

REPORT AS OF 31 MARCH 2019

Madrid, 26 April 2019

1Q19 MILESTONES

Corporate

- In line with PharmaMar's strategy of focusing on the pharmaceutical sector, the start of a process to divest subsidiary Zelnova, which manufactures and markets insecticide products for domestic use, air fresheners and other home care products it was announced in January. For this reason, the financial statements for March 2019 and 2018 present the figures for this subsidiary as 'available for sale/discontinued operations'.
- Group sales totaled €18.4 million in the first quarter of 2019, compared with €19.7 million in the same period of 2018 (-7%). No revenues from licensing agreements were booked in the first quarter of 2019 (vs. €6.6 million in the first quarter of 2018).

Oncology

- The Phase II trial with Lurbinectedin as monotherapy for treating relapsed small cell lung cancer met its primary endpoint from by both investigator and Independent Review Committee (IRC). This trial's primary endpoint is overall Response Rate (ORR) and secondary endpoints include duration of response (DOR), progression-free survival (PFS), overall survival (OS and safety.
- The efficacy data and safety profile from the Phase II trial with lurbinectedin as second-line treatment of small cell lung cancer was selected by the American Society of Clinical Oncology (ASCO) for an oral presentation which will take place on the 1st of June at its 19th Annual Meeting, in Chicago.
- PharmaMar received a positive response from the EMA with regard to the designation of Zepsyre® (Lurbinectedin) as an orphan drug for small cell lung cancer.

Diagnostics

• GENOMICA commenced clinical trials with a view to registering two of its products with the Chinese FDA: CLART® Enterobac and CLART® Sepsis.

Consumer Chemicals

 The companies in the Consumer Chemicals division (ZelnovaZeltia and Copyr) were classified as available for sale/discontinued operations.

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FIGURES TO MARCH 2019

	3/31/19	3/31/19	Var.
Yondelis	17.111	18.390	-7%
Yondelis/Aplidin API	149	58	157%
Yondelis commercial sales	16.962	18.332	-7%
Diagnostics	1.323	1.356	-2%
Sales	18.434	19.746	-7 %
Royalties	926	1.410	-34%
Licences	0	6.581	
Other (Diagnostics)	79	88	
TOTAL REVENUES	19.439	27.825	-30%
/ -			

(Thousand euro)

Total Group revenues

Oncology revenues, which are from sales of Yondelis®, amounted to €17.1 million in the first quarter of 2019, a 7% year-on-year difference (vs. €18.4 million in 1Q18).

The Diagnostics segment (Genómica) attained €1.3 million in sales, plus €0.08 million in other revenues in the period (vs. €1.4 million plus €0.09 million, respectively, in 1Q18).

Royalty revenues correspond to the Oncology segment. Royalties received from Janssen Products and Taiho Pharmaceutical Co. for sales from Yondelis in the United States, Japan and the rest of the world except the European Union amounted to €0.9 million in the first quarter of 2019 (vs. €1.4 million in the same period of 2018).

No revenues from royalties, licensing and other co-development agreements were booked in the first quarter of 2019. Revenues under this heading amounted to €6.6 million in the first quarter of 2018, mainly from the deal with Seattle Genetics Inc. (€4.1 million).

As a result, **total revenues** amounted to €19.4 million in the first quarter of 2019, compared with €27.8 million in the same period of 2018 (-30%).

Sales by companies in the Consumer Chemicals segment is not reflected in this item since they have been reclassified as available for sale in the first quarter of 2019 and the same period of 2018. Results of discontinued operations are show under "Results of discontinued operations".

Gross margin and EBITDA

The Group's gross margin was 93% of sales in the first quarter of 2019 (95% in 2018). (Calculated with respect to sales only, not including royalties or licensing revenues).

Group EBITDA in the first quarter of 2019 amounted to €-7 million euro (€-2.7 million in 2018).

