



## REPORT AT 30 JUNE 2020

Madrid, 30 July 2020

### 1H20 HIGHLIGHTS

#### Corporate

- Total Group revenues amounted to €169.1 million (vs. €41.4 million in 1H19).
- Licensing revenues totaled €115.0 million in the first half, mainly from the licensing agreement with Jazz Pharmaceuticals. In accordance with IFRS 15 on recognition of upfront and milestone payments, a total of €112.4 million in revenues had been recognized under this agreement as of 30 June 2020.
- Group net sales amounted to €52.6 million, an increase of 35% over the first half of 2019 (€39.0 million).
- The Shareholders' Meeting of PharmaMar approved the reverse-split and exchange of Company shares for newly-issued shares in the proportion of one new share for every 12 pre-existing shares of the Company, which took place on 22 July 2020.
- On 30 June, the Company distributed an ordinary dividend of 4 cent per share.
- Rating agency Axesor upgraded PharmaMar from B+ to BB-, with a positive outlook.

#### Oncology

- In June the US Food and Drug Administration (FDA) granted accelerated approval for Zepzelca™ (lurbinectedin) for the treatment of relapsed small cell lung cancer. With this approval, the company achieved one of the milestones contemplated in the licensing agreement with Jazz Pharmaceuticals, triggering a payment of USD 100 million (€88.5 million).
- The APLICOV-PC clinical trial with Aplidin® for treating COVID-19 commenced in Spain in April.
- In June, Australia's Therapeutic Goods Administration (TGA) granted lurbinectedin "Provisional Approval Pathway" designation, which allows for a faster review for approval of medicines that cover unmet therapeutic needs.
- PharmaMar signed an exclusive distribution and commercialization with Impilo Pharma AB (Inmedic Pharma) for anti-tumor drug lurbinectedin in the United Kingdom, Ireland, the Nordic countries, and some countries in Eastern Europe, the Middle East and North Africa.

#### Diagnostics

- Genómica realized €5.6 million in revenues, 110% more than in the first half of 2019 (€2.7 million).
- Genómica obtained the CE mark for its COVID-19 coronavirus diagnostics kits, certifying that they fulfil the essential requirements for in vitro diagnostic products, and it began marketing them in March.

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## FIGURES TO JUNE 2020

	06/30/2020	06/30/2019	Var.
Oncology Sales	46.950	36.291	29%
<i>Commercial Sales</i>	44.334	35.777	24%
<i>API sales</i>	2.616	514	409%
Diagnostics Sales	5.639	2.689	110%
<b>Sales</b>	<b>52.589</b>	<b>38.980</b>	<b>35%</b>
<b>Royalties</b>	<b>1.420</b>	<b>1.654</b>	<b>-14%</b>
<b>Licences</b>	<b>114.966</b>	<b>629</b>	
<b>Other (Diagnostics)</b>	<b>135</b>	<b>143</b>	
<b>TOTAL REVENUES</b>	<b>169.110</b>	<b>41.406</b>	<b>308%</b>

(Thousand euro)

### Total Group revenues

**Revenues** in the oncology segment, amounting to €47.0 million (vs.€36.3 million in 1H19), were almost entirely from Yondelis® sales but also include compassionate-use sales of Zepzelca™ (lurbinectedin) in some European countries, amounting to €5.9 million, and sales of Zepzelca™ vials to our partners, amounting to €1.5 million. Sales of the Yondelis raw materials to partners (Janssen and Taiho) amounted to €2.6 million in the first half of 2020 (vs.€0.5 million in the same period of 2019). Sales in oncology increased by 29% year-on-year.

Revenues in the diagnostics segment increased by 110% year-on-year to €5.6 million (vs. €2.7 million in the first half of 2019), mainly as a result of sales of the new COVID-19 diagnosis kit, which was released in March, and the distribution of the IgM/IgG antibody test for COVID-19.

**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 €1.4 million in the first half of 2020 (vs. €1.7 million in the same period of 2019).

**Revenues from licensing** and other co-development agreements, which also correspond entirely to the Oncology, amounted to €115 million in the first half of 2020, mostly under the licensing agreement for Zepzelca™ (lurbinectedin) in the United States with Jazz Pharmaceuticals.

