EDISON

Zeltia

Q314 results

Catalysts on the horizon

Pharma & biotech

Zeltia's Q314 results highlighted ongoing revenue and profit growth with Yondelis remaining the key contributor to revenue and net margin at oncology subsidiary PharmaMar. Looking beyond financials, Zeltia is approaching a catalyst-rich period, which has the potential to re-rate its valuation as PharmaMar's business matures. These catalysts relate to the wider Yondelis geographic opportunity (filings/approvals in Japan and the US) and development progress with Aplidin and PM01183, with ex-EU partnering potential for the latter.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/12	138.2	10.8	0.08	0.0	30.1	N/A
12/13	141.8	15.6	0.06	0.0	40.6	N/A
12/14e	152.7	16.7	0.07	0.0	36.1	N/A
12/15e	171.5	34.7	0.15	0.0	17.2	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments.

Yondelis: Approaching Japan and US filings in STS

Filings in STS (soft tissue sarcoma) in Japan (end-2014) and in the US (mid-2015) could lead to approvals in 2015/16, significantly boosting revenue through royalties and near-term milestones. Japan approval would trigger a Taiho milestone, with up to $20m potentially due from Janssen for the US.

Clinical data due for PM01183 and Aplidin

Read out of ADMYRE (Aplidin multiple myeloma Phase III) in 2015 could facilitate EMA filing within a year. Updates from ongoing PM01183 trials (eg Phase II BRCA data at the San Antonio Breast Cancer Symposium, 9-13 Dec) could catalyse an ex-European deal. Partnership prior to Phase III-start would accelerate profitability, although PharmaMar has the resources to fund some of the pivotal trials internally.

Financials: Revenues increasing; net debt falling

9M14 net sales increased 7% to €116.9m with growth in both biopharma and consumer chemical. Net Yondelis sales were €57.4m, up 8% on the prior period; this excludes milestones ($25m received from Janssen in 2014). Growing revenues coupled with stable opex (ex-R&D) will drive bottom-line growth; we forecast EBITDA improvement to €27.8m in FY14. Increased operating cash flow should further reduce net debt (9M14: €58.0m; FY14e: €55.9m).

Valuation: €930m SOTP, PM01183 prospects ignored

Our €930m (€4.19/share) valuation is based on a sum-of-the-parts DCF to 2025 (rNPV for the biopharma business; DCF for the chemicals division). It suggests the current market cap is largely supported by Yondelis, with limited value ascribed to earlier-stage assets, such as PM01183, which could drive significant value as part of a life cycle management strategy. Japan/US approval decisions for Yondelis in STS represent near-term upside as would Aplidin data or a PM01183 partnership.

6 November 2014

Price	**€2.56**
Market cap	**€569m**
	US$1.27/€
Net debt (€m) at end-Sept 2014	58.0
Shares in issue	222.2m
Free float	73.7%
Code	ZEL
Primary exchange	Madrid
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(10.0)	(7.9)	3.4
Rel (local)	(7.5)	(7.2)	(1.4)
52-week high/low		€3.1	€2.3

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/RoW and Taiho in Japan. The group also has subsidiaries active in consumer chemicals, molecular diagnostics and RNAi technology.

Next events

Yondelis: Japan filing in STS	Q414-H115
Yondelis: US STS data and filing	Q414-H115
PM01183: start of pivotal trials	Q414-H115
Partnering: PM01183	Undisclosed

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Update: Entering a catalyst-rich period

Zetlia's solid 9M14 performance, which demonstrated revenue and profit growth across both its biopharmaceuticals and consumer chemicals business divisions, has helped the company continue to improve its net debt position (now €58m, with cash and equivalents of €37.4m). Zeltia is not a financially-driven story, nor a one-product company despite the fact that European sales of Yondelis (€57.4m during 9M14) are an important contributor to revenue and to net margin. Investor focus instead rests on the development and expansion of Zeltia's world-leading marine-derived oncology therapeutics business, PharmaMar; in particular on the wider geographic opportunity for Yondelis and development progress across the pipeline.

