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UPDATE REPORT

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Caladrius (NASDAQ/CLBS)

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BUY: Caladrius Presents P-Values at AHA on the Primary Endpoint for the ESCaPE-CMD Trial

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The data presented showed a highly statistically significant improvement in coronary flow reserve correlating with symptom relief for patients with coronary microvascular dysfunction after a single intracoronary injection of CLBS16.

Investment Highlights

Caladrius presented data for CLBS16, at the American Heart Association (AHA) over the weekend. As mentioned the data showed a highly statistically significant improvement (p=0.0087) in coronary flow reserve correlating with symptom relief for patients with coronary microvascular dysfunction after a single intracoronary injection of CLBS16. The results for patients who have completed the six-month follow-up to date (17 of 20) were presented, with the results from the remaining patients expected by the end of 2019. The trial also evaluated changes from baseline to six months in chest pain frequency, Canadian Cardiovascular Society angina classification and Seattle Angina Questionnaire scores. A single administration of CLBS16 resulted in statistically significant improvements in all these measures of patient symptoms and function.

ESCaPE Trial Background. 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.

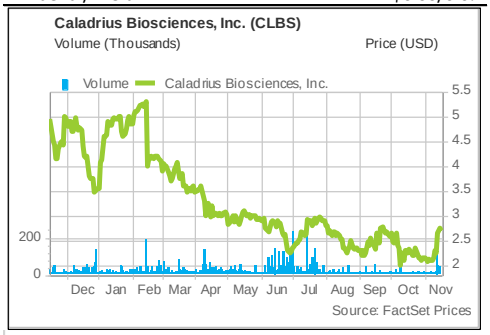
CLBS14 – No Option Refractory Angina (NORDA). As previously discussed the protocol is now finalized for the confirmatory Phase 3 trial NORDA of CLBS14. The protocol defines a prospective, randomized, double-blind, ~400 total subject trial with a primary endpoint of total exercise time at the 6-month follow-up visit. Considering resources, the trial is not planned to start until funding is secured (potentially with a partner) before beginning the study. We view this as prudent decision making.

CLBS12 - 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. The Japan trial is expected to complete enrollment 1H20 with data late 2020/early 2021, making a 2021 approval "possible".

Current Price	**$2.71**
Price Target	**$7.00**

Estimates	F2018A	F2019E	F2020E
Expenses ($000s)	$ 16,987	$ 20,242	$ 25,366
1Q March	$ 5,159	$ 4,592	$ 5,580
2Q June	$ 4,269	$ 5,346	$ 6,088
3Q September	$ 3,763	$ 5,072	$ 6,595
4Q December	$ 3,796	$ 5,232	$ 7,102
	F2018A	F2019E	F2020E
EPS (diluted)	$ (1.67)	$ (1.57)	$ (0.54)
1Q March	$ (0.52)	$ (0.44)	$ (0.12)
2Q June	$ (0.43)	$ (0.49)	$ (0.13)
3Q September	$ (0.36)	$ (0.47)	$ (0.14)
4Q December	$ (0.36)	$ (0.17)	$ (0.15)
EBITDA/Share	($1.67)	($0.17)	($0.15)
EV/EBITDA (x)	-	-5	-58

Stock Data	
52-Week Range	$2.00 - $5.44
Shares Outstanding (mil.)	10.4
Market Capitalization (mil.)	$28
Enterprise Value (mil.)	-$9
Debt to Capital	5%
Book Value/Share	$5.33
Price/Book	0.9
Average Three Months Trading Volume (K)	8
Insider Ownership	10.7%
Institutional Ownership	18.3%
Short interest (mil.)	0.4%
Dividend / Yield	$0.00/0.0%



Catalysts and Cash. Caladrius ended 3Q19 with $29M in cash versus a burn rate of $5M in the quarter. Data is 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. We note that waiting for capital before advancing CLBS14 should help preserve the balance sheet.

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).

