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INITIATION REPORT

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Caladrius (NASDAQ/CLBS)

February 27, 2019

BUY: Focus on Ischemic Disease

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Caladrius (CLBS) Biosciences is emerging today as a new company driven by an experienced management team with a strategic focus. The divestiture of the contract manufacturing business and spending controls combined with active cell therapy programs in ischemic disease, in our opinion, creates a viable cell therapy company.

Investment Highlights

The focus at Caladrius today is on cell therapy with an emphasis on CD34 technology for ischemic disease. This technology was developed in-part by world re-known cardiologist, Douglas Losordo M.D. in his career and at his time at Baxter (BAX; not rated). Dr. Losordo is the Chief Medical Officer at Caladrius today. Caladrius acquired certain rights for the CD34 technology specifically for refractory angina. Caladrius is developing this technology in the U.S. and in Japan. In Japan, Caladrius has been the recipient of the "SAKIGAKE" designation (a Japanese version of breakthrough status). The therapy is now in a Phase 2 trial, in Japan. Depending on the results it could be eligible for early conditional approval for the treatment of critical limb ischemia. In the U.S. Caladrius is developing the therapy for refractory angina. The rights to the technology with the prior clinical data sets, were licensed from Shire (SHPGY; not rated). The product has received the Regenerative Medicine Advanced Therapy – RMAT designation and is considered Phase 3 ready. Caladrius is also advancing the therapy for Coronary Microvascular Dysfunction – CMD.

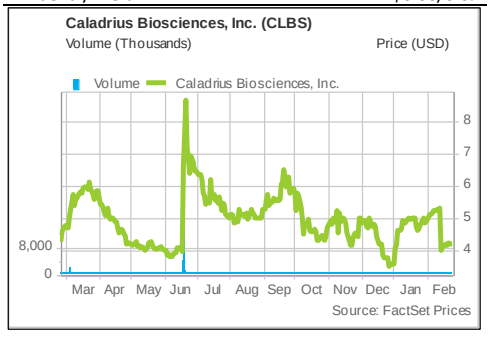
What is CD34? CD34 is a cell surface glycoprotein CD34 which is expressed on a small fraction of human bone marrow and progenitor cells. The CD34 population appears to be responsible for a significant amount of hematopoietic activity and cell signaling. These cells are believed among other things to promote the growth of micro-vasculature (blood supply). As such, Caladrius is developing an autologous approach to harvesting, isolating and returning the cells to patients through intramuscular, intracoronary and intramyocardial injection as represented by the three active programs: 1. CLBS12 (Critical Limb Ischemia or CLI, with a 51K patient market in Japan), CLBS14 (Coronary Microvascular Dysfunction or CMD, with 8.3M U.S. patients) and CLBS14 (No Option Refractory Disabling Angina or NORDA with just under 100k U.S. patients).

Immune Modulation Program, CLBS303. This autologous program extracts T regulatory cells from the patient, expands the "good cells" (ex vivo) and returns them to the body to achieve balance between normal quiescent cells (regulatory T cells) and active (T effector cells) cells. The theory is that the balance of quiescent and active cells is thus restored. When the body is deficient in T regulatory cells, an auto-immune disease is typically manifested. The Phase 2 work on this program reported disappointing results at the one-year interval. As such, we expect the program to be deprioritized, conserving resources to what we view as the more proven, less risky CD34 technology.

Current Price	**$4.20**
Price Target	**$7.00**

Estimates	F2018A	F2019E	F2020E
Expenses ($000s)	$ 17,041	$ 18,745	$ 25,017
1Q March	$ 5,159	$ 4,124	$ 5,504
2Q June	$ 4,269	$ 4,499	$ 6,004
3Q September	$ 3,763	$ 4,874	$ 6,504
4Q December	$ 3,850	$ 5,249	$ 7,005
	F2018A	F2019E	F2020E
EPS (diluted)	$ (1.68)	$ (1.17)	$ (0.53)
1Q March	$ (0.52)	$ (0.40)	$ (0.12)
2Q June	$ (0.43)	$ (0.44)	$ (0.13)
3Q September	$ (0.36)	$ (0.16)	$ (0.14)
4Q December	$ (0.37)	$ (0.17)	$ (0.15)
EBITDA/Share	($1.68)	($0.17)	($0.15)
EV/EBITDA (x)	-	0	5

Stock Data	
52-Week Range	$3.05 - $11.65
Shares Outstanding (mil.)	9.8
Market Capitalization (mil.)	$41
Enterprise Value (mil.)	$1
Debt to Capital	5%
Book Value/Share	$5.33
Price/Book	0.7
Average Three Months Trading Volume (K)	7
Insider Ownership	11.8%
Institutional Ownership	18.3%
Short interest (mil.)	0.2%
Dividend / Yield	$0.00/0.0%



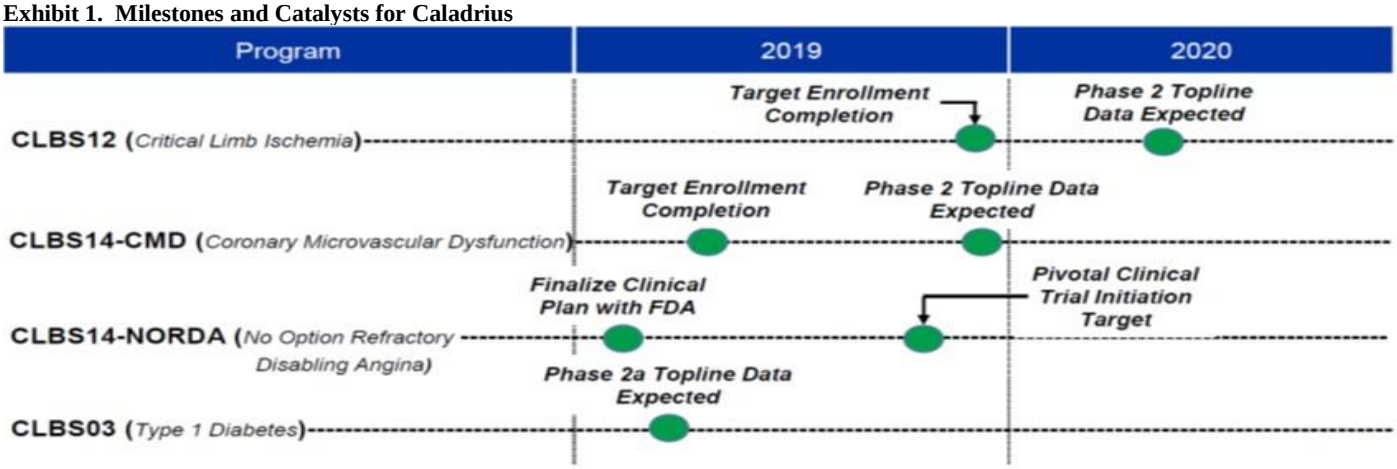
Initiation - February 27, 2019 - Buy - Price Target $7.00

Company Overview

In Roman mythology, the Caladrius is a bird that visits the ill and is said to be able to absorb patients' illnesses and fly away, dispersing the illness and healing both itself and the patient. We see Caladrius as a new company, with a strong capital structure, an experienced management team and strategic focus on CD34 based cell therapy for ischemic disease. Hopefully, Caladrius is poised to offer new hope in the form of innovative cell therapy in areas of great unmet medical need.