PharmaMar is approaching a catalyst-rich period, which has the potential to significantly re-rate Zeltia's share price. Our current Zeltia valuation of €930m or €4.19/share (previously €904m, or €4.07/share) suggests that the current c €570m market cap is largely supported by Yondelis, with limited value ascribed to earlier-stage development assets, particularly the second-generation programme PM01183, which we believe has the potential to drive significant future value.

Upcoming newsflow from Zeltia's three most advanced pipeline programmes represents important inflection points over the next two years and is summarised in Exhibit 1.

Exhibit 1: Pipeline newsflow

Product	Indication	Next news	Timing
Yondelis	STS	NDA filing in Japan by partner Taiho Pharmaceutical (milestone on approval in 2015)	Q414-H115
		Top-line results of Phase III L-sarcoma study: potential submission of full data for ASCO 2015 presentation	Q414-H115
		FDA filing for L-sarcoma by Janssen (J&J)	H215
	Ovarian cancer	Read out of 670-pt US Phase III trial; preceded by event driven interim OS analysis (308 deaths)	H218
PM01183	Ovarian cancer	Start of Phase III in platinum-resistant OC vs investigator choice (topotecan or Doxil/Caelyx). SPA pending	H115
		Updated overall survival data from Phase I/II	H115
	Endometrial cancer	Start of planned pivotal Phase III trial in <500-pts (design in development, dosing being fine-tuned)	2015
	Breast cancer	Data from stage one of Phase II trial in BRCA-mutated BC to be presented at San Antonio BC Symposium	9-12 Dec 2014
	SCLC	Start of pivotal Phase III trial in 300-pts planned	H215
	NSCLC	Read out of 120-pt Phase II trial in second-line NSCLC: recruitment continues on schedule	H215/H116
	All	Ex-Europe partnering deal	Undisclosed
Aplidin	Multiple myeloma	Completion of recruitment into ADMYRE trial	End-2014/Q115
		PFS and OS trend analysis for ADMYRE	Q115
		Final results/EMA filing (potential Chugai milestone)	Q415
		Recruitment begins into Mass Balance refractory neoplasia trial	2015
		CHMP recommendation (if positive, launch could be possible in 2017)	End-2016
	Lymphoma	Start of US Phase II trial in angioimmunoblastic T-cell lymphoma	Undisclosed
		US partnering deal	Undisclosed

Source: Edison Investment Research, company data

Assuming that filing with the Japanese regulator and the FDA by respective partners proceeds on track, the potential Yondelis approvals in 2015 (Japan) and 2016 (US) could be financially transformative for Zeltia. In these markets Yondelis is likely to be priced at a premium to Europe and royalty receipts should significantly boost revenues and profitability. Near-term milestones of $20m+ are also expected. Japanese approval would trigger an approval milestone from Taiho, and $20m is potentially due from Janssen ($10m development; $10m on approval). We believe that Yondelis approval by the FDA may additionally have positive knock-on effects on European sales in STS, as this has been the case for other oncology drugs (Eloxatin and Zevalin) that were approved by the FDA subsequent to its EMA approval.

Final data from the Phase III Aplidin multiple myeloma study in 2015 (recruitment completion is on track for year-end), and further updates from ongoing PM01183 trials (and pivotal trial start in ovarian, endometrial and small cell lung cancers), are major near-term value drivers that may catalyse a partnership for non-European territories. Assuming ultimate approval of these drugs, PharmaMar intends to retain production rights and to commercialise them through its existing

European sales infrastructure, in regions where it retains rights (Aplidin is licensed to Chugai for eight EU territories), with only modest future expansion, while partnering in the rest of the world. Aplidin's partnership with Chugai, a company with an established European specialist haem-oncology sales force, suggests potential higher market penetration from day one without the need for additional investment in commercialisation by PharmaMar in regions.

PM01183, a second-generation synthetic analogue of Yondelis, is being studied as a combination agent in an expanded Phase I/II trial in various solid tumours, and yielded promising Phase II data as a monotherapy in ovarian cancer. These data are being used to inform the design of pivotal trials planned for the coming year and also trigger conclusion of a deal as a number of parties have expressed an interest in PM01183. Partnership prior to Phase III-start would accelerate profitability, but PharmaMar does have the resources to fund at least some of these trials internally.