The licensing agreement for Zepzelca™ (lurbinectedin) signed with Jazz Pharmaceuticals in December 2019 came into force in January. PharmaMar collected an upfront payment of USD 200 million (€181 million). In June, Zepzelca™ (lurbinectedin) was approved for commercialization in the US by the FDA under the accelerated approval pathway. As a result, PharmaMar collected a regulatory milestone of USD 100 million (€88.5 million) from Jazz Pharmaceuticals. By application of the accounting standard on revenue recognition (IFRS 15), revenues from the licensing agreement are recognized on the basis of the degree of progress and/or compliance with the commitments acquired by PharmaMar under the agreement; consequently, a total of €112.4 million in revenues had been recognized as of 30 June 2020. Another €3 million were recognized as revenues under other licensing agreements.

As a result, **total revenues** amounted to €169.1 million in the first half of 2020, compared with €41.4 million in the same period of 2019.

### Gross margin and EBITDA

The Group's gross margin was 92.7% of revenues in the first half of 2020 (vs. 93.3% in the same period of 2019). (Calculated with respect to sales only, not including royalties or licensing revenues).

EBITDA in the period is calculated as follows:

	6/30/20	6/30/19
<b>Net result of continuing operations</b>	<b>113.789</b>	<b>(19.112)</b>
Income tax	1.501	3.353
Net financial income	(265)	2.081
Depreciation and amortization	3.739	3.894
<b>EBITDA</b>	<b>118.764</b>	<b>(9.784)</b>

(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 in year-on-year terms, from €27.9 million in the first half of 2019 to €24.3 million in the first half of 2020. The Oncology area spent €22.7 million on R&D, compared with €24.6 million in the same period of the previous year. That decline was due mainly to the fact that the first half of 2019 included expenditure on the Atlantis and Basket trials with Zepzelca™ (lurbinectedin) in small cell lung cancer, enrolment for which had concluded by the first half of 2020. The decline was also attributable, although to a lesser extent, to delays caused by the COVID-19 pandemic, which made it impossible to make visits for the purposes of monitoring and conclusion of processes. The reduction in R&D spending in the Diagnostics segment (€1.4 million) was due to conclusion of the NEDXA point-of-care diagnostics platform, with priority being given to development of the conventional CLART platform. The reduction in R&D spending in the RNAi segment (€0.3 million) is temporary, since the activities in the first half of 2020 were mainly preclinical, whereas expenditure in the same period of 2019 included the HELIX Phase III trial with tivanisiran. The protocol for a new Phase III trial with tivanisiran is currently being prepared.

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

	6/30/20	6/30/19	Dif <sup>a</sup>	
<b>R&amp;D expenses</b>	<b>24.251</b>	<b>27.916</b>	<b>-3.665</b>	<b>-13,1%</b>
Oncology	22.686	24.646	-1.960	-8,0%
Diagnostics	279	1.699	-1.420	-83,6%
RNAi	1.286	1.571	-285	-18,1%

(Thousand euro)

### Marketing and commercial expenses

Group marketing and commercial expenses amounted to €11.5 million in the first half of 2020, 9.6% less than in the same period of 2019 (€12.7 million), mainly as a result of fewer trips to specialized conferences due to COVID-19.

### Income from discontinued operations

In June 2019, the Group divested its entire stake in Zelnova Zeltia, a company in the consumer chemicals business. The consolidated result of that divestment was -€2.2 million.

### Income from continuing operations

Profit in the first half of 2020 (€113.8 million) reflects higher revenues, mainly under licensing agreements (€115 million in the first half of 2020, compared with €0.6 million in the same period of 2019). Additionally, sales increased by €13.6 million in the first half of 2020, driven by both Oncology and Diagnostics. Meanwhile, operating expenses overall declined by €1.1 million year-on-year. This resulted in a profit of €113.8 million in the first half of 2020, compared with a loss of -€21.3 in the same period of 2019.

## Cash and Debt

As of 30 June 2020, the net cash position (cash + cash equivalents + current financial assets) amounted to €228.1 million (vs. €20.9 million at 2019 year-end). Including non-current financial assets, the total was €249.2 million as of 30 June 2020 (€21.9 million as of 2019 year-end).

