



## REPORT AT 30 SEPTEMBER 2007

*Madrid, 25 October 2007*

### **PharmaMar:**

- The European Commission authorised the sale of Yondelis® in the European Union for the treatment of soft-tissue sarcoma.
- Pharma Mar made its first commercial sales of Yondelis®.

### **Group:**

- R&D expenditure totalled 36 million euro
- The net cash position (cash + cash equivalents + current financial assets - short-term borrowings) amounted to 56.5 million euro.
- Group revenues amounted to 66.9 million euro (4.2% more than in the same period of 2006).

M<sup>a</sup> Luisa de Francia  
CFO  
ZELTIA, S.A.

José Abascal, 2. Madrid  
Telephone 91.444.45.00

## 1. KEY AGGREGATES

<i>Thousand euro</i>	30 Sep. 2007	30 Sep. 2008	CHANGE (%)
Revenue	66,931	64,260	+ 4.2
Investment in R&D	35,909	36,852	-2.6
Marketing expenses	22,204	19,407	+ 14.4
General, administration and other operating expenses	14,047	15,529	- 9.5
Net income attributable to the parent company	-32,341	-32,559	+ 0.7
Cash and cash equivalents plus current financial assets	86,273	83,453	
Current debt	29,818	37,814	
Non-current debt*	56,052	43,631	
<i>*Approximately 47% of non-current debt is interest-free.</i>			

- Group net revenues totalled 66.9 million euro in 9M07, 4.2% more than in the same period of 2006 (64.3 million euro). Revenues at the consumer chemicals subsidiaries totalled 60.8 million euro (59.5 million euro in 2006) and accounted for 91% of total Group revenues in 9M07 (95% in 2006). Revenues in the Biotechnology business totalled 5.7 million euro in 9M07.
- R&D expenditure amounted to 35.9 million euro. PharmaMar accounted for 25.6 million euro of R&D expenditure, and Neuropharma for 9.3 million euro. The slight decline with respect to September 2006 (-2.6%) is due to completion of recruitment for some of PharmaMar's largest clinical trials. New trials will commence in the fourth quarter. The favourable euro/dollar exchange rate meant that product development in US dollars was cheaper in euro terms; this includes clinical trials and pre-clinical research conducted in the US (PharmaMar USA).
 

As a result of applying International Financial Reporting Standards (IFRS), R&D expenditure must be considered as an expense in the year instead of an asset. Therefore, higher R&D expenditure means a larger expense in the income statement, i.e. greater losses.
- Marketing and commercial expenses amounted to 22.2 million euro in 9M07, up 14.4% with respect to 2006. The Consumer Chemicals companies accounted for 18.2 million euro (17.1 million euro in 2006) as they stepped up marketing and advertising campaigns to support new brands and product lines.
- The net cash position at 30 September 2007, defined as cash and cash equivalents, plus current financial assets (86.3 million euro) minus short-term financial debt (29.8 million euro), totalled 56.5 million euro. Long-term debt amounted to 56 million euro, of which 29.5 million euro was bank debt

and 26.5 million euro was in the form of research and development loans from official bodies which are repayable over 10 years, interest free, with a three-year repayment holiday.

<b>Cash and cash equivalents + current financial investments</b>	<b>86,273</b>
<b>Short-term interest-bearing debt</b>	<b>29,818</b>
<b>Long-term interest-bearing debt</b>	<b>56,052</b>
. Credit institutions	29,530
. Government agencies: R&D funding	26,522

*Thousand euro*

## BUSINESS PERFORMANCE.

Below is an overview of the group companies' business performance in the first three quarters of 2007.

### Consumer chemicals:

#### Xylazel

Third-quarter sales were affected by construction industry performance (saturation of the housing market and more restrictive mortgage lending conditions).

Xylazel's sales were 6.1% lower than in the same period of 2006, but the decline was unevenly distributed, since water-based paints and rust-proofing products increased sales by 3%-7%.

The increase in promotional activities in September led to sales in the month 3% higher than in 2006; the campaigns will continue in the remainder of the year and we are confident that this will maintain the upswing after a decline in previous months.