Sensitivities

Zeltia's biopharma division is subject to various sensitivities common to speciality pharmaceutical companies, including potential clinical or regulatory failure or delay, manufacturing and commercialisation risks (launch, uptake, pricing, reimbursement and competition) and reliance on partners for ex-Europe markets. The company's chemical business is predominantly exposed to economic factors, although raw material costs, environmental/regulatory requirements and external weather conditions may also have an impact on sales or margins.

Key stock-specific sensitivities for the core oncology business include, but are not limited to:

- **Yondelis**: European sales growth; outcome of ongoing US clinical trials; outcome of FDA and Japanese MHRW approval decisions; timing of milestones from partners and sales achieved.
- **Aplidin**: outcome of the ADMYRE trial; development progress in T-cell lymphoma; timing and economics of any additional licensing deal(s).
- **PM01183**: development progress in various indications; deal timing and economics.
- **Discovery**: new NCEs to come from marine discovery capability; potential collaborations.

Valuation

We have updated our sum-of-the-parts DCF analysis to 2015, which increases our Zeltia valuation to €930m or €4.19 per share (previously €904m or €4.07 per share). US dollar weakening against the euro (we use an updated US$1.27/€ FX down from US$1.35/€) accounts for about 70% of the valuation increase, with Zeltia's improved net debt position (€58.02m at end-Q314) underpinning the remainder. We have also rolled forward our model to reflect the passage of time. Our valuation breakdown and key assumptions are shown in Exhibit 2.

We use a risk-adjusted net present value (rNPV) method to discount future cash flows for the biopharmaceuticals business and have applied a standard DCF model for the chemicals division. We use a 7.5% WACC for the chemicals division, 10% for central costs and the commercial segment of the biopharma business (ie Yondelis European and RoW revenues, and the associated sales and marketing infrastructure) and 12.5% for the rest of the biopharma business, which is our standard discount rate assumption for development-stage therapeutics companies. Cash flows are taxed at a 25% Spanish corporate tax rate from 2020, tapering up from a lower rate of 21% from 2014 onwards reflecting accumulated tax losses.

Our model suggests that Zeltia's c €570m market cap is largely supported by Yondelis, with limited value ascribed to earlier-stage programmes, principally PM01183. Our current assessment of PM01183's value is based on conservative assumptions, and we only estimate peak sales in

indications where there is a clear plan to advance PM01183, although it has potential in other cancers. We believe PM01183 could be worth considerably more as the development programme progresses (eg in NSCLC) and expands (eg into breast cancer, platinum-sensitive ovarian cancer or STS), particularly as part of a Yondelis life cycle management strategy. On confirmation of further development plans and additional data on PM01183's clinical profile, we expect to refine our assumptions, potentially including additional indications. We will also take a similar approach with Aplidin, where our current valuation assessment focuses only on the fourth-line multiple myeloma opportunity; future line extensions (including as a combination therapy) would represent upside.