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

	6/30/2020	12/31/2019
<b>Non current debt</b>	<b>40.927</b>	<b>53.063</b>
Bank debt	6.109	15.291
Obligations and bonds	16.574	16.549
Govt. Agencies: R&D funding	18.244	21.223
<b>Current debt</b>	<b>18.524</b>	<b>29.655</b>
Credit facilities	5.197	11.583
Effects and certifications	611	2.241
Bank loan	6.845	10.497
Govt. Agencies: R&D funding	5.092	4.883
Interest and others	779	451
<b>Total financial debt</b>	<b>59.451</b>	<b>82.718</b>
<b>Cash&amp;cash equivalents + non current and current financial investment</b>	<b>249.158</b>	<b>21.924</b>
<b>TOTAL NET CASH / (DEBT)</b>	<b>189.707</b>	<b>(60.794)</b>

(Thousand euro)

There were two receipts in the first half of 2020 under the Zepzelca™ (lurbinectedin) licensing agreement with Jazz Pharmaceuticals: a €181 million upfront payment, and an €88.5 million milestone payment triggered by FDA approval.

Two bank loans amounting to €9.0 million as of 1 January 2020 were repaid early during the period, and repayments of other loans from banks and official bodies amounted to €7.2 million.

As of 30 June 2020, the Group had €10.3 million available in credit lines (€2.1 million as of 31 December 2019).

## Effects of COVID-19

The COVID-19 pandemic had the following effects on the Group's activities: in March, the Diagnostics segment developed its own diagnostic kits and signed a distribution agreement for the fast diagnostic test of IgM and IgG antibodies to COVID-19. As a result, this segment booked €5.6 million in revenues in the period, a 110% increase year-on-year. The Oncology segment commenced the APLICOV-PC clinical trial with Aplidin® (plitidepsin) for treating COVID-19 patients, whose goal is to assess the efficacy and safety of plitidepsin in COVID-19 patients requiring hospital admission. At the date of this report, the trial was still enrolling patients.

The Group did not need to avail itself of furlough or layoff measures.

Commercial activity was unaffected by the situation; in fact, Oncology sales increased by 29% in the first half.

Following suitable analysis, it was concluded that it was not necessary to adjust asset or liability valuations. Production capacity was not affected, and both the Oncology and Diagnostics segments have sufficient raw materials and inventories to maintain regular sales of Yondelis, supply launch product of Zepzelca™ (lurbinectedin) and continue with the clinical trials that are under way, and to continue selling diagnostic kits, respectively. All the Group's material agreements remain in force in the same terms.

No bad debts are expected in the area of trade accounts receivable. A significant percentage of the Group's sales are to government institutions; accordingly, default risk is low.

As of 30 June 2020, the Group had a net cash position of €189.7 million (net of current and non-current debt), and €10.3 million available in credit lines. Debt maturities in the next twelve months amount to €12.6 million. None of the existing loans is subject to covenants.

At the date of this report, the Group's ability to continue as a going concern is well assured.

The directors and managers of the Group constantly monitor the situation in order to anticipate any financial or non-financial impacts that might arise.

## **BUSINESS PERFORMANCE.**

Below is an overview of research and development activities in the first half of 2020.

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

#### **A) YONDELIS®:**

In May, PharmaMar signed an agreement with Key Oncologics for the commercialization of Yondelis in South Africa, Namibia and Botswana. In June, PharmaMar signed a licensing agreement for commercialization of Yondelis in the territories of Taiwan, Hong Kong and Macao.

In January, it signed an agreement with Valeo Pharma for the commercialization of Yondelis® in Canada.

#### **Soft tissue sarcoma**

As of 30 June 2020, 25 post-authorization trials were under way, 15 of them active (11 enrolling new patients). The other trials were in the process of closing or data analysis or were pending the presentation of results. Three additional trials are scheduled to commence in the coming months.

The LMS 02 investigator initiated trial (Phase II, with trabectedin + doxorubicin as first-line treatment of patients with leiomyosarcoma, including uterine) was accepted for an oral presentation at ASCO 2020.

#### **Ovarian cancer**

There were a total of 14 trials in this indication in the first half of 2020: 7 were active, 3 were closing, 2 had closed in the period, and 1 was in the activation phase.

#### **B) Zepzelca™ (lurbinectedin)**

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

On 15 June 2020 the US Food and Drug Administration (FDA) approved Zepzelca™ (lurbinectedin) for treating patients with small-cell lung cancer who had experienced progression after platinum-based chemotherapy. Lurbinectedin benefited from accelerated approval based on the Overall Response Rate (ORR) and Duration of Response (DoR). The FDA approval was based on data from an open multi-center single-arm trial in which the drug was tested as a single agent in 105 platinum-sensitive and platinum-resistant adult patients with relapsed small cell lung cancer.

