

Caladrius (NASDAQ/CLBS)

August 12, 2019

BUY: Phase 3 Protocol for NORDA Set For 2020

Caladrius announced 2Q19 Results. The highlight in the quarter was really the progress made with the NORDA program. The Phase 3 protocol is set now for an N=400 patient pivotal trial expected to begin in 2020.

Jason H. Kolbert

Head of Healthcare Research

646-465-6891

jkolbert@dawsonjames.com

Investment Highlights

CLBS14 – No Option Refractory Angina (NORDA). The key announcement in the quarter was the fact that the design, the trial protocol has been 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.

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.

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. The preliminary results from the first 30% of the patients to complete the six-month follow-up appear promising with evidence that improved CFR is associated with symptomatic improvement.

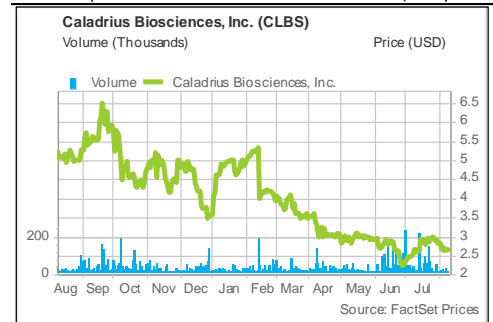
Catalysts and Cash. Caladrius ended 2Q19 with \$34M in cash versus a burn rate of \$5M in the quarter. Data is coming around two key programs: Coronary Microvascular Dysfunction – CMD and Critical Limb Ischemia (CLI) and we see an opportunity on good data for the company to commercialize its CD34 cell therapy product line.

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	\$2.60
Price Target	\$7.00

Estimates	F2018A	F2019E	F2020E
Expenses (\$000s)	\$ 16,987	\$ 20,028	\$ 25,366
1Q March	\$ 5,159	\$ 4,592	\$ 5,580
2Q June	\$ 4,269	\$ 5,346	\$ 6,088
3Q September	\$ 3,763	\$ 4,858	\$ 6,595
4Q December	\$ 3,796	\$ 5,232	\$ 7,102
	F2018A	F2019E	F2020E
EPS (diluted)	\$ (1.67)	\$ (1.25)	\$ (0.53)
1Q March	\$ (0.52)	\$ (0.44)	\$ (0.12)
2Q June	\$ (0.43)	\$ (0.49)	\$ (0.13)
3Q September	\$ (0.36)	\$ (0.15)	\$ (0.14)
4Q December	\$ (0.36)	\$ (0.16)	\$ (0.15)
EBITDA/Share	(\$1.67)	(\$0.16)	(\$0.15)
EV/EBITDA (x)	-	-6	-66

Stock Data		
52-Week Range	\$2.16	\$6.83
Shares Outstanding (mil.)	10.4	
Market Capitalization (mil.)	\$27	
Enterprise Value (mil.)	-\$10	
Debt to Capital	6%	
Book Value/Share	\$5.33	
Price/Book	0.9	
Average Three Months Trading Volume (K)	25	
Insider Ownership	10.8%	
Institutional Ownership	17.5%	
Short interest (mil.)	0.2%	
Dividend / Yield	\$0.00/0.0%	



Update - August 12, 2019 - Buy - Price Target \$7.00

Please find Important Disclosures beginning on Page 4.