3/31/19	3/31/19
(10.436)	(2.506)
248	(2.752)
1.069	1.011
2.011	1.594
(7.108)	(2.653)
	(10.436) 248 1.069 2.011

(Thousand euro)

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

R&D expenditure

R&D expenditure declined in year-on-year terms, from €19.9 million in the first quarter of 2018 to €15.2 million in the first quarter of 2019.

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

	3/31/19	3/31/19	Dif ^a
R&D expenses	15.209	19.916	-4.707 -23,6%
Oncology	13.319	18.366	-5.047 -27,5%
Diagnostics	1.056	521	535 102,7%
RNAi	834	1.029	-195 -19,0%
(Thousand euro)			

Zepsyre® (lurbinectedin) accounted for most of R&D spending in 2019, mainly due to the considerable expense associated with clinical trials with this compound in small cell lung cancer, and to other pre-clinical and clinical trials.

Marketing and commercial expenses

The Group had €6.2 million in marketing and commercial expenses in the period, a 7% decrease year-on-year (€6.7 million in 2018), mainly in the oncology segment.

Income from continuing operations

Income before taxes from continuing operations amounted to a loss of €10.2 million in the first quarter of 2018, compared with €5.3 million in the same period of 2018.

Income from discontinued operations

In January 2019, the Group granted a mandate for the sale of PharmaMar subsidiary ZelnovaZeltia, which produces and markets insecticides for domestic use, air fresheners and other home care products; as a result, its assets and liabilities were reclassified as available for sale as of 31 March 2019 and 2018 and are reported under discontinued operations.

Additionally, on 20 September 2018, PharmaMar sold its 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 as of 31 March 2018 were restated to reclassify them as discontinued operations.

Cash and Debt

As of 31 March 2019, the net cash position (cash + cash equivalents + current financial assets) amounted to €13.8 million (vs. €26.9 million at 2018 year-end). Including non-current financial assets, this item amounted to €14.6 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:

3/31/19	3/31/19
61.773	64.922
22.009	24.279
16.514	16.501
23.250	24.142
32.852	28.483
16.154	12.911
2.612	2.064
10.343	10.244
2.334	2.248
1.409	1.016
94.625	93.405
14.650	27.760
70.075	CE CAE
-/9.9/5	-65.645
	61.773 22.009 16.514 23.250 32.852 16.154 2.612 10.343 2.334 1.409

Non-current debt was reduced by €3.1 million in the first quarter of 2019, while current debt increased by €4.3 million, mainly due to greater recourse to credit lines.

The balance of cash and cash equivalents plus financial assets declined by €13.1 million.

BUSINESS PERFORMANCE.

Below is an overview of business performance in the first quarter 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

During the first quarter of 2019, there were a total of 26 ongoing post-authorization trials in collaboration with a number of European cooperatives, 14 of which were active and 9 continued enrolling patients at a satisfactory pace. The other trials were in the process of closing, pending the presentation of results. Additionally, four trials are in the activation phase.

Ovarian cancer

There are 12 trials ongoing in this indication, eight of them active and six recruiting. Four trials are in the process of activation.

At a plenary session of the Society of Gynecologic Oncology (SGO) annual meeting in Hawaii on 18 March, Janssen presented final data from the Phase III randomized trial comparing Yondelis® in combination with Doxil®/Caelyx® against Doxil®/Caelyx® as monotherapy for treating patients with relapsed advanced epithelial ovarian cancer, primary peritoneal cancer or Fallopian tube cancer.

Other indications

The analysis of the results of 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), is currently ongoing.

c) ZEPSYRE® (Lurbinectedin)

Small-cell lung cancer

Recruitment concluded in August 2018 (613 patients) 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, 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 overall survival (OS), which is its primary endpoint. Based on the current and estimated future event rate, we expect the OS data to be available in Q1 2020 as opposed to our prior estimate of year end 2019.

PharmaMar was also present at the 10th China Healthcare Investment Conference, held in Shanghai on 26-28 March, where the latest developments of the company and of lurbinectedin in treating lung cancer were presented.

