



## REPORT AT 31 MARCH 2014

*Madrid, 29 April 2014*

### 1Q14 HIGHLIGHTS

#### **Group**

- Group net sales amounted to 34.2 million euro (+11%). Yondelis accounted for 19.7 million euro (+18%)
- Revenues increased in both business segments—Biopharmaceuticals (+16%) and Consumer Chemicals (+5%).
- Group EBITDA amounted to 19.4 million euro, 10% more than in the previous year. The oncology area was the main contributor to this growth, accounting for 21.8 million euro of consolidated EBITDA
- Attributable net profit increased by 7%.
- Operating cash flow totalled 8.2 million euro.
- Total net debt has been cut by 11% since the beginning of the year.

#### **Oncology**

- The FDA has approved the strategy proposed by PharmaMar for the PM1183 (lurbinectidin) production process
- The pivotal registration trial with Yondelis® in Japan for the treatment of soft tissue sarcoma produced positive results and, consequently, Taiho Pharmaceuticals plans to present a marketing application for that therapeutic use to the Japanese regulatory authorities.
- 

#### **Diagnostics**

- Exports to Latin America increased.

M<sup>a</sup> Luisa de Francia  
CFO  
ZELTIA, S.A.  
Plaza Descubridor Diego de Ordás, 3  
Madrid  
Telephone 91.444.45.00

José Luis Moreno  
Head of Investor Relations  
ZELTIA, S.A.  
Plaza Descubridor Diego de Ordás, 3  
Madrid  
Telephone 91.444.45.00

**FIGURES TO MARCH 2014**

<b>Period</b>	<b>03/31/2014</b>	<b>03/31/2013</b>	<b>Δ%</b>
<b>Net Revenue (€ 000)</b>			
Consumer Chemicals	13.153	12.558	4,7%
Biopharmaceuticals	20.871	18.042	15,7%
Unallocated	186	215	-13,5%
<b>Total Group</b>	<b>34.210</b>	<b>30.815</b>	<b>11,0%</b>
Cost of goods sold (€ 000)	8.134	7.975	
Gross Income	<b>26.076</b>	<b>22.840</b>	<b>14,2%</b>
Gross Margin	76,22%	74,12%	
<b>Other operating revenues</b>			
Consumer Chemicals	97	6	
Biopharmaceuticals	18.815	19.340	
Unallocated	2	0	
	<b>18.914</b>	<b>19.346</b>	<b>-2,2%</b>
<b>TOTAL REVENUE</b>	<b>53.124</b>	<b>50.161</b>	<b>5,9%</b>
<b>EBITDA (€ 000)</b>			
Consumer Chemicals	684	366	
Biopharmaceuticals	20.709	18.979	
Unallocated	-2.034	-1.759	
<b>Total Group</b>	<b>19.359</b>	<b>17.586</b>	<b>10,1%</b>
<b>R&amp;D Expenditure</b>			
Oncology	9.565	8.511	
Other	1.802	2.376	
<b>Total Group</b>	<b>11.367</b>	<b>10.887</b>	<b>4,4%</b>
<b>Marketing &amp; Commercial Expenses</b>			
Consumer Chemicals	3.511	3.637	-3,5%
Biopharmaceuticals	6.013	5.469	9,9%
Other	2	2	
<b>Total Group</b>	<b>9.526</b>	<b>9.108</b>	<b>4,6%</b>
<b>Income for the year attributable to equity-holders of the parent company</b>	<b>16.898</b>	<b>15.818</b>	<b>6,8%</b>
<b>Profit for the year from discontinued operations</b>	<b>-112</b>	<b>-194</b>	

*(Thousand euro)*

**Net sales**

Group net sales amounted to 34.2 million euro in 1Q14, 11% more than in the same period of 2013 (30.8 million euro).

Net sales in the Biopharmaceutical business amounted to 20.9 million euro (18.0 million euro in 1Q13), a 16% increase. That figure breaks down as follows: 19.7 million euro at PharmaMar from Yondelis sales (16.7 million euro in 1Q13) and 1.2 million euro at Genómica (1.3 million euro in 1Q13).