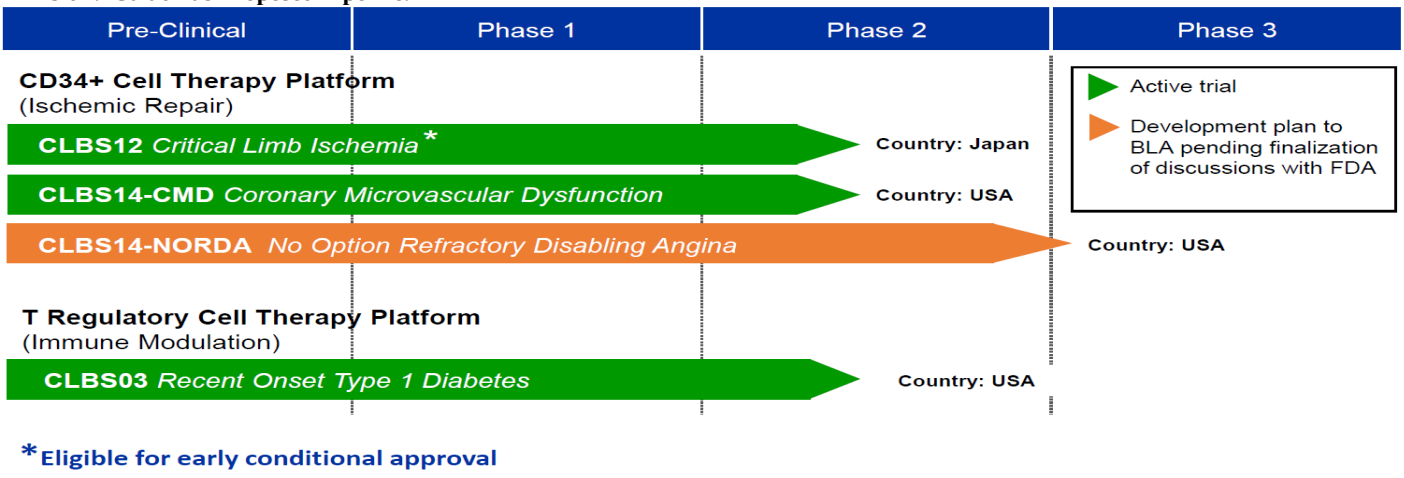
Caladrius was born from the old company, NeoStem which itself was born from several different assets including Progenitor Cell Therapy (PCT), a clinical-stage contract manufacturing company and Amorcyte a CD34 bone marrow-derived cell therapy company. Caladrius Chief Medical Officer is Dr. Douglas Losordo, is a pioneer in the use of CD34 cells to treat ischemic disease. Dr. Losordo over-saw Baxter's efforts to use GCSF apheresis derived CD34 cells and has been instrumental in driving the current CD34 programs at the company. NeoStem previously sponsored multiple academic research programs, including that of Dr. Jeffrey Bluestone Ph.D., who developed over the past 25 years an understanding of the basic processes that control T cell activation and immune tolerance in autoimmunity and organ transplantation. Dr. Bluestone's work is represented at Caladrius today by CLBS303 program. This program recently reported disappointing results, and as a result, we expect it to be placed on the back-burner. Caladrius CEO, David Mazzo, who is a highly experienced Biotech CEO has been busy. Dr. Mazzo (Ph.D.), made several key decisions that appear to have transformed the company. We see the divestiture of PCT as one of the key decisions that recapitalized the company (PCT was sold to Hitachi (To:6501: not rated) for ~$75M) which has been combined with a much-reduced capital expenditures rate and a strategic focus on clinical development. As such the message has become clear to us, Caladrius is a cell therapy company developing clinical assets.

Exhibit 1. Milestones and Catalysts for Caladrius



Source: Caladrius and Dawson James

Exhibit 2. Caladrius Proposed Pipeline.



Source: Dawson James

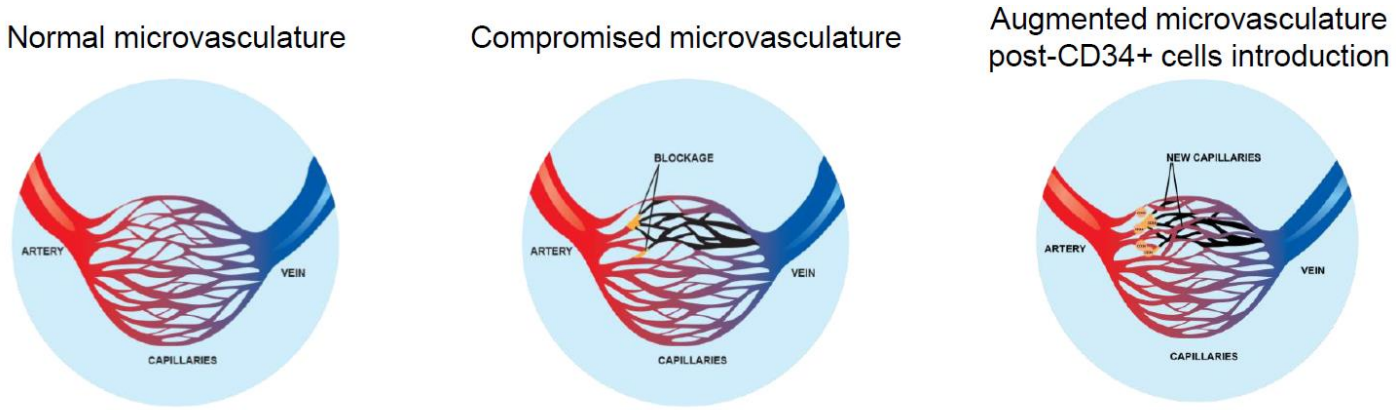
Bull Case: Success in ischemic disease can represent significant market opportunities for the company. From Critical Limb Ischemia in Japan with 51k patients (300k in the U.S. and 560k in Europe) Coronary Microvascular Dysfunction (CMD) with a U.S. market size of 8.3M patients, 6.0M in Europe and 1M in Japan. Proof of concept may first arise in Japan, or it could begin with success in the No Option Refractory Disabling Angina (NORDA) U.S. market of just 100k patients. The product in Japan, CLBS12 has SAKIGAKE designation and is in a Phase 2 CLI trial. Good data could drive an early conditional approval in CLI, which could have the added effect to drive investor interest in the other CD34 programs, and as such, create a value inflection. Investors may move from non-believers to assessing the market opportunity to treat ischemic disease.

Bear Case: Bears are suspicious that Regenerative Medicine may never achieve the success or valuations that the market has awarded to CAR-T companies. Multiple companies such as Athersys (ATHX: not rated), Mesoblast (MESO: not rated), Cytori (CYTX: not rated), Pluristem (PSTI: not rated), Vericel (VCEL; not rated), Cesca (KOOL, not rated) and NeoStem (NBS now Caladrius), to name a few, have had mixed to negative results in treating ischemic diseases with cell therapy. In the case of NeoStem the company ran a prior Phase 2 clinical trial with a bone marrow-derived CD34 cell therapy (AMR-001) to treat heart attacks (STEMI's). The data failed to impress with mixed results. Bulls will believe a signal was demonstrated on the mortality endpoint (p=0.004), but BEARS will argue the data was mixed. Bull or BEAR, back in November of 2014 it was clear that NeoStem lacked the funds to move AMR-001 forward in a definitive pivotal trial and this example has been replayed in the regenerative medicine space multiple times. As such, BEARS will believe that even with more relaxed regulations in Japan, the U.S. and Europe that the current trials lack a large enough sample size to convince users (the medical community) and payers to believe that cell therapy works and creates a new option for patients with ischemic disease.

