

## Pharming Group NV Interim Report January - September 2015

**Leiden, The Netherlands, 28 October 2015**, Biotech company Pharming Group N.V. (“Pharming” or “the Company”) (Euronext Amsterdam: PHARM) presents its (unaudited) financial report for the first nine months ended 30 September 2015.

### SUMMARY OF OPERATIONAL HIGHLIGHTS DURING AND AFTER THE THIRD QUARTER 2015

- Prescriptions of RUCONEST® in the US rise by 29% between Q2 and Q3 2015
- FDA grants RUCONEST® extended data exclusivity from 2021 to 2026 for added protection from biosimilar competition
- HAEi Global Access Program for RUCONEST® goes live
- Straight debt non-dilutive financing of €15.6 million secured from Oxford Finance LLC and Silicon Valley Bank
- Robin Wright proposed for election as CFO

### CEO’s Commentary

We are very pleased with the increasing revenues this year; during the third quarter, the number of prescriptions for our lead product RUCONEST® increased by 29%, which indicates more patients are using RUCONEST® to deal with their Hereditary Angioedema (HAE) attacks. We expect to see the effect of this increase in prescriptions continuing through the fourth quarter. The acquisition of our US partner Salix by Valeant Pharmaceuticals International (Valeant) in the first half of 2015 has led to a revision in the way RUCONEST® is being marketed in the US. Valeant is concentrating sales effort on larger HAE clinics, which deal with significant numbers of patients with acute HAE attacks, the indication for which RUCONEST® is approved.

In July, we completed a straight debt financing of \$17 million (€15.6 million) with Oxford Finance and Silicon Valley Bank. This non-dilutive financing is a milestone for us as it reflects recognition of the strengthening cash flows from sales and license deals in the company and allows us to secure working capital for our growing sales activity without calling on shareholders for their support.

Also in July, we went live with the “HAEi GAP” (the Hereditary Angioedema International Patient Organization’s Global Access Program) in collaboration with Clinigen Group PLC, to provide patients with access to RUCONEST® in countries where the drug is not yet commercial available. On behalf of their patients, physicians may request RUCONEST® through an ethically and regulation-compliant “Named Patient Program” mechanism. The first requests under this program have already been received by Clinigen.

In September, we proposed Robin Wright as our new Chief Financial Officer (CFO) and statutory director. Robin is a Fellow of the Institute of Chartered Accountants in England & Wales, he has a strong background in finance and investor relations as well as business development and licensing. He has extensive senior level experience as a CFO of public companies in both the pharmaceutical and biotechnology industries. Robin’s experience, both as an operational CFO for public companies

# PHARMING

and as a former investment banker brings important additional strengths, experience and perspectives to our Board of Management and we look forward to confirming his appointment in the EGM later today.

In addition, we have stepped up our research and development activities. We have two ongoing studies: A randomised, double-blind placebo controlled Phase II study for RUCONEST® in prophylaxis of HAE, and a Phase II pediatric study for treatment of HAE in young children (2-13 years of age), progressing during the quarter. These studies are expected to finish during the first half of 2016. We have also begun work on new programs for Pompe and Fabry disease with leads for relevant protein therapeutic molecules through our rabbit founder technology platform. We will provide more details on these new programs once we have preliminary data and clarity on the development pathways and expected timelines.

After the quarter end, we received notification from the U.S. Food and Drug Administration (FDA) that they have granted RUCONEST® extended data exclusivity (from 7 years to 12 years), which means that no bio-similar version of RUCONEST® can be approved in the US before July 2026. This should enable us to develop our current pipeline of products to full commercialisation before revenues from RUCONEST® come under generic competition.

Sijmen De Vries  
Chief Executive Officer

## FINANCIAL SUMMARY

<i>Amounts in €m</i>	<i>2015 July-Sept</i>	<i>2014 July-Sept</i>	<i>2015 Jan-Sept</i>	<i>2014 Jan-Sept</i>	<i>% increase</i>
<b><i>Income Statement</i></b>					
Revenue	3.3	1.3	8.5	3.8	123%
Gross Profit	1.9	0.1	4.8	1.2	300%
Operating Result	(3.0)	(4.3)	(9.1)	(9.7)	6%
<b><i>Balance Sheet</i></b>					
Cash & marketable securities			34.9	23.6	
<b><i>Share Information</i></b>					
Earnings per share before dilution (€)			(0.014)	(0.046)	
Earnings per share after dilution (€)			(0.012)	(0.040)	

## FINANCIAL HIGHLIGHTS

### Revenues

Revenues increased in the first nine months of 2015 to €8.5 million from €3.8 million in 2014, an increase of 123%, as a result of considerably increased product sales of €6.8 million compared to €2.2 million in 2014. RUCONEST® sales in the U.S. amounted to €5.1 million and sales in the EU amounted to €1.6 million.