Exhibit 2: Zeltia sum-of-the-parts DCF

Product	rNPV (€m)	NPV/share (€)	Assumptions
FCF of chemicals business	50.97	0.23	7.5% WACC, 2% growth rate, accounts for 25% of group capex and depreciation and amortisation
Yondelis (Europe)	820.72	3.69	10% WACC. STS (second line): peak sales of €80m with 35% penetration; ovarian cancer (third-line platinum sensitive): peak sales of €100m with 22% penetration. First generics in 2022.
Yondelis (US)	65.41	0.29	STS (second line): peak sales of $160m with 80% success probability, 2016 launch; ovarian cancer (third-line platinum sensitive) peak sales of $190m, 65% risk adjustment, 2020 launch; both assume 15% royalty
Yondelis (Japan)	44.36	0.20	STS only: peak sales of €120m; 90% success probability; launch 2016; 15% royalty
Yondelis (milestones)	12.86	0.06	Known milestones for 2015 only – Janssen: $20m in aggregate for development and US approval; Taiho: Japan approval. Risk-weighting applied; assumes $/€ FX rate of 1.27.
Aplidin (multiple myeloma)	112.00	0.50	Global peak sales of $300m assuming 40% of MM patients ultimately receive fourth line therapy and 25% penetration; pricing of $25k in EU with 25% US premium; 65% success probability; launch 2018; sold by Chugai in eight European territories (assume effective royalty of 25%) and direct in other EU regions, assume 15% royalty in US; includes Chugai milestones of €5m on deal signing in 2014 and €20m of near-term regulatory milestones out of €30m total. No milestones included for other territories at this stage.
PM01183 (ovarian cancer)	290.81	1.31	Ovarian cancer (third-line platinum-resistant): peak sales of €492m with 65% success probability, 2019 launch; sold direct in Europe with 15% royalty in US
PM01183 (SCLC and endometrial cancer)	17.32	0.08	Combined peak sales of $525m; 15% success probability; launch 2020; 15% royalty
PM01183 (milestones)	9.59	0.04	Only assumes receipt of €25m signing milestone in 2014 (50% risk weighted)
Sylentis	4.52	0.02	Cumulative peak sales of $250m; 25% probability of success; potential launch 2019; 10% royalty
Genomica	34.69	0.16	Conservative 2% growth rate
R&D	(131.27)	(0.59)	Approximate split 35% discovery and preclinical: 65% clinical development
SG&A	(249.63)	(1.12)	10% WACC. Expenses relate to biopharma infrastructure and Yondelis sales force
Unallocated central costs	(80.38)	(0.36)	10% WACC
Capex	(13.71)	(0.06)	75% of group capex for biopharma business
Net cash/(debt)	(58.02)	(0.26)	At end-Q314
Total	**930.23**	**4.19**	

Source: Edison Investment Research. Note: WACC of 12.5% used except where indicated otherwise.

Financials

Zeltia's 9M14 net revenues of €116.9m were up 7% on 9M13 (€109.2m), with similar growth in Biopharmaceuticals (9M14: €61.2m vs 9M13: €57.4m) and Consumer Chemicals (9M14: €55.1m vs 9M13: €51.2m) with the balance being unallocated. €57.4m or 94% of the Biopharmaceuticals revenues were attributable to Yondelis, net sales of which grew 8% on the prior year period (we forecast 10% growth for FY14e). Gross margin was 71.9%. Other revenues of €23m primarily related to the $25m (€18.3m) Yondelis milestone received from Janssen earlier in the year; the remainder included the partial recognition of the €5m upfront payment from Chugai under its Aplidin licensing agreement, and royalties on non-EU Yondelis sales. We expect Yondelis-associated milestone revenues for Japan and the US will make a recurring contribution, which will continue into 2015, being replaced by recurring royalties from 2016.

R&D spending is predominantly focused on the biopharma business (€33.29m in 9M14, net of €3.8 of capitalised R&D). We forecast FY14 R&D costs of €42.75m in FY14 (net of €4m in capitalised R&D) given the ongoing Aplidin Phase III ADMYRE trial, the planned start of PM01183 pivotal trials and more modest investment into Sylentis's bamosiran Phase IIb glaucoma study. A proportion of R&D is capitalised (we assume c 10%). Our SG&A estimates of c €60m per year (9M14: €45.6m;

FY14e: €62.7m) does not include c €8m of unallocated central costs (classed as 'other expenses' in the P&L), and we note the potential to leverage the existing biopharma sales force to market additional cancer drugs. Growing revenues coupled with stable operating expenditure (ex-R&D) should enable Zeltia to grow its bottom line, and we forecast EBITDA improvement from €23.8m in FY13 to €27.8m in FY14. Increased operating cash flow is likely to result in a continuing reduction in net debt (FY13: €65.4m; 9M14 €58.0m; to FY14e: €55.9m).

