



REPORT AT 30 SEPTEMBER 2019

Madrid, 23 October 2019

9M19 MILESTONES

Corporate

- Net sales of Yondelis amounted to €54 million in the first nine months of 2019.
- The income statement as of 30 September 2018 was restated to reflect the sale of PharmaMar subsidiary ZelnovaZeltia, S.A. in June 2019.

Oncology

- In the fourth quarter of 2019, PharmaMar will file an application for accelerated approval of lurbinectedin (Zepsyre) for treating relapsed small cell lung cancer in the United States.
- PharmaMar signed a new licensing agreement for Yondelis® with Janssen: Janssen retains exclusive marketing and distribution rights in the United States for Yondelis®. The new agreement will enable PharmaMar to distribute Yondelis® in over 40 countries where it has already been approved.

Diagnostics

- Genómica signed an exclusive agreement with Marusan Pharma Biotech Corporation for distribution of its products in Japan. Work to register CLART®HPV and autoclart® plus with the Japanese regulator (PMDA) will commence in the fourth quarter of this year.

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FIGURES TO SEPTEMBER 2019

	09/30/2019	09/30/2018	Var.	
Oncology	53.970	57.425	-3.455	-6%
<i>Yondelis/Aplidin API</i>	593	65	528	
<i>Yondelis commercial sales</i>	53.377	57.360	-3.983	-7%
Diagnostics	3.965	4.153	-188	-5%
Sales	57.935	61.578	-3.643	-6%
Royalties	2.435	2.582	-147	-6%
Licences	1.914	24.396	-22.482	
Other (Diagnostics)	188	228	-40	
TOTAL REVENUES	62.472	88.784	-26.312	-30%

(Thousand euro)

Total Group revenues

Sales in the oncology segment, relating entirely to Yondelis®, amounted to €54.0 million, compared to €57.4 million booked in the same period of 2018.

In the first nine months of 2019, the Diagnostics segment (Genómica) attained €4.0 million in sales, plus €0.2 million in other revenues (€4.2 million plus €0.2 million, respectively, in the same period 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 €2.4 million in the first nine months of 2019 (€2.6 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, Ltd. 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 and, consequently, the upfront payment will be recognized in PharmaMar's income statement in line with the progress with such activities. As a result, €1.9 million were recognized as revenues in the first nine months of 2019.

In comparison, licensing revenues amounted to €24.4 million in the first nine months 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; additionally, €2 million was received related to the commercialization agreement with Impilo Pharma (IMMEDICA group) to promote and distribute Yondelis® in certain European countries.

Consequently, **total revenues** amounted to €62.5 million in the first nine months of 2019, compared with €88.8 million in the same period of 2018, where €19.8 million of the difference was due to these licensing revenues.

Gross margin and EBITDA

The Group's gross margin on revenues was 93.2% in the first nine months of 2019 vs. 94.4% in 2018. (Calculated with respect to sales only, not including royalties or licensing revenues).

Group EBITDA amounted to -€12.4 million in the first nine months of 2019 (-€1.6 million in the same period of 2018).

	9/30/19	9/30/18
Net result of continuing operations	(24.769)	(14.000)
Income tax	3.544	4.286
Net financial income	2.875	2.914
Depreciation and amortization	5.937	5.156
EBITDA	(12.413)	(1.644)

(Thousand euro)

(EBITDA includes all revenues and expenses from business activities except for depreciation and amortization, provisions, net interest income and tax expenses).

R&D expenditure

R&D expenditure declined by 27.3% in year-on-year terms, from €56.9 million in the first nine months of 2018 to €41.3 million in the same period of 2019.

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

	9/30/19	9/30/18	Dif ^a	
R&D expenses	41.325	56.878	-15.553	-27,3%
Oncology	37.207	49.801	-12.594	-25,3%
Diagnostics	1.892	3.139	-1.247	-39,7%
RNAi	2.226	3.938	-1.712	-43,5%

(Thousand euro)

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

R&D spending declined by 27.3% in the first nine months of 2019 with respect to the same period of 2018. That reduction was concentrated in the oncology segment (-€12.6 million). This is due to the fact that a number of Phase III trials were open and active in the first nine months of 2018, but were no longer active in 2019 although they remain open until they are definitively concluded.

Marketing and commercial expenses

Marketing and commercial expenses amounted to €18.2 million in the period, a 9% decrease year-on-year (€20.0 million in 2018), mainly in the oncology segment.

Income from discontinued operations

On 28 June 2019, PharmaMar completed the sale of its subsidiary, ZelnovaZeltia, manufacturer and marketer of 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 and the consolidated outcome of the transaction were booked as income from discontinued operations as of 30 September 2019 and 2018, to which end the income statement as of 30 September 2018 was restated.

