



## REPORT AT 30 SEPTEMBER 2017

Madrid, 24 October 2017

### 9M17 MILESTONES

#### **Corporate**

- The Group's total revenues increased by 0.6% with respect to the same period last year.
- Net profit increased by 13% year-on-year.

#### **Oncology**

- PharmaMar presented data on several clinical trials with Zepsyre (PM1183) and Yondelis at the European Society for Medical Oncology (ESMO) meeting.
- PharmaMar commenced clinical trials in cancer patients with a new compound: PM14.
- PharmaMar commenced a quadruple combination trial with Aplidin in multiple myeloma.

#### **Diagnostics**

- Korea's Food and Drug Administration has approved marketing of the CLART® HPV (Human Papillomavirus) diagnostic kit.
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#### **RNAi**

- Sylentis presents new preclinical data on topical treatment of an interference RNA for retinal diseases by avoiding ocular injections

#### **Consumer Chemicals**

- The Consumer Chemicals division increased revenues by 2.1% in the period.

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## FIGURES TO SEPTEMBER 2017

REVENUES	September 2017	September 2016	
<b>Sales</b>	<b>129.397</b>	<b>131.130</b>	<b>-1,3%</b>
Biopharmaceutical Area	68.990	71.946	-4,1%
<i>Oncology Segment</i>	<i>64.590</i>	<i>67.024</i>	<i>-3,6%</i>
<i>Diagnostic Segment</i>	<i>4.400</i>	<i>4.922</i>	<i>-10,6%</i>
Consumer Chemicals Segment	60.407	59.184	2,1%
<b>Royalties</b>			
Oncology Segment	<b>3.887</b>	<b>4.210</b>	<b>-7,7%</b>
<b>Licenses and co-developement agreements</b>			
Oncology Segment	<b>7.104</b>	<b>4.229</b>	<b>68,0%</b>
<b>Services Rendered</b>			
Not assigned	<b>13</b>	<b>49</b>	<b>-73,5%</b>
<b>TOTAL REVENUES</b>	<b>140.401</b>	<b>139.618</b>	<b>0,6%</b>

*(Thousand euro)*

### Total Group revenues

The **Group's total revenues** amounted to €140.4 million, a 0.6% increase with respect to the same period of 2016 (€139.6 million), driven by licensing revenues in the Oncology business and good sales performance in the Consumer Chemicals business.

**Total revenues in the Oncology segment** (sales, royalties and licensing revenues) amounted to €75.6 million, 0.2% more than in the same period of 2016 (€75.4 million). Yondelis sales amounted to €64.6 million, a decline on the same period of 2016 due basically to price erosion in some European countries; royalties from Yondelis partners amounted to €3.9 million and licensing revenues to €7.1 million.

**Net sales by the Consumer Chemicals companies** totalled €60.4 million, a 2.1% increase year-on-year (€59.2 million in 9M16), boosted by sales of new products and international sales.

The Diagnostics segment reported €4.4 million in sales (€4.9 million in 9M16).

### EBITDA

The Group's adjusted EBITDA amounted to -€3.7 million in the first nine months of 2017 (-€5.6 million in the same period of 2016), as follows:

	09/30/2017	09/30/2016
<b>Net Income (Loss)</b>	<b>(14.480)</b>	<b>(16.608)</b>
Tax	691	804
Interest expense	3.734	4.635
Amortización expense	5.494	5.583
<b>EBITDA</b>	<b>(4.561)</b>	<b>(5.586)</b>
One-off compensation	850	0
<b>ADJUSTED EBITDA</b>	<b>(3.711)</b>	<b>(5.586)</b>

*(Thousand euro)*

The improvement in EBITDA reflects the improvement in net profit as a result of the aforementioned revenue growth plus containment of commercial expenses and a reduction in R&D expenditure, both of which are detailed below.

The adjustment to EBITDA is the indemnity for termination of an executive's contract in the Consumer Chemicals segment.