Our Take: We believe that there is a preponderance of data related to CD34 cell therapy showing that there is an effect. Our confidence is driven by more than just the data from prior trials mentioned above, which were under-powered, and as such concluded in mixed results. We believe that the regenerative medicine space as an industry has suffered from a lack of capital, which in turn forced trial sizes and duration to be reduced, triggering mixed results which then set then reset the cycle. In many ways, we see the regenerative space as the opposite of CAR-T. In CAR-T, where often data in a single patient (N=1) created definitive proof of concept and sent valuations soaring. Of course, in the case of CAR-T, patients who were gravely ill, miraculously achieved complete remission. This is not the case in ischemic disease, regardless of whether we are talking about CLI, AMI or even a stroke. The good news is that global regulations have changed. The recognition that Regenerative Medicine is generally safe should translate into more product being approved with smaller trials, provided a viable efficacy signal is realized. We believe that is happening now, all around us, at companies like Mesoblast, Athersys and Cytori and Caladrius too. We also see that autologous therapies are viable; one can look to CAR-T here to establish proof of concept. We combine this with a savvy, experienced senior management team, better financial controls, and a pure therapeutics business model and conclude that Caldrius should be in a good position to realize a valuation gain, on good data from CD34 CLI program in Japan and the CMD/NORDA U.S. programs.

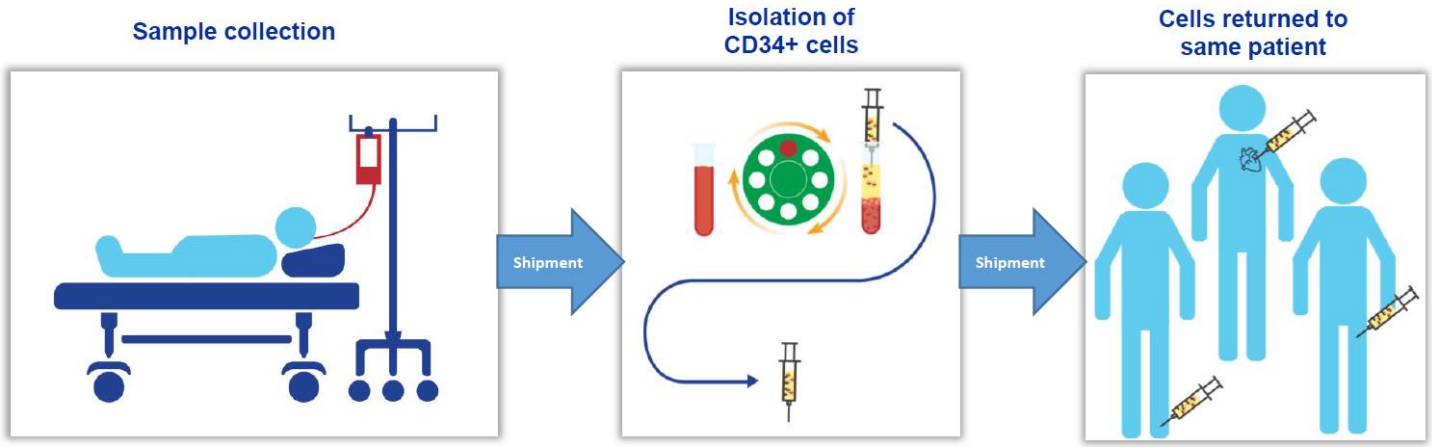
Finances: Caladrius has publicly stated that the company expects to have ended 2018 with close to $43M in cash on the balance sheet which should support 18 months of operations.

Exhibit 3. Overwhelming Evidence Exists in Support of the Effects of CD34 Cells on the Promotion of New Blood Vessel Growth. In one study of greater than 700 subjects in randomized, double-blind placebo-controlled trials, showed consistent evidence of therapeutic benefit and tolerance. Improved mortality, reduced chest pain and increased exercise tolerance in refractory angina. Reduced amputation in critical limb ischemia. Improved function in claudication.



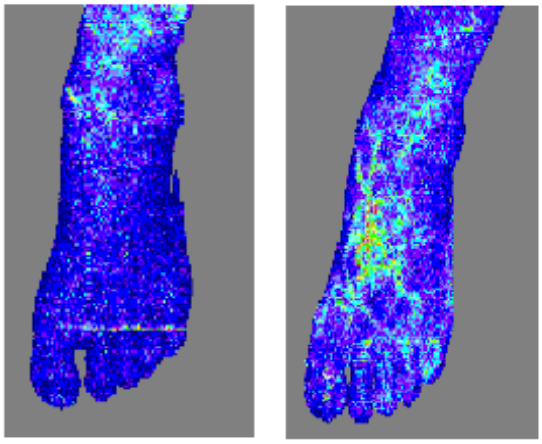
Source: Losordo et al. Circ Res 2011.; Povsicet al. JACC Cardiovasc Interv. 2016; Losordo et al. Circ Cardiovasc Interv2012; From US study (n=17); Not yet published

Exhibit 4. The Process is "Simple, Scalable and Economical" to Acquire the Cells. Three days before harvest the patient is treated with GCSF to mobilize CD34 cells from bone marrow to peripheral blood.



Source: Caladrius

Exhibit 5. Before and After Doppler Images of Treated Patient. The after image (right) shows a viable blood supply and tissue perfusion.



Source: Caladrius

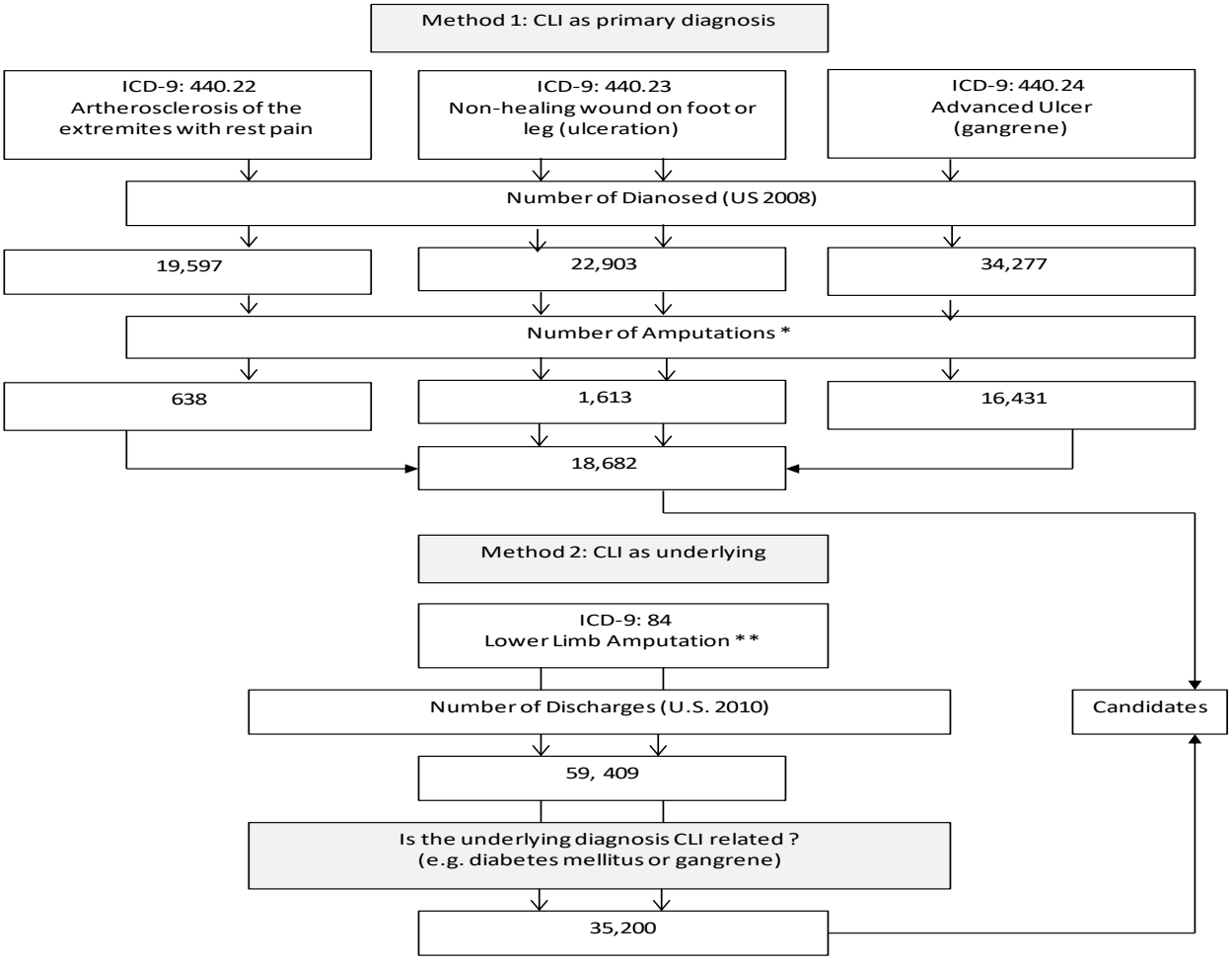
Exhibit 6. CLBS12 phase 2 study in Japan. Awarded SAKIGAKE ("breakthrough") designation with priority review eligible for early conditional approval.