Other license fee income amounted to €1.7 million, which was in line with 2014. This license fee income reflects the release of accrued deferred license fees following receipt of €21.0 million upfront and milestone payments in 2010 and 2013 from SOBI, Salix and SIPI.

# PHARMING

---

Cost of product sales in the first nine months of 2015 amounted to €3.9 million (2015: €2.2 million). In the first nine months of the year, the Company incurred a net release of inventory impairments (€0.15 million), related to reallocation of inventories to the different markets with different prices, based on sales forecasts by management, commercial partners and clinical programs. Actual sales can differ from these forecasts.

## **Gross profit**

Gross profit increased by €3.6 million to €4.8 million in the first nine months of 2015, an increase of 300%, mainly as a result of an improving “product mix” from sales in the US by our partner Valeant, direct commercialization by Pharming in Austria, Germany and the Netherlands and a gain due to a net release of impairments of inventories.

## **Operating costs**

Operating costs increased to €13.9 million in 2015 from €10.9 million in 2014, an increase of 28%. Research and Development (R&D) costs increased by €1.2 million to €10.3 million in 2015, mainly due to costs for the new R&D site in France, increased R&D activities in the Netherlands and increased costs for clinical studies. General and Administrative costs increased to €2.7 million from €1.8 million in 2014, mainly as a result of increased (non-cash) share-based compensation and increased consultancy, training and recruitment costs. Marketing and Sales costs amounted to €0.9 million. These were costs for direct commercialization activities by Pharming in Germany, Austria, the Netherlands and other countries in the world (outside US and EU). In 2014, no direct commercialization of RUCONEST® took place. The inventories of RUCONEST® increased to €16.7 million from €13.4 million as per 31 December 2014 in preparation of expected sales and ahead of a planned temporary closing of the third party fill and finish production facilities in the last quarter of 2015, as a new operator takes over the site.

## **Operating result**

As a result of the increase in gross profit and despite the increase of operating costs due to increased investment in new programs, the operating loss of €9.1 million in 2015 was improved relative to last year’s loss (€9.7 million). This represents a 6% improvement.

## **Financial income and expenses**

The 2015 net gain on financial income and expenses was €3.2 million, compared to a €9.2 million net loss on financial income and expenses in the first nine months of 2014. The financial income and expenses reflected the (non-cash) revaluation of warrants, exchange rate effects on foreign currencies and interest payments on the new debt financing.

## **Net result**

As a result of the above items, the net loss decreased by €13.0 million to €5.9 million in the first nine months of 2015 (first nine months 2014: €18.9 million), an improvement of 69%. The net loss per share decreased by 70% to €0.014 (2014: €0.046).

## **FINANCIAL POSITION**

The cash position increased during the first nine months of 2015 as a result of the increased revenues and debt financing compensating for cash outflow from operating activities. Total cash and cash equivalents (including restricted cash) increased by €0.7 million from €34.4 million at the end of 2014 to €35.1 million at the end of September 2015. The increase follows from net cash outflows from operations of €13.0 million and investing activities of €0.8 million with net cash inflows from

financing activities amounting to €14.2 million, as a result of the new debt financing and positive exchange rate effects of €0.3 million.

## **EQUITY POSITION**

The Company's equity position amounted to €25.6 million at the end of September 2015 (31 December 2014: €29.8 million). In addition, it should be noted that the Company has a significant amount of deferred license fee income (September 2015: €10.6 million) regarding non-refundable license fees received in 2010 and 2013, which will be recognised in the statement of income over the term of the license agreements involved.

The number of outstanding shares as of 30 September 2015 was 408.3 million and the fully-diluted number of shares was 480.1 million.

## **OUTLOOK**

For the remainder of 2015, the Company expects:

- Increasing sales of RUCONEST® from US partner Valeant, EU partner SOBI and Israel partner Megapharm, the start of RUCONEST® sales through the HAEi Global Access Program and from the direct commercialisation of RUCONEST® in Austria, Germany and the Netherlands.
- Continued investments in building inventories of sufficient quantities of RUCONEST® to meet demand.
- Continuing investment in the Phase II clinical trial of RUCONEST® for Prophylaxis of HAE; these costs are shared 50/50 with US partner Valeant.
- Continuing investments in development of new pipeline projects.

No financial guidance for 2015 is provided.

