Cytori Therapeutics

Pharma & biotech

2 October 2015

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 six-month 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.

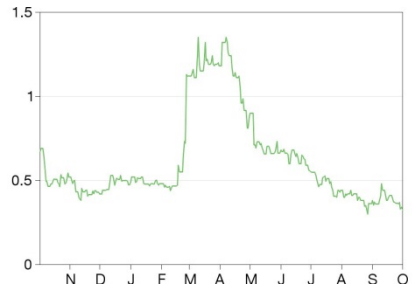
Consensus estimates

Year end	Revenue ($m)	PBT ($m)	EPS ($)	DPS ($)	P/E (x)	Yield (%)
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

Source: Bloomberg

Price	$0.32
Market cap	$51m

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

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
245 Park Avenue, 39th Floor
10167, New York
US

Sydney +61 (0)2 9258 1161
Level 25, Aurora Place
88 Phillip St, Sydney
NSW 2000, Australia

Wellington +64 (0)48 948 555
Level 15, 171 Featherston St
Wellington 6011
New Zealand