Design	• Prospective, open label, controlled, randomized trial (1:1 w/SOC) CLI patients
Primary Endpoint	• Time to continuous CLI-free status (2 consecutive monthly visits, adjudicated independently)
Study Size	• 30 patients with no-option CLI plus 5 patients with Buerger's Disease; ~10 centers in Japan
Dose	• Up to 10^6 autologous G-CSF-mobilized peripheral blood-derived CD34+ cells/kg per affected limb
Control/Comparator	• Standard of Care drugs approved in Japan (e.g., antiplatelets, anticoagulants and vasodilators) • Choice of pharmacotherapy will be made by the investigators according to protocol
Mode of administration	• Intramuscular, 20 injections in affected lower limb in single administration
Timing/Cost	• First patient enrolled in December 2017 with final results expected early 2020 • <$7 million costs remain to study completion (fully funded)

Source: Caladrius

PHYSICIANS and PAYERS' VIEWS ON DCM/CLI. Cardiologists may have an increased appetite for alternative therapies surrounding critical limb ischemia (CLI), but they tend to have conservative viewpoints. As such we estimate a gradual market penetration if a new cell therapy. From a cost perspective, critical limb ischemia (CLI) is very costly, often requiring surgical intervention and hospitalization. Any simple, cost-effective analysis will show a reduction in cost by treatment with cellular therapies rather than surgeries or hospital stay. Insurance companies are likely to see cost savings as long as the treatment demonstrates efficacy and safety.

Exhibit 7. The CLI Treatment Tree. There is no single ICD-9 code for a diagnosis of CLI, and limb loss and other procedures associated with CLI may be coded in the health system under multiple other diagnosis codes including peripheral arterial disease, diabetes, cardiovascular disease, and trauma (Ziegler-Graham, Arch Phys Med Rehabil, 2008). The exhibit provides an estimate of the number of amputations using only CLI diagnosis codes; therefore, this is a fairly significant underestimate of the numbers of CLI patients and amputations. There are no primary population sources for current estimates of the rate of amputation in CLI patients. Older statistics put the rate at 220,000 to 240,000 major and minor amputations performed yearly in CLI patients in the US and Europe (this includes data from the US Department of Health and Human Services, National Center for Health Statistics).



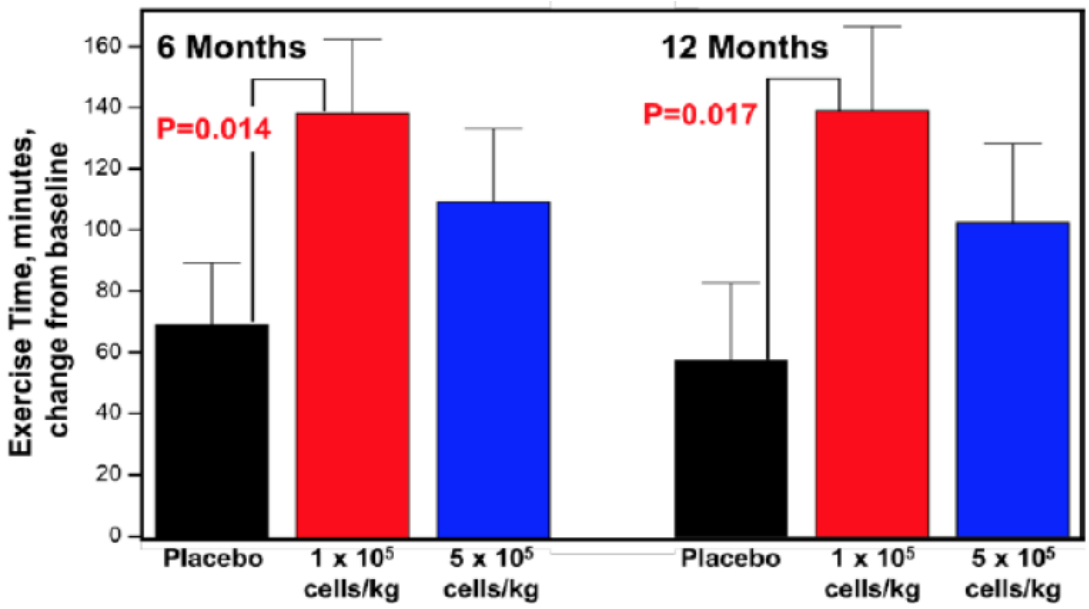
Source: US Agency for Healthcare Research and Quality
* CCS principal procedure 157: amputation of lower extremity
** excludes minor amputations, such as removal of toes or amputations through the foot.

Exhibit 8. CLBS14-CMD Phase 1b/2a Proof of Concept Study (ESCaPE-CMD). The trial is currently enrolling patients in the U.S.

Design	• Interventional, open label, proof-of-concept trial
Primary Endpoint	• Safety and the evaluation of adverse events
Secondary Endpoints	• Changes from baseline to 6 months for coronary flow reserve, endothelial-dependent microvascular function, time to angina; other cardiovascular metrics
Study Size	• 20 patients at 2 centers in the USA (Cedars Sinai, LA & Mayo Clinic)
Dose	• Up to 300 x 10^6 CD34+ cells
Control	• No control arm
Mode of administration	• Single intracoronary infusion
Timing/Cost	• First patient enrolled April 2018 with final results expected by end of 2019 • NIH grant covers majority of costs • <$0.5 million CLBS costs remain to study completion (fully funded)

Source: Caladrius

Exhibit 9. Change in Exercise Time at Six and 12 Months in NORDA Patients After One Injection of Cells.



