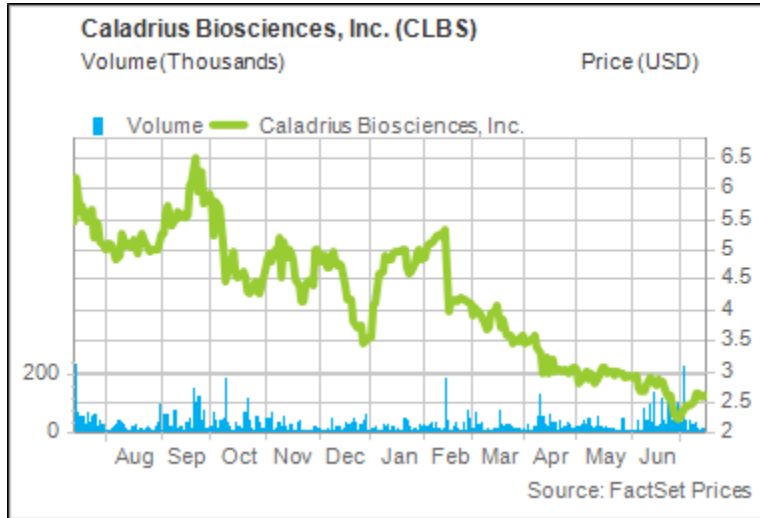
Caladrius Inc.: Income Statement (\$'000)																
YE December 31	2018A	1Q19A	2Q19E	3Q19E	4Q19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
<b>Product sales</b>																
Cell Therapy - CLI Japan								11,463	19,297	30,871	54,020	68,072	88,956	94,451	96,132	97,709
Cell Therapy - CLI USA								-	-	-	-	25,863	32,979	67,283	102,954	140,031
Cell Therapy - CLI Europe								-	-	-	-	33,243	67,822	103,777	141,151	
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								-	-	32,164	66,934	104,467	144,930	188,501	235,362	244,895
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
<b>Total Product Sales</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>11,463</b>	<b>19,297</b>	<b>63,035</b>	<b>186,056</b>	<b>401,622</b>	<b>676,908</b>	<b>948,698</b>	<b>1,234,486</b>	<b>1,465,236</b>
<b>Expenses</b>																
Cost of Goods Sold - Products	-	-	-	-	-	-	-	4,012	6,561	23,936	61,747	138,391	209,841	284,610	358,001	410,266
<b>% COGS (of product revenues)</b>								<b>35%</b>	<b>34%</b>	<b>38%</b>	<b>33%</b>	<b>34%</b>	<b>31%</b>	<b>30%</b>	<b>29%</b>	<b>28%</b>
Research and Development	7,594	2,038	2,005	2,172	2,339	8,353	14,000	17,000	18,700	21,000	23,100	25,410	27,951	30,746	33,821	37,203
<b>%R&amp;D</b>								<b>68%</b>	<b>43%</b>	<b>37%</b>	<b>43%</b>	<b>37%</b>	<b>31%</b>	<b>33%</b>	<b>35%</b>	<b>38%</b>
General and Administrative	9,393	2,554	2,480	2,686	2,893	10,332	11,366	12,502	13,752	18,000	25,000	27,500	34,000	40,000	44,000	48,400
<b>%SG&amp;A</b>								<b>58%</b>	<b>46%</b>	<b>40%</b>	<b>46%</b>	<b>40%</b>	<b>38%</b>	<b>42%</b>	<b>46%</b>	<b>50%</b>
<b>Total expenses</b>	<b>16,987</b>	<b>4,592</b>	<b>4,485</b>	<b>4,858</b>	<b>5,232</b>	<b>19,167</b>	<b>25,366</b>	<b>33,514</b>	<b>39,013</b>	<b>62,936</b>	<b>109,847</b>	<b>191,301</b>	<b>271,792</b>	<b>355,356</b>	<b>435,822</b>	<b>495,869</b>
Operating Income (Loss)	(16,987)	(4,592)	(4,485)	(4,858)	(5,232)	(19,167)	(25,366)	(22,051)	(19,717)	9,598	95,976	241,171	405,115	593,343	798,664	969,367
Other expense	824	227	194	214	214	848	799	799	799	799	799	799	799	799	799	799
Interest expense	(5)	(2)	(2)	(0)	(0)	(2)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
<b>Total other income</b>	<b>819</b>	<b>227</b>	<b>192</b>	<b>214</b>	<b>214</b>	<b>846</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>793</b>	<b>793</b>
<b>Pretax Income</b>	<b>(16,168)</b>	<b>(4,365)</b>	<b>(4,293)</b>	<b>(4,645)</b>	<b>(5,018)</b>	<b>(18,321)</b>	<b>(24,572)</b>	<b>(21,258)</b>	<b>(18,923)</b>	<b>10,391</b>	<b>96,769</b>	<b>241,964</b>	<b>405,909</b>	<b>594,136</b>	<b>799,458</b>	<b>970,160</b>
Income Tax Benefit (Provision)	-	-	-	-	-	-	-	-	-	-	-	24,196	73,064	118,827	199,864	291,048
<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)	(2)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>GAAP Net Income (loss)</b>	<b>(16,168)</b>	<b>(4,367)</b>	<b>(4,293)</b>	<b>(4,645)</b>	<b>(5,018)</b>	<b>(18,321)</b>	<b>(24,572)</b>	<b>(21,258)</b>	<b>(18,923)</b>	<b>10,391</b>	<b>96,769</b>	<b>217,768</b>	<b>332,845</b>	<b>475,309</b>	<b>599,593</b>	<b>679,112</b>
<b>GAAP-EPS</b>	<b>(1.67)</b>	<b>(0.44)</b>	<b>(0.43)</b>	<b>(0.23)</b>	<b>(0.25)</b>	<b>(1.34)</b>	<b>(0.70)</b>	<b>(0.47)</b>	<b>(0.42)</b>	<b>0.23</b>	<b>2.11</b>	<b>5.24</b>	<b>7.20</b>	<b>10.24</b>	<b>12.87</b>	<b>14.52</b>
GAAP EPS (dil)	(1.67)	(0.44)	(0.43)	(0.15)	(0.17)	(0.91)	(0.54)	(0.32)	(0.28)	0.15	1.40	3.12	4.70	6.63	8.25	9.23
Wgtd Avg Shrs (Bas) - '000s	9,689	10,027	10,037	20,047	20,067	15,045	35,140	45,296	45,477	45,659	45,842	46,026	46,210	46,395	46,581	46,768
Wgtd Avg Shrs (Dil) - '000s	9,689	10,027	10,037	30,047	30,348	20,115	45,720	66,345	67,210	68,086	68,973	69,872	70,783	71,706	72,640	73,587

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

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Market Outperform (Buy)	40	85%	12	30%
Market Perform (Neutral)	7	15%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	47	100%	12	26%

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