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

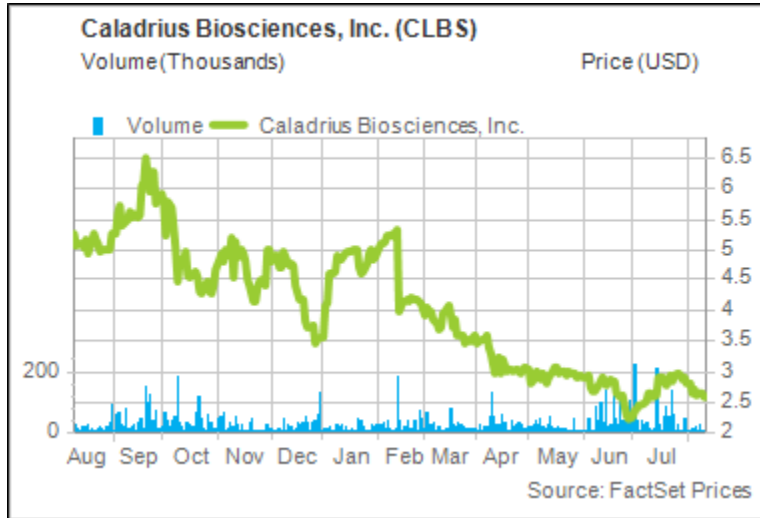
Caladrius Inc.: Income Statement (\$'000)																	
YE December 31	2018A	1Q19A	2Q19A	3Q19E	4Q19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	
Product sales																	
Cell Therapy - CLI Japan								11,463	19,297	30,871	54,020	68,072	88,956	94,451	96,132	97,709	
Cell 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	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	
%R&D											68%	43%	37%	31%	33%	35%	38%
General and Administrative	9,393	2,554	2,358	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	
%SG&A											58%	46%	40%	38%	42%	46%	50%
Total expenses	16,987	4,592	5,346	4,858	5,232	20,028	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)	(4,858)	(5,232)	(20,028)	(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	214	214	864	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	214	214	863	793	793	793	793	793	793	793	793	793	793	
Pretax Income	(16,168)	(4,365)	(5,137)	(4,645)	(5,018)	(19,165)	(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)														
GAAP Net Income (loss)	(16,168)	(4,367)	(5,140)	(4,645)	(5,018)	(19,165)	(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)	(0.23)	(0.25)	(1.40)	(0.69)	(0.47)	(0.41)	0.23	2.09	5.20	7.15	10.16	12.77	14.41	
GAAP EPS (dil)	(1.67)	(0.44)	(0.49)	(0.15)	(0.16)	(0.94)	(0.53)	(0.32)	(0.28)	0.15	1.40	3.10	4.68	6.59	8.21	9.18	
Wgt'd Avg Shrs (Bas) - '000s	9,689	10,027	10,393	20,403	20,424	15,312	35,497	45,655	45,838	46,021	46,206	46,391	46,576	46,763	46,950	47,138	
Wgt'd Avg Shrs (Dil) - '000s	9,689	10,027	10,393	30,403	30,707	20,383	46,084	66,714	67,584	68,465	69,357	70,261	71,176	72,104	73,044	73,996	

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

Dawson James Securities, Inc. (the “Firm”) is a member of the Financial Industry Regulatory Authority (“FINRA”) and the Securities Investor Protection Corporation (“SIPC”).

The Firm does not make a market in the securities of the subject company(s). The Firm has NOT engaged in investment banking relationships with CLBS in the prior twelve months, as a manager or co-manager of a public offering and has NOT received compensation resulting from those relationships. The Firm may seek compensation for investment banking services in the future from the subject company(s). The Firm has NOT received any other compensation from the subject company(s) in the last 12 months for services unrelated to managing or co-managing of a public offering.

Neither the research analyst(s) whose name appears on this report nor any member of his (their) household is an officer, director or advisory board member of these companies. The Firm and/or its directors and employees may own securities of the company(s) in this report and may increase or decrease holdings in the future. As of July 31, 2019, the Firm as a whole did not beneficially own 1% or more of any class of common equity securities of the subject company(s) of this report. The Firm, its officers, directors, analysts or employees may affect transactions in and have long or short positions in the securities (or options or warrants related to those securities) of the company(s) subject to this report. The Firm may affect transactions as principal or agent in those securities.

Analysts receive no direct compensation in connection with the Firm's investment banking business. All Firm employees, including the analyst(s) responsible for preparing this report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of the Firm and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

Although the statements in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst’s judgment as of the date of this report and are subject to change without notice.

Information about valuation methods and risks can be found in the “STOCK VALUATION” and “RISK ANALYSIS” sections of this report.

The securities of the company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.

Rating Definitions:

- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 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.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	43	86%	13	30%
Market Perform (Neutral)	7	14%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	50	100%	13	26%

Analyst Certification:

The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his (their) personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst’s compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) all Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.