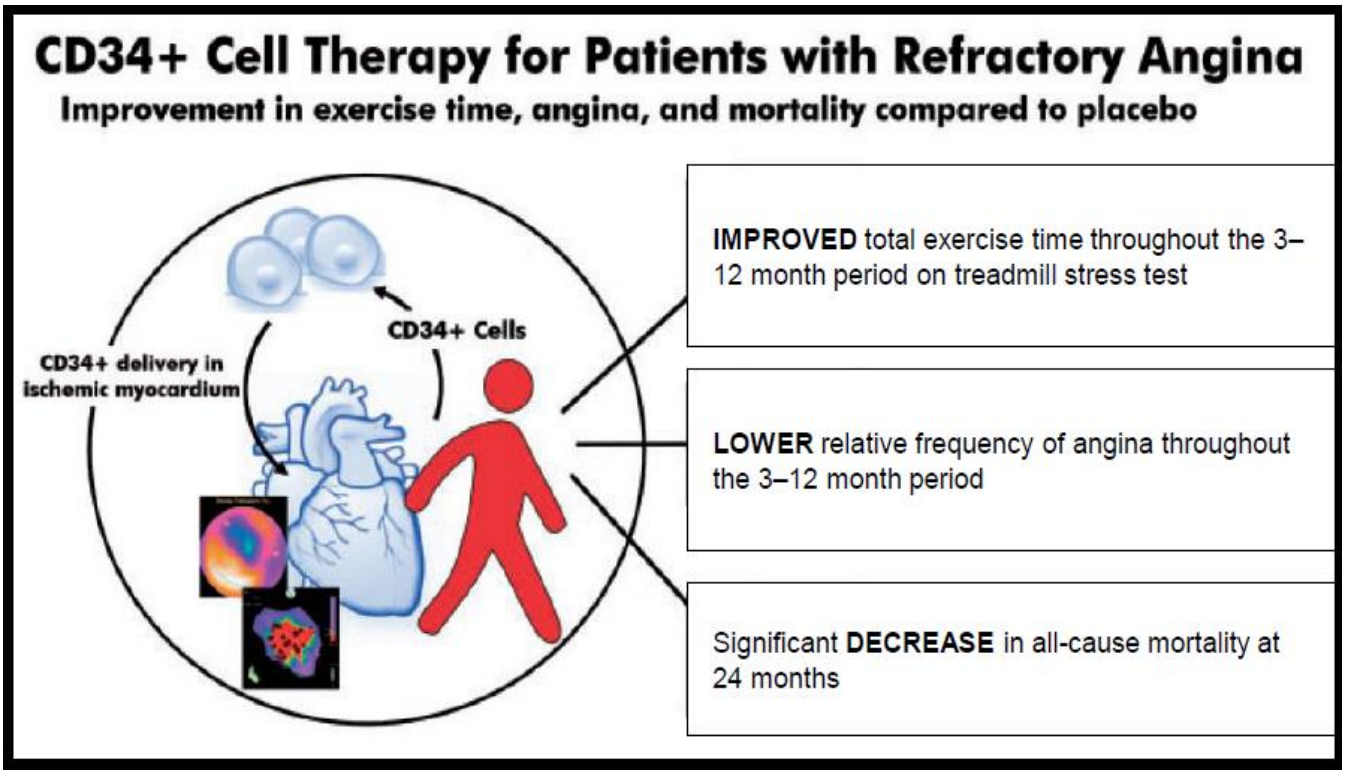
Source: Caladrius

Exhibit 10. Phase 1,2 and Partial Phase 3 Studies have been completed. [1] Compelling results of patient-level pooled -analysis published in European Heart Journal European Heart Journal, 1/2018.

1 *Losordo, D.W., et al., Intramyocardial transplantation of autologous CD34+++ stem cells for intractable angina: a phase I/Iiadouble-blind, randomized controlled trial. Circulation, 2007. 115(25): p. 3165-3172*

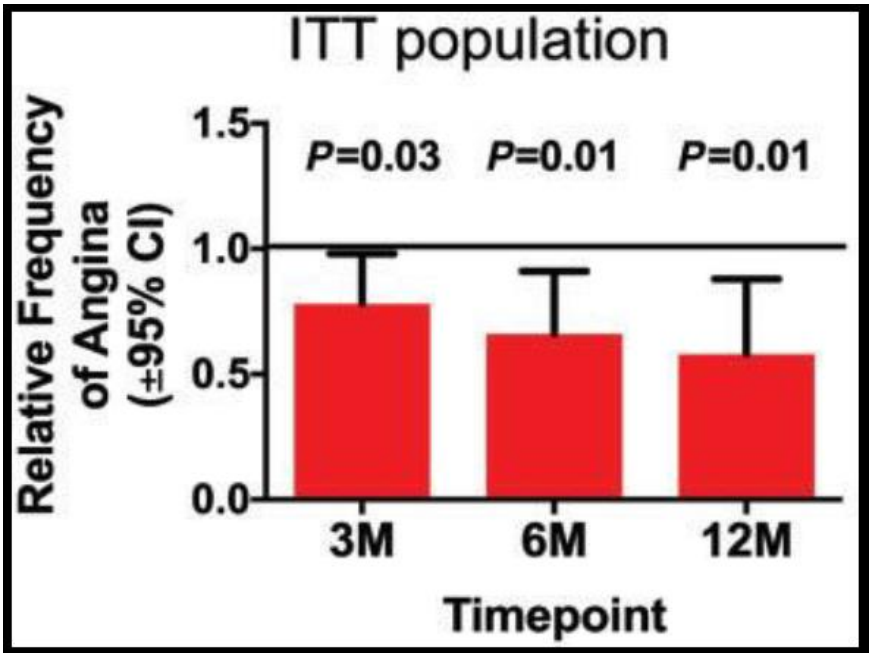
Losordo, D.W., et al., Intramyocardial, autologous CD34+++ cell therapy for refractory angina. CircRes, 2011. 109(4): p. 428-36.

Povsic, T.J., et al., The RENEW Trial: Efficacy and Safety of Intramyocardial Autologous CD34++(+) Cell Administration in Patients With Refractory Angina. JACC Cardiovasc Interv, 2016. 9(15): p. 1576-85.



Source: Caladrius

Exhibit 11. Pooled Angina Frequency Results. [2]



Source: Caladrius

[2] *Losordo, D.W., et al., Intramyocardial transplantation of autologous CD34+++ stem cells for intractable angina: a phase I/Iiadouble-blind, randomized controlled trial. Circulation, 2007. 115(25): p. 3165-3172*

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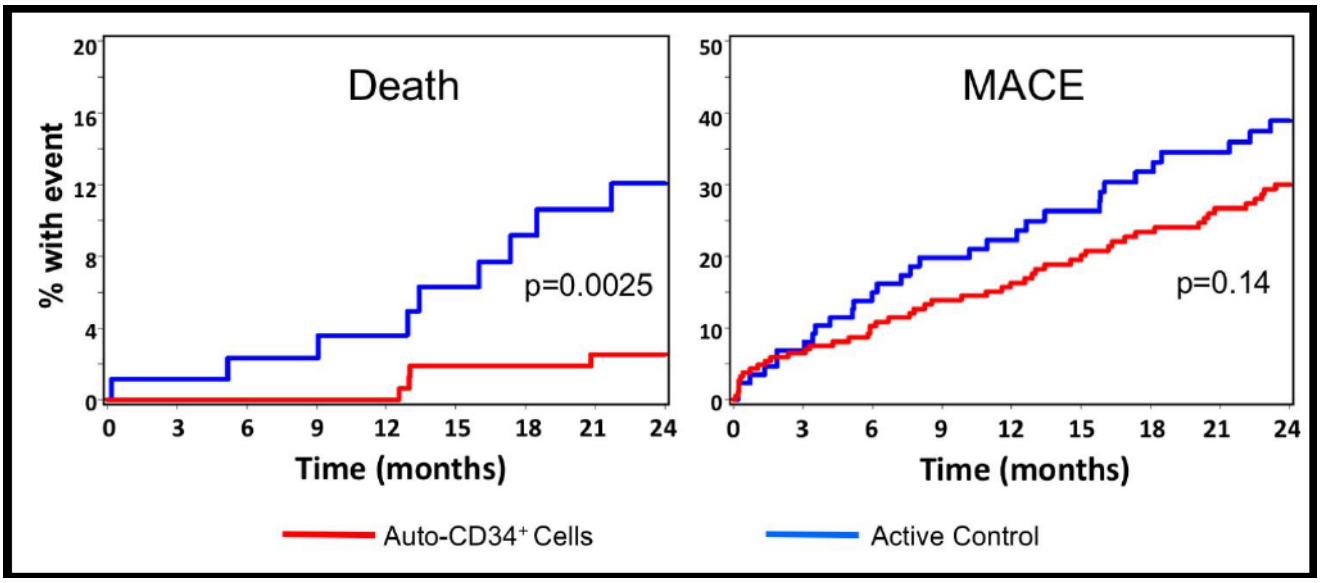
Exhibit 12. Major Cardiac Events (MACE) Results.[2]



Source: Caladrius

Modeling Assumptions

We model CLI, Microvascular Dysfunction and No Option Refractory Disabling Angina (NORDA) in Japan, the U.S. and in Europe and apply probability of success estimates to each indication in each country.

