

# PharmaMar reports EBITDA of €20.6 million (+6%) in the first quarter of 2022

- Total revenues increased to €53 million in the first quarter (+4%).
- Good performance of oncology business drove recurring revenues (sales plus royalties), to €46 million (+7%).
- Oncology royalty revenues grew by 27% to €11 million.
- Attributable net income amounted to €22 million.
- PharmaMar generated €36 million in cash from operating activities in the first quarter with net cash increasing to €206 million as of March 31<sup>st</sup> 2022.

Madrid, April 28<sup>th</sup>, 2022. – PharmaMar Group (MSE: PHM) reported total revenues of  $\in$ 53 million in the quarter ending March 31<sup>st</sup> 2022, up 4% year-on-year. The good performance of the oncology business led to recurring revenues (sales plus royalties), growing by 7% in the first three months of the year to  $\in$ 46 million. Of this, revenues of Zepzelca<sup>®</sup> (lurbinectedin) in Europe under the early access program were  $\in$ 8.7 million, up 1% year-on-year.

The good performance of the oncology revenues is also reflected in royalty revenues, which grew by 27% to the end of the first quarter to  $\in$ 11 million<sup>1</sup>.

In the case of non-recurring revenues from licensing agreements, these mainly relate to the revenue recognition from the licensing agreement entered into with Jazz Pharmaceuticals, leading to a recognition of  $\in$ 7.2 million for the quarter, compared with  $\in$ 8 million recognized in the first quarter of the previous year.

During the first three months of the year, R&D expenditure amounted to  $\in$ 19 million, an increase of 29% compared with the first quarter of the previous year, due to the clinical trials under way.

<sup>&</sup>lt;sup>1</sup> As our partner, Jazz Pharmaceuticals, has not yet reported its financial results for the first quarter of 2022, the royalties recorded in the first quarter of this year are an estimation based on our available information.



As a result, PharmaMar Group reported an EBITDA of  $\in$  20.6 million in the first quarter of 2022, 6% higher than in the same period of 2021.

PharmaMar Group generated €36 million in operating cash flow over the period. As a result, PharmaMar Group's total cash and cash equivalents amounted to €249 million at the end of the first quarter. The Group's total financial debt was reduced to €44 million, from €46 million at the end of the previous year. As a result, net cash increased by 23%, from €167 million in December 2021 to €206 million to March  $31^{st}$ .

PharmaMar Group reported a net income of  $\in$  22 million at the end of Q12022, slightly lower than in the same period of 2021.

# Results conference call for analysts and investors

PharmaMar will host a conference call for analysts and investors on Friday, April 29<sup>th</sup>, 2022, at 13:00 (CET). The numbers to connect to the teleconference are: +34 91 901 16 44 (from Spain), +1 646 664 1960 (from the US or Canada) or +44 20 3936 2999 (other countries). Participants' access code: 250969.

The teleconference and the recording of the webcast can be accessed on PharmaMar's website by visiting the <u>Events Calendar</u> section of the Company's website at <u>www.pharmamar.com</u>.

## Legal warning

This press release does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

## About PharmaMar

PharmaMar is a biopharmaceutical company focused on the research and development of new oncology treatments, whose mission is to improve the healthcare outcomes of patients afflicted by serious diseases with our innovative medicines. The Company is inspired by the sea, driven by science, and motivated by patients with serious diseases to improve their lives by delivering novel medicines to them. PharmaMar intends to continue to be the world leader in marine medicinal discovery, development and innovation. PharmaMar has developed and now commercializes Yondelis<sup>®</sup> in Europe by itself, as well as Zepzelca<sup>®</sup> (lurbinectedin), in the US; and Aplidin<sup>®</sup> (plitidepsin), in Australia, with different partners. In addition, it has a pipeline of drug candidates and a robust R&D oncology program. PharmaMar has other clinical-stage programs under development for several types of solid cancers: lurbinectedin and ecubectedin. Headquartered in Madrid (Spain), PharmaMar has subsidiaries in Germany, France, Italy, Belgium, Austria, Switzerland and The United States. PharmaMar also wholly owns other companies: GENOMICA, a



molecular diagnostics company; and Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi). To learn more about PharmaMar, please visit us at <u>www.pharmamar.com</u>.