Yondelis net sales increased by 18% year-on-year. Gross sales increased by approximately 24% year-on-year. This sector accounted for 61% of Group net sales.

Net sales by the Consumer Chemicals subsidiaries totalled 13.2 million euro (12.6 million euro in 1Q13), a 5% increase year-on-year. This segment contributed 39% of the Group's total sales in 1Q14.

### **Other operating revenues**

This section reflects revenues from royalties, subsidies, and licensing agreements, including milestone and similar payments.

Other operating revenues totalled 18.9 million euro in 1Q14 (19.3 million euro in 1Q13). In 2014, PharmaMar collected 25 million dollars (18.3 million euro) under the new action plan signed in 2011 with Janssen Products LP. (Johnson & Johnson Pharmaceutical Research & Development, LLC.) to intensify the development of Yondelis® in the US for soft tissue sarcoma and relapsed ovarian cancer. The remainder of operating revenues came from royalties, subsidies and other minor items.

### **Total revenues and revenues from outside Spain**

Group revenues (net sales plus other operating revenues) totalled 53.1 million euro in the first quarter of 2014 (50,2 million euro in 1Q13), of which 71% (38.8 million euro) came from outside Spain.

In the Biopharmaceutical segment, sales outside Spain accounted for 92% of the total.

### **EBITDA**

Group EBITDA from continuing operations totalled 19.4 million euro in the first quarter of 2014, i.e. a 10% increase on 1Q13 (17.6 million euro). The oncology area was the main contributor to this performance, accounting for 21.8 million euro (20.5 million euro in 1Q13).

The EBITDA margin improved considerably due to Yondelis's growing contribution to total revenues and also to growth in consumer chemical sales, not to mention more efficient management of costs in all divisions.

(EBITDA: earnings before interest, taxes, depreciation and amortization)

### **R&D expenditure**

R&D expenditure increased by 4.4% year-on-year, to 11.4 million euro in 1Q14 (10.9 million euro in 1Q13). R&D expenditure amounted to 9.6 million euro in Oncology in 1Q14 (8.5 million euro in 1Q13) and 1.2 million euro in Diagnostics and RNA interference (1.9 million euro in 1Q13).

### **Marketing and commercial expenses**

Marketing and commercial expenses amounted to 9.5 million euro in 1Q14 (9.1 million euro in 1Q13), an increase of 400 thousand euro (4%).

### **Income from discontinued operations**

Due to the discontinuation of the Group's activities relating to the Central Nervous System (mainly Alzheimer's disease) under Noscira, earnings for this area are reflected in a single line item: "Income from discontinued operations". That line item amounted to -0.11 million euro in 1Q14 and -0.19 million euro in 1Q13. Noscira is currently being liquidated.

## Income attributable to the parent company

Income attributable to the parent company amounted to 16.9 million euro, compared with 15.8 million euro in 1Q13. This performance is due to the general improvement in revenues Group-wide, particularly in oncology, and also to improved margins.

## Cash and Debt

The cash position (cash + cash equivalents + current financial assets) amounted to 33.3 million euro (28.9 million euro at 31 December 2013). The Group's total debt amounted to 91.4 million euro (94.3 million euro at 31 December 2013).

The breakdown of current and non-current debt is as follows:

	03/31/2014	12/31/2013
<b>Non current Debt</b>	<b>42.579</b>	<b>52.941</b>
Bank debt	19.243	25.151
Govt. agencies: R&D funding (interest free)	23.336	23.790
Others	0	4.000
<b>Current Debt</b>	<b>48.874</b>	<b>41.327</b>
Credit facilities	14.238	10.959
Effects and certifications	2.435	1.836
Bank loan	22.765	22.648
Govt. agencies: R&D funding (interest free)	4.264	3.992
Others and Interests	5.172	1.892
<b>Total debt</b>	<b>91.453</b>	<b>94.268</b>
<b>Cash and acash equivalents + financial investments current and non current</b>	<b>34.083</b>	<b>29.683</b>
<b>TOTAL NET DEBT</b>	<b>-57.370</b>	<b>-64.585</b>

The debt with Govt. Agencies is registered at amortised cost based on the effective interest method.