Exhibit 3: Financial summary

€'000s	2011	2012	2013	2014e	2015e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	152,486	138,229	141,824	152,709	171,452
Cost of Sales	(42,955)	(39,793)	(37,900)	(43,362)	(45,437)
Gross Profit	109,531	98,436	103,924	109,347	126,015
EBITDA	29,675	20,473	23,817	27,782	47,868
Operating Profit (before GW and except.)	24,848	15,985	20,735	22,048	42,071
Intangible Amortisation	(997)	(1,418)	(1,779)	(495)	(1,882)
Other (milestones and royalties)	24,712	23,549	22,858	25,706	29,048
Exceptionals	0	0	0	0	0
Operating Profit	23,851	14,567	18,956	21,554	40,189
Net Interest	(5,724)	(5,056)	(5,690)	(5,352)	(7,377)
Other	(159)	(85)	535	0	0
Profit Before Tax (norm)	18,965	10,844	15,580	16,696	34,693
Profit Before Tax (FRS 3)	17,968	9,426	13,801	16,201	32,812
Tax	(2,511)	5,048	(1,960)	(860)	(1,543)
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	16,454	15,892	13,620	15,836	33,150
Profit After Tax (FRS 3)	15,457	14,474	11,841	15,341	31,269
Minority interests	6,114	2,868	189	(27)	0
Discontinued operations	(16,830)	(10,749)	(708)	(74)	0
Net income (normalised)	22,568	18,760	13,809	15,809	33,150
Net income (FRS3)	4,741	6,593	11,322	15,240	31,269
Average Number of Shares Outstanding (m)	220.6	220.8	220.2	222.2	222.2
EPS - normalised (€)	0.10	0.08	0.06	0.07	0.15
EPS - FRS 3 (€)	0.02	0.03	0.05	0.07	0.14
Dividend per share (€)	0.00	0.00	0.00	0.00	0.00
Gross Margin (%)	71.8	71.2	73.3	71.6	73.5
EBITDA Margin (%)	19.5	14.8	16.8	18.2	27.9
Operating Margin (before GW and except.) (%)	16.3	11.6	14.6	14.4	24.5
BALANCE SHEET					
Fixed Assets	88,285	93,399	93,475	94,403	85,867
Intangible Assets	19,873	22,292	25,138	26,788	24,906
Tangible Assets	33,862	29,794	27,959	26,786	20,132
Other	34,550	41,313	40,378	40,829	40,829
Current Assets	159,726	106,431	95,895	116,274	124,235
Stocks	25,309	23,502	22,232	23,760	24,897
Debtors	80,636	41,956	38,630	46,022	42,276
Cash	49,325	34,428	28,835	39,499	50,069
Other	4,456	6,545	6,198	6,993	6,993
Current Liabilities	(89,367)	(87,355)	(74,058)	(85,379)	(83,284)
Creditors	(36,681)	(32,621)	(32,731)	(35,090)	(32,995)
Short term borrowings	(52,686)	(54,734)	(41,327)	(50,289)	(50,289)
Long Term Liabilities	(93,947)	(73,749)	(65,877)	(58,896)	(57,696)
Long term borrowings	(83,060)	(62,016)	(52,941)	(45,098)	(45,098)
Other long term liabilities	(10,887)	(11,733)	(12,936)	(13,798)	(12,598)
Net Assets	64,697	38,726	49,435	66,402	69,122
CASH FLOW					
Operating Cash Flow	(4,589)	5,751	15,489	15,277	18,243
Net Interest	565	876	1,057	(1,852)	(7,377)
Tax	(258)	(308)	(201)	(538)	(1,153)
Capex	(3,055)	(2,029)	(2,095)	(2,705)	857
Acquisitions/disposals	0	0	447	4	0
Financing	125	1,368	0	0	0
Other	2,405	(3,824)	5,760	(7,685)	0
Net Cash Flow	(4,807)	1,834	20,457	2,501	10,571
Opening net debt/(cash)	81,618	86,421	82,322	65,433	55,888
Exchange rate movements	0	0	0	0	0
Other	4	2265	(3,568)	7044	0
Closing net debt/(cash)	86,421	82,322	65,433	55,888	45,318

Source: Edison Investment Research, company accounts. Note: Discontinued operations/minority interest relate to CNS subsidiary Noscira, which is in the process of being wound up.

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