As a result of this approval, Jazz Pharmaceuticals was able to make Zepzelca™ (lurbinectedin) commercially available in the United States early in July this year. PharmaMar will collect royalties on net sales ranging between high teens to 30%. As indicated in the section on Revenues, that accelerated approval resulted in PharmaMar collecting €88.5million (USD 100 million) and it could collect an additional USD 150 million once full approval is obtained as well as other milestones related to future sales or approval in the US.

## **ATLANTIS trial**

The ATLANTIS pivotal Phase III trial compares the activity and safety of the combination of lurbinectedin, an anti-tumor drug of marine origin, plus doxorubicin, against physician's choice of 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 the second half of 2020.

## **Basket trial**

Enrolment concluded for the Phase II basket trial with Lurbinectedin 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.

## **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 and with atezolizumab.

The American Society of Clinical Oncology (ASCO) accepted a poster discussion from PharmaMar on the combination with irinotecan for its annual meeting, which was held online in May 2020.

## **Phase I trial in Japan**

This trial, designed to ascertain the dosage for Lurbinectedin 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) APLIDIN®**

The APLICOV-PC trial with Aplidin® (plitidepsin) for treating COVID-19 patients commenced in April; the goal is to assess the efficacy and safety of plitidepsin in COVID-19 patients requiring hospital admission.

Aplidin® produced positive results with nanomolar potency in in vitro trials with human coronavirus HCoV-229E at Spain's National Centre for Biotechnology (CNB), which forms part of the Spanish National Research Council (CSIC). These studies confirmed the hypothesis that the therapeutic target of Aplidin® (EF1A) is crucial for the multiplication and propagation of the virus. These results were corroborated by Boryung Pharmaceutical, PharmaMar's partner in South Korea.

## **D) PM184**

The Phase I dose escalation trial assessing the combination of PM184 with gemcitabine, conducted at two centers (one in Spain and one in the United States), concluded enrolment and is now in the patient monitoring phase.

## **E) PM14**

Recruitment continues for the clinical development program with this new molecule. The main endpoint of this Phase I trial is to identify the optimal dose for administration of PM14 in patients with advanced solid tumors, and to define the compound's safety profile and assess its pharmacokinetics and pharmacogenetics in treated patients.

## **2.- Diagnostics Genómica**

Genómica's 1H20 revenues amounted to €5.8 million (€2.9 million euro in 1H19). This growth was driven basically by the sale of COVID-19 molecular diagnostic kits, which amounted to €2.6 million in the first half, and the distribution of the fast test for detecting IgM/IgG antibodies to COVID-19, whose sales amounted to €0.5 million in the period.

On 6 March 2020, Genómica obtained the CE mark for commercialization of its COVID-19 diagnostic kits: "CLART®COVID-19" (based on Genómica's CLART® technology) and "qCOVID-19" (based on Real-Time technology).

In June, an agreement was signed with Medsol Corporation for Medical Equipment Import and Trading granting exclusive rights to import Genómica products into Egypt.

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

During the second quarter of 2020, the Company continued to work on the regulatory documentation, clinical trial protocol and selection of a CRO to manage and monitor the trial in the United States in order to advance with the clinical development of Tivanisiran for treating dry eye syndrome.

Additionally, all the regulatory documentation and the design of the Phase I trial with SYL1801 were completed in the second quarter of 2020, and the trial is due to commence in the second half of 2020. The company is also working on other RNAi candidates for topical treatment of retinal diseases. Those candidates' efficacy has been analyzed using preclinical models of a number of retinal pathologies.

<b>BALANCE SHEET</b>		
<i>(Thousand euro)</i>	<b>06/30/2020</b>	<b>12/31/2019</b>
<b>ASSETS</b>		
<b>Non-current assets</b>	<b>92.757</b>	<b>74.730</b>
Property, plant & equipment	21.783	22.452
Investment properties	845	845
Intangible assets	4.785	6.074
Right-of-use assets	3.335	3.345
Goodwill	0	0
Long-term financial assets	21.052	1.029
Deferred tax assets	40.956	40.984
<b>Current assets</b>	<b>259.470</b>	<b>49.977</b>
Inventories	9.576	8.902
Customer and other receivables	18.282	11.530
Current financial assets	19.214	3.257
Other current assets	3.506	8.649
Cash & cash equivalents	208.892	17.638
<b>TOTAL ASSETS</b>	<b>352.227</b>	<b>124.706</b>

