



## **Cytori Therapeutics**

## Scleroderma therapy efficacy maintained

Recent data suggest the therapeutic benefits following a single administration of Cytori's ADRCs can persist for at least one year in patients with scleroderma-associated impaired hand function (SAIHF). Pivotal studies in SAIHF and urinary incontinence are underway.

## Scleradec-I therapy benefit sustained at 12 months

12-month follow-up data from the open-label Scleradec-I study assessing a single administration of Cytori Cell Therapy (ECCS-50) in 12 patients with SAIHF were recently published in Rheumatology. Hand function, as measured through the Cochin, and quality of life, determined using the Scleroderma Health Activity Questionnaire, improved from baseline by 51.3% and 46.8%, respectively, at 12 months (p≤0.001 for both). The Visual Analogue Scale for hand pain also showed a reduction vs baseline, nearing significance (p=0.052). This builds on previously reported six-month data showing improvements across multiple indicators.

### US pivotal scleroderma study underway

Cytori started the 80-patient pivotal Phase III study assessing ECCS-50 in patients with SAIHF in July 2015. The firm received clearance from the US FDA to allow the cell therapy processing device used in this study to include technological updates that improve ECCS-50 manufacturing efficiency. The primary endpoint is the sixmonth change in the Cochin score (12-month change is a secondary endpoint) and recruitment is expected to take one year. Top-line data are expected in H217. A European randomized Phase III trial (Scleradec II) should begin in Q415.

## **Enrolment started in Japanese Phase III UIT study**

In September, Cytori, in collaboration with Nagoya University, started the ADRESU Phase III Japanese trial studying Cytori Cell Therapy (ECCI-50) in men with urinary incontinence after prostatic surgery. The 45-patient study is substantially funded by the Japanese health ministry, and the primary endpoint will be the number of patients who experience reduction of urinary leakage volume 52 weeks after treatment. Cytori will seek approval in this indication if results are positive.

## Valuation: EV of \$46m, upside driven by future data

After raising \$2.2m (net) in August 2015 and given an H115 operating cash burn rate of \$9.8m, we estimate Q315 net cash at c \$5.0m. Given \$16.2m long-term debt at end Q215, we estimate gross cash (c \$21m) should last into Q316, likely including the readout of the ongoing 90-patient Phase II knee osteoarthritis study.

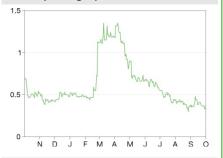
Year	Revenue	PBT	EPS	DPS	P/E	Yield
end	(\$m)	(\$m)	(\$)	(\$)	(x)	(%)
12/13	7.1	(26.2)	(0.39)	0.0	N/A	N/A
12/14	5.0	(37.4)	(0.48)	0.0	N/A	N/A
12/15e	14.15	(30.0)	(0.23)	0.0	N/A	N/A
12/16e	28.58	(18.25)	(0.12)	0.0	N/A	N/A

Pharma & biotech

2 October 2015



#### Share price graph



# Share details Code CYTX Listing NASDAQ Shares in issue 158.5m

#### **Business description**

Cytori is a US company focused on the development of patient-derived (autologous) adipose-derived regenerative cells (ADRCs) for the treatment of impaired hand function in scleroderma, osteoarthritis of the knee, and radiation exposure-associated deep thermal burns.

#### Bull

- Cytori's lead programme (scleroderma) recently began Phase III trials in an orphan indication with significant sales potential.
- Cytori's approach requires no off-site processing, so generated ADRCs can be administered to the patient on the same day of extraction.
- Current commercial product contract revenue (including Celution and consumables) provide meaningful cash burn offset.

#### Bear

- Financing or partnership likely required by H216 to continue scleroderma studies and/or advance osteoarthritis programme to Phase III.
- Several competitors emerging in cell/regenerative therapy area, also targeting inflammatory diseases.
- Osteoarthritis is a relatively high-risk indication for new product or drug development.

Analysts					
Pooya Hemami, CFA	+1 646 653 7026				
Christian Glennie	+44 (0)20 3077 5727				
healthcare@edisongroup.com					

QUICKVIEW NOTES USE CONSENSUS EARNINGS ESTIMATES.



Edison, the investment intelligence firm, is the future of investor interaction with corporates. Our team of over 100 analysts and investment professionals work with leading companies, fund managers and investment banks worldwide to support their capital markets activity. We provide services to more than 400 retained corporate and investor clients from our offices in London, New York, Frankfurt, Sydney and Wellington. Edison is authorised and regulated by the Financial Conduct Authority (<a href="https://www.fsa.gov.uk/register/firmBasicDetails.do?sid=181584">www.fsa.gov.uk/register/firmBasicDetails.do?sid=181584</a>). Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Services only. Edison Investment Research Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison and is not regulated by the Australian Securities and Investment Commission. Edison Germany is a branch entity of Edison Investment Research Limited (4794244). <a href="https://www.edisongroup.com">www.edisongroup.com</a>

#### DISCLAIMER

Copyright 2015 Edison Investment Research Limited. All rights reserved. This report has been commissioned by Cytori Therapeutics and prepared and issued by Edison for publication globally. All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report. Opinions contained in this report represent those of the research department of Edison at the time of publication. The securities described in hervestment Research may not be eligible for sale in all jurisdictions or to certain categories of investors. This research is issued in Australia by Edison Aus and any access to it, is intended only for "wholesale clients" within the meaning of the Australian Corporations Act. The Investment Research is distributed in the United States by Edison US to major US institutional investors only. Edison US is registered as an investment adviser with the Securities and Exchange Commission. Edison US reliase upon the "publishers' exclusion" from the definition of investment adviser post and diviser. Act of 1940 and corresponding state securities and Exchange Commission. Edison US reliased using the securities and exchange Commission. Edison US reliased to the publishers' exclusion" from the definition of investment advisers and to the information provided by us should not be construed by any subscribe or more website is not intended to be, and should not be construed in any manner whatsoever as, personalised advice. We publish information advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. This document is provided in investment research. Edison has a res