## **The Board of Management**

Sijmen de Vries, CEO  
Bruno Giannetti, COO

## **ABOUT PHARMING GROUP N.V.**

Pharming Group N.V. is developing innovative products for the treatment of unmet medical needs. RUCONEST® (conestat alfa) is a recombinant human C1 esterase inhibitor approved for the treatment of angioedema attacks in patients with HAE in the US, Israel, all 28 EU countries plus Norway, Iceland and Liechtenstein. RUCONEST® is commercialised by Pharming in Austria, Germany and the Netherlands.

RUCONEST® is distributed by Swedish Orphan Biovitrum AB (publ) (SS: SOBI) in the other EU countries and in Azerbaijan, Belarus, Georgia, Iceland, Kazakhstan, Liechtenstein, Norway, Russia, Serbia and Ukraine.

# PHARMING

RUCONEST® is partnered with Valeant Pharmaceuticals International, Inc. (NYSE: VRX/TSX: VRX), through its subsidiary Salix Pharmaceuticals, Ltd. in North America.

RUCONEST is also being investigated in a randomized Phase II clinical trial for prophylaxis of HAE and in a Phase II clinical trial for the treatment of HAE in young children (2-13 years of age). RUCONEST® is also being evaluated for various additional follow-on indications unrelated to HAE.

Pharming has a unique GMP-compliant, validated platform for the production of recombinant human proteins that has proven capable of producing industrial volumes of high quality recombinant human protein in a more economical way compared to current cell-based technologies. Leads for Enzyme Replacement Therapy (ERT) in Pompe and Fabry's diseases are under early evaluation. The platform is partnered with Shanghai Institute of Pharmaceutical Industry (SIPI), a Sinopharm Company, for joint global development of new products. Pre-clinical development and manufacturing will take place at SIPI and are funded by SIPI. Pharming and SIPI initially plan to utilise this platform for the development of recombinant human Factor VIII for the treatment of Haemophilia A.

Additional information is available on the Pharming website: [www.pharming.com](http://www.pharming.com).

## Forward-looking statements

*This press release may contain forward-looking statements including without limitation those regarding Pharming's (the "Company") financial projections, market expectations, developments, partnerships, plans, strategies and capital expenditures.*

*The Company cautions that such forward-looking statements may involve certain risks and uncertainties, and actual results may differ. Risks and uncertainties include without limitation the effect of competitive, political and (macro) economic factors, legal claims, the Company's ability to protect intellectual property, fluctuations in exchange and interest rates, changes in tax rates, changes in legislation and the Company's ability to identify, develop and successfully commercialize new products, markets or technologies.*

*As a result, the Company's actual performance, position and financial results may differ materially from the plans, goals and expectations set forth in such forward-looking statements. The Company assumes no obligation to update any forward-looking statements or information, which speak as of their respective dates, unless required by law or regulations.*

## Contact

Sijmen de Vries, CEO: T: +31 71 524 7400

FTI Consulting

Julia Phillips/ Victoria Foster Mitchell, T: +44 203 727 1136

## Conference call information

Today, Chief Executive Officer Sijmen de Vries will discuss the 3rd quarter results in a conference call at 9:30am (CET). To participate, please call one of the following numbers 10 minutes prior to the call:

From the Netherlands: +31 (0) 20 721 9158

From the UK: +44 (0) 20 3450 9987

From Belgium: +32 (0) 2 400 3463

From France: +33 (0) 1 76 77 22 24

From Germany: +49 (0) 69 2222 10621

From Switzerland: +41 (0) 22 592 7641

**Conference ID: 4212850**

**PHARMING GROUP N.V.**

**CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (UNAUDITED)**

**For the first nine months ended 30 September 2015**

Consolidated Statement of Income

Consolidated Statement of Comprehensive Income

Consolidated Balance Sheet

Consolidated Statement of Cash Flows

## CONSOLIDATED STATEMENT OF INCOME For the first nine months ended 30 September

Amounts in €'000, except per share data

	Jan - Sep 2015	Jan - Sep 2014
Product sales	6,829	2,193
License fees	1,655	1,650
<b>Revenues</b>	<b>8,484</b>	<b>3,843</b>
Costs of product sales	(3,882)	(2,189)
Inventory impairments	150	(474)
<b>Costs of sales</b>	<b>(3,732)</b>	<b>(2,663)</b>
<b>Gross profit</b>	<b>4,752</b>	<b>1,180</b>
<b>Other income</b>	<b>106</b>	<b>92</b>
Research and development	(10,315)	(9,165)
General and administrative	(2,747)	(1,770)
Marketing and sales	(867)	-
<b>Costs</b>	<b>(13,929)</b>	<b>(10,935)</b>
<b>Operating result</b>	<b>(9,070)</b>	<b>(9,663)</b>
<b>Financial income and expenses</b>	<b>3,171</b>	<b>(9,208)</b>
<b>Result before income tax</b>	<b>(5,899)</b>	<b>(18,871)</b>
Income tax expense	-	-
<b>Net result for the year from continuing operations</b>	<b>(5,899)</b>	<b>(18,871)</b>
Net result for the year from discontinued operations	-	-
<b>Net result for the year</b>	<b>(5,899)</b>	<b>(18,871)</b>
<b>Attributable to:</b>		
Owners of the parent	(5,899)	(18,871)
Non-controlling interests	-	-
<b>Total net result</b>	<b>(5,899)</b>	<b>(18,871)</b>
Basic earnings per share (€) from continuing operations	(0.014)	(0.046)

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME For the first nine months ended 30 September

Amounts in €'000

	Jan - Sep 2015	Jan - Sep 2014
<b>Net result for the year</b>	<b>(5,899)</b>	<b>(18,871)</b>
Currency translation differences	6	-
<b>Items that may be subsequently reclassified to profit or loss</b>	-	-
<b>Other comprehensive income, net of tax</b>	-	-
<b>Total comprehensive income for the year</b>	<b>(5,893)</b>	<b>(18,871)</b>
<b>Attributable to:</b>		
Owners of the parent	(5,893)	(18,871)
Non-controlling interests	-	-

## CONSOLIDATED BALANCE SHEET

As at date shown

Amounts in €'000

	30 September 2015	31 December 2014
Intangible assets	737	777
Property, plant and equipment	5,561	5,598
Restricted cash	200	200
<b>Non-current assets</b>	<b>6,498</b>	<b>6,575</b>
Inventories	16,676	13,404
Trade and other receivables	4,134	1,554
Cash and cash equivalents	34,852	34,185
<b>Current assets</b>	<b>55,662</b>	<b>49,143</b>
<b>Total assets</b>	<b>62,160</b>	<b>55,718</b>
Share capital	4,083	4,077
Share premium	281,841	282,260
Other reserves	42	36
Accumulated deficit	(260,389)	(256,530)
<b>Shareholders' equity</b>	<b>25,577</b>	<b>29,843</b>
Loans	13,479	-
Deferred license fees income	8,360	10,022
Finance lease liabilities	836	965
Other liabilities	-	15
<b>Non-current liabilities</b>	<b>22,675</b>	<b>11,002</b>
Deferred license fees income	2,207	2,200
Derivative financial liabilities	1,704	4,266
Trade and other payables	7,980	7,781
Loans	1,822	-
Finance lease liabilities	195	626
<b>Current liabilities</b>	<b>13,908</b>	<b>14,873</b>
<b>Total equity and liabilities</b>	<b>62,160</b>	<b>55,718</b>

## CONSOLIDATED STATEMENT OF CASH FLOWS For the first nine months ended 30 September

Amounts in €'000

	Jan - Sep 2015	Jan - Sep 2014
Receipts from license partners, including product sales	5,956	1,651
Receipt of Value Added Tax	964	712
Interest received	117	136
Other receipts	19	283
Payments of third party fees and expenses, including Value Added Tax	(7,327)	(5,471)
Payments of manufacturing expenses	(8,024)	(7,684)
Net compensation paid to (former) board members and (former) employees	(2,752)	(1,707)
Payments of pension premiums, payroll taxes and social securities, net of grants settled	(1,909)	(1,604)
<b>Net cash flows from operating activities</b>	<b>(12,956)</b>	<b>(13,684)</b>
Purchases of property, plant and equipment	(800)	-
Acquisition of business	-	(500)
<b>Net cash flows from investing activities</b>	<b>(800)</b>	<b>(500)</b>
Proceeds of equity and warrants issued	-	19,375
Proceeds of debt capital	15,524	-
Payments of transaction fees and expenses	(608)	(697)
Payments of finance lease liabilities	(658)	(139)
Payments of debt capital	(89)	-
<b>Net cash flows from financing activities</b>	<b>14,169</b>	<b>18,539</b>
<b>Increase/(decrease) of cash</b>	<b>413</b>	<b>4,355</b>
Exchange rate effects	254	301
Cash and cash equivalents at 1 January	34,385	19,152
<b>Total cash at 30 September</b>	<b>35,052</b>	<b>23,808</b>
Of which restricted cash	200	176
<b>Cash and cash equivalents at 30 September</b>	<b>34,852</b>	<b>23,632</b>