(EBITDA: earnings before interest, taxes, depreciation and amortisation). Adjusted EBITDA includes the adjustment referred to in the preceding paragraph.

## R&D expenditure

R&D expenditure declined by 3% year-on-year (-€1.7 million). The Oncology area has spent €51.4 million so far in 2017 (€53.2 million in 9M16), while the Diagnostics and RNA interference areas have spent €4.9 million (€5.1 million in 9M16). In 2017, the Oncology area capitalised €0.8 million of R&D expenses.

R & D	September 2017	September 2016	
Oncology Segment	-51.443	-53.236	-3,4%
Diagnostic Segment	-1.173	-1.755	-33,2%
RNAi Segment	-3.700	-3.386	9,3%
Consumer Chemicals Segment	-137	-255	-46,3%
- Capitalization R&D	785	1.227	
<b>TOTAL R &amp; D</b>	<b>-55.668</b>	<b>-57.405</b>	<b>-3,0%</b>

(Thousand euro)

The slight decrease in the Oncology segment is mainly due to the completion of two of the Phase III trials that were under way in the first nine months of 2016; this effect will be offset by newly-commenced trials as the year advances. The decline in the Diagnostics segment is due to completion of part of the lab-on-a-chip project, which entailed higher expenditure in 2016. The increase in expenditure in the RNAi segment is due to commencement in the first quarter of a Phase III trial with Tivanisiran for dry eye syndrome.

## Marketing and commercial expenses

Group marketing and commercial expenses amounted to €34 million in 9M17 (€35.2 million in 9M16). Within that total, the Oncology area accounted for €17.7 million (€18.2 million in 9M16). Commercial expenses in the Consumer Chemicals segment amounted to €14.7 million in 9M17 (€15.4 million in 9M16). The decrease in commercial expenses in the Oncology area is due to the cost improvement achieved by in-sourcing Yondelis® distribution logistics; the decrease in the Consumer Chemicals segment is due to a reduction in promotional costs for insecticides and household products in the domestic market.

## Income attributable to the parent company

Income attributable to the parent company amounted to a loss of €14.5 million in the first nine months of 2017, compared with a loss of €16.6 million in the same period of 2016.

This difference is due primarily to factors mentioned above: growth in total revenues (+€0.8 million), generally stable operating costs, and a decline in financial expenses (-€0.7 million).

## Cash and Debt

Cash and cash equivalents plus current and non-current financial assets amounted to €32.6 million (€33.5 million at 2016 year-end). The Group's total interest-bearing debt (current and non-current) amounted to €98.9 million at the end of September 2017 (€95.5 million at 31 December 2016). In the first nine months of 2017, the Company arranged €13.5 million in new long-term loans and repaid €11.9 million in loans from banks and official agencies.

The breakdown of total debt, at amortised cost, classified as current and non-current, together with current and non-current financial assets and cash and cash equivalents, is shown in the table below:

	09/30/2017	12/31/2016
<b>Long term interest bearing debt</b>	<b>71.678</b>	<b>67.583</b>
Bank debt	30.883	25.351
Govt. agencies: R&D funding (interest free debt)	16.350	16.350
Obligations and bonds	24.445	25.882
<b>Short term interest-bearing debt</b>	<b>27.253</b>	<b>27.906</b>
Credit facilities	10.941	10.958
Effects and certifications	2.625	1.238
Bank loan	8.041	10.685
Govt. agencies: R&D funding (interest free debt)	5.059	4.438
Interest and others	587	587
<b>Total financial debt</b>	<b>98.931</b>	<b>95.489</b>
<b>Cash &amp; cash equivalents + no current and current financial investments</b>	<b>32.566</b>	<b>33.505</b>
<b>TOTAL NET DEBT</b>	<b>-66.365</b>	<b>-61.984</b>

*(Thousand euro)*

## BUSINESS PERFORMANCE.

Below is an overview of the group companies' business performance through September 2017.