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Or please visit our website at www.pharmamar.com



## **REPORT AS OF 31 MARCH 2022**

# 28 April 2022

## MILESTONES

## Corporate

- Recurring revenues (sales plus royalties) increased by 7% in the first quarter of 2022 with respect to the same period of 2021.
- Revenues totaled €53.2 million in the first quarter of 2022, 4% more than in the year-ago quarter (€51.3 million)
- Royalties from sales of Yondelis and Zepzelca by our partners in their respective territories amounted to €11.0 million, a 27% increase year-on-year.
- Operating cash flow amounted to €35.8 million in the first quarter of 2022 (vs. €14.4 million in 1Q21).
- The net cash balance amounted to €205.7 million, an increase of 23% on 2021 year-end (€167 million).
- In January, the Company collected USD25 million (€22.1 million) from Jazz Pharmaceuticals, the first commercial milestone payment for Zepzelca, which was earned in December 2021.
- Rating agency AXESOR maintains the company's BB+ long-term rating, with a stable outlook.

## Oncology

- PharmaMar organized an investor webinar with oncologists who are opinion leaders in small-cell lung cancer. The event was titled "Small Cell Lung Cancer: Today, until Tomorrow, US & EU".
- Life Science Alliance published a paper entitled "*Pre-clinical and randomized phase I studies of plitidepsin in adults hospitalized with COVID-19*" that reports on a trial of the in-vitro activity of plitidepsin against the main variants of SARS-CoV-2, including Omicron.

## Diagnostics

Market launch of qFlu A&B Full Typing, an in-vitro influenza typing diagnostic kit that detects Influenza A (H1N1pdm 2009 and H3N2) and Influenza B (Victoria lineage) using real-time RT-PCR.

## RNAi

- A second Phase III trial has commenced in the United States to assess the safety of *tivanisiran* in patients with dry eye disease.
- We inaugurated a 400-square-meter plant to produce oligonucleotides, the first of its type in Spain.

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## FIGURES TO MARCH 2022

	03/31/2022	03/31/2021	Var.
RECURRING REVENUE	45.942	43.084	7%
Oncology sales	33.560	33.200	1%
Diagnostics sales	1.378	1.213	14%
Royalties	11.004	8.671	27%
NON RECURRING REVENUE	7.244	8.177	-11%
License Agreements	7.194	8.140	-12%
Other	50	37	35%
TOTAL REVENUES	53.186	51.261	4%
(Thousand euro)			

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#### Group revenue:

**Recurring revenue**, i.e. net sales plus royalties from sales by partners, increased by 7% year-on-year to €45.9 million in the first quarter of 2022 (from €43.1 million in the year-ago quarter).

Net revenues in the oncology segment amounted to  $\leq 33.6$  million in the first quarter of 2022, up 1% on the year-ago quarter ( $\leq 33.2$  million). Net sales of Yondelis amounted to  $\leq 17.4$  million, down slightly from  $\leq 18.9$  million in the year-ago quarter, due to pricing pressure. Revenues from Zepzelca in Europe under the early access program were basically stable, amounting to  $\leq 8.7$  million, up 4% on the  $\leq 8.4$  million in the same period of 2021. Sales of Yondelis and Zepzelca raw materials to partners rose from  $\leq 5.9$  million in 1Q21 to  $\leq 7.4$  million in 1Q22 (+24%). Diagnostics revenues increased slightly in the first quarter to  $\leq 1.4$  million, from  $\leq 1.2$  million in the year-ago quarter, mainly as a result of the increase in COVID-19 test sales.

**Royalty** revenues amounted to €11.0 million in the first quarter of 2022, up from €8.7 million in the year-ago quarter (+27%). That figure includes royalties from Yondelis sales by our partners in the United States and Japan (€0.8 million) and from Zepzelca sales by our US partner Jazz Pharmaceuticals (€10.2 million in 1Q22). The latter figure is an internal estimate since the figures for sales by Jazz in that period were not available at the date of publishing this report.

**Non-recurring revenue**, from **out-licensing agreements**, amounted to  $\notin$ 7.1 million in 1Q22, compared with  $\notin$ 8.2 million in the yearago quarter. Those figures relate to the recognition, on the basis of progress with the contractual commitments, of amounts collected in 2020 as a result of the  $\notin$ 300 million licensing agreement for Zepzelca with Jazz Pharmaceuticals.

## R&D

Group **R&D** spending increased by 29% year-on-year to €19.0 million in the first quarter of 2022 (€14.7 million in the year-ago quarter).

Oncology spent €16.1 million on R&D in the period, including €5.3 million on clinical trials to develop plitidepsin (Aplidin) for the treatment of COVID-19, which are recognized in this segment. Expenditure directly on oncology in the period was due to progress with the Phase III trials with lurbinectedin, as well as progress in clinical trials of this molecule in combination with other agents and the conduct of the clinical trial with ecubectedin in solid tumors.

