EDISON

PharmaMar

Financial update

Full year 2017 results

Pharma & biotech

PharmaMar recently reported financial results for 2017. Sales for the year were down 0.9% to €162.6m compared to 2016. Yondelis sales fell 4.1% to €84.6m, mainly due to pricing erosion in Europe. However, the consumer chemicals division continues to grow and was up 3.4% for the year to €72.0m. Importantly, the company's Phase III trial testing Zepsyre® in small cell lung cancer (SCLC) patients is around 75% enrolled and expected to be fully enrolled in the middle of this year with data in H119.

Year end	Sales revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/16	164.0	(24.7)	(10.8)	0.0	N/A	N/A
12/17	162.6	(22.7)	(12.0)	0.0	N/A	N/A
12/18e	168.8	5.8	2.6	0.0	67.3	N/A
12/19e	177.3	7.2	2.7	0.0	64.8	N/A

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

ATLANTIS trial in SCLC patients progressing nicely

PharmaMar announced that the 600-patient ATLANTIS trial of Zepsyre in relapsed SCLC patients is around 75% enrolled, with enrolment expected to complete in June/July. With this timing in mind, top-line data are expected around H119. As a reminder, in previous data at the same dose being used in ATLANTIS, Zepsyre demonstrated PFS of 5.3 months, which is higher than the three to four months typically seen with Topotecan, the current standard of care.

SCLC could be a significant opportunity

There is a significant unmet medical need in SCLC and there are very limited options, with the last FDA approval coming in 1996. It is an extremely aggressive disease with median survival from diagnosis at only two to four months without treatment. Also, even those who do get treated usually relapse. Overall survival at five years is only 5-10%, according to the National Cancer Institute. Around 80,000 patients are diagnosed with the cancer every year in the US and Europe.

Zepsyre endometrial cancer trial on deck

Beyond SCLC, PharmaMar is also about to embark on a 500-patient Phase III trial in second-line endometrial cancer. Zepsyre had previously demonstrated a 44% response rate and median progression-free survival (PFS) of 7.8 months in this patient population, which is noteworthy as these patients are typically chemo-resistant with PFS closer to 3.2 months. We expect the Phase III to be initiated around the middle of this year.

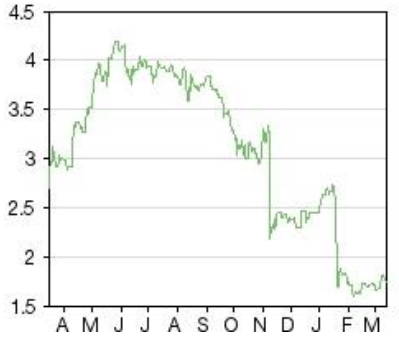
Valuation: Decreased to €1.12bn or €5.04 per share

We are decreasing our valuation to €1.12bn or €5.04/share from €1.35bn or €6.06/share as we have removed Zepsyre in breast cancer from our model following company comments on its earnings call regarding de-emphasis of the programme due to a shifting treatment paradigm. We have also lowered our estimates for Yondelis due to continued pricing pressure. This was partly mitigated by rolling forward our NPVs.

14 March 2018

Price	**€1.75**
Market cap	**€390m**
	$1.22/€
Net debt (€m) at end December 2017	67.3
Shares in issue	222.7m
Free float	80%
Code	PHM
Primary exchange	BME
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	7.8	(29.1)	(35.3)
Rel (local)	7.3	(25.0)	(33.3)
52-week high/low		€4.2	€1.6

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

SCLC Phase III trial enrolment completion	June/July 2018
Endometrial trial Phase III initiation	Mid-2018

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Edison profile page

Results for 2017

PharmaMar reported that sales fell by 0.9% €162.6m in 2017 to from €164.0m in 2016. Sales in the biopharmaceutical area fell 4.0% to €90.6m. This was mainly due to a 4.1% decline in Yondelis sales to €84.6m caused by price erosion in Europe. Sales in the consumer chemical segment grew by 3.4% to €72.0m, mainly thanks to chalky finish paints and other Rust-Oleum products.

R&D expenditure in 2017 rose slightly by 0.2% to €78.5m, mainly due to a 0.3% rise in R&D related to the oncology segment (mainly Zepsyre clinical trials). Marketing and commercial expenses fell by 6% to €44.8m. This was mainly due to lower spending in the oncology segment, partly as a result of in-sourcing distribution logistics, as well as fewer commercial actions.

Adjusted EBITDA for the group was a loss of €7.4m compared to a loss of €11.0m in 2016, a relative improvement of 33%. The improvement is due to cost containment of commercial and R&D expenses.