<b>BALANCE SHEET</b>		
<i>(Thousand euro)</i>	<b>06/30/2020</b>	<b>12/31/2019</b>
<b>EQUITY</b>		
<b>Shareholders' equity</b>	<b>107.434</b>	<b>11.373</b>
Share capital	11.132	11.132
Share premium	71.278	71.278
Treasury shares	(11.412)	(1.500)
Revaluation and other reserves	13	15
Retained earnings and other reserves	36.422	(69.552)
<b>Minority interest</b>	<b>(3.936)</b>	<b>(3.918)</b>
<b>TOTAL EQUITY</b>	<b>103.497</b>	<b>7.455</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>	<b>140.282</b>	<b>56.810</b>
Financial debt	40.927	53.063
Lease liabilities	1.898	1.719
Non-current deferred revenues	97.284	1.851
Other non-current liabilities	174	177
<b>Current liabilities</b>	<b>108.447</b>	<b>60.441</b>
Supplier and other accounts payables	15.170	19.332
Financial debt	18.524	29.655
Lease liabilities	1.492	1.678
Provisions for other liabilities & expenses	4.561	5.734
Current deferred revenues	62.102	1.465
Other current liabilities	6.597	2.577
<b>TOTAL LIABILITIES</b>	<b>248.729</b>	<b>117.251</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>352.227</b>	<b>124.706</b>



CONDENSED CONSOLIDATED STATEMENTS OF PROFIT OR LOSS		
<i>Thousand euro</i>	06/30/2020	06/30/2019
Revenue:		
Revenue from contracts with customers	52.589	38.980
Revenue from licensing and development agreements (excluding royalties)	114.966	629
Royalties	1.420	1.654
Other	135	143
	<b>169.110</b>	<b>41.406</b>
Cost of sales	(3.854)	(2.593)
Marketing expenses	(11.495)	(12.736)
General and administrative expenses	(8.439)	(6.934)
Research and development expenses	(24.252)	(27.916)
Net impairment on financial assets	(167)	(5)
Other operating expenses	(6.304)	(5.430)
Other results	426	531
<b>Net operating result</b>	<b>115.025</b>	<b>(13.677)</b>
<b>Net financial results</b>	<b>265</b>	<b>(2.082)</b>
<b>Result of the period before income taxes</b>	<b>115.290</b>	<b>(15.759)</b>
Income tax benefit / (expense)	(1.501)	(3.353)
<b>Result for the period from continuing operations</b>	<b>113.789</b>	<b>(19.112)</b>
<b>Result for the period from discontinued operations</b>	<b>0</b>	<b>(2.217)</b>
Equity holders of the parent company	0	(2.217)
Result for the period	113.789	(21.329)
<b>Equity holders of the parent company</b>	<b>113.808</b>	<b>(21.320)</b>
Non-controlling interests	(19)	(9)

**CONSOLIDATED CASH FLOW STATEMENT**
**EUR**
**06/30/2020**
**TOTAL NET OPERATING CASH FLOW**
**268.341**
**Income before taxes** **115.290**
*Profit before tax from continuing operations* 115.290

**Adjustments for:** **3.353**

Depreciation and amortization 3.709

Provision for impairment of accounts receivable 35

Finance income (98)

Finance costs 1.606

Share based payments 122

Deferred income - grants (248)

Effects of exchange rate changes (1.773)

**Changes in working capital:** **151.206**

Inventories (675)

Trade and other receivables (6.787)

Other assets and liabilities 7.685

Trade and other accounts payable (5.335)

Deferred or accrual items 156.318

**Other cash flow from operations:** **(1.508)**

Financial expenses (1.606)

Financial revenues 98

**TOTAL NET INVESTING CASH FLOW** **(36.941)**
**Investments payments:** **(36.941)**

Purchases of property, plant &amp; equipment and intangible assets (960)

Other financial assets (35.981)

**TOTAL NET FINANCING CASH FLOW** **(41.914)**
**Collections and (payments) in connection with equity instruments:** **(9.043)**

Acquisition (18.932)

Disposal 9.889

**Collections and (payments) in connection with financial liabilities:** **(16.835)**

Loans received 76

Refund and amortization (16.911)

**Other financing cash flow:** **(7.219)**

Other financing receipts / (payments) (7.219)

**Dividends paid to company's shareholders** **(8.817)**
**Effects of exchange rate changes on cash and cash equivalents** **1.767**
**TOTAL NET CASH FLOW** **191.253**

Beginning balance of cash and cash equivalents 17.638

**ENDING BALANCE OF CASH AND CAHS EQUIVALENTS** **208.892**