Basket trial in advanced solid tumors

Enrolment concluded for the Phase II basket trial with Zepsyre® as monotherapy in selected indications such as 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, and patient progress is currently being monitored

The cohort of patients with small cell lung cancer (105 patients) met its primary endpoint, Overall Response Rate (ORR) by both investigator and Independent Review Committee (IRC)

The trial results were selected by the American Society of Clinical Oncology (ASCO) for an oral presentation which will take place the 1st of June at its 19th Annual Meeting, which begins in Chicago on 1 June.

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.

Phase I trial in Japan

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

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 centers: one in Spain and the other in the United States.

Colorectal cancer

The Phase II trial in colorectal cancer completed enrolment, having enrolled 36 patients and treated 30. The trial data are currently being analyzed.

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

Genomica reported €1.402 million in revenues in the first quarter of 2019, compared with €1.428 million in the same period of 2018.

The international market accounted for 35% of revenues (€492 thousand), in line with previous years.

Domestic revenues increased by 4% to €814 thousand, compared with €785 thousand in 2018, after adjusting for the effect of the Castilla y León Regional Government's campaign for prevention and early detection of cervical cancer, whose budget was cut to €57 thousand in 1Q19, from €129 thousand in 1Q18.

In connection with the deadlines set in the agreement with Beijing Clear Medi-tech Co., registration documents for CLART®Enterobac and CLART®Septibac were filed with the Chinese FDA in the first quarter of 2019 with the support of our distributor.

Genómica has decided to concentrate growth in the traditional CLART technology via cooperation contracts with Chinese pharmaceutical companies.

3.- RNA interference: Sylentis

The results of the Helix trial with Tivanisiran, an RNAi for treating dry-eye syndrome, were announced on 31 January. Although the trial did not meet its primary end-point, in terms of ocular pain and total corneal staining outcomes, 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. This had been established as a secondary end-point of the trial. In terms of biomarkers for the disease, Tivanisiran proved superior to its comparator by logging a 125% increase in mucin, which is linked to improvements in the tear film, and a 13% reduction in the inflammatory marker HLA-DR.

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. Candidate SYL1801 for topical treatment of agerelated macular degeneration completed pre-clinical efficacy trials with similar results in animal models to the current standard treatment, which is an anti-VGF antibody administered via intraocular injection.

4.- Consumer chemicals:

ZelnovaZeltia and Copyr (household insecticides, air fresheners and other household products)

In line with PharmaMar's strategy of focusing on the pharmaceutical sector, in January it announced the start of a process to divest subsidiary Zelnova, which manufactures and markets insecticide products for domestic use, air fresheners and other home care products. For this reason, the financial statements for March 2019 and 2018 present the figures for this subsidiary under assets available for sale/discontinued operations.

Zelnova-Copyr total revenues increased by a sizeable 16.6% year-on-year in the first quarter of 2019. Both companies and all business lines contributed to growth:

Zelnova: Insecticides - domestic market: +17%. Insecticides - exports: +49%. OTC: +81%. Air fresheners: +13%

Copyr: Environmental hygiene: +45%. Home & Gardening: +22%. Ecological agriculture: +12%

As for costs, the prices of the main raw materials (bottles, active ingredients, butane, solvents, etc.) were stable. The company maintains its policy of actively seeking and adopting alternative suppliers that offer competitive prices. Measures are also being taken to enhance productivity in order to reduce costs and enable the Company to enhance competitiveness.