The Group had credit lines totalling 26.5 million euro at 31 March 2014. The unused balance under those credit lines was 12.3 million euro at 31 March 2013.

## **BUSINESS PERFORMANCE.**

Below is an overview of the group companies' business performance in the first quarter of 2014.

### **B) Biopharmaceuticals**

#### **1.- Oncology: PharmaMar**

##### **a) Yondelis®:**

###### **Soft-tissue sarcoma**

After completion of recruitment for the Phase III pivotal multi-centre randomized controlled (2:1) trial in L-sarcomas (leiomyosarcomas and liposarcomas) being conducted by Janssen, which seeks to obtain registration for Yondelis® in the US and the rest of the world, the results are being analysed to assess the efficacy of Yondelis® in comparison with dacarbazine for treating L-sarcomas.

Recruitment has concluded in the two registration trials sponsored by Taiho in patients with translocation-related sarcomas, the goal of which is obtain registration for Yondelis® in Japan.

As a result, Taiho Pharmaceuticals Co., Ltd. has announced that the pivotal registration trial with Yondelis® in soft tissue sarcoma produced positive results and that, consequently, it plans to present a marketing application for that therapeutic use to the Japanese authorities.

Taiho Pharmaceuticals has also announced that the results of the trial will be presented at the ASCO meeting, which will be held in Chicago from 30 May to 3 June this year.

The observational and post-authorisation trials with Yondelis® in cooperation with various European and American groups are also advancing on schedule. Specifically, recruitment is advancing in the Y-IMAGE prospective, multi-centre observational trial to evaluate the response to treatment with Yondelis® in line with standard clinical practice. Recruitment of patients for the trial in Germany (GISG) with Yondelis® in combination with gemcitabine is also advancing on schedule. Recruitment for the observational trial required by the Dutch authorities to obtain the reimbursement of Yondelis® has concluded and the results are being analysed.

###### **Ovarian cancer**

Recruitment continues satisfactorily for the pivotal clinical trial in ovarian cancer in the US, sponsored by Janssen.

Recruitment also continues for the Phase II trial to evaluate the efficacy of Yondelis® + bevacizumab, with and without carboplatin, which is being promoted by the Mario Negri Institute in Milan.

The OvaYond observational trial has begun enrolling ovarian cancer patients being treated with Yondelis® and PLD in Germany in actual practice.

A Phase II multi-centre randomized trial has commenced to assess the activity and safety of the combination of bevacizumab + Yondelis®, with and without carboplatin, in platinum-sensitive relapsed ovarian cancer patients.

The data from the Phase II trial with Yondelis® in patients with advanced breast cancer who are carriers of the BRCA1 and BRCA2 mutations and the BRCAness phenotype is currently being analysed.

###### **Other indications**

Recruitment is continuing in the ATREUS Phase II trial promoted by the Mario Negri Institute for Pharmacological Research (IRCCS) in cooperation with the Department of Medical Oncology at San

Gerardo Hospital (Monza, Italy) to evaluate the activity and safety of Yondelis® in malignant pleural mesothelioma (MPM).

**b) Aplidin®**

**Multiple myeloma**

Recruitment for the ADMYRE Phase III trial is advancing satisfactorily following the positive recommendation by the Independent Data Monitoring Committee (IDMC) in December 2012.

**c) Zalypsis®**

**Multiple Myeloma:**

Analysis of the data from all the patients recruited in the second stage of the Phase II trial with Zalypsis® as monotherapy against multiple myeloma is continuing.

**d) PM01183**

**Resistant/refractory ovarian cancer**

The randomized Phase II trial in patients with platinum-resistant/refractory ovarian cancer having concluded, assessment of progression free survival (PFS) has been completed and overall survival (OS) continues to be monitored. The results of this trial will be published in the form of an oral presentation at the annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago in June.

The Phase III (registration) trial in this indication is currently being designed.

