

Caladrius (NASDAQ/CLBS)

March 6, 2020

BUY: Funded Through Data CLI and NORDA

Caladrius announced 4Q19 Result in line with expectations. The company spent approx. \$5M in the quarter and ended the year with \$25M in cash. Our model, and confirmed by management, suggests the company is funded through the next set of data results over the coming year.

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Investment Highlights

Catalysts and Cash. Caladrius ended 4Q19 with \$25M in cash versus a burn rate of \$5M in the quarter. Data is coming for 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.

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 ongoing clinical trial in Japan. The Japan trial is expected to complete enrollment 1H20 with data late 2020/early 2021, making a 2021 approval “possible”.

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 (\$70M +/-), the trial is not planned to start until funding is secured (potentially with a partner). We view this as prudent decision making.

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.

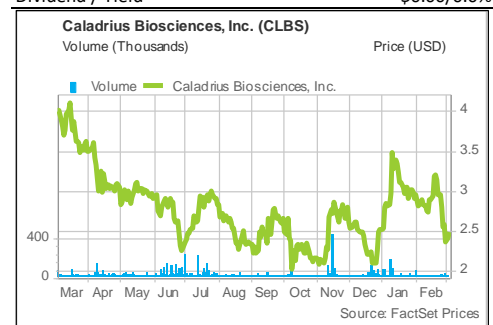
Valuation. For Caladrius we use our highest discount rate of 30% in our free cash flow to the firm (FCFF), discounted EPS, and Sum of the Parts (SOP) models. Our models go out ten years to 2029, and include project dilution. We triangulate FCFF, discounted EPS (2022), and sum-of-the-parts models. We then average and equally weight each model to derive an NPV, which is rounded to the nearest whole number to set our target price. 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 **\$2.37**
 Price Target **\$7.00**

| Estimates | F2018A | F2019A | F2020E |
|--------------------------|-----------|-----------|-----------|
| Expenses (\$000s) | \$ 16,987 | \$ 20,093 | \$ 24,226 |
| 1Q March | \$ 5,159 | \$ 4,592 | \$ 5,330 |
| 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) | \$ (0.51) |
| 1Q March | \$ (0.52) | \$ (0.44) | \$ (0.11) |
| 2Q June | \$ (0.43) | \$ (0.49) | \$ (0.12) |
| 3Q September | \$ (0.36) | \$ (0.47) | \$ (0.13) |
| 4Q December | \$ (0.36) | \$ (0.47) | \$ (0.14) |

| | | | |
|---------------|----------|----------|----------|
| EBITDA/Share | (\$1.67) | (\$0.47) | (\$0.14) |
| EV/EBITDA (x) | - | -7 | -85 |

| Stock Data | | |
|---|-------------|--------|
| 52-Week Range | \$2.00 | \$4.20 |
| Shares Outstanding (mil.) | 10.4 | |
| Market Capitalization (mil.) | \$25 | |
| Enterprise Value (mil.) | -\$12 | |
| Debt to Capital | 6% | |
| Book Value/Share | \$5.33 | |
| Price/Book | 0.9 | |
| Average Three Months Trading Volume (K) | 24 | |
| Insider Ownership | 12.3% | |
| Institutional Ownership | 18.2% | |
| Short interest (mil.) | 0.0% | |
| Dividend / Yield | \$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