#### Zelnova:

This year, Zelnova has begun to obtain the synergy expected from the acquisition in May 2006 of Italian company Copyr, SpA.

In particular, Copyr increased sales by 19% with respect to the same period of 2006 (9.5 million euro, vs. 8 million euro) in all business lines, particularly in Home & Gardening (garden and household pesticides), where sales increased by 33% and are expected to maintain this trend in the future.

As a result of our presence in Italy, we have entered into commercial and cooperation agreements with Italian companies, including an agreement with a leading distributor to handle Zelnova's Kill-Paff and Coopermatic brands in Italy while Zelnova will distribute a line of sunscreen lotions in Spain.

Copyr SpA also signed a major agreement with a Spanish company to develop products for ecological agriculture based on natural pyrethrin. Copyr is one of the few companies in Europe in a position to obtain authorisation for formulations with natural pyrethrins.

Consolidated sales increased by 5.5% with respect to 2006, and all business lines expanded, particularly exports (+17.5%).

The table below shows the change in revenues in the various channels.

(Thousand euro)	2006	2007	Change
Own brands in Spain	31,705	32,794	+ 1,089 (+3.4%)
Retailer brands in Spain	5,253	5,578	+ 325 (+6.2%)
Exports	5,183	6,089	+ 906 (+17.5%)
Total net sales	42,141	44,461	+ 2,320 (+5.5%)

## Biotechnology:

### PharmaMar:

#### Yondelis

The European Commission authorised the sale of Yondelis® in the European Union for the treatment of **soft-tissue sarcoma**. The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) had issued a positive opinion on such authorisation two months previously. The EMA's positive opinion was based on the results of the STS-201 randomised comparative trial of previously-treated sarcoma, the largest of its type to date (270 patients). Yondelis® will be the first new drug for this therapeutic use to reach the market in three decades.

At the date of this report, commercial sales of Yondelis® had begun in Germany and the United Kingdom. Sales in those countries and the rest of Western Europe are covered by a sales network established for PharmaMar under an agreement with Innovex (Quintiles Group), which handles promotion and marketing of the drug. UK company IDIS Ltd. has been engaged to provide logistics services for Western Europe.

Regarding the use of Yondelis® for **ovarian cancer**, the pivotal Phase III trial in combination with liposomal doxorubicin (Caelyx/Doxil) completed recruitment in May when it attained a total of 672 patients; events are being monitored as planned. An application to market Yondelis® in combination with CAELYX/DOXIL for ovarian cancer in the USA and the European Union may be presented in 2008.

As for the use of Yondelis® to treat **breast cancer**, the stratified Phase II clinical trial on patients with metastatic breast cancer, chosen on the basis of the tumor's pharmacogenomic characteristics, has commenced recruitment at over 20 hospitals in the USA. If the initial results are positive, the study will continue as a pivotal trial and will include up to 321 patients.

The European Cancer Organisation (**ECCO**) conference in Barcelona on 23-27 September included a satellite symposium entitled *Improving therapeutic results in soft-tissue sarcoma: Can we do more?*, which was attended by over 200 oncologists; the symposium discussed Yondelis's contribution to the unmet medical needs arising with soft-tissue sarcoma.

#### Aplidin

Development of Aplidin® continues as monotherapy on adult and paediatric patients with solid and/or haematological tumours. Over 600 patients have been treated to date.

At the same time, progress is being made with pre-clinical and clinical trials of Aplidin® in combination with other chemotherapies.

Development plans for Aplidin® as monotherapy against neuroblastoma have been completed following a meeting with the European Medicines Agency (EMA), which provided scientific advice on preparing the study.

## **Kahalalide F**

Patient recruitment has concluded for the three Phase II studies to assess Kahalalide F's efficacy and safety profile on patients with solid tumours, hepatocellular carcinoma, advanced malignant melanoma and non-small-cell lung cancer. The results are currently being analysed to decide on the strategy to be applied in the future.

