EDISON

PharmaMar

R&D day update

We see value in self-commercialisation

Pharma & biotech

At its recent R&D day in New York, PharmaMar flagged endometrial cancer as a likely fourth indication for lurbinectedin (data to be presented at ASCO). It confirmed that it is on track to achieve the key milestones of an approval decision for Aplidin for multiple myeloma in Europe, and Phase III results for lurbinectedin in ovarian cancer this year, with the most likely timing in Q4. The company emphasised its goal of commercialising lurbinectedin itself in the US market, prompting us to adopt self-commercialisation as our base case valuation scenario, which lifts our valuation by 16% to €1.50bn (vs €1.29bn), or €6.75/share (vs €5.79/share).

Year end	Sales revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/15	162.0	5.9	3.0	0.0	126.3	N/A
12/16	164.0	(24.7)	(10.8)	0.0	N/A	N/A
12/17e	176.4	5.8	2.6	0.0	145.8	N/A
12/18e	195.3	14.0	6.3	0.0	60.2	N/A

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

Four potential catalysts in Q4

Updated timelines presented at the R&D day suggest that four significant events are likely to occur in the fourth quarter. In addition to a decision on the marketing application for Aplidin in multiple myeloma in Europe, and results from the 443-patient Phase III trial of lurbinectedin in platinum-resistant ovarian cancer, the completion of recruitment in the lurbinectedin small cell lung cancer Phase III trial and initiation of a pivotal study in BRCA2+ breast cancer are also expected Q417.

Endometrial cancer likely fourth lurbinectedin indication

PharmaMar flagged endometrial cancer as a likely fourth indication to be developed for lurbinectedin, supported by data to be presented at ASCO in June. It is targeting a potential launch in 2022/23, so the development timeframe will be similar to that planned for BRCA2+ breast cancer. Endometrial cancer is estimated to cause ~61,000 new cases and ~11,000 deaths from in the US each year (vs 22,000 new cases and 14,000 deaths for ovarian cancer). We anticipate including endometrial cancer in our valuation model once the ASCO data are available.

Modest salesforce planned for US commercialisation

PharmaMar indicated that it is planning for a team of 90 people to support all lurbinectedin commercialisation activities in the US (if approved), including sales, medical affairs and market access support. This compares to its EU salesforce of ~80. We estimate the US commercialisation team would cost ~US$23m/year.

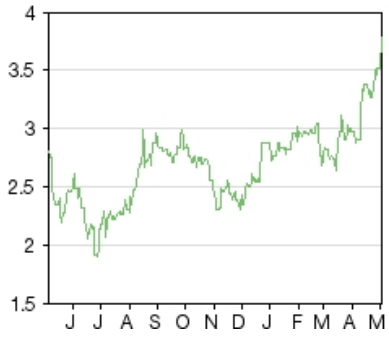
Valuation: Lifted to €1.50bn (€6.75/share)

We increase our valuation to €1.50bn (vs €1.29bn), or €6.75/share (vs €5.79/share) as we adopt self-commercialisation of lurbinectedin in the US as our base case strategy vs our prior assumption of co-promotion. We assume self-commercialisation will deliver a 50% operating margin (including an allowance for the cost of ongoing R&D to support market uptake).

3 May 2017

Price	**€3.79**
Market cap	**€839m**
	$1.1/€
Net debt (€m) at end March 2017	53.5
Shares in issue	221.3m
Free float	73%
Code	PHM
Primary exchange	BME
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	28.3	28.0	38.3
Rel (local)	22.4	11.3	15.3
52-week high/low		€3.8	€1.9

Business description

PharmaMar is a Spanish biopharmaceutical company with a core focus on the development of marine-based drugs for cancer. Yondelis is approved in the US, EU and Japan, and is partnered with Janssen (J&J) in the US and Taiho in Japan. The group also has consumer chemicals, molecular diagnostics and RNAi operations.