Critical Limb Ischemia (CLI)

1. CLI in Japan. We assume that the CLI indication is approved in Japan and commercialized by 2021 at a price equivalent of $30k per treatment, which could prove conservative. We estimate the market share as modest initially and at peak reaching 28% by 2029. We assign our highest success probability (among all the indications and countries) to CLI in Japan of 60%. This is based on our belief that with efficacy and new Japanese regulations Caladrius could see a rapid approval.
2. CLI in the U.S. and Europe. Here we assume a longer time line to the market, 2025 for the U.S., and 2016 for Europe with just a 15% probability of success. We caveat this assumption with the idea, that Caladrius may receive RMAT designation, setting the stage for a modest N=150 patient Phase 2/3 CLI trial which could create a more accelerated path to the marketplace. For now, for purposes of conservatism, we do not assume such. We also assume a much lower probability of success for CLI in the U.S. based on a combination of factors including the long history of failed CLI trials in the states and the fact that Caladrius U.S. and European focus is really on Coronary Microvascular Dysfunction and NORDA. We expect CLI to be staged behind these programs, but that could change. As such we heavily discount CLI's U.S. and EU impact on Caladrius' valuation.

Coronary Microvascular Dysfunction (CMD)

1. We estimate that U.S. approval in CMD is possible by 2024, Europe by 2026, and Japan first by 2023 although Japan represents the smallest of the three markets (but still large at an estimated prevalence of 1M patients) versus the U.S. at over 8M and Europe at 6M patients.
2. We assume Japanese pricing of just $20k per treatment (fewer cells versus other indications such as CLI) however this may change, followed by U.S. pricing of 25k and for Europe an assumed price of $24k. We assume just a 15% probability of approval in CMD in Europe and the U.S., but in Japan, we increase that to 40% since MOHW will be familiar with the therapy through the CLI indication.

No Option Refractory Disabling Angina (NORDA)

1. We estimate that U.S. approval in NORDA could arrive by 2023. This is a smaller niche market versus CLI or CMD but still substantial at a prevalence of 90k patients. We anticipate a higher price of $100k per therapy course. We assume a modest market share at just 6% by 2029 and a 15% probability of success with similar assumptions for Europe. For Japan, we see an even smaller market, 30k annual patients. We maintain a 15% probability of success and similar market share assumptions in Japan too. We see Japan as a fast follower for NORDA.

Exhibit 13. Therapeutic (Product) Models

Japan CLI Target Market	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
51K "No Option" CLI at baseline:	51,000	51,510	51,510	51,510	51,510	50,995	50,485	49,980	49,480	48,985	48,496	48,011
Market Size Growth (Annual)	1.0%	0.0%	0.0%	0.0%	-1.0%	-1.0%	-1.0%	-1.0%	-1.0%	-1.0%	-1.0%	-1.0%
% with Tissue Loss	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
CLI Patients with Tissue Loss (subset of No Options)	25,500	25,755	25,755	25,755	25,755	25,497	25,242	24,990	24,740	24,493	24,248	24,005
% viable for Therapy (insurance, co-morbidities) et al	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
CLI Target Patient Population	20,400	20,604	20,604	20,604	20,604	20,398	20,194	19,992	19,792	19,594	19,398	19,204
Market Share Penetration	0%	0%	0%	3%	5%	8%	14%	18%	24%	26%	27%	28%
Price Per Procedure	$ 30,000	30,300	30,603	30,909	31,218	31,530	31,846	31,527	31,212	30,900	30,591	30,285
Price Growth	1%	1%	1%	1%	1%	1%	-1%	-1%	-1%	-1%	-1%	-1%
Probability of Success	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Annual Sales (M)	$ -	$ -	$ -	$ 11	$ 19	$ 31	$ 54	$ 68	$ 89	$ 94	$ 96	$ 98

Source: Dawson James

U.S.A. CLI Target Market	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
300K "No Option" CLI at baseline:	300,000	303,000	306,030	309,090	312,181	315,303	318,456	321,641	324,857	328,106	331,387	334,701
Market Size Growth (Annual)	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
% with Tissue Loss	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
CLI Patients with Tissue Loss (subset of No Options)	150,000	151,500	153,015	154,545	156,091	157,652	159,228	160,820	162,429	164,053	165,693	167,350
% viable for Therapy (insurance, co-morbidities) et al	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
CLI Target Patient Population	75,000	75,750	76,508	77,273	78,045	78,826	79,614	80,410	81,214	82,026	82,847	83,675
Market Share Penetration	0%	0%	0%	0%	0%	0%	0%	4%	5%	10%	15%	20%
Price Per Procedure	$ 50,000	50,500	51,005	51,515	52,030	52,551	53,076	53,607	54,143	54,684	55,231	55,783
Price Growth	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Probability of Success	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
Annual Sales (M)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 26	$ 33	$ 67	$ 103	$ 140

Source: Dawson James

European CLI Target Market	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
560K "No Option" CLI at baseline:	560,000	565,600	571,256	576,969	582,738	588,566	594,451	600,396	606,400	612,464	618,588	624,774
Market Size Growth (Annual)	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
% with Tissue Loss	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
CLI Patients with Tissue Loss (subset of No Options)	280,000	282,800	285,628	288,484	291,369	294,283	297,226	300,198	303,200	306,232	309,294	312,387
% viable for Therapy (insurance, co-morbidities) et al	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
CLI Target Patient Population	140,000	141,400	142,814	144,242	145,685	147,141	148,613	150,099	151,600	153,116	154,647	156,194
Market Share Penetration	0%	0%	0%	0%	0%	0%	0%	0%	3%	6%	9%	12%
Price Per Procedure	$ 45,000	45,450	45,905	46,364	46,827	47,295	47,768	48,246	48,729	49,216	49,708	50,205
Price Growth	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Probability of Success	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
Annual Sales (M)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 33	$ 68	$ 104	$ 141

Source: Dawson James

Japan Coronary Microvascular Dysfunction	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Cardiovascular Disease Patients	1,000,000	1,010,000	1,020,100	1,030,301	1,040,604	1,051,010	1,061,520	1,072,135	1,082,857	1,093,685	1,104,622	1,115,668
Growth Rate - Incidence	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
CMD Patients Eligible for Treatment	750,000	757,500	765,075	772,726	780,453	788,258	796,140	804,102	812,143	820,264	828,467	836,751
Growth Rate - Incidence	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Qualified patients (EF, Consent, Insurance)	50%	50%	50%	50%	51%	51%	52%	52%	53%	53%	54%	54%
Change Rate in % who qualify					1%	1%	1%	1%	1%	1%	1%	1%
Viable Treatment Population	187,500	189,375	191,269	193,181	394,129	402,051	410,132	418,376	426,785	435,363	444,114	453,041
Market Share						1%	2%	3%	4%	5%	6%	6%
Treated Patients						4,021	8,203	12,551	17,071	21,768	26,647	27,182
Price of Therapy - (Annual 2% increase)						$20,000	$20,400	$20,808	$21,224	$21,649	$22,082	$22,523
Revenues (000)						$ 80,410	$ 167,334	$ 261,167	$ 362,326	$ 471,251	$ 588,406	$ 612,237
Probability of Success						40%	40%	40%	40%	40%	40%	40%
Annual Sales (M)	$ -	$ -	$ -	$ -	$ -	$ 32	$ 67	$ 104	$ 145	$ 189	$ 235	$ 245