In parallel to the oncology studies, recruitment continued for the controlled pilot Phase II study to assess the efficacy and safety of Kahalalide F on patients with severe psoriasis. The data are currently being evaluated.

## **Zalypsis**

There are currently four Phase I trials under way with ZALYPSIS® on patients with advanced solid tumours and lymphoma.

Eight hospitals in Europe and the USA are working with PharmaMar on the clinical development of ZALYPSIS®, and all trials are proceeding as planned, in order to establish the maximum tolerated dose, the recommended dose and the product safety profile for each administration protocol under assessment.

## **PM02734**

The Phase I programme for PM02734 comprises two clinical trials, in the US, Spain and the United Kingdom. These trials are assessing various administration schedules and are designed to determine safety and tolerability and to identify the maximum tolerated dose (MTD) and recommended dose (RD) of PM02734 administered to patients with advanced malignant solid tumours.

Recruiting continues on schedule in both these trials.

## **NeuroPharma**

### **NP-12**

In July, the German authorities (BfArM) approved a clinical trial involving the repeated administration of NP-12 in increasing doses to healthy volunteers. The trial commenced in August at CRO Parexel's Berlin unit. The study is proceeding and the data gathering phase is expected to be completed in late October.

This trial explores the safety and pharmacokinetics of NP-12 in elderly patients receiving repeat doses of the compound over several days. Information is also being collected about a number of proteomic and genomic markers of the compound's activity for possible use in future trials.

Preparatory work continues for the first Phase II trial in which NP-12 will be administered to Alzheimer patients for the first time. A CRO has been chosen to assist Neuropharma in conducting this trial, and implementation of the protocol will commence shortly.

### **NP-61**

In view of the good tolerance of NP-61 observed in the first Phase I trial (which commenced in April), CRO MDS's clinical pharmacology unit in Belfast is testing it on additional groups of young and

elderly subjects to better explore the dosage range. The first bioanalytical and pharmacokinetic tests have been performed and the studies of activity markers are about to conclude.

### **Other candidates**

Work is proceeding on the search for candidates for clinical development, including notably:

A GSK-3 inhibitor obtained from a programme of analogues of one of the marine prototypes identified by our internal biological screening process.

A powerful neuroprotective agent in cell cultures, obtained from a programme of analogues of a metabolite isolated from marine micro-organisms.

A very selective inhibitor of butyrylcholinesterase (BuChE), obtained in cooperation with a group from Florence University.

A decision about future development of these compounds will be made in the next quarter and priorities will be established based on the preliminary results.

### **Genómica:**

At 30 September, CLINICAL ARRAYS® HPV (for detecting and typing Human Papillomavirus) had established itself as the company's star product, accounting for 58% of its total sales, which amounted to 2.5 million euro (1.6 million euro in 9M06). Sixty-six percent of total sales of CLINICAL ARRAY® kits were in Spain (up 38% on 9M06), and 34% were exported; the kit has been highly successful in export markets, since exports accounted for just 8% of CLINICAL ARRAYS® HPV kit sales in 9M06.

CLINICAL ARRAYS® PneumoVir (an in vitro clinical diagnosis kit capable of detecting, in one pass, a range of viruses that cause respiratory infections) was launched in June. To date, a number of demos have been given at laboratories in Spain and other countries in preparation from the winter, when respiratory infections tend to flare up. The response to date suggests that the product will perform well in the market.

Sales of traditional kits are proceeding as expected.

<b>BALANCE SHEET</b> <i>(Thousand euro)</i>	30 Sept 07	31 Dec 06
<b>ASSETS</b>		
<b>Non-current assets</b>	<b>85.137</b>	<b>86.392</b>
Property, plant & equipment	39.684	41.463
Investment properties	8.350	8.350
Intangible assets	10.792	10.823
Deferred tax assets	21.602	21.953
Long-term financial assets	2.161	1.255
Goodwill	2.548	2.548
<b>Current assets</b>	<b>140.627</b>	<b>138.013</b>
Inventories	13.322	10.779
Customer and other receivables	32.689	22.292
Current financial assets	70.355	46.531
Other current assets	8.343	4.472
Cash & cash equivalents	15.918	53.939
<b>TOTAL ASSETS</b>	<b>225.764</b>	<b>224.405</b>