Next events

Aplidin approval in Europe	Q417
Lurbinectedin ovarian Phase III results	Q417
Initiate lurbinectedin breast cancer pivotal trial	Q417

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Edison profile page

Self-commercialisation of lurbinectedin preferred in US

PharmaMar has highlighted that its preferred strategy is to self-commercialise lurbinectedin in the US as well as in Europe, which has led us to adopt US self-commercialisation as our base case valuation scenario (we already assumed self-commercialisation Europe, supported by the existing Yondelis sales infrastructure).

The company is planning for a team of 90 people to support all lurbinectedin commercialisation activities in the US; based on an assumed cost of US$250,000 per head, we estimate that the US commercialisation team would cost ~US$23m/year.

We estimate that supporting initial US commercialisation of lurbinectedin may cost around €25m, which PharmaMar should be able to fund from operating cash flow (depending on the timing of potential milestone payments from the Taiho and Chugai licensing deals for lurbinectedin and Aplidin) or from debt funding. We note that PharmaMar had €20m that was available from revolving lines of credit at the end of Q117, and we expect that additional debt finance would be available at acceptable terms to fund the market launch of lurbinectedin, if it was required.

We see potential for the US operations to reach break-even in the second year that lurbinectedin is on the market, and to earn an operating margin in excess of 70% at our forecast peak US ovarian cancer sales of €87m. However, for valuation purposes we assume an average operating margin of 50% for lurbinectedin in the US, including allowances for launch costs and for ongoing R&D to support market uptake.

Valuation

Our valuation of PharmaMar has increased to €1.50bn (vs €1.29bn), or €6.75/share (vs €5.79/share). The main changes to our forecast assumptions are that we have:

- adopted self-commercialisation of lurbinectedin in the US as our base case scenario (earning an operating margin equivalent to 50% of net sales) versus our previous base case assumption of a co-promotion arrangement earning a 35% operating margin;
- delayed first generic competition for Yondelis in Europe to 2024 (vs 2022) based on commentary at the R&D day; and
- with the longer period of Yondelis market exclusivity in Europe and the pending approval decision for Aplidin later this year, we have increased risk weightings applied to SG&A and R&D expenditure, as this spending is now more likely to happen.

Our valuation is based on a sum-of-the-parts DCF model (project-based rNPV for the biopharma business and free cash flow [FCF] for the chemicals division to 2026), as shown in Exhibit 1.

Exhibit 1: PharmaMar sum-of-the-parts DCF

Product	rNPV (€m)	rNPV/ share (€)	Assumptions
Chemicals business FCF	96.8	0.43	7.5% WACC, 3% growth rate from 2019 onwards, accounts for 45% of group capex.
Yondelis (Europe)	566.3	2.55	Second-line STS peak sales of €93m with 40% penetration; third-line ovarian cancer peak sales of €37m with 8% penetration into addressable platinum sensitive market. First potential generics in 2024. 10% WACC.
Yondelis (US)	134.7	0.61	STS (second-line) peak sales of $130m, launched 2016; peak sales in platinum-sensitive ovarian cancer of $50m, 65% risk adjustment, 2020 launch; both assume 15% royalty from J&J and 47% gross margin on sales of raw materials.
Yondelis (Japan)	22.4	0.10	STS only: peak sales of €34m; 15% royalty from Taiho. 10% WACC.
Aplidin (multiple myeloma)	207.9	0.94	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; 90% success probability in Europe, 65% in the US; launch 2018 in Europe, 2021 in the US; sold by Chugai in eight European territories (assume effective royalty of 25%) and direct in other EU regions, assume 25% royalty in US; includes €20m of near-term regulatory milestones out of €30m total Chugai milestones. No milestones included for other territories at this stage.
Lurbinectedin (resistant ovarian cancer)	316.8	1.43	Third-line, platinum-resistant ovarian cancer: peak sales of €193m; US and EU: 65% success probability, 2019 launch - sold direct in Europe and the US; Japan: 50% success probability, 2021 launch, 20% royalty.
Lurbinectedin (SCLC)	633.3	2.85	Peak sales of €680m; US and EU: 65% success probability, 2020 launch sold direct in Europe and US; Japan: 50% success probability, 2022 launch, 20% royalty.
Lurbinectedin (breast – BRCA2 mutated)	133.2	0.60	Peak sales of €250m; 45% success probability; US and EU: 2021 launch - sold direct in Europe and US; Japan: 50% success probability, 2023 launch, 20% royalty.
Lurbinectedin upfront and milestones	43.7	0.20	Chugai upfront €30m, plus Chugai Japan development milestones assumed to be €35m of ~€70m total potential Chugai milestone payments (assumed to average €7m/year over 2017-21), risked at 50-90%; no Chugai sales-based milestones or milestones for other territories included in our forecasts at this stage.
Sylentis	6.8	0.03	Cumulative peak sales of $200m, with 20% probability of success, potential launch 2021, 10% royalty.
Genomica	55.8	0.25	Conservative 2% growth rate.
R&D	(337.7)	(1.52)	12.5% WACC.
SG&A	(303.1)	(1.36)	10% WACC.
Capex	(15.8)	(0.07)	55% of group capex for biopharma business.
Net debt	(62.0)	(0.28)	At end-FY16.
Total	**1,499.2**	**6.75**	