**Endometrial cancer.**

The strategy and design for a pivotal Phase III trial in patients with endometrial cancer are also currently being developed.

**Advanced breast cancer**

Recruitment continues on schedule for the Phase II clinical trial in patients with advanced breast cancer selected on the basis of the presence of mutations, known or otherwise, of the BRCA 1 or 2 genes (hereditary cancer).

**Non-small-cell lung cancer (NSCLC)**

Recruitment is continuing on schedule for the Phase II randomized trial in patients with non-small cell lung cancer. This trial was implemented after good efficacy results were obtained in the Phase I trial in combination with gemcitabine.

**Advanced leukaemia**

An amendment to the Phase I clinical trial with this compound as monotherapy to treat advanced leukaemia has been submitted to the ethics committee at MD Anderson (Houston, Texas) with a view to including patients with myelodysplastic syndrome and to optimising the dose.

**Combination trials**

The combination trial with PM01183 and doxorubicin has been reopened and patient recruitment is advancing satisfactorily with a view to confirming the excellent preliminary activity observed in patients with endometrial cancer, NSCLC, and neuroendocrine tumours.

Since the primary endpoint (defining the recommended dose in the trial in combination with capecitabine in patients with breast, colorectal or pancreatic cancer) was achieved, a new cohort of patients has commenced with an infusion pattern of one day every 3 weeks in order to optimize the dose of PM01183.

The combination trial with paclitaxel weekly, with or without added bevacizumab, in patients with selected solid tumours is under way and currently in the dose escalation phase.

The trial in combination with cisplatin in patients with solid tumours is awaiting only the approval from the ethics committees and regulatory agencies.

The FDA has accepted PharmaMar's proposal for the PM1183 production process and the intermediate products from which the company will produce the drug have been approved. FDA approval confirms the strategy established by PharmaMar for producing PM1183, the process for which is now fully defined.

#### **e) PM060184**

Recruitment continues on schedule for two Phase I trials under way in the United States, France and Spain. The preliminary results evidence that the drug is active in several tumour types. The recommended dose for the weekly patterns evaluated in both trials has been defined and new patterns are being explored to optimize drug efficacy and safety.

### **2.- Diagnostics: Genómica**

Revenues amounted to 1.2 million euro in 1Q14, i.e. approximately 100 thousand euro less than in the same period last year. This reduction is due firstly to conclusion of the contract with the Spanish Civil Guard forensics unit to provide human identification services via DNA analysis, and secondly to a slowdown of exports to other euro area countries; however the latter effect was offset by excellent performance of sales in Brazil, where the company continues to expand (by 40% with respect to 1Q13).

Domestic sales rose 10% in the first quarter.

### **3.- RNA interference: Sylentis**

The company continued to advance its R&D lines in 1Q14, working to develop new formulations for RNAi-based compounds for eye diseases.

As regards the two compounds under clinical development, the Phase IIA clinical trial with SYL040012 (dose identification) in glaucoma was completed in 2013. This trial, in patients with ocular hypertension and glaucoma, was performed at 11 centres in Spain, Germany and Estonia. A new clinical trial with SYL040012 (Phase IIB) commenced at the end of 2013 to determine the dose and its efficacy vs. a control. During the first quarter of 2014, the clinical trial protocol was designed and the hospitals that will participate in the trial were selected: a total of 21 centres in Spain, Germany, Estonia and the United States.

With respect to the second clinical trial under way with SYL1001, we have requested authorization from the Spanish Agency of Medicines and Medical Devices (AEMPS) for a pilot trial in patients with eye discomfort associated with dry eye syndrome. In January 2014, the Spanish Medicines and Health Products Agency approved an application to change the dose in this clinical trial. Recruitment is continuing using the new dose and is expected to be completed in the first half of 2014.

## **B) Consumer chemicals:**

### **1.- Xylazel (varnishes and paints for protecting wood and metal)**

Gross sales amounted to 3.6 million euro in the first quarter of 2014, 13.7% more than in the same period last year. Sales improved in all distribution channels except the industrial channel. Additionally, all regions except northern Spain registered an increase in sales. Exports rose by 5.9%.