<b>BALANCE SHEET</b> <i>(Thousand euro)</i>	30 Sept 07	31 Dec 06
<b>EQUITY</b>		
<b>Shareholders' equity</b>	<b>93.063</b>	<b>98.494</b>
Share capital	11.000	10.785
Share premium	309.270	283.980
Treasury shares	-24.807	-26.388
Revaluation and other reserves	-21	-84
Retained earnings and other reserves	-202.379	-169.799
<b>Minority interest</b>	<b>4.779</b>	<b>8.678</b>
<b>TOTAL EQUITY</b>	<b>97.842</b>	<b>107.172</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>	<b>60.944</b>	<b>48.010</b>
Financial debt	56.052	42.998
Derivatives	19	0
Deferred tax liabilities	3.994	4.070
Non-current deferred revenues	501	586
Other non-current liabilities	378	356
<b>Current liabilities</b>	<b>66.978</b>	<b>69.223</b>
Supplier and other accounts payables	23.688	18.530
Financial debt	29.818	40.719
Provisions for other liabilities & expenses	5.154	4.593
Current deferred revenues	3.464	3.451
Other current liabilities	4.854	1.930
<b>TOTAL LIABILITIES</b>	<b>127.922</b>	<b>117.233</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>225.764</b>	<b>224.405</b>

<b>INCOME STATEMENT</b>			
<i>Thousand euro</i>	<b>30 Sept 07</b>	<b>30 Sept 06</b>	<b>Chg. (%)</b>
Net revenues	66.931	64.260	4,2%
Cost of sales	-30.168	-28.202	7,0%
<b>Gross income</b>	<b>36.763</b>	<b>36.058</b>	<b>2,0%</b>
General and administration expenses	-8.711	-11.440	-23,9%
Research & development expenses	-35.909	-36.852	-2,6%
Marketing & commercial organisation expenses	-22.204	-19.407	14,4%
Other operating expenses	-5.336	-4.089	30,5%
Other operating revenues	4.528	7.211	-37,2%
Other revenues and (expenses)	27	76	-64,5%
Depreciation, amortisation and provisions	-4.393	-4.573	-3,9%
<b>Net operating profit (loss) (EBIT)</b>	<b>-35.235</b>	<b>-33.016</b>	<b>6,7%</b>
Net financial results	-961	-290	231,4%
<b>Loss before taxes</b>	<b>-36.196</b>	<b>-33.306</b>	<b>8,7%</b>
Corporate income tax in the period	0	0	
<b>Loss for the year</b>	<b>-36.196</b>	<b>-33.306</b>	<b>8,7%</b>
<b>Attributable to minority interest</b>	<b>3.855</b>	<b>747</b>	<b>416,1%</b>
<b>Attributable to equity holders of the parent</b>	<b>-32.341</b>	<b>-32.559</b>	<b>-0,7%</b>

<b>CASH FLOW at 30 June 2007</b>	
<i>Thousand euro</i>	
<b>Period loss</b>	<b>-32.341</b>
Adjustments to period loss	7.457
Change in working capital	-11.811
<b>CASH FLOW FROM ORDINARY ACTIVITIES</b>	<b>-36.695</b>
Acquisitions of property, plant & equipment	-2.665
Disposals of property, plant & equipment	0
<b>CASH FLOW FROM INVESTMENTS</b>	<b>-2.665</b>
(Cancellation)/Granting of long term loans	10.851
Capital increase (net)	26.301
Reduction of share premium	-1.089
<b>CASH FLOW FROM FINANCING</b>	<b>36.064</b>
<b>TOTAL NET CASH FLOW IN THE PERIOD</b>	<b>-3.296</b>
OPENING BALANCE (1/1/2007)*	59.751
CLOSING BALANCE (30/09/2007)*	56.455
Net (decrease)/increase in cash	-3.296

(\*) Calculated as current financial assets + cash & cash equivalents - current financial debt)