The consolidated outcome of the sale of ZelnovaZeltia saw, -€2.2 million recognized as income from discontinued activities as of 30 September 2019. Income from discontinued activities as of 30 September 2018, in the amount of €12.9 million, relates to ZelnovaZeltia (€2.2 million) and the outcome of the sale of Xylazel on 28 September 2018 (€10.7 million).

Income from continuing operations

Income from continuing operations amounted to a loss after taxes of €27.0 million in the first nine months of 2019, compared with a loss of €1.1 million in the same period of 2018. Those losses, combined with prior years' losses, resulting in the consolidated net worth being negative in the amount of €9.2 million. The net worth of Pharma Mar, S.A., the group parent company, is positive and balanced.

Cash and Debt

As of 30 September 2019, the net cash position (cash + cash equivalents + current financial assets) amounted to €27 million (vs. €26.9 million at 2018 year-end). Including non-current financial assets, this item amounted to €27.8 million (€27.8 million at 2018 year-end).

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

	9/30/19	12/30/18	Var.
Non current debt	56.896	64.922	-8.026
Bank debt	17.937	24.279	-6.342
Obligations and bonds	16.537	16.501	36
Govt. Agencies: R&D funding	22.422	24.142	-1.720
Current debt	28.721	28.485	236
Credit facilities	11.988	12.912	-924
Effects and certifications	1.726	2.064	-338
Bank loan	10.438	10.245	193
Govt. Agencies: R&D funding	4.290	2.248	2.042
Interest and others	279	1.016	-737
Total financial debt	85.617	93.407	-7.790
Cash&cash equivalents + non current and current financial investment	27.828	27.760	68
TOTAL NET DEBT	-57.789	-65.647	7.858

(Thousand euro)

Non-current debt was reduced by €8.0 million in the first nine months of 2019, while current debt increased by €0.2 million, mainly due to higher maturities of loans from official bodies in the next twelve months, being partly offset by lower use of credit lines and commercial discounting. The balance of cash and cash equivalents plus current and non-current financial assets was in line with the level at 2018 year-end. Total net debt had been reduced by €7.9 million.

BUSINESS PERFORMANCE.

Below is an overview of the group companies' business performance through September 2019.

1.- Oncology segment: PharmaMar

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

a) YONDELIS®:

Strategic agreements

PharmaMar signed a new licensing agreement with Janssen Products, LP (Janssen) for Yondelis® (trabectedin) to replace the 2001 licensing agreement between them.

Under the new agreement, Janssen has exclusive rights to sell and distribute Yondelis® in the United States. The milestone payments and royalties on net sales of the product by Janssen in the United States are the same as in the 2001 licensing agreement.

PharmaMar retains exclusive rights to produce the active ingredient, trabectedin, which it will supply to Janssen for clinical and commercial purposes.

At the same time, PharmaMar and Janssen signed a framework product transfer agreement under which Janssen transfers to PharmaMar all rights to the compound in the other territories that were licensed to Janssen, i.e. all the countries in the world except the United States, Europe and Japan (the latter licensed to Taiho Pharmaceuticals Co. Ltd.).

This transfer agreement will be phased in gradually, depending on the regulatory requirements in each country. Janssen and PharmaMar have undertaken to ensure the supply of Yondelis® during the transfer. Janssen will continue to sell the product until the commercialization authorizations have been transferred. This framework transfer agreement will enable PharmaMar to distribute Yondelis® in over 40 additional countries in which the product is already approved. PharmaMar plans to market Yondelis® through local partners and does not rule out filing new applications and obtaining regulatory authorizations in countries where the product is currently not approved.

Soft-tissue sarcoma

In the third quarter of 2019, 24 post-authorization trials were under way, 15 of them active (10 enrolling new patients). The other trials were in the process of closing and data analysis or were pending the presentation of results. Six additional trials are scheduled to commence in the coming months.

At the annual meeting of the European Society for Medical Oncology (ESMO), held in Barcelona from 27 September to 1 October, a trial with trabectedin in combination with low doses of radiotherapy was presented which evidenced meaningful activity in a broad range of soft tissue sarcoma in patients with advanced metastatic disease, which offers additional options for tumor reduction beyond first-line treatment. The trial attained its primary endpoint, seeing the overall response rate (ORR) of 55.6%.

Ovarian cancer

There are 15 trials ongoing in this indication, ten of them active and seven recruiting.

b) ZEPSYRE® (Lurbinectedin)

Small-cell lung cancer

Enrolment concluded for the Phase II basket trial with Zepsyre® as monotherapy in 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. The primary endpoint — overall response (ORR) — was attained in the small cell lung cancer cohort.