The RNAi segment increased R&D spending to €2.4 million in the period, reflecting progress with the first of two Phase III trials in the US with tivanisiran in dry eye disease associated with Sjögren's syndrome, and commencement of the safety trial associated with that Phase III trial, and the Phase I trial in Spain with SYL18001 in macular degeneration.

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

	03/31/22	03/31/21	Var.	
R&D expenses	19.028	14.703	4.325	29%
Oncology	16.089	12.972	3.117	24%
Diagnostics	528	241	287	119%
RNAi	2.411	1.490	921	62%
(Thousand euro)				

#### Other operating expenses

Other operating, commercial, administrative and corporate expenses amounted to €13.9 million in the first quarter of 2022, an increase of 7% year-on-year (€12.9 million).

# EBITDA

Group EBITDA amounted to €20.6 million in the first quarter of 2022 (€19.4 million in the year-ago quarter).

	03/31/22	03/31/21
Net result	21.975	24.181
Income tax	(1.352)	(2.302)
Net financial income	(1.609)	(3.773)
Depreciation and amortization	1.615	1.328
EBITDA	20.629	19.434

(Thousand euro)

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

The 6% increase in EBITDA to €20.6 million in 1Q22, from €19.4 million in 1Q21, is the result of higher operating result at March 2022 compared to March 2021.

## **Cash and Debt**

As of 31 March 2022, cash and cash equivalents plus current and non-current financial assets amounted to €249.3 million, a 17% increase on the year-ago quarter (€212.6 million), mainly because of the receipt this quarter of a milestone payment that was earnedin December 2021 under the Zepzelca licensing agreement with Jazz Pharmaceuticals.

In the first quarter of 2022, loans from banks and official agencies amounting to  $\notin$ 3.4 million were repaid and no new loans were arranged. Total interest-bearing debt was reduced by 4% ( $\notin$ 2 million) with respect to 2022 year-end.

The net cash balance increased by 23% with respect to the end of last year.

For the purpose of comparing balance sheet figures, the Group's total net financial position at amortized cost is detailed below:

03/31/2022	12/31/2021	Var.
31.417	33.386	-1.969
4.279	4.669	-390
16.668	16.654	14
10.470	12.063	-1.593
12.183	12.212	-29
4.065	3.745	320
2.966	3.864	-898
3.383	4.077	-694
1.769	526	1.243
43.600	45.598	-1.998
249.311	212.602	36.709
205.711	167.004	38.707
	31.417 4.279 16.668 10.470 12.183 4.065 2.966 3.383 1.769 43.600 249.311	31.417       33.386         4.279       4.669         16.668       16.654         10.470       12.063         12.183       12.212         4.065       3.745         2.966       3.864         3.383       4.077         1.769       526         43.600       45.598         249.311       212.602

(Thousand euro)

#### **RESEARCH AND DEVELOPMENT**

Below is an overview of research and development activities.

## 1.- Oncology segment: PharmaMar

## Compounds:

#### A) Trabectedin (YONDELIS)

#### Soft tissue sarcoma

There are currently 22 post-authorization trials under way, of which 7 are enrolling patients. The other trials are in the process of closing and data analysis or are pending the presentation of results. A new trial is currently in the activation phase and will commence shortly.

### **Ovarian cancer**

A total of 11 trials in this indication were being managed in the first quarter of 2022, of which eight are active and one is in the activation phase.

#### **B)** Lurbinectedin (ZEPZELCA)

#### Small-cell lung cancer

The LAGOON pivotal Phase III trial as second-line treatment for relapsed small cell lung cancer that was agreed upon with the FDA received the green light from the first ethics committee in the USA in December 2021. This is a three-arm trial comparing lurbinectedin as monotherapy or in combination with irinotecan against investigator's choice of irinotecan or topotecan. If the outcome is positive, the trial could serve in a confirmatory capacity for the USA, and could serve as a registration trial for territories outside the USA.

The Imforte Phase III trial conducted by our partner Jazz Pharmaceuticals to assess Zepzelca<sup>®</sup> in combination with a PD-L1 inhibitor for treating small cell lung cancer is enrolling satisfactorily. The trial, which is sponsored by Roche and co-financed by Jazz, will measure progression-free survival and overall survival with Zepzelca<sup>®</sup> in combination with atezolizumab as compared with atezolizumab as monotherapy. This collaborative research will provide information on a potentially novel first-line treatment option for small cell lung cancer.