Source: Dawson James

USA Coronary Microvascular Dysfunction	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Cardiovascular Disease Patients	8,300,000	8,383,000	8,466,830	8,551,498	8,637,013	8,723,383	8,810,617	8,898,723	8,987,711	9,077,588	9,168,364	9,260,047
Growth Rate - Incidence	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
CMD Patients Eligible for Treatment	6,225,000	6,287,250	6,350,123	6,413,624	6,477,760	6,542,538	6,607,963	6,674,043	6,740,783	6,808,191	6,876,273	6,945,035
Growth Rate - Incidence	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Qualified patients (EF, Consent, Insurance)	25%	25%	25%	25%	25%	26%	26%	26%	26%	27%	27%	27%
Change Rate in % who qualify					1%	1%	1%	1%	1%	1%	1%	1%
Viable Treatment Population	1,556,250	1,571,813	1,587,531	1,603,406	1,635,634	1,668,511	1,702,048	1,736,259	1,771,158	1,806,758	1,843,074	1,880,120
Market Share						0%	1%	3%	4%	5%	6%	6%
Treated Patients						0	17,020	52,088	70,846	90,338	110,584	112,807
Price of Therapy - (Annual 2% increase)						$25,000	$25,500	$26,010	$26,530	$27,061	$27,602	$28,154
Revenues (000)						$ -	$ 434,022	$ 1,354,803	$ 1,879,567	$ 2,444,616	$ 3,052,354	$ 3,175,980
Probability of Success						15%	15%	15%	15%	15%	15%	15%
Annual Sales (M)	$ -	$ -	$ -	$ -	$ -	$ -	$ 65	$ 203	$ 282	$ 367	$ 458	$ 476

Source: Dawson James

Europe Coronary Microvascular Dysfunction	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Cardiovascular Disease Patients	6,000,000	6,060,000	6,120,600	6,181,806	6,243,624	6,306,060	6,369,121	6,432,812	6,497,140	6,562,112	6,627,733	6,694,010
Growth Rate - Incidence	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
CMD Patients Eligible for Treatment	4,500,000	4,545,000	4,590,450	4,636,355	4,682,718	4,729,545	4,776,841	4,824,609	4,872,855	4,921,584	4,970,800	5,020,508
Growth Rate - Incidence	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Qualified patients (EF, Consent, Insurance)	25%	25%	25%	25%	25%	26%	26%	26%	26%	27%	27%	27%
Change Rate in % who qualify					1%	1%	1%	1%	1%	1%	1%	1%
Viable Treatment Population	1,125,000	1,136,250	1,147,613	1,159,089	1,182,386	1,206,152	1,230,396	1,255,127	1,280,355	1,306,090	1,332,342	1,359,123
Market Share						0%	0%	0%	1%	2%	3%	5%
Treated Patients						0	0	0	12,804	26,122	39,970	67,956
Price of Therapy - (Annual 2% increase)						$24,000	$24,480	$24,970	$25,469	$25,978	$26,498	$27,028
Revenues (000)						$ -	$ -	$ -	$ 326,093	$ 678,602	$ 1,059,130	$ 1,836,711
Probability of Success						15%	15%	15%	15%	15%	15%	15%
Annual Sales (M)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 49	$ 102	$ 159	$ 276

Source: Dawson James

Japan NORDA	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Cardiovascular Disease Patients	30,000	30,300	30,603	30,909	31,218	31,530	31,846	32,164	32,486	32,811	33,139	33,470
Growth Rate - Incidence	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
NORDA Patients Eligible for Treatment	22,500	22,725	22,952	23,182	23,414	23,648	23,884	24,123	24,364	24,608	24,854	25,103
Growth Rate - Incidence	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Qualified patients (EF, Consent, Insurance)	75%	75%	75%	75%	76%	77%	77%	78%	79%	80%	80%	81%
Change Rate in % who qualify					1%	1%	1%	1%	1%	1%	1%	1%
Viable Treatment Population	5,625	5,681	5,738	5,795	17,736	18,092	18,456	18,827	19,205	19,591	19,985	20,387
Market Share						1%	2%	3%	4%	5%	6%	6%
Treated Patients						181	369	565	768	980	1,199	1,223
Price of Therapy - (Annual 2% increase)						$50,000	$51,000	$52,020	$53,060	$54,122	$55,204	$56,308
Revenues (000)						$ 9,046	$ 18,825	$ 29,381	$ 40,762	$ 53,016	$ 66,196	$ 68,877
Probability of Success						15%	15%	15%	15%	15%	15%	15%
Annual Sales (M)	$ -	$ -	$ -	$ -	$ -	$ 1	$ 3	$ 4	$ 6	$ 8	$ 10	$ 10

Source: Dawson James

USA NORDA	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Cardiovascular Disease Patients	90,000	90,900	91,809	92,727	93,654	94,591	95,537	96,492	97,457	98,432	99,416	100,410
Growth Rate - Incidence	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
CMD Patients Eligible for Treatment	67,500	68,175	68,857	69,545	70,241	70,943	71,653	72,369	73,093	73,824	74,562	75,308
Growth Rate - Incidence	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Qualified patients (EF, Consent, Insurance)	75%	75%	75%	75%	76%	77%	77%	78%	79%	80%	80%	81%
Change Rate in % who qualify					1%	1%	1%	1%	1%	1%	1%	1%
Viable Treatment Population	16,875	17,044	17,214	17,386	53,207	54,277	55,368	56,481	57,616	58,774	59,955	61,161
Market Share						1%	2%	3%	4%	5%	6%	6%
Treated Patients						543	1,107	1,694	2,305	2,939	3,597	3,670
Price of Therapy - (Annual 2% increase)						$100,000	$102,000	$104,040	$106,121	$108,243	$110,408	$112,616
Revenues (000)						$ 54,277	$ 112,950	$ 176,288	$ 244,570	$ 318,095	$ 397,174	$ 413,260
Probability of Success						15%	15%	15%	15%	15%	15%	15%
Annual Sales (M)	$ -	$ -	$ -	$ -	$ -	$ 8	$ 17	$ 26	$ 37	$ 48	$ 60	$ 62

Source: Dawson James

Europe NORDA	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Cardiovascular Disease Patients	50,000	50,500	51,005	51,515	52,030	52,551	53,076	53,607	54,143	54,684	55,231	55,783
Growth Rate - Incidence	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
CMD Patients Eligible for Treatment	37,500	37,875	38,254	38,636	39,023	39,413	39,807	40,205	40,607	41,013	41,423	41,838
Growth Rate - Incidence	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Qualified patients (EF, Consent, Insurance)	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%
Change Rate in % who qualify					1%	1%	1%	1%	1%	1%	1%	1%
Viable Treatment Population	9,375	9,469	9,563	9,659	29,267	29,560	29,855	30,154	30,455	30,760	31,067	31,378
Market Share						0%	0%	0%	1%	2%	3%	5%
Treated Patients						0	0	0	305	615	932	1,569
Price of Therapy - (Annual 2% increase)						$65,000	$66,300	$67,626	$68,979	$70,358	$71,765	$73,201
Revenues (000)						$ -	$ -	$ -	$ 21,008	$ 43,284	$ 66,887	$ 114,845
Probability of Success						15%	15%	15%	15%	15%	15%	15%
Annual Sales (M)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 3	$ 6	$ 10	$ 17

Source: Dawson James

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).

Exhibit 14. Free Cash Flow Model.

