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Zeltia

Pharma & biotech

5 March 2014

Price	€2.81
Market cap	€624m

Charting a course into clearer waters

Zeltia has made significant progress in weathering the storms of recent years. FY13 results demonstrate improved profitability and cash flows, which have further reduced the debt burden. Ex-US ex-Japan Yondelis sales have resumed their growth trajectory (net revenues up 10% to €73m) following the resolution of Doxil supply issues in May. Looking forward, clinical data in H214 for Zeltia's two key products could be transformative. Janssen's 2015 FDA filing of Yondelis rests on positive Phase III sarcoma results, while Taiho could file in Japan by year-end on the back of its pivotal Phase II study. Full data from the Phase II PM01183 study in ovarian cancer could form the basis of a lucrative licensing deal.

Yondelis: Expecting key data by year-end

Janssen's 586-pt US Phase III study in L-sarcoma completed recruitment in December and is expected to render results in H214. Positive data would support an FDA filing in 2015 and trigger payment of $20m of milestones to Zeltia ($10m development; $10m on approval). Pivotal data from the Taiho soft tissue sarcoma (STS) study should support Japanese filing in H214 (milestone due on approval).

PM01183: A promising second-generation compound

Top-line Phase II platinum resistant/refractory ovarian cancer (OC) data from the open-label comparator study showed median progression-free survival for the total population of 4.8 mths for PM01183 vs 1.7 mths for topotecan (p=0.0004). 30.3% of pts had an objective response (OR) to PM01183 vs none on topotecan; clinical benefit (OR + stable disease) was 82% for PM01183 vs 50% for topotecan. Overall survival data will be available this year (potentially at a major cancer congress) and could secure a partnership. Three pivotal Phase III OC trials should start H214-H115.

Financials: Biopharma back on course

The European Doxil shortage (Q311-Q213) weighed on FY12 results. Revenue growth in FY13 (3% to €142m) was driven by the 9% improvement in biopharma sales to €79m. EBITDA increased 16.6% to €23.8m; EBITDA margin benefited from the greater contribution of the higher-margin biopharma segment and ongoing cost controls. Net profit rose 72% to €11.3m, which coupled with positive operating cash flow of €16.1m contributed to a c 20% decline in total debt (net debt: €64.6m).

Valuation: Catalysts to drive upside

Zeltia's share price has doubled in the past 12-months; however, potential upside remains from near-term clinical/regulatory catalysts, and the prospect of licensing.

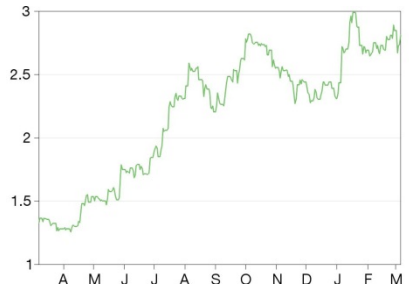
Consensus estimates

Year end	Revenue (€m)	PBT* (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/12	138.2	9.4	0.08	0.0	N/A	N/A
12/13	141.8	13.8	0.10	0.0	N/A	N/A
12/14e	160.0	21.4	0.11	0.0	N/A	N/A
12/15e	172.4	25.0	0.14	0.0	N/A	N/A

Source: Company accounts, Bloomberg. Note: *PBT represents continuing operations.

Zeltia is a research client of Edison Investment Research Limited

Share price graph



Share details

Code	ZEL
Listing	Madrid
Shares in issue	222.2m

Business description

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, molecular diagnostics and RNAi technology.

Bull

- Growing cancer pipeline with novel mechanisms of action.
- Approx $30m of J&J/Taiho milestones for Yondelis may fall due in 2015.
- Phase III US Yondelis data, expected in H214 (STS) and H118 (OC), could lead to US approval.

Bear

- Protracted licensing process for PM01183.
- Potential Yondelis regulatory delay(s).
- Macroeconomic climate and/or adverse weather conditions hold back consumer chemicals.

Analysts

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EDISON QUICKVIEW NOTES USE CONSENSUS EARNINGS ESTIMATES.

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