

Zeltia – QuickView

25 February 2013

Investment summary: Turning a corner

Zeltia is approaching a material catalyst this year in the form of the read-out from its Phase II study of lurbinectedin (PM01183) in platinum resistant ovarian cancer. If positive, this could form the basis of a licensing deal that could transform Zeltia's fortunes. This, and the more positive sales outlook for Yondelis (trabectedin), which has been hampered by recent Doxil supply shortages, should support further pipeline development and ultimately help Zeltia transition into a cancer pure-play.

A safer and more efficacious Yondelis...

Lurbinectedin is, like Yondelis, a minor groove DNA-binder, but it has improved pharmacokinetics that confer less cumulative toxicity with a more convenient dosing schedule. In a cross-trial comparison of various agents in platinum resistant ovarian cancer, some 27% patients achieved an overall response on lurbinectedin (vs 7% for Yondelis), and 73% achieved disease control (vs 50% for Yondelis).

...competitive vs next-generation products

There are just three agents in Phase III studies for platinum resistant ovarian cancer: vintafolide (Endocyte/Merck & Co), Avastin (bevacizumab, Roche) and trebananib (Amgen). In this same cross-trial comparison, vintafolide showed a 17% overall response rate and Avastin, a partial response rate of 16%. Should its superior efficacy be replicated in Phase III, lurbinectedin may have a competitive advantage provided it is better tolerated than Yondelis. However, recent failures (eg Eisai's farletuzumab) highlight the challenge of developing novel agents for ovarian cancer.

Phase II data could be a major catalyst

The drug met its primary endpoint in stage one of the Phase II study, with 27% of the 22 patients achieving an overall response (with a median PFS of 4.0 months). 60 patients are randomised 1:1 (with crossover) to either lurbinectedin or topotecan in stage two. These data are due in H213 and could be the catalyst for a partnership that should support mid- to late-stage development in other solid tumour types; activity has already been demonstrated in breast, lung and pancreatic cancers. Two Phase II studies in lung cancer (non-small cell and small cell lung cancer) are due to start in mid-2013, and a Phase II trial in breast cancer is due to read-out in 2015.

Valuation: Hinges on positive data

Zeltia stock has fallen c 30% in the last year largely due to declining sales of Yondelis and the Phase II failure of Alzheimer's drug tideglusib (Nypta). This has given it a lower profile, just at a time when the Doxil issues are being resolved and its debt situation is improving. Thus a material pipeline catalyst and the chance of a licensing deal could give new impetus to a recovery in the shares this year.

Consensus estimates

Year end	Revenue (€m)	PBT (€m)	EPS (c)	DPS (c)	P/E (x)	Yield (%)
12/11	152.5	1.1	2.3	0.0	58.7	N/A
12/12e	142.4	1.8	2.9	0.0	46.6	N/A
12/13e	160.0	10.6	8.0	0.0	16.9	N/A
12/14e	180.0	20.2	9.0	0.0	15.0	N/A

Source: Bloomberg

Price €1.35
Market cap €301m

Share price graph



Share details

Code ZEL
Listing Madrid
Sector Pharma & biotech
Shares in issue 222.2m

Business

Zeltia is a Spanish biopharmaceutical group with a core focus on the development of marine-based drugs for cancer. Its only marketed product, Yondelis, is approved in the EU and partnered with Janssen (J&J) in the US. The group also has subsidiaries active in consumer chemicals, diagnostics and RNAi technology.

Bull

- Growing cancer pipeline with novel mechanisms of action.
- Revised J&J deal: \$35m milestones may fall due in 2014-15.
- Phase III US Yondelis trials expected to read-out in H214 (STS) and H118 (OC) could lead to FDA approval.
- Guided to be sustainably profitable from 2015.

Bear

- PM01183 disappoints in OC.
- Doxil re-supply fails to benefit Yondelis in the EU.
- Poor macroeconomic climate holds back consumer chemicals.

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