Clinical updates

PharmaMar also provided a slew of clinical updates related to its pipeline. It announced that the 600-patient ATLANTIS trial of Zepsyre in relapsed SCLC patients is around 75% enrolled, with enrolment expected to complete in June/July. Data are expected in H119. The primary endpoint is PFS comparing patients treated with the combination of Zepsyre and doxorubicin to the control arm where patients are treated with either Topotecan or the CAV regimen, a combination of cyclophosphamide, Adriamycin (the brand name for doxorubicin) and vincristine. We have increased confidence in the success of the SCLC trial compared to the recently failed CORAIL ovarian trial because in previous data at the same dose being used in ATLANTIS, Zepsyre demonstrated PFS of 5.3 months, which is higher than the three to four months typically seen with Topotecan, the current standard of care. In CORAIL, Zepsyre was being tested in a new body surface area-based dosing regimen, which had been untested in the Phase II in ovarian cancer patients.

PharmaMar also expects to initiate a 500-patient Phase III trial in second-line endometrial cancer around mid-2018. It expects data to be available around three years from the first patient enrolled. Patients will either receive 2.0mg/m^2 of Zepsyre plus 40mg/m^2 of doxorubicin or 60mg/m^2 of doxorubicin with a primary endpoint of overall survival. In previous data, which combined 2.0mg/m^2 of Zepsyre with 40mg/m^2 of doxorubicin, the combination demonstrated a 44% response rate and a PFS of 7.8 months. These data are encouraging as PFS is typically closer to 3.2 months in similar patients.[1]

The company was planning a registrational trial in 116 BRCA2 mutated, HR-positive, HER2-negative metastatic breast cancer patients but, due to a shifting treatment landscape in breast cancer, it has decided to de-emphasise the programme. Also in breast cancer, PM184, which is also a marine-derived drug, did not attain the necessary efficacy threshold in the first stage of the Phase II trial in HR-positive advanced breast cancer patients, and the trial is being concluded. A dose-escalation trial of PM184 with gemcitabine in multiple cancers is continuing to enrol patients.

PharmaMar also expects a response to its appeal on the negative CHMP recommendation in Europe for Aplidin for treating multiple myeloma in the next two months.

[1] Nagao et al., Applicability of the concept of “platinum sensitivity” to recurrent endometrial cancer., *Gynecologic Oncology* 2013 Dec; 131(3):567-73.

Valuation

We are decreasing our valuation to €1.12bn or €5.04/share from €1.35bn or €6.06/share as we have removed Zepsyre in breast cancer from our model following company comments on the conference call regarding its de-emphasis due to a shifting treatment landscape. We have also decided to make our Yondelis projections more conservative across the board due to continued pricing pressure and other commercial challenges. In Europe, the area where Yondelis sales have the most direct impact on PharmaMar's top line, we have lowered our peak sales estimates for Yondelis in STS to €80m from €87m and have lowered our third-line ovarian cancer peak sales estimate to €30m from €37m. This was partly mitigated by rolling forward our NPVs.

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

Product	rNPV (€m)	rNPV/ share (€)	Assumptions
Chemicals business FCF	136.0	0.61	7.5% WACC, 3% growth rate from 2019 onwards, accounts for 45% of group capex.
Yondelis (Europe)	512.2	2.30	Second-line soft-tissue sarcoma (STS) peak sales of €80m with 35% penetration; third-line ovarian cancer peak sales of €30m with 8% penetration into addressable platinum sensitive market. First potential generics in 2024. 10% WACC.
Yondelis (US)	112.4	0.50	STS (second-line) peak sales of $100m, launched 2016; peak sales in platinum-sensitive ovarian cancer of $50m, 65% risk adjustment, 2020 launch; both assume 15% royalty from J&J.
Yondelis (Japan)	24.6	0.11	STS only: peak sales of €34m; 15% royalty from Taiho. 10% WACC.
Aplidin (multiple myeloma)	54.9	0.25	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; 30% success probability in Europe, 30% in the US; launch in 2021 in the US and EU; 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 regulatory milestones out of €30m total Chugai milestones. No milestones included for other territories at this stage.
Zepsyre (SCLC)	712.5	3.20	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.
Zepsyre (endometrial cancer)	218.0	0.98	Peak sales of €198m; US and EU: 65% success probability, 2022 launch sold direct in Europe and US; Japan: 50% success probability, 2023 launch, 20% royalty.
Zepsyre upfront and milestones	17.9	0.08	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	7.3	0.03	Cumulative peak sales of $200m, with 20% probability of success, potential launch 2021, 10% royalty.
Genomica	57.5	0.26	Conservative 2% growth rate.
R&D	(348.4)	(1.56)	12.5% WACC.
SG&A	(299.2)	(1.34)	10% WACC.
Capex	(16.4)	(0.07)	55% of group capex for biopharma business.
Net cash/(debt)	(67.3)	(0.30)	At Q417
Total	1,122.0	5.04	

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

Financials

As mentioned above, we have lowered our Yondelis forecasts across the board which, coupled with lower than expected 2017 Yondelis sales, has led us to lower our 2018 sales estimate (which includes biopharmaceuticals and the consumer chemicals business) from €184.0m to €168.8m. We have made slight adjustments to our R&D and SG&A expense estimates. Our 2018 R&D estimate has increased by approximately €0.8m and our SG&A estimate has decreased by €1.5m. We have also introduced our 2019 estimates, in which we expect continued slow growth for the base business (which will change if Zepsyre is successful in SCLC) and continued expense control.