A retrospective data collection study has been launched in France that will include patients who have received lurbinectedin as part of the "ATU nominative" (named-patient authorization) program, also called "French Early Access Program", to describe the clinical and demographic characteristics of these patients by assessing overall survival, real-world progression-free survival, etc. This study is being headed by Intergroupe Francophone de Cancérologie Thoracique and Groupe Français de Pneumo-Cancérologie, and the principal investigator is Professor Nicolas Girard of the Institut Curie (Paris).

## Combination trials with Zepzelca (lurbinectedin)

During the first quarter, recruitment continued on schedule for the Phase I trials with lurbinectedin in combination with irinotecan, pembrolizumab or atezolizumab.

Specifically, the combination trial with irinotecan is advancing in the expansion process in small cell lung cancer, synovial sarcoma and neuroendocrine tumors, as planned.

#### Phase I trial in China

The trial being conducted by our partner, Luye, to ascertain the dose of Zepzelca in Chinese patients ended patient enrolment and is currently in the monitoring phase.

## C) Ecubectedin (PM14)

The first Phase I/II trial with ecubected in attained the optimal dose in patients with advanced solid tumors. It is currently enrolling in the expansion of Phase II for certain tumors.

#### **Combination trials**

Recruitment for the Phase I/II trial with this compound in combination with irinotecan is progressing satisfactorily. The Phase Ib trial in combination with atezolizumab is also recruiting satisfactorily.

## D) Virology Unit: Plitidepsin (APLIDIN®)

## Ppitidepsin)

The NEPTUNE multicenter, randomized, controlled Phase III clinical trial to determine the efficacy and safety of two dosages of plitidepsin versus active control in adult patients requiring hospitalization for the treatment of moderate COVID-19 infection continues with patient enrolment in Europe and Latin America.

## **Extension of the APLICOV-PC Phase II trials**

During the first quarter of the year, PharmaMar commenced an extension trial in a cohort of adult patients infected with SARS-CoV-2 who required hospitalization and had been treated with plitidepsin in the APLICOV-PC trial, in order to assess the frequency of post-COVID-19 morbidity and characterize the sequelae profile in patients who participated in that trial. Enrolment for this trial has concluded and the clinical study report will be issued shortly.

# 2.- Diagnostics Genómica

Genómica ended 1Q22 with  $\pounds$ 1.4 million in net revenues ( $\pounds$ 1.2 million in the year-ago quarter). The increase was due to a year-on-year increase in sales of COVID-19 diagnostic tests ( $+\pounds$ 0.2 million), as well as higher sales of PneumoVir due to the launch of Fast CLART<sup>®</sup> PneumoVir and the spread of respiratory diseases ( $+\pounds$ 0.1 million). Both increases were partially offset by poorer performance in the international market ( $-\pounds$ 0.1 million) due to postponement of some orders to the second quarter.

Diagnostic sales in the domestic market amounted to  $\leq 1.1$  million in the first quarter of 2022 ( $\leq 0.9$  million in the year-ago quarter). The international market accounted for 12% of sales, with revenues amounting to  $\leq 173$  thousand in the quarter (down 33% on  $\leq 260$  thousand in the year-ago quarter).

## 3.- RNA interference: Sylentis

The Phase III trial with tivanisiran for treating dry eye disease associated with Sjögren's syndrome continued in the first quarter of 2022. The trial, which will enroll 200 patients, is being conducted at 31 hospitals in the USA. The primary endpoint is efficacy (signs and symptoms) and the secondary endpoint is safety.

In April, the first patient was enrolled in the USA in a new Phase III trial to assess the long-term safety of tivanisiran for treating the signs and symptoms of dry eye disease. This multicenter, randomized study will enroll approximately 300 patients with mild to severe dry eye disease. The primary endpoint is to evaluate the safety of tivanisiran when administered in the form of eye drops in both eyes once daily for one year. Efficacy (signs and symptoms) will also be assessed in those patients. The design of the long-term safety study has been cleared by the FDA and will be part of the marketing application, which will comprise three trials: the Phase III efficacy trial, which started in March 2021; the ongoing long-term safety study; and an longer-term efficacy confirmation trial.

The first Phase I trial with SYL1801 for treating and/or preventing choroid neovascularization, a common cause of retinal diseases such as age-related macular degeneration (AMD) and diabetic retinopathy, has concluded. It involved 36 healthy volunteers and was conducted at Hospital Universitario Ramón y Cajal in Madrid with two treatment intervals: a single ascending dose or multiple ascending doses for seven consecutive days. All doses of SYL1801 were administered as ophthalmic solution and were found to be safe and well tolerated during the trial.