### **A) Biopharmaceutical area:**

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

**1.1. The current status of compounds in the clinical development pipeline is described below.**

##### **a) YONDELIS®:**

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

During the third quarter of 2017, there were a total of 16 ongoing post-authorisation trials in collaboration with a number of European cooperatives, 10 of which were actively enrolling patients at a satisfactory pace. Additionally, three new trials are in the preparation and activation phase.

##### **Ovarian cancer**

At present, nine post-approval trials are under way in this indication, seven of which are actively recruiting, and there are four new trials in the activation phase.

The INNOVATYON Phase III trial headed by the MaNGO cooperative (Mario Negri Gynecologic Oncology Group) concluded recruitment satisfactorily.

##### **Other indications**

Recruitment is concluding 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), whose aim is to evaluate the activity and safety of Yondelis® in malignant pleural mesothelioma (MPM).

Recruitment for the EORTC 1320-BTG Phase II trial in recurrent meningioma concluded in the third quarter.

Work has commenced to activate the TOP-ART trial which combines trabectedin and olaparib in treating solid tumours with DNA repair defects.

## **b) APLIDIN®**

### **Multiple Myeloma**

In September 2016, PharmaMar filed an application with the European Medicines Agency (EMA) for authorisation to market Aplidin® (plitidepsin) in combination with dexamethasone for treating relapsed or refractory multiple myeloma on the basis of the ADMYRE pivotal Phase III trial. The EMA's assessment is ongoing.

Recruitment continues on schedule in the Phase II trial with Aplidin® in combination with bortezomib and dexamethasone in patients with double refractory multiple myeloma.

The Phase I trial with Aplidin® in combination with bortezomib and dexamethasone in patients with relapsed or refractory multiple myeloma continues recruiting in the expansion phase following the good results obtained in the first stage, which were presented at the American Society of Clinical Oncology (ASCO) meeting in 2016.

The new Phase I trial with Aplidin® in combination with bortezomib, pomalidomide and dexamethasone in patients with multiple myeloma exposed to proteasome inhibitors and refractory to lenalidomide has started after obtaining approval from the regulators and ethics committees.

### **T cell lymphoma**

The registration trial with Aplidin® as monotherapy in patients with angioimmunoblastic T-cell lymphoma continues recruiting at centres in Spain, the Czech Republic, Italy and the United States. The trial will include 60 patients at approximately 25 centres in Europe and the US.

## **c) ZEPSYRE (PM1183)**

### **Platinum-resistant ovarian cancer**

The CORAIL Phase III pivotal trial in patients with platinum-resistant ovarian cancer to assess Zepsyre® as monotherapy vs. topotecan or pegylated liposomal doxorubicin completed recruitment in October 2016. The patients are currently under observation to determine progression-free survival and the trial's secondary end-points.

### **Advanced breast cancer**

In the Phase II clinical trial in advanced breast cancer, the A1 arm, consisting of patients with BRCA 1 or 2 mutations who had been pre-treated with Poly (ADP-ribose) polymerase (PARP) inhibitors, is currently recruiting.

The Zepsyre® registration strategy for BRCA2-related breast cancer was agreed upon with the FDA in December 2016. The CRO to conduct the trial was chosen in August and the process of selecting centres and countries has commenced.

### **Small-cell lung cancer**

Recruitment is continuing satisfactorily for the ATLANTIS pivotal Phase III trial that compares the activity and safety of the combination of Zepsyre® (lurbinectidin), a drug of marine origin, plus doxorubicin with topotecan or CAV (cyclophosphamide, adriamycin and vincristine) for treating patients with small cell lung cancer who have relapsed after a first round of platinum treatment. Recruitment is currently ongoing in Europe, the United States, Canada, Latin America and the Middle East.