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

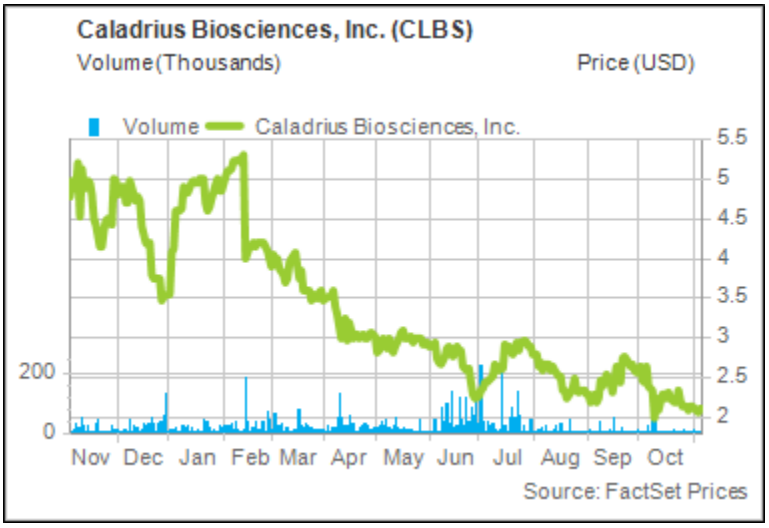
Caldrius Inc.: Income Statement ($000)																
YE December 31	2018A	1Q19A	2Q19A	3Q19A	4Q19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Product sales																
Cell Therapy - CLI Japan								11,463	19,297	30,871	54,020	68,072	88,956	94,451	96,132	97,709
Cell Therapy - 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
Total Product Sales	-	-	-	-	-	-	-	11,463	19,297	63,035	186,056	401,622	676,908	948,698	1,234,486	1,465,236
Expenses																
Cost of Goods Sold - Products	-	-	-	-	-	-	-	4,012	6,561	23,936	61,747	138,391	209,841	284,610	358,001	410,266
% COGS (of product revenues)								35%	34%	38%	33%	34%	31%	30%	29%	28%
Research and Development	7,594	2,038	2,988	3,004	2,339	8,353	14,000	17,000	18,700	21,000	23,100	25,410	27,951	30,746	33,821	37,203
%R&D										68%	43%	37%	31%	33%	35%	38%
General and Administrative	9,393	2,554	2,358	2,068	2,893	10,332	11,366	12,502	13,752	18,000	25,000	27,500	34,000	40,000	44,000	48,400
%SG&A										58%	46%	40%	38%	42%	46%	50%
Total expenses	16,987	4,592	5,346	5,072	5,232	20,242	25,366	33,514	39,013	62,936	109,847	191,301	271,792	355,356	435,822	495,869
Operating Income (Loss)	(16,987)	(4,592)	(5,346)	(5,072)	(5,232)	(20,242)	(25,366)	(22,051)	(19,717)	9,598	95,976	241,171	405,115	593,343	798,664	969,367
Other expense	824	227	209	175	175	786	799	799	799	799	799	799	799	799	799	799
Interest expense	(5)			(0)	(0)	(0)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Total other income	819	227	209	175	175	786	793	793	793	793	793	793	793	793	793	793
Pretax Income	(16,168)	(4,365)	(5,137)	(4,897)	(5,057)	(19,456)	(24,572)	(21,258)	(18,923)	10,391	96,769	241,964	405,909	594,136	799,458	970,160
Income Tax Benefit (Provision)	-		-		-	-	-	-	-			24,196	73,064	118,827	199,864	291,048
Tax Rate												10%	18%	20%	25%	30%
Less: Loss from continuing operations attributable to noncontrolling interests	(1)	(2)	(3)	(1)												
GAAP Net Income (loss)	(16,168)	(4,367)	(5,140)	(4,898)	(5,057)	(19,456)	(24,572)	(21,258)	(18,923)	10,391	96,769	217,768	332,845	475,309	599,593	679,112
GAAP-EPS	(1.67)	(0.44)	(0.49)	(0.47)	(0.25)	(1.65)	(0.70)	(0.47)	(0.42)	0.23	2.11	5.25	7.21	10.26	12.89	14.54
GAAP EPS (dil)	(1.67)	(0.44)	(0.49)	(0.47)	(0.18)	(1.32)	(0.57)	(0.33)	(0.29)	0.16	1.46	3.23	4.88	6.88	8.56	9.58
Wgtd Avg Shrs (Bas) - '000s	9,689	10,027	10,393	10,411	20,000	12,708	35,073	45,228	45,409	45,591	45,774	45,957	46,141	46,326	46,512	46,698
Wgtd Avg Shrs (Dil) - '000s	9,689	10,027	10,393	10,411	28,000	14,708	43,345	63,940	64,773	65,617	66,473	67,339	68,217	69,106	70,006	70,919

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

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2) **Neutra**l: The analyst believes the price of the stock is fairly valued for the next 12-18 months;
3) **Sel**l: 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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	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	28	82%	4	14%
Market Perform (Neutral)	6	18%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	34	100%	4	12%

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