	Average	$ 7

	Price Target	$ 9
	Year	2019

DCF Valuation Using FCF (mln):

units ('000)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
EBIT	(17,951)	(24,223)	(20,874)	(18,501)	10,391	96,769	241,964	405,909	594,136	799,458	970,160
Tax Rate	0%	0%	0%	0%	0%	0%	10%	18%	20%	25%	30%
EBIT(1-t)	(17,951)	(24,223)	(20,874)	(18,501)	10,391	96,769	217,768	332,845	475,309	599,593	679,112
CapEx											
Depreciation											
Change in NWC											
FCF	(17,951)	(24,223)	(20,874)	(18,501)	10,391	96,769	217,768	332,845	475,309	599,593	679,112
PV of FCF	(17,951)	(18,633)	(12,351)	(8,421)	3,638	26,063	45,116	53,044	58,268	56,541	49,262
Discount Rate	30%										
Long Term Growth Rate	1%										
Terminal Cash Flow	2,365,184										
Terminal Value YE2029	171,566										
NPV	406,142										
NPV-Debt	-										
Shares out (thousands)	46,494	2029E									
NPV Per Share	$ 9										

Source: Dawson James

Exhibit 15. Discounted-EPS Model.

Current Year		2019
Year of EPS		2029
Earnings Multiple		10
Discount Factor		30%
Selected Year EPS	$	9.27
NPV	$	7

Source: Dawson James

	Discount Rate and Earnings Multiple Varies, Year is Constant 2029 EPS						
Earnings Multiple	6.7	5%	10%	15%	20%	25%	30%
	0	**$0.00**	$0.00	$0.00	$0.00	$0.00	$ -
	5	$25.74	$16.16	$10.36	$6.77	$4.50	$ 3.04
	10	$51.47	$32.33	$20.73	$13.54	$9.00	$ 6.08
	15	$77.21	$48.49	$31.09	$20.31	$13.50	$ 9.12
	20	$102.95	$64.65	$41.45	$27.08	$18.01	$ 12.16
	25	$128.68	$80.81	$51.81	$33.85	$22.51	$ 15.20
	30	$154.42	$96.98	$62.18	$40.62	$27.01	$ 18.25
	35	$180.16	$113.14	$72.54	$47.39	$31.51	$ 21.29

Source: Dawson James

Exhibit 16. Sum-of-the-Parts Model.

CLI- Japan	1%	30%	4	60%	$163	$562
NPV						$0.63
CLI- USA	1%	30%	10	15%	$934	$3,219
NPV						$0.19
CLI- Europe	1%	30%	10	15%	$941	$3,245
NPV						$0.19
Coronary Microvascular Dysfunction USA	1%	30%	5	15%	$3,176	$10,952
NPV						$2.38
Coronary Microvascular Dysfunction Europe	1%	30%	7	15%	$1,837	$6,333
NPV						$0.81
Coronary Microvascular Dysfunction Japan	1%	30%	4	40%	$612	$2,111
NPV						$1.59
NORDA USA	1%	30%	4	15%	$413	$1,425
NPV						$0.40
NORDA Europe	1%	30%	6	15%	$115	$396
NPV						$0.07
NORDA Japan	1%	30%	4	15%	$69	$238
NPV						$0.07
Net Margin						25%
MM Shrs OS (2029E)						46
Total						$6

Source: Dawson James

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 17. Income Statement

Caldrius Inc.: Income Statement ($000)																
YE December 31	2018E	1Q19E	2Q19E	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									-	-	-	-	3,027	6,177	9,451	12,855
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	646,693	887,053	1,140,160	1,336,940
Expenses																
Cost of Goods Sold - Products	-	-	-	-	-	-	-	4,012	6,561	23,936	61,747	138,391	200,475	266,116	330,646	374,343
% COGS (of product revenues)								35%	34%	38%	33%	34%	31%	30%	29%	28%
Research and Development	7,936	1,921	2,095	2,270	2,444	8,730	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	9,105	2,203	2,404	2,604	2,804	10,015	11,017	12,118	13,330	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	17,041	4,124	4,499	4,874	5,249	18,745	25,017	33,130	38,591	62,936	109,847	191,301	262,426	336,862	408,467	459,946
Operating Income (Loss)	(17,041)	(4,124)	(4,499)	(4,874)	(5,249)	(18,745)	(25,017)	(21,667)	(19,294)	9,598	95,976	241,171	384,267	550,191	731,693	876,994
Other expense	799	178	194	214	214	799	799	799	799	799	799	799	799	799	799	799
Interest expense	(5)	(3)	(2)	(0)	(0)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)
Total other income	793	174	192	214	214	793	793	793	793	793	793	793	793	793	793	793
Pretax Income	(16,247)	(3,950)	(4,307)	(4,660)	(5,035)	(17,951)	(24,223)	(20,874)	(18,501)	10,391	96,769	241,964	385,060	550,985	732,486	877,787
Income Tax Benefit (Provision)	-		-		-	-	-	-	-			24,196	69,311	110,197	183,122	263,336
Tax Rate												10%	18%	20%	25%	30%
Less: Loss from continuing operations attributable to noncontrolling interests																
GAAP Net Income (loss)	(16,247)	(3,950)	(4,307)	(4,660)	(5,035)	(17,951)	(24,223)	(20,874)	(18,501)	10,391	96,769	217,768	315,749	440,788	549,365	614,451
GAAP-EPS	(1.68)	(0.40)	(0.44)	(0.24)	(0.25)	(1.33)	(0.69)	(0.46)	(0.41)	0.23	2.12	5.27	6.87	9.56	11.86	13.21
GAAP EPS (dil)	(1.68)	(0.40)	(0.44)	(0.16)	(0.17)	(0.90)	(0.53)	(0.32)	(0.28)	0.15	1.41	3.13	4.48	6.17	7.59	8.38
Wgtd Avg Shrs (Bas) - '000s	9,662	9,764	9,774	19,784	19,804	14,781	34,876	45,030	45,211	45,392	45,574	45,756	45,940	46,124	46,308	46,494
Wgtd Avg Shrs (Dil) - '000s	9,662	9,764	9,774	29,784	30,082	19,851	45,450	66,073	66,934	67,806	68,690	69,585	70,492	71,411	72,342	73,284

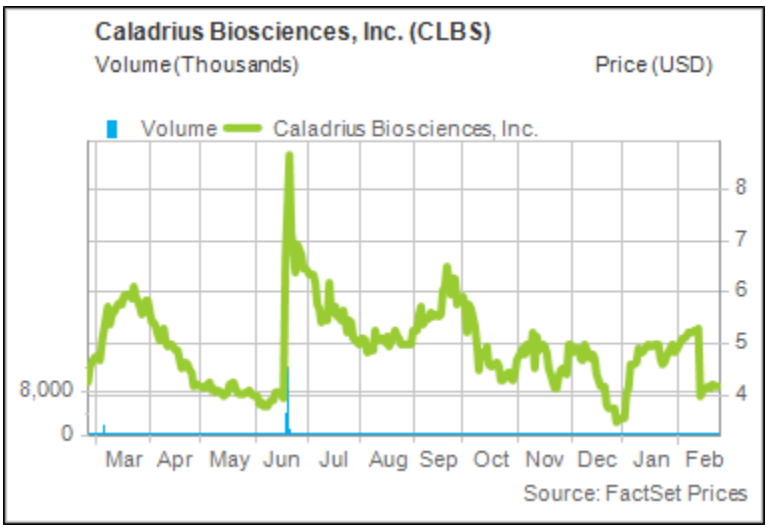
Source: Dawson James estimates

Companies mentioned in this report:

Athersys (ATHX- Not Rated)
BioTime (BTX – Buy Rated)
Cytori (CYTX-Not Rated)
Cesca (KOOL-Not rated)
Mesoblast (MESO-Not Rated)
Pluristem (PSTI-Not Rated)
Vericel (VCEL- Not Rated)

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:
Initiated – Buy – February 27, 2019 – Price Target $7.0

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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) **Neutra**l: The analyst believes the price of the stock is fairly valued for the next 12-18 months;
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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.

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	37	88%	10	27%
Market Perform (Neutral)	5	12%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	42	100%	10	24%

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