In connection with this trial's results with small cell lung cancer, the US Food & Drug Administration (FDA) accepted a proposal by the company to file for accelerated approval of a New Drug Application (NDA) for lurbinectedin as monotherapy in second-line treatment of small cell lung cancer.

The FDA's accelerated approval process allows for earlier approval of drugs that treat serious conditions, and that fill an unmet medical need based on a surrogate endpoint.

The application will be based on data from the Phase II basket trial with lurbinectedin as monotherapy for treating second line small cell lung cancer, which enrolled 105 patients at 39 centers in over 9 countries in Western Europe and the United States. The trial achieved its primary endpoint of Overall Response Rate (ORR). Secondary endpoints included Duration of Response (DOR), Progression Free Survival (PFS), Overall Survival (OS) and safety. The data was presented at an oral session during the American Society for Clinical Oncology (ASCO annual meeting) in Chicago on June 1st 2019.

The ATLANTIS pivotal Phase III trial that compares the activity and safety of the combination of Zepsyre® (lurbinectedin) plus doxorubicin against topotecan or CAV (cyclophosphamide + adriamycin + vincristine) for treating patients with small cell lung cancer who have relapsed after a first round of platinum treatment continues to follow overall survival, its primary endpoint. The next update on ATLANTIS will be once we have data, which we currently expect in 2020. The ATLANTIS trial completed enrolment in July 2018.

Single-agent trial in advanced solid tumors

Also, at the European Society for Medical Oncology (ESMO) meeting held in Barcelona from September 27th to October 1st, SAKK (Swiss Group for Clinical Cancer Research), in cooperation with PharmaMar, presented an oral session on the results of the Phase II trial with lurbinectedin as monotherapy in treating relapsed malignant pleural mesothelioma. Entitled “Lurbinectedin as second or third line palliative chemotherapy in malignant pleural mesothelioma (MPM): A multi-center, single-arm Phase II trial”, the presentation showed the results of a trial involving 42 patients with progressive MPM that achieved its primary endpoint of progression free survival (PFS) with 52.4% patients at 12 weeks.

Combination trials

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

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

The analysis of 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 in Barcelona in September.

The results of the Phase I trial in combination with irinotecan were also presented as a poster at the European Society for Medical Oncology (ESMO) meeting in Barcelona in September 2019.

Phase I trial in Japan

This trial, designed to ascertain the dosage for Zepsyre® in Japanese patients, attained its primary endpoint by determining the recommended dose for that population. Enrolment concluded and the treated patients are in the process of being evaluated.

c) PM184

The Phase I dose escalation trial assessing the combination of PM184 with gemcitabine concluded enrolment and is now in the patient tracking phase.

d) PM14

The main endpoint of the Phase I trial, which is still actively recruiting, is to identify the optimal dose for administration of PM14 in patients with advanced solid tumors; it also seeks to define the compound's safety profile and assess its pharmacokinetics and pharmacogenetics in treated patients.

2.- Diagnostics Genómica

Genómica ended the third quarter of 2019 with €4.2 million in revenues, compared with €4.4 million in the same period of 2018.

The domestic market in diagnostics performed in accordance with expectations, with sales up 7% to €2.6 million (€2.4 million in the same period of 2018).

International sales amounted to €1.4 million in the first nine months of 2019, 33% of the total (€1.8 million in 2018), although it should be noted that the backlog of unfilled orders from Latin America and Asia stood at €0.4 million at the end of the quarter.

Additionally, in July an exclusive distribution agreement for Genómica products in Japan was signed with Marusan Pharma Biotech Corporation in July. Work to register CLART®HPV and autoclart® plus with the Japanese regulator (PMDA) will commence in the fourth quarter of this year.

3.- RNA interference: Sylentis

The centers involved in the Helix Phase III trial with tivanisiran (SYL1001), an RNAi for treating dry-eye syndrome, were closed in the third quarter of 2019 and the final report was drafted. The next clinical trial is currently being designed in order to advance with the product's clinical development.

The company is also working on other RNAi candidates for treating retinal diseases. Those candidates' efficacy was analyzed using pre-clinical models of a number of retinal pathologies. Candidate SYL1801 for topical treatment of age-related macular degeneration completed regulatory pre-clinical toxicology trials in two animal species which evidenced that the product has a good safety profile, with no toxicological effects of SYL1801 being observed following continuous ocular administration.

4.- Consumer chemicals:

As of 30 September 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), 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.

CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION <i>(Thousand euro)</i>	September 30, 2019	December 31, 2018
ASSETS		
Non-current assets		
Property, plant and equipment	22.807	26.637
Investment property	845	6.071
Intangible assets	3.949	16.658
Right-of-use assets	3.666	0
Goodwill	0	2.548
Non-current financial assets	822	884
Deferred tax assets	29.696	29.768
	61.786	82.566
Current assets		
Inventories	8.541	20.616
Trade and other receivables	11.682	23.549
Financial assets at amortised cost	3.597	4.131
Other assets	3.522	4.069
Cash and cash equivalents	23.409	22.745
	50.751	75.110
TOTAL ASSETS	112.537	157.676

CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION <i>(Thousand euro)</i>	September 30, 2019	December 31, 2018
EQUITY		
Share capital	11.132	11.132
Share premium	71.278	71.278
Treasury shares	(2.104)	(2.243)
Revaluation reserves	13	12
Retained earnings and other reserves	(85.615)	(58.806)
Total capital and reserves attributable to equity holders of the parent company	(5.296)	21.373
Non-controlling interests	(3.913)	(3.900)
TOTAL EQUITY	(9.209)	17.473
LIABILITIES		
Non-current liabilities		
Borrowings	56.897	64.922
Lease liabilities	1.943	0
Non-current deferred income	1.961	2.120
Other non-current liabilities	176	779
	60.977	67.821
Current liabilities		
Trade and other payables	19.198	34.511
Borrowings	28.722	28.483
Lease liabilities	1.765	0
Provisions for other liabilities and charges	6.131	6.266
Current deferred income	2.546	168
Other current liabilities	2.406	2.954
	60.769	72.382
TOTAL LIABILITIES	121.746	140.203
TOTAL EQUITY AND LIABILITIES	112.537	157.676

CONDENSED CONSOLIDATED STATEMENTS OF PROFIT OR LOSS		
(Thousand euro)	September 30, 2019	(*) Restated September 30, 2018
Revenue:		
Revenue from contracts with customers	57.935	61.578
Revenue from licensing and development agreements (excluding royalties)	1.914	24.396
Royalties	2.435	2.582
Other	188	228
	62.472	88.784
Cost of sales	(3.954)	(3.440)
Gross profit	58.518	85.344
Marketing expenses	(18.222)	(19.963)
General and administrative expenses	(10.072)	(9.171)
Research and development expenses	(41.325)	(56.878)
Net impairment on financial assets	(1)	0
Other operating expenses	(7.965)	(6.664)
Other results	717	532
Operating loss	(18.350)	(6.800)
Finance costs	(3.148)	(3.314)
Finance income	273	400
Finance costs - net	(2.875)	(2.914)
Result of the period before income taxes	(21.225)	(9.714)
Income tax benefit / (expense)	(3.544)	(4.286)
Result for the period from continuing operations	(24.769)	(14.000)
Result for the period from discontinued operations		
Result is attributable to:	(2.217)	12.869
Equity holders of the parent company	(2.217)	12.869
Result for the period	(26.986)	(1.131)
Result is attributable to:		
Equity holders of the parent company	(26.972)	(1.117)
Non-controlling interests	(14)	(14)

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

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

(Thousand euro)

**September
30, 2019**

Cash flows from operating activities

Result before taxes:	(22.894)
<i>Result before taxes from continuing operations</i>	<i>(21.225)</i>
<i>Result from discontinued operations</i>	<i>(1.669)</i>
Adjustments for:	10.728
Depreciation and amortization	4.561
Provision for impairment of accounts receivable	7
Impairment losses of property, plant and equipment	(81)
Finance income	(10)
Finance costs	2.885
Results on disposals of intangible assets	3
Share based payments	202
Deferred income - grants	(172)
Loss on subsidiary sale	3.269
Other adjustments to profit or loss	65
Changes in working capital:	(11.790)
Inventories	(2.058)
Trade and other receivables	(16.653)
Other assets and liabilities	(1.924)
Trade and other accounts payable	5.762
Deferred or accrual items	3.083
Other cash flows from operations:	(2.875)
Interest paid	(2.885)
Interest received	10
Income tax received	0

Net cash outflow from operating activities

(26.831)

Cash flows from investing activities

Acquisitions:	(723)
Group companies, associates and business units	0
Property, plant and equipment, intangible assets and investment property	(655)
Other financial assets	(68)
Proceeds from:	35.924
Group companies, associates and business units	33.386
Property, plant and equipment, intangible assets and investment property	28
Other financial assets	2.511

Net cash inflow from investing activities

35.202

Cash flows from financing activities

Receipts and (payments) in connection with equity instruments:	79
Purchase of treasury shares	(5.613)
Proceeds from shares issued	5.692
Receipts and (payments) in connection with financial liabilities:	(7.786)
Proceeds from borrowings	3.030
Repayment of borrowings	(10.817)

Net cash inflow (outflow) from financing activities

(7.708)

Net increase (decrease) in cash and cash equivalents

663

Cash and cash equivalents at beginning of the period	22.745
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Cash and cash equivalents at end of the period

23.409