Cerulean

Pharma & biotech

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Positive data announced for CRLX101 in RCC

In conjunction with its FY14 results, Cerulean announced strong top-line interim data for CRLX101 in its lead indication of relapsed renal cell carcinoma (RCC). The combination treatment with Avastin achieved its primary endpoint of four-month progression free survival (PFS) in at least 50% of patients, showing significant improvement over the current standard of care. Cerulean also confirmed that current cash holdings and recent financing with Hercules provide the company with resources to fund ongoing trials for both CRLX101 and CRLX301 through to Q316.

CRLX101 Phase Ib/II in RCC solidifies earlier findings

Cerulean provided data from an interim analysis (IA) of its ongoing Phase Ib/II study. Data generated from 22 patients enrolled showed a median progression free survival (PFS) of 9.9 months vs the current standard of care of approximately 3.5 months, and trending upwards from an earlier analysis in the first 11 patients showing PFS of 7.6 months. RECIST (response evaluation criteria in solid tumours) rate was 23% vs the standard of care at just 2-4%. Detailed data from the trial will be presented at ASCO 2015 and submitted for publication in a peer reviewed journal later in the year. Seven patients are still being treated. CRLX101 in combination with Avastin has shown to be well tolerated in this and other studies in more than 250 patients.

Randomised Phase II trial in RCC underway

CRLX101's potential is significant in relapsed RCC, with an estimated 20-40% of RCC patients experiencing disease recurrence. Existing treatment options are limited. In August 2014 Cerulean initiated a Phase II trial in 3rd- and 4th-line RCC. Up to 110 patients are being enrolled at ~30 centres in the US in the study. This aims to show a 2.3-month improvement in median PFS over the comparator, which is predicted to show 3.5 months PFS. Top-line primary endpoint data and overall response rate data for the Phase II trial are anticipated in Q216.

Valuation: Potential price inflections on key data

We estimate Cerulean had net cash of ~$43m at end-February (including a ~$12m draw-down on its $26m debt facility), resulting in an EV of ~$171m; we suggest this is conservative when considering the strong early data, established proof of principle and positive safety profile for its lead drug candidate. Additional trials are underway for CRLX101 plus Avastin in platinum-resistant ovarian cancer (Phase II) and combined with CRT in non-metastatic rectal cancer (Phase Ib/II). A second treatment, CRLX301, is in Phase I in solid tumours. We expect potential share price catalysts related to updated clinical data for each of these trials by year end.

Consensus forecasts

Year end	Revenue ($m)	PBT ($m)	EPS ($)	DPS ($)	P/E (x)	Yield (%)
12/14	0.1	(23.3)	(1.60)	0.0	N/A	N/A
12/15e	0.0	(44.9)	(2.11)	0.0	N/A	N/A
12/16e	1.0	(57.3)	(2.31)	0.0	N/A	N/A

Source: Bloomberg

Price	$10.66
Market cap	$214m

Share price graph

Share details

Code	CERU
Listing	NASDAQ
Shares in issue	20.1m

Business description

Cerulean is a US-based oncology-focused company with a differentiated nanoparticle-drug conjugate platform. Lead product CRLX101 combined with Avastin is in Phase II clinical trials in 3rd- and 4th-line RCC and 2nd- and 3rd-line ovarian cancer. CRLX101in combination with chemoradiotherapy is also in Phase Ib/IIa in neoadjuvant rectal cancer.

Bull

- Two high-potential products in clinical development.
- Research platform with potential to piggyback off numerous >$1bn launched oncology products.
- Upcoming clinical catalysts in 2015.

Bear

- Limited data from larger-scale trials on lead compounds.
- Limited cash reserves to develop full pipeline.
- Company's ability to commercialise products is unproven.

Analysts

Katherine Genis CFA +1 (646) 653 7026

Dr Mick Cooper +44 (0)20 3077 5734

healthcare@edisongroup.com

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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