Exhibit 2: Financial summary

€'000s	2015	2016	2017	2018e	2019e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Sales (Bipharmaceutical and Consumer Chemicals)	161,992	164,035	162,618	168,816	177,307
Cost of Sales	(45,705)	(43,971)	(45,688)	(46,832)	(48,630)
Gross Profit	116,287	120,064	116,930	121,984	128,678
R&D Expenses (net)	(60,291)	(78,423)	(78,541)	(77,651)	(65,951)
Sales, General and Administrative Expenses	(74,067)	(71,550)	(65,501)	(58,840)	(59,888)
Other (milestones and royalties)	31,825	16,913	16,765	38,333	22,799
EBITDA	17,578	(11,463)	(8,219)	17,743	19,494
Operating Profit (before amort. and except.)	11,297	(18,706)	(17,681)	10,573	12,109
Depreciation & Amortisation	(6,281)	(7,243)	(9,462)	(7,170)	(7,385)
Exceptionals	0	0	0	0	0
Operating Profit	11,297	(18,706)	(17,681)	10,573	12,109
Net Interest	(5,388)	(5,993)	(5,002)	(4,806)	(4,865)
Other	0	0	(177)	0	0
Profit Before Tax (norm)	5,909	(24,699)	(22,683)	5,767	7,244
Profit Before Tax (as reported)	5,909	(24,699)	(22,860)	5,767	7,244
Tax	654	592	(3,904)	0	(1,304)
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	6,563	(24,107)	(26,587)	5,767	5,940
Profit After Tax (FRS 3)	6,563	(24,107)	(26,764)	5,767	5,940
Minority interests	25	25	19	0	0
Discontinued operations	0	0	(48)	0	0
Net income (normalised)	6,588	(24,082)	(26,745)	5,767	5,940
Net income (FRS3)	6,588	(24,082)	(26,793)	5,767	5,940
Average Number of Shares Outstanding (m)	222.2	222.2	222.2	222.7	222.7
EPS - normalised (c)	3.0	(10.8)	(12.0)	2.6	2.7
EPS - FRS 3 (c)	0.03	(10.8)	(12.1)	2.6	2.7
Dividend per share (c)	0.00	0.00	0.00	0.00	0.00
Gross Margin (%)	71.8%	73.2%	71.9%	72.3%	72.6%
EBITDA Margin (%)	10.9%	-7.0%	-5.1%	10.5%	11.0%
Operating Margin (before GW and except.) (%)	7.0%	-11.4%	-10.9%	6.3%	6.8%
BALANCE SHEET					
Fixed Assets	99,804	100,145	94,544	92,382	89,688
Intangible Assets	29,377	27,448	22,760	24,560	26,060
Tangible Assets	30,624	31,141	31,207	27,245	23,051
Other	39,803	41,556	40,577	40,577	40,577
Current Assets	112,135	120,992	93,176	90,948	94,829
Stocks	22,990	22,158	23,904	25,661	26,646
Debtors	40,200	62,652	31,388	39,313	41,291
Cash and current financial assets	45,625	32,367	31,759	19,848	20,766
Other	3,320	3,815	6,125	6,125	6,125
Current Liabilities	(70,623)	(87,164)	(83,110)	(75,320)	(68,761)
Creditors	(41,994)	(59,258)	(56,715)	(48,925)	(42,366)
Short term borrowings	(28,629)	(27,906)	(26,395)	(26,395)	(26,395)
Long Term Liabilities	(68,280)	(85,478)	(81,626)	(74,392)	(74,392)
Long term borrowings	(64,973)	(67,583)	(73,607)	(73,607)	(73,607)
Other long term liabilities	(3,307)	(17,895)	(8,019)	(785)	(785)
Net Assets	73,036	48,495	22,984	33,618	41,363
CASH FLOW					
Operating Cash Flow	10,195	(3,040)	543	(2,097)	11,779
Net Interest	252	(5,000)	(5,002)	(4,806)	(4,865)
Tax	654	(374)	3,000	0	(1,304)
Capex	(9,221)	(6,093)	(4,580)	(5,008)	(4,692)
Acquisitions/disposals	0	129	0	0	0
Financing	6,169	(632)	769	0	0
Other	0	0	0	0	0
Net Cash Flow	8,049	(15,010)	(5,270)	(11,910)	918
Opening net debt/(cash)	54,886	46,910	61,984	67,266	79,177
Exchange rate movements	0	0	0	0	0
Other	(73)	-64	-12	0	0
Closing net debt/(cash)	46,910	61,984	67,266	79,177	78,259

Source: Company accounts, Edison Investment Research.

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