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

Financials

PharmaMar reported that total sales rose by 4% to €41.6m in Q117. This comprised flat sales of €24.3m in the biopharmaceutical segment, whereas sales in the consumer chemical segment grew by 10% to €17.4m.

Q117 sales of marketed anti-cancer drug, Yondelis, were flat at €22.5m (vs €22.7m in Q116). This compares to 7% growth in commercial sales of Yondelis in 2016 and is below our forecast 8% growth in Yondelis sales for the year, but it is still early in the year and quarterly sales can be lumpy.

Yondelis royalties from partners J&J (Janssen) in the US and RoW ex-Europe and Chugai in Japan totalled €1.7m, slightly behind the €1.8m reported in Q116 (likely boosted by pipeline fill) but ahead of the €1.3m/quarter average over the course of 2016. Royalties appear to be on an upward trend compared to recent quarters, reflecting continued growth in Yondelis sales in the US and Japan.

The recognition of €2.2m of deferred revenue from the €30m upfront payment from the Chugai licence deal for lurbinectedin in Japan lifted total revenue to €45.5m, up 8% on the previous corresponding period.

The completion of two Phase III trials saw R&D expense fall by 5% to €18.0m but, with additional Phase III trials in breast cancer and possibly also endometrial cancer expected to commence later this year, we expect total R&D expense for the full year to rise by 11% to €88.4m (before deducting capitalised R&D).

Adjusted EBITDA for the group was €0.9m for the quarter. We expect EBITDA to remain positive over the course of the year, with increased R&D expenses in the second half more than offset by (risk-adjusted) milestone payments for Aplidin approval. At this early stage of the year we leave our forecasts unchanged.

The company had €41.1m cash and financial assets and total net debt of €53.5m at the end of March 2017. Net debt fell by €8.5m over the quarter, reflecting the receipt of the €30 Chugai upfront received in January 2017. The modest net debt, combined with anticipated revenue growth flowing from recent Yondelis launches in the US and Japan, puts PharmaMar in a robust financial position to fund its clinical trial programme and pursue self-commercialisation of lurbinectedin in the US and Europe (if approved).