It is important to note that the growth in revenues was due to an increase in volume, not in prices.

Raw material procurement prices fell by 1.6%, packaging prices by 0.2%. As a result, both EBITDA and net profit improved with respect to the previous year. EBITDA amounted to 175 thousand euro in the first quarter of 2014, compared with -13 thousand euro in the same period of 2013.

## 2.- Zelnova and Copyr (household insecticides, air fresheners and other household cleaning products)

In the first quarter, combined sales by Zelnova-Copyr increased by 151 thousand euro (+1.6%) with respect to 1Q13. This increase is due primarily to good sales performance at Copyr in its Home & Garden and Ecological Agriculture lines (in the latter case, because of Europe-wide expansion of its line of ecological products based on natural pyrethrins). Revenues in Spain declined by 0.4 million euro, basically because certain customers delayed their summer insecticide orders by several weeks. Nevertheless, this reduction is not very significant since sales are highly seasonal and are concentrated in the second and third quarters.

The table below shows the regional breakdown of sales; foreign sales expanded, offsetting the decline in the domestic market and vindicating the policy of internationalisation implemented by the company in recent years. At present, 50% of sales are made outside Spain.

(Thousand euro)	1Q2013	1Q2014	Change	
Sales in Spain	5.310	4.897	-413	- 7.8%
Sales in other countries	4.320	4.884	+564	+ 13.1%
Total net sales	9.630	9.781	+151	+1.6%

As for costs, the price of butane rose considerably (+15%) in January and February and then declined slightly (-5%) in March. It is expected to be more stable in the coming months. The prices of other raw materials increased slightly and are generally stable.

The Company maintains its policy of improving margins by actively seeking cheaper suppliers worldwide and by improving productivity in all areas.

The increase in revenues, coupled with cost savings and the recovery in margins, boosted EBITDA by 7% to 700 thousand euro (from 655 thousand euro) and income by 32% to 283 thousand euro (from 214 thousand euro).

The projection for 2014 is for a recovery to previous years' levels, with revenues and profits expected to exceed the 2013 figures.

<b>BALANCE SHEET</b> <i>(Thousand euro)</i>	<b>03-31-2014</b>	<b>12-31-2013</b>
<b>ASSETS</b>		
<b>Non-current assets</b>	<b>93.767</b>	<b>93.471</b>
Property, plant & equipment	27.857	27.959
Investment properties	6.970	6.980
Intangible assets	23.019	22.590
Goodwill	2.548	2.548
Long-term financial assets	809	848
Deferred tax assets	32.564	32.546
<b>Assets classified as held for sale and discontinued operations</b>	<b>0</b>	<b>4</b>
<b>Current assets</b>	<b>111.435</b>	<b>95.895</b>
Inventories	25.796	22.232
Customer and other receivables	44.350	38.630
Current financial assets	13.648	6.377
Receivable from public authorities	5.595	3.847
Other current assets	2.420	2.351
Cash & cash equivalents	19.626	22.458
<b>TOTAL ASSETS</b>	<b>205.202</b>	<b>189.370</b>

<b>BALANCE SHEET</b> <i>(Thousand euro)</i>	<b>03-31-2014</b>	<b>12-31-2013</b>
<b>EQUITY</b>		
<b>Shareholders' equity</b>	<b>69.674</b>	<b>53.228</b>
Share capital	11.110	11.110
Share premium	323.286	323.286
Treasury shares	(6.456)	(6.029)
Revaluation and other reserves	4	3
Retained earnings and other reserves	(258.270)	(275.142)
<b>Minority interest</b>	<b>(3.822)</b>	<b>(3.793)</b>
<b>TOTAL EQUITY</b>	<b>65.852</b>	<b>49.435</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>	<b>55.635</b>	<b>65.877</b>
Financial debt	42.579	52.941
Derivatives	95	95
Deferred tax liabilities	9.049	9.031
Non-current deferred revenues	3.239	3.166
Other non-current liabilities	673	644
<b>Current liabilities</b>	<b>83.715</b>	<b>74.058</b>
Supplier and other accounts payables	27.655	24.426
Financial debt	48.874	41.327
Provisions for other liabilities & expenses	3.986	5.482
Current deferred revenues	22	25
Other current liabilities	3.178	2.798
<b>TOTAL LIABILITIES</b>	<b>139.350</b>	<b>139.935</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>205.202</b>	<b>189.370</b>