Also in April, we inaugurated a 400-square-meter plant for producing oligonucleotides, the first in Spain, which will serve the needs of Sylentis and other pharmaceutical companies.

CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION	March 31, 2022	December,31 2021
(Thousand euro)		
ASSETS		
Non-current assets		
Property, plant and equipment	26,637	26,961
Investment property	845	845
Intangible assets	3,074	3,233
Right-of-use assets	4,002	3,644
Non-current financial assets	27,723	10,722
Deferred tax assets	26,598	27,750
	88,879	73,155
Current assets		
Inventories	15,733	10,535
Trade and other receivables	30,801	50,908
Financial assets at amortised cost	69,333	88,532
Other assets	21,027	31,907
Cash and cash equivalents	152,255	113,348
	289,149	295,230
TOTAL ASSETS	378,028	368,385

CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION	March 31, 2022	December,31 2021
(Thousand euro)	2022	2021
EQUITY		
Share capital	11,013	11,013
Share premium	71,278	71,278
Treasury shares	(21,989)	(25,679)
Revaluation reserves	20	19
Retained earnings and other reserves	141,479	121,287
Total capital and reserves attributable to equity holders of the parent company	201,801	177,918
TOTAL EQUITY	201,801	177,918
LIABILITIES	201,001	177,510
Non-current liabilities		
Borrowings	31,417	33,386
Lease liabilities	1,943	1,916
Non-current deferred income	62,031	68,634
Other non-current liabilities	188	186
	95,579	104,122
Current liabilities		
Trade and other payables	26,353	29,269
Borrowings	12,183	12,212
Lease liabilities	2,154	1,819
Outstanding remunerations	4,475	7,546
Current deferred income	28,755	29,667
Other current liabilities	6,728	5,832
	80,648	86,345
TOTAL LIABILITIES	176,227	190,467
TOTAL EQUITY AND LIABILITIES	378,028	368,385

CONDENSED CONSOLIDATED STATEMENTS OF PROFIT OR LOSS			
(Thousand euro)	March 31, 2021	March 31, 2022	
Revenue:			
Revenue from contracts with customers	34,938	34,413	
Revenue from licensing and development agreements	7,194	8,140	
Royalties	11,004	8,671	
Other	50	37	
	53,186	51,261	
Cost of sales	(3,789)	(5,932)	
Gross Result	49,397	45,329	
Marketing expenses	(6,019)	(5,474)	
General and administrative expenses	(5,183)	(4,868)	
Research and development expenses	(19,028)	(14,703)	
Net impairment on financial assets	(53)	97	
Other operating expenses Other results	(2,695)	(2,601) 326	
other results	2,595	520	
Operating Result	19,014	18,106	
Finance costs	(1,520)	(886)	
Finance income	3,129	4,659	
Finance costs - net	1,609	3,773	
Result of the period before income taxes	20,623	21,879	
Income tax benefit / (expense)	1,352	2,302	
Result for the period	21,975	24,181	

CONSOLIDATED CASH FLOW STATEMENT	EUR (Thousand)
	03/31/2022
TOTAL NET OPERATING CASH FLOW	35,818
Income before taxes Profit before tax from continuing operations	<b>20,623</b> 20,623
Adjustments for: Depreciation and amortization Impairment losses of property, plant and equipment Finance income Finance costs Results on disposals of tangible/intangible assets Share based payments Deferred income - grants	(11) 1,515 60 (90) 628 (13) 92 (56)
Effects of exchange rate changes Changes in working capital: Inventories Trade and other receivables Other assets and liabilities Trade and other accounts payable Deferred or accrual items	(2,148) <b>2,668</b> (5,197) 20,067 1,206 (5,949) (7,459)
Other cash flow from operations: Financial expenses Financial revenues Income tax (collections/payments)	<b>12,539</b> (628) 90 13,077
TOTAL NET INVESTING CASH FLOW Investment payments: Purchases of property, plant & equipment and intangible assets Disvestment receipts: Other financial assets	2,578 (511) (511) 3,089 3,089
TOTAL NET FINANCING CASH FLOW Collections and (payments) in connection with equity instruments: Acquisition Disposal Collections and (payments) in connection with financial liabilities: Refund and amortization IFRS16 Payment Other financing cash flow: Other financing receipts / (payments)	(752) 1,808 (8,661) 10,468 (3,925) (3,362) (563) 1,366 1,366
EFFECTS OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	1,263
TOTAL NET CASH FLOW	38,907
Beginning balance of cash and cash equivalents	113,348
ENDING BALANCE OF CASH AND CAHS EQUIVALENTS	152,255