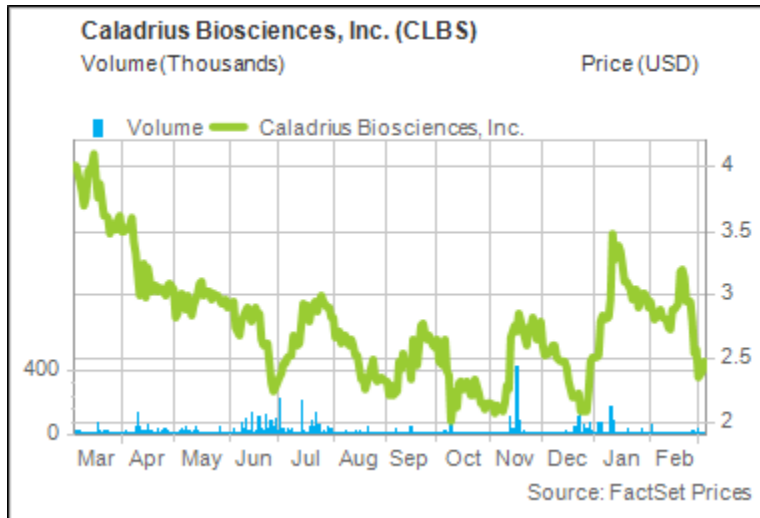
| Caladrius Inc.: Income Statement (\$'000) | | | | | | | | | | | | | | | | |
|--|-----------------|-----------------|----------------|----------------|----------------|----------------|-----------------|-----------------|-----------------|---------------|----------------|----------------|----------------|----------------|------------------|------------------|
| YE December 31 | 2018A | 2019A | 1Q20E | 2Q20E | 3Q20E | 4Q20E | 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 | 476,397 |
| Cell Therapy - Coronary Microvascular Dysfunction Europe | | | | | | | | - | - | - | - | 48,914 | 101,790 | 158,869 | 275,507 | 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 | 10,797 | 3,080 | 3,360 | 3,640 | 3,920 | 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 | 9,296 | 2,250 | 2,454 | 2,659 | 2,863 | 10,226 | 11,248 | 12,373 | 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 | 20,093 | 5,330 | 5,814 | 6,299 | 6,783 | 24,226 | 32,260 | 37,634 | 62,936 | 109,847 | 191,301 | 271,792 | 355,356 | 435,822 | 495,869 |
| Operating Income (Loss) | (16,987) | (20,093) | (5,330) | (5,814) | (6,299) | (6,783) | (24,226) | (20,797) | (18,337) | 9,598 | 95,976 | 241,171 | 405,115 | 593,343 | 798,664 | 969,367 |
| Other expense | 824 | 740 | 178 | 194 | 214 | 214 | 799 | 799 | 799 | 799 | 799 | 799 | 799 | 799 | 799 | 799 |
| Interest expense | (5) | (0) | (3) | (2) | (0) | (0) | (5) | (5) | (5) | (5) | (5) | (5) | (5) | (5) | (5) | (5) |
| Total other income | 819 | 740 | 174 | 192 | 214 | 214 | 793 | 793 | 793 | 793 | 793 | 793 | 793 | 793 | 793 | 793 |
| Pretax Income | (16,168) | (19,353) | (5,155) | (5,622) | (6,085) | (6,570) | (23,432) | (20,004) | (17,544) | 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) | (9) | | | | | | | | | | | | | | |
| GAAP Net Income (loss) | (16,168) | (19,362) | (5,155) | (5,622) | (6,085) | (6,570) | (23,432) | (20,004) | (17,544) | 10,391 | 96,769 | 217,768 | 332,845 | 475,309 | 599,593 | 679,112 |
| GAAP-EPS | (1.67) | (1.87) | (0.15) | (0.16) | (0.17) | (0.18) | (0.66) | (0.44) | (0.38) | 0.23 | 2.09 | 5.19 | 7.14 | 10.15 | 12.75 | 14.39 |
| GAAP EPS (dil) | (1.67) | (1.88) | (0.11) | (0.12) | (0.13) | (0.14) | (0.51) | (0.30) | (0.26) | 0.15 | 1.40 | 3.11 | 4.69 | 6.61 | 8.23 | 9.20 |
| Wgtd Avg Shrs (Bas) - '000s | 9,689 | 10,323 | 35,500 | 35,536 | 35,571 | 35,607 | 35,553 | 45,711 | 45,894 | 46,078 | 46,262 | 46,448 | 46,634 | 46,820 | 47,008 | 47,196 |
| Wgtd Avg Shrs (Dil) - '000s | 9,689 | 10,323 | 45,820 | 45,866 | 45,912 | 45,958 | 45,889 | 66,517 | 67,384 | 68,262 | 69,152 | 70,053 | 70,966 | 71,891 | 72,828 | 73,777 |

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

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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) **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.

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| Ratings Distribution | Company Coverage | | Investment Banking | |
|----------------------------|------------------|------------|--------------------|-------------|
| | # of Companies | % of Total | # of Companies | % of Totals |
| Market Outperform (Buy) | 22 | 85% | 3 | 14% |
| Market Perform (Neutral) | 4 | 15% | 1 | 25% |
| Market Underperform (Sell) | 0 | 0% | 0 | 0% |
| Total | 26 | 100% | 4 | 15% |

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