### **Combination trials**

As regards Phase I combination trials, recruitment was completed for the combinations with doxorubicin, cisplatin, capecitabine and paclitaxel with or without bevacizumab. The latter two trials produced promising preliminary results in a range of breast cancer types, among others; consequently, the next stages of development are currently being assessed. The efficacy data from the combination trials in small cell lung cancer were presented at the European Society for Medical Oncology (ESMO) meeting in Madrid on 8-12 September 2017.

Recruitment continues on schedule for the Phase I trial in combination with irinotecan.

## **Basket trial in advanced solid tumours**

Recruitment is continuing for the Phase II trial with Zepsyre® as monotherapy in indications chosen on the basis of the drug's action mechanism or on the basis of its activity as observed in previous combination trials. Those indications are small cell lung cancer, neuroendocrine tumours, carcinoma of the head and neck, germ cell cancer, endometrial cancer, bile duct cancer, cancer of unknown primary, Ewing sarcoma and breast cancer with BRCA 1/2 mutation. Recruitment is ongoing for the small cell lung cancer and breast cancer cohorts. The trial is being conducted in Spain, France, Belgium, the United States, Germany, Italy, Switzerland and the United Kingdom. The efficacy results from this trial in small cell lung cancer were presented at the European Society for Medical Oncology (ESMO) meeting in Madrid on 8-12 September 2017.

### **d) PM184**

The Phase I dose escalation trial assessing the combination of PM184 with gemcitabine continues recruitment on schedule. This trial is being conducted at two centres: one in Spain and the other in the United States. Enrolment is expected to be focused on specific diseases where clinical benefit has been observed, such as non-small cell lung cancer, breast cancer, and head and neck tumours.

Recruitment for the Phase II trial with PM184 in hormone-receptor positive advanced breast cancer patients is proceeding on schedule.

### **e) PM14**

On 13 September, the first patient was enrolled in a clinical development programme for a new molecule: PM14. The first trial is expected to include approximately 50 patients with a confirmed diagnosis of advanced solid tumour for which there is no standard treatment available. It will be conducted at centres in France and Spain.

## **1.2. Attendance at conferences**

At the annual meeting of the American Society of Clinical Oncology (ASCO), PharmaMar presented new results for lurbinectedin, an RNA polymerase II inhibitor undergoing clinical research in advanced endometrial cancer, concluding that this molecule is effective both as monotherapy and in combination with doxorubicin. The results obtained in endometrial cancer with lurbinectedin, both as monotherapy and in combination with doxorubicin, support continuing with clinical development to conduct a Phase III registration trial, the design of which has already been approved by the FDA.

The results were presented of a Phase I dose-seeking trial assessing the safety, tolerability, pharmacokinetics and pharmacodynamics of the combination of lurbinectedin and olaparib in advanced solid tumours, where synergistic activity was observed between the two molecules.

PharmaMar also presented a comparison of two clinical trials which concluded that Yondelis® and lurbinectedin are most active in metastatic BRCA2-related breast cancer.

## **2.- Diagnostics Genómica**

Genómica ended the third quarter of 2017 with €4.6 million in revenues, down from €4.9 million in the same period of 2016 due basically to a decline in sales in Brazil.

Nevertheless, sales in the Middle East and Asia increased by 33% to €228 thousand, compared with €172 thousand in the same period of 2016, as a direct consequence of distribution agreements signed in India, Thailand and Korea (after obtaining the necessary permits from Korea's FDA).

Sales rose 6% in Europe to €1.095 million. Exports accounted for 39% of revenues in the period.

Domestic sales amounted to €2.4 million in the period, enhanced by the renewal of the contract with the Castilla y León regional government for the supply of the material required to carry out high-oncogenic risk Human Papillomavirus (HPV) assays.

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

During the third quarter of 2017, research and development continued on new lines of RNA interference (RNAi) for treating diseases of the retina, such as age-related macular degeneration and diabetic retinopathy.

Sylentis product SYL1001 (Tivanisiran) for treating dry-eye syndrome has commenced a Phase III clinical trial (HELIX trial). By the end of the third quarter, 49 patients had been randomised in the participating countries. The US Patent Office has given notice that the application to patent the Tivanisiran dosage has been accepted and the patent is expected to be granted shortly.

Clinical development of Bamosiran for treating glaucoma continued in combination with commercial drug Latanoprost.

## **B) Consumer chemicals:**

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

In the first nine months of 2017, net sales amounted to €16.5 million, 4.4% more than in the same period of 2016 (€15.8 million). This growth in sales continues to be driven by chalky-finish paints (with Rust-Oleum co-branding) and other Rust-Oleum products (Universal, Speciality and Mode).

Exports accounted for 12% of Xylazel's total revenues.

Average procurement prices increased overall as a result of the increase in prices of petroleum derivatives and titanium dioxide (close to 4%).

As a result, EBITDA in the first nine months of 2017 amounted to €2.4 million, 9% more than in the same period of last year (€2.2 million).

Net profit 2017 totalled €1.6 million, a 14% increase with respect to the same period of 2016 (€1.4 million).

### **2.- ZelnovaZeltia and Copyr (household insecticides, air fresheners and other household products)**

In the first nine months of 2017, combined sales by ZelnovaZeltia and Copyr amounted to €44 million, an increase of €0.5 million (+1.2%) with respect to the same period of 2016. This increase is attributable basically to good sales performance by Copyr in its Ecological Agriculture (sales in Italy and the rest of Europe of ecological products based on natural pyrethrins), Italian Large Retailers, and Home & Garden lines. In the Spanish market, the presence in the large retailer channel was expanded, offsetting the slight decline in sales via traditional wholesalers.

Sales outside Spain now account for 52.5% of total revenues. This is very positive for the company's future prospects and is the result of dedicating resources and efforts to foreign markets in the last few years.

The prices of the main raw materials had a varied performance in the period: metal prices (aerosol cans) increased, and those of petroleum derivatives (butane and solvents) were volatile: the price increase at the beginning of the year has been partially corrected, and prices overall are now slightly higher than last year. Prices of other components (active ingredients, paper, cardboard, plastic, etc.) were stable.

Normalised EBITDA (adjusted for the termination of the former General Manager) was in line with 2016: €3.7 million.

<b>BALANCE SHEET</b> <i>(Thousand euro)</i>	<b>09/30/2017</b>	<b>12/31/2016</b>
<b>ASSETS</b>		
<b>Non-current assets</b>	<b>98.411</b>	<b>100.145</b>
Property, plant & equipment	30.978	31.141
Investment properties	6.119	6.119
Intangible assets	23.143	24.900
Goodwill	2.548	2.548
Long-term financial assets	1.024	1.138
Deferred tax assets	34.599	34.299
<b>Assets classified as held for sale and discontinued operations</b>	<b>0</b>	<b>0</b>
<b>Current assets</b>	<b>104.299</b>	<b>120.992</b>
Inventories	23.144	22.158
Customer and other receivables	44.259	62.652
Current financial assets	17.872	18.077
Other current assets	5.354	3.815
Cash & cash equivalents	13.670	14.290
<b>TOTAL ASSETS</b>	<b>202.710</b>	<b>221.137</b>

<b>BALANCE SHEET</b> <i>(Thousand euro)</i>	<b>09/30/2017</b>	<b>12/31/2016</b>
<b>EQUITY</b>		
<b>Shareholders' equity</b>	<b>39.107</b>	<b>52.358</b>
Share capital	11.132	11.110
Share premium	71.278	69.189
Treasury shares	(4.484)	(3.247)
Revaluation and other reserves	13	11
Retained earnings and other reserves	(38.832)	(24.705)
<b>Minority interest</b>	<b>(3.877)</b>	<b>(3.863)</b>
<b>TOTAL EQUITY</b>	<b>35.230</b>	<b>48.495</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>	<b>82.783</b>	<b>85.478</b>
Financial debt	71.678	67.583
Non-current deferred revenues	10.290	16.790
Other non-current liabilities	815	1.105
<b>Current liabilities</b>	<b>84.697</b>	<b>87.164</b>
Supplier and other accounts payables	36.470	39.175
Financial debt	27.253	27.906
Provisions for other liabilities & expenses	7.692	6.988
Current deferred revenues	10.050	10.012
Other current liabilities	3.232	3.083
<b>TOTAL LIABILITIES</b>	<b>167.480</b>	<b>172.642</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>202.710</b>	<b>221.137</b>

<b>INCOME STATEMENT</b>		
<i>Thousand euro</i>	<b>09/30/2017</b>	<b>09/30/2016</b>
Revenues:		
Product Sales	129.397	131.130
Co-development	7.104	4.229
Licensing agreements	3.887	4.210
Other income	13	49
	<b>140.401</b>	<b>139.618</b>
Cost of sales	(37.655)	(36.292)
Other operating revenues	679	563
Marketing & commercial organisation expenses	(33.986)	(35.209)
General and administration expenses	(15.932)	(15.444)
Research & development expenses	(55.668)	(57.405)
Other operating expenses	(7.894)	(7.000)
<b>Net operating profit (loss) (EBIT)</b>	<b>(10.055)</b>	<b>(11.169)</b>
Net financial results	(3.734)	(4.635)
<b>Result from continuing operations</b>	<b>(13.789)</b>	<b>(15.804)</b>
Corporate income tax in the period	(691)	(804)
<b>Profit (Loss) for the year</b>	<b>(14.480)</b>	<b>(16.608)</b>
Profit for the year	(14.480)	(16.608)
<b>Attributable to owners of the parent</b>	<b>(14.466)</b>	<b>(16.589)</b>
Attributable to minority interest	(14)	(19)

**CONSOLIDATED CASH FLOW STATEMENT****09/30/2017**

<b>TOTAL NET OPERATING CASH FLOW</b>	<b>(2.017)</b>
<b>Income before taxes</b>	<b>(13.789)</b>
<b>Adjustments for:</b>	<b>3.272</b>
Amortisation and depreciation	5.265
Other adjustments	(1.993)
<b>Changes in working capital:</b>	<b>12.032</b>
<b>Other cash flow from operations:</b>	<b>(3.532)</b>
Financial expenses	80
Financial revenues	(3.612)
<b>TOTAL NET INVESTING CASH FLOW</b>	<b>(3.116)</b>
<b>Investments payments:</b>	<b>(20.356)</b>
Purchases of property, plant & equipment and intangible assets	(3.437)
Other financial assets	(16.920)
<b>Disvestment receipts:</b>	<b>17.330</b>
Purchases of property, plant & equipment and intangible assets	92
Other financial assets	17.239
<b>Other investing cash flow:</b>	<b>(90)</b>
Other investment receipts / (payments)	(90)
<b>TOTAL NET FINANCING CASH FLOW</b>	<b>2.403</b>
<b>Collections and (payments) in connection with equity instruments:</b>	<b>(979)</b>
Acquisition	(5.965)
Disposal	4.986
<b>Collections and (payments) in connection with financial liabilities:</b>	<b>1.575</b>
Issue	13.520
Refund and amortization	(11.945)
<b>Other financing cash flow:</b>	<b>1.807</b>
Other financing receipts / (payments)	1.807
<b>TOTAL NET CASH FLOW</b>	<b>(2.730)</b>
Net increase / (decrease) in cash and cash equivalents	(2.730)
Beginning balance of cahs and cash equivalents	14.290
<b>ENDING BALANCE OF CASH AND CAHS EQUIVALENTS</b>	<b>11.560</b>