

# Caladrius Biosciences

**Pharma & biotech**
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## Cell therapy platforms for unmet need

Caladrius is developing cell therapy (CT) products that extract, expand and bolster a patient's own (autologous) immune cells to treat diseases. CLBS03 is a potentially transformative Phase II candidate for recent-onset type I diabetes (T1D), and CLBS14 and CLBS12 target ischemic injury conditions.

### CLBS03 immune modulation for T1D

CLBS03 seeks to reduce or halt disease progression by preserving the patient's insulin-producing beta pancreas cells (BPC). Immune T regulatory cells (Tregs) normally modulate the activity of effector T-cells, helping to ensure that host cells are not attacked. In autoimmune diseases like T1D, deficient Treg activity may permit effector T-cells to attack the body's own cells (eg BPC in T1D). CLBS03 modifies the patient's Tregs before reintroduction, aiming to restore immune tolerance to BPC. If effective, this can reduce the need for lifelong insulin therapy.

### Recruitment completed in CLBS03 Phase II T1D study

Two Phase I trials of autologous expanded Tregs demonstrated safety and effect durability (a single dose was detectable at 12 months). In one of the studies, c 66% of children treated (n=12) were in remission at 12 months vs only 20% of control (n=10). A double-blinded 110-pt Phase II trial evaluating CLBS03 in adolescents with recent onset T1D began in Q116 and completed enrolment in Q118. An interim analysis on c 50% of patients at six months of follow-up was deemed non-futile for therapeutic effect. The 12-month top-line data are expected in Q119.

### CD34 platform targeting ischemia indications

Caladrius's CD34+ cell therapy candidates (CLBS14 and CLBS12) are intended to promote the new blood vessel formation in conditions resulting from ischemia (lack of oxygenated blood flow). A 35-pt Phase II open-label CLBS12 study started in Q118 in Japan (data expected in H219) for critical limb ischemia, a painful condition that often leads to amputation. The trial can be sufficient for a conditional approval in Japan if preliminary effectiveness is shown. A US grant-funded Phase I/II CLBS14 study in coronary microvascular dysfunction is planned to start in Q218.

### Valuation: Negative EV given \$55m net cash

Caladrius had \$55.1m net cash at YE17 (excluding \$5m in restricted cash). Assuming its forward operating cash burn rate is consistent with its 2017 rate of \$20.9m, the company should have sufficient funds to generate top-line data CLBS03 and CLBS12 programs, key potential value drivers.

#### Consensus estimates

Year end	Revenue (\$m)	PBT (\$m)	EPS (\$)	DPS (\$)	P/E (x)	Yield (%)
12/16	0.0	(31.3)	(4.74)	0.00	N/A	N/A
12/17	0.0	(27.7)	(1.78)	0.00	N/A	N/A
12/18e	0.0	(26.3)	(3.05)	0.00	N/A	N/A
12/19e	0.0	(30.6)	(2.32)	0.00	N/A	N/A

Source: Bloomberg

**Price** **\$4.10**  
**Market cap** **\$39m**

#### Share price graph



#### Share details

Code CLBS  
 Listing NASDAQ  
 Shares in issue 9.55m

#### Business description

Caladrius Biosciences is developing cell therapy (CT) products targeting selected autoimmune and cardiology indications. Its lead candidate, CLBS03, an ex vivo expanded polyclonal T regulatory CT for the treatment of recent-onset type I diabetes (T1D), recently completed enrolment in a Phase II trial.

#### Bull

- Large market opportunity in T1D, with over 18,000 newly diagnosed patients in the US each year.
- CLBS03 granted fast-track and orphan drug designations from US FDA.
- Proprietary regulatory T-cell immunomodulatory platform could potentially be out-licensed or applied to other autoimmune indications.

#### Bear

- High development risk in targeted indications and high reliance on external suppliers/manufacturing.
- Additional funding or partnerships will be needed to advance CLBS03 through pivotal studies.
- Prior Phase II study of autologous CD34 infusion in post-ST-elevation myocardial infarction (STEMI) did not reach perfusion/imaging endpoint.

#### Analysts

Pooya Hemami, CFA +1 (646) 653 7026  
 Maxim Jacobs, CFA +1 (646) 653 7027  
[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)

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