BALANCE SHEET		
(Thousand euro)	03/31/19	12/31/2018
ASSETS		
Non-current assets	65.987	
Property, plant & equipment	21.966	26.637
Investment properties	845	
Intangible assets	5.691	
Right-of-use assets	3.933	
Goodwill	0	2.548
Long-term financial assets	872	884
Deferred tax assets	32.680	29.768
Assets classified as held for sale and discontinued operations	60.235	0
Current assets	39.881	75.110
Inventories	9.967	20.616
Customer and other receivables	12.504	23.549
Current financial assets	3.393	4.131
Other current assets	3.633	4.069
Cash & cash equivalents	10.385	22.745
TOTAL ASSETS	166.103	157.676

BALANCE SHEET		
(Thousand euro)	03/31/19	12/31/2018
EQUITY		
Shareholders' equity	11.401	21.372
Share capital	11.132	11.132
Share premium	71.278	71.278
Treasury shares	(1.635)	(2.243)
Revaluation and other reserves	15	12
Retained earnings and other reserves	(69.389)	(58.806)
Minority interest	(3.904)	(3.899)
TOTAL EQUITY	7.497	17.473
LIABILITIES		
Non-current liabilities	66.122	67.821
Financial debt	61.773	64.922
Lease liabilities	2.136	0
Derivatives	0	0
Non-current deferred revenues	2.038	2.120
Other non-current liabilities	175	779
Liabilities classified as held for sale	23.843	0
Current liabilities	68.641	72.381
Supplier and other accounts payables	23.756	34.511
Financial debt	32.852	28.483
Lease liabilities	1.814	0
Derivatives	0	0
Provisions for other liabilities & expenses	7.033	6.266
Current deferred revenues	122	168
Other current liabilities	3.064	2.952
TOTAL LIABILITIES	158.606	140.202
TOTAL LIABILITIES AND EQUITY	166.103	157.676

INCOME STATEMENT		
Thousand euro	03/31/19	03/31/18
Revenues:		
Product Sales	18.434	19.746
Co-development	0	6.581
Licensing agreements	926	1.410
Other income	79	88
	19.439	27.825
Cost of sales	(1.294)	(1.016)
Marketing & commercial organisation expenses	(6.193)	(6.654)
General and administration expenses	(3.228)	(3.006)
Research & development expenses	(15.209)	(19.916)
Net impairment on financial assets	(25)	0
Other operating expenses	(2.880)	(1.852)
Other operating revenues	271	372
Net operating profit (loss) (EBIT)	(9.119)	(4.247)
Net financial results	(1.069)	(1.011)
Result before income tax	(10.188)	(5.258)
Corporate income tax in the period	(248)	2.752
Result from continuing operations	(10.436)	(2.506)
Result from discontinued operation	(49)	1.188
Attributable to equity holders	(49)	1.188
Profit for the year	(10.485)	(1.318)
Attributable to owners of the parent	(10.481)	(1.314)
Attributable to minority interest	(4)	(4)

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

CONSOLIDATED CASH FLOW STATEMENT EUR (Thousand)

31/03/19

TOTAL NET OPERATING CASH FLOW	(14.720)
Income before taxes	(10.079)
Profit before tax from continuing operations Profit before tax from discontinued operations	(10.189) 111
Adjustments for:	3.726
Amortisation and depreciation Other adjustements	1.434 2.293
Changes in working capital:	(7.305)
Other cash flow from operations:	(1.062)
Financial expenses Financial revenues	(1.055) (7)
TOTAL NET INVESTING CASH FLOW	700
Investments payments:	(66)
Purchases of property, plant & equipment and intangible assets	(59)
Other financial assets	(7)
Disvestment receipts: Purchases of property, plant & equipment and intangible assets	766 29
Other financial assets	737
TOTAL NET FINANCING CASH FLOW	1.658
Collections and (payments) in connection with equity instruments:	439
Acquisition Disposal	(1.058) 1.497
Collections and (payments) in connection with financial liabilities:	(3.170)
Loans received	896
Refund and amortization	(4.066)
Other financing cash flow:	4.390
Other financing receipts / (payments)	4.390
TOTAL NET CASH FLOW	(12.361)
Beginning balance of cash and cash equivalents	22.745
ENDING BALANCE OF CASH AND CAHS EQUIVALENTS	10.385