Exhibit 2: Financial summary

€'000s	2014	2015	2016	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	149,652	161,992	164,035	176,370	195,263
Cost of Sales	(40,765)	(45,705)	(43,971)	(46,817)	(49,231)
Gross Profit	108,887	116,287	120,064	129,553	146,032
R&D Expenses (gross)	(52,456)	(63,549)	(79,780)	(88,443)	(79,416)
Capitalised in-house R&D	5,979	3,258	1,357	2,024	1,800
Sales, General and Administrative Expenses	(57,043)	(74,067)	(71,550)	(62,552)	(64,698)
Other (milestones and royalties)	28,060	31,825	16,913	43,284	28,627
EBITDA	25,704	17,578	(11,463)	17,844	26,263
Operating Profit (before GW and except.)	22,095	11,297	(18,706)	10,384	18,579
Depreciation & Amortisation	(5,467)	(6,281)	(7,243)	(7,460)	(7,684)
Exceptionals	0	0	0	0	0
Operating Profit	20,237	11,297	(18,706)	10,384	18,579
Net Interest	(5,762)	(5,388)	(5,993)	(4,576)	(4,533)
Other	0	0	0	0	0
Profit Before Tax (norm)	16,333	5,909	(24,699)	5,808	14,046
Profit Before Tax (as reported)	14,475	5,909	(24,699)	5,808	14,046
Tax	(1,304)	654	592	0	0
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	15,029	6,563	(24,107)	5,808	14,046
Profit After Tax (FRS 3)	13,171	6,563	(24,107)	5,808	14,046
Minority interests	20	25	25	0	0
Discontinued operations	(76)	0	0	(48)	0
Net income (normalised)	15,049	6,588	(24,082)	5,808	14,046
Net income (FRS3)	13,115	6,588	(24,082)	5,760	14,046
Average Number of Shares Outstanding (m)	222.2	222.2	222.2	222.2	222.2
EPS - normalised (c)	6.8	3.0	(10.8)	2.6	6.3
EPS - FRS 3 (c)	0.06	0.03	(0.11)	0.03	0.06
Dividend per share (c)	0.00	0.00	0.00	0.00	0.00
Gross Margin (%)	72.8%	71.8%	73.2%	73.5%	74.8%
EBITDA Margin (%)	17.2%	10.9%	-7.0%	10.1%	13.4%
Operating Margin (before GW and except.) (%)	14.8%	7.0%	-11.4%	5.9%	9.5%
BALANCE SHEET					
Fixed Assets	99,473	99,804	100,145	98,237	96,062
Intangible Assets	28,836	29,377	27,448	29,472	31,272
Tangible Assets	29,218	30,624	31,141	27,208	23,234
Other	41,419	39,803	41,556	41,556	41,556
Current Assets	101,916	112,135	120,992	111,592	119,342
Stocks	24,404	22,990	22,158	25,653	26,976
Debtors	36,989	40,200	62,652	41,073	45,472
Cash and current financial assets	35,511	45,625	32,367	41,052	43,079
Other	5,012	3,320	3,815	3,815	3,815
Current Liabilities	(82,626)	(70,623)	(87,164)	(79,043)	(79,487)
Creditors	(38,160)	(41,994)	(59,258)	(51,137)	(51,581)
Short term borrowings	(44,466)	(28,629)	(27,906)	(27,906)	(27,906)
Long Term Liabilities	(58,694)	(68,280)	(85,478)	(76,478)	(68,688)
Long term borrowings	(47,003)	(64,973)	(67,583)	(67,583)	(67,583)
Other long term liabilities	(11,691)	(3,307)	(17,895)	(8,895)	(1,105)
Net Assets	60,069	73,036	48,495	54,307	67,230
CASH FLOW					
Operating Cash Flow	23,475	10,195	(3,040)	18,813	12,070
Net Interest	(1,000)	252	(5,000)	(4,576)	(4,533)
Tax	(366)	654	(374)	0	0
Capex	(10,179)	(9,221)	(6,093)	(5,552)	(5,510)
Acquisitions/disposals	4	0	129	0	0
Financing	(2,905)	6,169	(632)	0	0
Other	0	0	0	0	0
Net Cash Flow	9,029	8,049	(15,010)	8,685	2,028
Opening net debt/(cash)	64,585	54,886	46,910	61,984	53,299
Exchange rate movements	0	0	0	0	0
Other	670	(73)	-64	0	0
Closing net debt/(cash)	54,886	46,910	61,984	53,299	51,272

Source: Edison Investment Research, PharmaMar accounts.

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