EDISON

QuickView

Caladrius Biosciences

Pharma & biotech

8 May 2018

Price	$4.10
Market cap	$39m

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 (TID), and CLBS14 and CLBS12 target ischemic injury conditions.

CLBS03 immune modulation for TID

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 TID, deficient Treg activity may permit effector T-cells to attack the body's own cells (eg BPC in TID). 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 TID 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 TID 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

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 (TID), recently completed enrolment in a Phase II trial.

Bull

- Large market opportunity in TID, 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

EDISON

Edison is an investment research and advisory company, with offices in North America, Europe, the Middle East and AsiaPac. The heart of Edison is our world-renowned equity research platform and deep multi-sector expertise. At Edison Investment Research, our research is widely read by international investors, advisers and stakeholders. Edison Advisors leverages our core research platform to provide differentiated services including investor relations and strategic consulting. Edison is authorised and regulated by the Financial Conduct Authority. Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Pty Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. www.edisongroup.com

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
295 Madison Avenue, 18th Floor
10017, New York
US

Sydney +61 (0)2 8249 8342
Level 12, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia