



## REPORT AT 30 JUNE 2019

Madrid, 29 July 2019

### 1H19 HIGHLIGHTS

#### **Corporate**

- As part of its strategy of focusing on the pharmaceutical sector, in June PharmaMar divested its consumer chemicals subsidiary, Zelnova Zeltia, which manufactures and markets insecticide products for domestic use, air fresheners and other home care products, for €33.4 million.
- In April, PharmaMar signed a licensing agreement with Luye Pharma Group, Ltd. for the development and marketing of lurbinectedin (Zepsyre) for treating small cell lung cancer and potentially other indications in the territories of China, Hong Kong and Macao. PharmaMar received an upfront payment of USD 5 million (€4.5 million) and may collect additional payments in the future for the attainment of regulatory or commercial milestones, as well as royalties on sales.

#### **Oncology**

- The American Society of Clinical Oncology (ASCO) selected a paper from PharmaMar for an oral presentation at its annual meeting: "Efficacy and safety profile of Lurbinectedin in second-line SCLC patients: results from a phase II single-agent trial". Dr. Paz-Ares, the lead author of the paper, presented updated efficacy data on lurbinectedin as monotherapy in treating small cell lung cancer, as well as key safety data.
- ASCO also picked that presentation for the "Best of ASCO" meetings to be held in three US cities and 30 other cities on five continents. "Best of ASCO" is an initiative that condenses the most outstanding content of the ASCO Annual Meeting in a two-day program. The goal of this initiative is to provide worldwide access to cutting-edge science.

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## FIGURES TO JUNE 2019

	06/30/2019	06/30/2018	Var.
Oncology	36.291	38.750	-6%
<i>Yondelis/Aplidin API</i>	514	200	157%
<i>Yondelis commercial sales</i>	35.777	38.550	-7%
Diagnostics	2.689	2.919	-8%
<b>Sales</b>	<b>38.980</b>	<b>41.669</b>	<b>-6%</b>
<b>Royalties</b>	<b>1.654</b>	<b>2.250</b>	<b>-26%</b>
<b>Licences</b>	<b>629</b>	<b>22.357</b>	
<b>Other (Diagnostics)</b>	<b>143</b>	<b>132</b>	
<b>TOTAL REVENUES</b>	<b>41.406</b>	<b>66.408</b>	<b>-38%</b>

(Thousand euro)

### **Total Group revenues**

**Sales** in the oncology segment, relating entirely to Yondelis®, amounted to €36.3 million, 6% lower than the €38.8 million booked in the same period of 2018.

The Diagnostics segment (Genómica) attained €2.7 million in sales, plus €0.1 million in other revenues in the first half of 2019 (€2.9 million plus €0.1 million, respectively, in the first half of 2018).

**Royalty revenues** correspond to the Oncology segment. Royalties received from Janssen Products and Taiho Pharmaceutical Co. for sales of Yondelis in the United States, Japan and the rest of the world except the European Union amounted to €1.7 million in the first half of 2019 (€2.3 million in the same period of 2018).

In connection with **revenues from licensing and other co-development agreements**, in April 2019 a licensing and marketing agreement was signed with Luye Pharma Group for lurbinectedin (Zepsyre) covering the territories of China, Hong Kong and Macao, for which PharmaMar collected a non-reimbursable upfront payment of €4.5 million. The agreement provides for certain activities to be conducted in connection with the agreement and, consequently, the upfront payment will be recognized in PharmaMar's income statement in line with the progress with such activities. As a result, €629 thousand were recognized as revenues in the first half of 2019.

Revenues under this heading amounted to €22.4 million in the first half of 2018. Of that amount, €4.1 million related to the agreement signed with Seattle Genetics Inc. and €18.1 million to the licensing agreement with Chugai for Zepsyre in Japan, whose early cancellation resulted in the recognition of deferred revenues in the amount of €15.1 million plus new revenue in the amount of €3 million.

Consequently, **total revenues** amounted to €41.4 million in the first half of 2019, compared with €66.4 million in the same period of 2018.

### **Gross margin and EBITDA**

The Group's gross margin on sales was 93.3% in the first half of 2019 (94.6% in 2018). (Calculated with respect to sales only, not including royalties or licensing revenues).

Group EBITDA in the first half of 2019 amounted to €-9.7 million (€3.3 million in 2018).

	6/30/19	6/30/18
<b>Net result of continuing operations</b>	<b>(19.111)</b>	<b>532</b>
Income tax	3.353	(2.846)
Net financial income	2.081	1.978
Depreciation and amortization	3.894	3.620
<b>EBITDA</b>	<b>(9.783)</b>	<b>3.284</b>

(Thousand euro)

(EBITDA: revenues and expenses before interest, taxes, depreciation and amortization and income from discontinued operations).

### R&D expenditure

R&D expenditure declined by close to 30.9% in year-on-year terms, from €40.4 million in the first half of 2018 to €27.9 million in the first half of 2019.

The breakdown of R&D expenditure is shown in the next table:

	6/30/19	6/30/18	Dif <sup>a</sup>	
<b>R&amp;D expenses</b>	<b>27.916</b>	<b>40.392</b>	<b>-12.476</b>	<b>-30,9%</b>
Oncology	24.646	36.198	-11.552	-31,9%
Diagnostics	1.699	1.581	118	7,5%
RNAi	1.571	2.613	-1.042	-39,9%

(Thousand euro)

The main investment in the first half of 2019 was in our compound Zepsyre® (lurbinectedin), to advance with clinical trials in small cell lung cancer and a number of pre-clinical trials in other indications.

R&D spending declined by 30.9% in the first half of 2019 with respect to the same period of 2018, mainly in the oncology segment (€-11.6 million). This is because a number of Phase III trials were open and active in the first half of 2018, and those trials were no longer active in the first half of 2019 although they remain open until they are definitively concluded.

### Marketing and commercial expenses

Marketing and commercial expenses amounted to €12.7 million in the period, a 9% decrease year-on-year (€14.0 million in 2018), mainly in the oncology segment.

### Result for the period from discontinued operations

In June 2019, PharmaMar completed the sale of its subsidiary, Zelnova Zeltia, which manufactures and markets insecticide products for domestic use, air fresheners and other home care products, for €33.4 million. The results of this subsidiary through 28 June 2019 were booked as income from discontinued operations in 2019 and 2018.

Additionally, on 20 September 2018, PharmaMar sold subsidiary Xylazel, S.A., which manufactures, supplies and distributes products for wood and metal treatment, protection and decoration, special paints and other similar and related products, as well as other products for the construction industry. The financial statements for the first half of 2018 were restated to reclassify that company under discontinued operations.

## Result for the period

Income after taxes from continuing operations amounted to a loss of €21.3 million in the first half of 2019, compared with a loss of €3.1 million in the same period of 2018.

## Cash and Debt

As of 30 June 2019, the net cash position (cash + cash equivalents + current financial assets) amounted to €42.7 million (vs. €26.9 million at 2018 year-end). Including non-current financial assets, this item amounted to €43.6 million and €27.8 million, respectively.

For the purpose of comparing the balance sheet figures, the Group's total net interest-bearing debt at amortized cost is detailed below:

	6/30/19	12/31/18
<b>Non current debt</b>	<b>58.823</b>	<b>64.922</b>
Bank debt	20.570	24.279
Obligations and bonds	16.524	16.501
Govt. Agencies: R&D funding	21.729	24.142
<b>Current debt</b>	<b>30.773</b>	<b>28.483</b>
Credit facilities	12.932	12.911
Effects and certifications	1.965	2.064
Bank loan	10.811	10.244
Govt. Agencies: R&D funding	3.864	2.248
Interest and others	1.201	1.016
<b>Total financial debt</b>	<b>89.596</b>	<b>93.405</b>
<b>Cash&amp;cash equivalents + non current and current financial investment</b>	<b>43.588</b>	<b>27.760</b>
<b>TOTAL NET DEBT</b>	<b>-46.008</b>	<b>-65.645</b>

(Thousand euro)

Non-current debt was reduced by €6.1 million in the first half of 2019, while current debt increased by €2.3 million, mainly due to higher loan maturities in the next twelve months, both bank loans (€+0.6 million) and loans from official authorities (€+1.6 million). Cash and cash equivalents plus financial assets increased by €15.8 million; as a result, the reduction in debt and increase in cash resulted in a €19.6 million improvement in total net debt.

## **BUSINESS PERFORMANCE.**

Below is an overview of the group companies' business performance in the first half of 2019.

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

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

##### **a) YONDELIS®:**

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

At the end of the second quarter of 2019, there were a total of 27 ongoing post-authorization trials in collaboration with a number of European cooperatives, 14 of which were active and 9 were still enrolling patients at a satisfactory pace. The other trials were in the process of closing and data analysis or were pending the presentation of results. Four additional trials are scheduled to commence in the coming months.

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

There are 15 trials ongoing in this indication, nine of them active and six recruiting.

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

The results of the ATREUS Phase II trial to assess the efficacy and safety of trabectedin in treating malignant pleural mesothelioma were presented at the 2019 Mesothelioma Meeting organized by the IASLC (International Association for the Study of Lung Cancer) in New York in July. This trial is being promoted by the Mario Negri Institute for Pharmacological Research (IRCCS).

##### **c) ZEPSYRE® (Lurbinectedin)**

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

The ATLANTIS pivotal Phase III trial compares the activity and safety of the combination of Zepsyre® (lurbinectedin), a drug of marine origin, plus doxorubicin, against 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.

The trial is currently monitoring patient survival, which is its primary endpoint. The data from this trial are expected to be available in 2020.

PharmaMar presented the latest data from this trial at the IASLC Small Cell Lung Cancer Meeting in New York in April 2019.

###### **Single-agent trial in advanced solid tumors**

This is a Phase II trial with Zepsyre® as monotherapy in selected indications including small cell lung cancer, neuroendocrine tumors, 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. In patients with second-line small cell lung cancer (105 patients treated), the trial attained its primary endpoint with an Overall Survival (OS) rate of 35.2%. According to investigator assessment, OS was 45% in platinum-sensitive patients and 22.2% in platinum-resistant patients. The median Duration of Response (DoR) was 5.3 months in general, 6.2 months in sensitive patients and 4.7 months in resistant patients.

These results were presented by Dr. Luis Paz Ares in an oral session at the ASCO meeting.

ASCO also picked PharmaMar's abstract for the "Best of ASCO" meetings to be held in three US cities and 30 other cities on the five continents. "Best of ASCO" is an initiative that condenses the most outstanding content of the ASCO Annual Meeting in a two-day program.

Additionally, a sub-analysis of the patients in this cohort was selected for presentation as a poster at the IASLC World Conference on Lung Cancer to be held in Barcelona in September 2019.

### **Combination trials**

As regards Phase I combination trials, recruitment was completed for the combinations with doxorubicin, cisplatin, capecitabine and paclitaxel with or without bevacizumab.

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

The abstract on combination trials with lurbinectedin+paclitaxel and lurbinectedin+irinotecan in the cohort of patients with small cell lung cancer was selected for presentation as a poster at the IASLC World Conference on Lung Cancer to be held in Barcelona in September 2019.

### **Phase I trial in Japan**

This trial, designed to ascertain the dosage for Zepsyre® in Japanese patients, is still in the active enrolment phase.

### **d) PM184**

The Phase I dose escalation trial assessing the combination of PM184 with gemcitabine concluded enrolment and is now in the patient tracking phase. This trial is being conducted at two centers: one in Spain and the other in the United States.

### **e) PM14**

The main endpoint of the Phase I trial with PM14 is to identify the optimal dose for administration in patients with advanced solid tumors, and to define the compound's safety profile and assess its pharmacokinetics and pharmacogenetics in treated patients. The trial, being conducted at Vall d'Hebron hospital (Barcelona), Doce de Octubre hospital (Madrid) and Institut Gustave Roussy (Paris), is expected to enroll approximately 50 patients with a confirmed diagnosis of advanced solid tumor for which there is no standard treatment available. This trial is actively recruiting.

## **2.- Diagnostics Genómica**

Genómica reported €2.8 million in revenues in the first half of 2019, compared with €3.1 million in the same period of 2018.

International revenues amounted to €0.9 million in the first half of 2019, 32% of the total (€1.24 million in 2018), mainly due to the postponement of orders by customers in the Middle East and Europe which are expected to be offset in the second half of the year.

The domestic market in diagnostics performed in accordance with expectations, with sales up 5% to €1.9 million (€1.8 million in 2018).

The agreements with Beijing Clear Medi-tech Co. to register the CLART®Enterobac and CLART®Septibac products with the Chinese regulators are advancing as expected.

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

The Helix trial with tivanisiran in dry-eye syndrome was presented at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO), held in Vancouver from 23 April to 2 May. Although the Helix trial did not attain its primary end-point, it evidenced an improvement ( $p=0.035$ ) vs. the comparator in reducing central corneal damage in patients with moderate to severe dry eye syndrome following one month of Tivanisiran, which was identified as a secondary end-point in the trial protocol. Evidence of improvements in signs and symptoms in the most severe cases of dry eye syndrome and in patients with Sjögren's syndrome was also presented at the ARVO meeting.

The company is also working on other RNAi candidates for treating eye allergies and retinal diseases. Those candidates' efficacy was analyzed using pre-clinical models of those pathologies.

### **4.- Consumer chemicals:**

As of 30 June 2019, the consumer chemicals business was presented under discontinued operations in the Group's income statement.

The sale of subsidiary Zelnova Zeltia, S.A. (Zelnova Zeltia), comprising also its Italian subsidiary, Copyr, S.p.A, to companies Allentia Invest, S.L. y Safoles, S.A., which are owned directly and indirectly by, among others, Mr. Pedro Fernández Puentes, a director of PharmaMar, and persons related to him, who acquired 100% of the shares of Zelnova, was completed in June.

The consideration for 100% of the shares of Zelnova was €33.4 million. The sale resulted in a loss of €2.2 million in the consolidated income statement. Upon completion of the sale, Zelnova and subsidiary Copyr, S.p.A. ceased to belong to the PharmaMar Group.

<b>CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION</b> <i>(Thousand euro)</i>	<b>June 30,</b> <b>2019</b>	<b>December 31,</b> <b>2018</b>
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, plant and equipment	23.108	26.637
Investment property	845	6.071
Intangible assets	4.763	16.658
Right-of-use assets	3.512	0
Goodwill	0	2.548
Non-current financial assets	868	884
Deferred tax assets	29.768	29.768
	<b>62.864</b>	<b>82.566</b>
<b>Current assets</b>		
Inventories	9.089	20.616
Trade and other receivables	11.678	23.549
Financial assets at amortised cost	3.394	4.131
Other assets	3.386	4.069
Cash and cash equivalents	39.327	22.745
	<b>66.874</b>	<b>75.110</b>
<b>TOTAL ASSETS</b>	<b>129.738</b>	<b>157.676</b>

<b>CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION</b> <i>(Thousand euro)</i>	<b>June 30,</b> <b>2019</b>	<b>December 31,</b> <b>2018</b>
<b>EQUITY</b>		
Share capital	11.132	11.132
Share premium	71.278	71.278
Treasury shares	(2.235)	(2.243)
Revaluation reserves	14	12
Retained earnings and other reserves	(80.060)	(58.806)
<b>Total capital and reserves attributable to equity holders of the parent company</b>	<b>129</b>	<b>21.373</b>
<b>Non-controlling interests</b>	<b>(3.909)</b>	<b>(3.900)</b>
<b>TOTAL EQUITY</b>	<b>(3.780)</b>	<b>17.473</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Borrowings	58.823	64.922
Lease liabilities	1.794	0
Non-current deferred income	1.914	2.120
Other non-current liabilities	177	779
	<b>62.708</b>	<b>67.821</b>
<b>Current liabilities</b>		
Trade and other payables	25.182	34.511
Borrowings	30.773	28.483
Lease liabilities	1.749	0
Provisions for other liabilities and charges	5.446	6.266
Current deferred income	3.936	168
Other current liabilities	3.724	2.954
	<b>70.810</b>	<b>72.382</b>
<b>TOTAL LIABILITIES</b>	<b>133.518</b>	<b>140.203</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>129.738</b>	<b>157.676</b>

CONDENSED CONSOLIDATED STATEMENTS OF PROFIT OR LOSS		
<i>Thousand euro</i>	06/30/2019	Restated 06/30/2018
Revenue:		
Revenue from contracts with customers	38.980	41.669
Revenue from licensing and development agreements (excluding royalties)	629	22.357
Royalties	1.654	2.250
Other	143	132
	<b>41.406</b>	<b>66.408</b>
Cost of sales	(2.593)	(2.238)
Marketing expenses	(12.736)	(14.014)
General and administrative expenses	(6.934)	(6.220)
Research and development expenses	(27.916)	(40.392)
Net impairment on financial assets	(5)	0
Other operating expenses	(5.430)	(4.499)
Other results	531	619
<b>Net operating result</b>	<b>(13.677)</b>	<b>(336)</b>
<b>Net financial results</b>	<b>(2.081)</b>	<b>(1.978)</b>
<b>Result of the period before income taxes</b>	<b>(15.758)</b>	<b>(2.314)</b>
Income tax benefit / (expense)	(3.353)	2.846
<b>Result for the period from continuing operations</b>	<b>(19.111)</b>	<b>532</b>
<b>Result for the period from discontinued operations</b>	<b>(2.217)</b>	<b>2.511</b>
Equity holders of the parent company	(2.217)	2.511
Result for the period	(21.328)	3.043
<b>Equity holders of the parent company</b>	<b>(21.319)</b>	<b>3.051</b>
Non-controlling interests	(9)	(8)

(\*) Restated to show ZelnovaZeltia and Xylazel as discontinued operations

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

(Thousand euro)	June 30, 2019
<b>Cash flows from operating activities</b>	
<b>Result before taxes:</b>	<b>(17.428)</b>
<b>Adjustments for:</b>	<b>8.213</b>
Depreciation and amortization	3.031
Provision for impairment of accounts receivable	14
Impairment losses of property, plant and equipment	(81)
Finance income	(6)
Finance costs	2.066
Results on disposals of intangible assets	(8)
Share based payments	128
Deferred income - grants	(222)
Loss on subsidiary sale	3.269
Other adjustments to profit or loss	22
<b>Changes in working capital:</b>	<b>(4.075)</b>
Inventories	(2.606)
Trade and other receivables	(16.657)
Other assets and liabilities	(349)
Trade and other accounts payable	11.060
Deferred or accrual items	4.477
<b>Other cash flows from operations:</b>	<b>(2.060)</b>
Interest paid	(2.066)
Interest received	6
<b>Net cash outflow from operating activities</b>	<b>(15.350)</b>
<b>Cash flows from investing activities</b>	
<b>Acquisitions:</b>	<b>(298)</b>
Property, plant and equipment, intangible assets and investment property	(242)
Other financial assets	(56)
<b>Proceeds from:</b>	<b>36.083</b>
Group companies, associates and business units	33.386
Property, plant and equipment, intangible assets and investment property	29
Other financial assets	2.668
<b>Net cash inflow from investing activities</b>	<b>35.785</b>
<b>Cash flows from financing activities</b>	
<b>Receipts and (payments) in connection with equity instruments:</b>	<b>(44)</b>
Purchase of treasury shares	(3.560)
Proceeds from shares issued	3.516
<b>Receipts and (payments) in connection with financial liabilities:</b>	<b>(3.809)</b>
Proceeds from borrowings	3.730
Repayment of borrowings	(7.539)
<b>Net cash inflow (outflow) from financing activities</b>	<b>(3.853)</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>16.582</b>
Cash and cash equivalents at beginning of the period	22.745
<b>Cash and cash equivalents at end of the period</b>	<b>39.327</b>