<b>INCOME STATEMENT</b>			
<i>Thousand euro</i>	<b>03-31-2014</b>	<b>03-31-2013</b>	<b>Chg. (%)</b>
Net revenues	34.211	30.815	<b>11,0%</b>
Cost of sales	(8.134)	(7.975)	
<b>Gross income</b>	<b>26.077</b>	<b>22.840</b>	<b>14,2%</b>
Other operating revenues	18.914	19.346	
Marketing & commercial organisation expenses	(9.526)	(9.108)	
General and administration expenses	(4.825)	(4.891)	
Research & development expenses	(11.367)	(10.887)	
Capitalised in-house work	961	1.046	
Other operating expenses	(2.155)	(1.889)	
<b>Net operating profit (loss) (EBIT)</b>	<b>18.079</b>	<b>16.457</b>	<b>9,9%</b>
Net financial results	(881)	(566)	
<b>Result from continuing operations</b>	<b>17.198</b>	<b>15.891</b>	<b>8,2%</b>
Corporate income tax in the period	(218)	69	
<b>Profit (Loss) for the year</b>	<b>16.980</b>	<b>15.960</b>	
<b>Discontinued operations</b>	<b>(112)</b>	<b>(194)</b>	
Attributable to owners of the parent	(82)	(142)	
Attributable to minority interest	(30)	(52)	
Profit for the year	16.868	15.766	
<b>Attributable to owners of the parent</b>	<b>16.898</b>	<b>15.818</b>	<b>6,8%</b>
Attributable to minority interest	(30)	(52)	

<b>Net operating profit (loss) (EBIT)</b>	18.079	16.457	<b>9,9%</b>
<b>Amortisation and depreciation</b>	1.281	1.129	
<b>EBITDA</b>	<b>19.360</b>	<b>17.586</b>	<b>10,1%</b>

**CONSOLIDATED CASH FLOW STATEMENT**

03/31/2014

<b>NET CASH FLOW FROM ORDINARY ACTIVITIES</b>	<b>8.161</b>
<b>Profit/(loss) before tax</b>	<b>17.086</b>
Profit before tax from continuing operations	17.198
Profit before tax from discontinued operations	(112)
<b>Adjustments for:</b>	<b>1.409</b>
Amortisation and depreciation	1.281
Other adjustments	128
<b>Variation in working capital</b>	<b>(9.040)</b>
<b>Other net cash flow</b>	<b>(1.294)</b>
Financial expenses	(1.200)
Financial revenues	187
Income tax received/(paid)	(218)
Other adjustments	(63)
<b>NET INVESTMENT CASH FLOW</b>	<b>(7.716)</b>
Purchases of property, plant & equipment and intangible assets	(588)
Other financial assets	(7.128)
<b>CASH FLOW IN FINANCING ACTIVITIES</b>	<b>(3.277)</b>
Emission	0
<b>Collections and (payments) in connection with equity instruments:</b>	<b>(462)</b>
Amortisation	323
Acquisition	(785)
Sales of treasury shares	0
<b>Collections and (payments) in connection with financial liabilities:</b>	<b>(5.706)</b>
Debt with credit entities (+)	1.400
Repayment from debt with credit entities (-)	(7.106)
<b>Other net financing activities cash flow</b>	<b>2.891</b>
<b>NET DECREASE/INCREASE IN CASH AND CAHS EQUIVALENTS</b>	<b>(2.832)</b>
<b>STARTING BALANCE OF CASH AND CASH EQUIVALENTS</b>	<b>22.458</b>
<b>ENDING BALANCE OF CASH AND CAHS EQUIVALENTS</b>	<b>19.626</b>