Pharming Group NV

Netherlands / Biotechnology
Primary exchange: Euronext Amsterdam / Secondary exchange: Frankfurt
Bloomberg: PHARM NA
ISIN: NL0010391025

Q2 results/phase II HAE prophylaxis trial

RATING	**BUY**
PRICE TARGET	**€1.00**
Return Potential	354.5%
Risk Rating	High

US SALES PICK UP/EXCELLENT PHASE II PROPHYLAXIS RESULTS

Q2 delivered the expected sequential improvement in US Ruconest sales. Just as importantly, preliminary results of the phase II clinical trial of Ruconest for prophylaxis of HAE published on 18 July were excellent. Ruconest showed a clinically and statistically significant reduction in attack frequency both in twice weekly and once weekly dosing. The primary efficacy endpoint was the number of HAE attacks per 28 day treatment period. Patients on placebo had a mean of 7.2 attacks per four week treatment period which was reduced to a mean of 2.7 attacks on Ruconest twice weekly and a mean of 4.4 attacks on Ruconest once weekly. The secondary endpoint was clinical response, defined as a ≥ 50% reduction in the number of attacks from treatment with placebo to treatment with Ruconest. In the per-protocol population of patients, which included patients who completed the study without any major deviations (n=23), 96% of patients on twice weekly Ruconest and 57% of patients on once weekly Ruconest had at least a 50% reduction in their attack frequency. We expect Pharming to announce next steps later in H2 following consultation with the FDA and EMA. In our view, first revenues from Ruconest in the indication HAE prophylaxis are realistic well before the end of this decade. The US market for prophylaxis of HAE is expected to be worth USD700m in 2017 (up from USD500m in 2014). The only product currently approved for HAE prophylaxis in the US is Shire's Cinryze. If Ruconest is approved for HAE prophylaxis in the US, it will be the only product approved for both acute attacks and prophylaxis. The availability of one product for both indications has the potential to simplify management of the disease. We maintain our Buy recommendation and price target of €1.00.

Q2 results in line with our expectations Pharming's Q2 results were close to our forecasts. The most important number in the report - US sales of Ruconest - came in at €2.0m (Q2/15: €2.4m) and exactly matched our projection. (p.t.o).

FINANCIAL HISTORY & PROJECTIONS

	2011	2012	2013	2014	2015	2016E
Revenue (€m)	3.00	10.61	6.84	21.19	10.83	12.86
Y-o-y growth	423.4%	253.7%	-35.5%	209.6%	-48.9%	18.8%
EBIT (€m)	-18.50	-17.46	-6.91	2.88	-12.83	-12.25
EBIT margin	-6.2%	-164.6%	-101.0%	13.6%	-118.5%	-95.2%
Net income (€m)	-17.20	-24.09	-15.06	-5.77	-9.96	-13.21
EPS (diluted) (€)	-0.36	-0.33	-0.07	-0.02	-0.02	-0.03
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-18.03	-10.16	-8.05	-3.23	-17.32	-16.02
Net gearing	n.a.	n.a.	-302.8%	-109.9%	-67.0%	0.4%
Liquid assets (€m)	3.78	5.27	16.97	34.19	31.64	13.65

RISKS

The main risks to our price target include slower sales growth for Ruconest in the EU and the US than we currently model.

COMPANY PROFILE

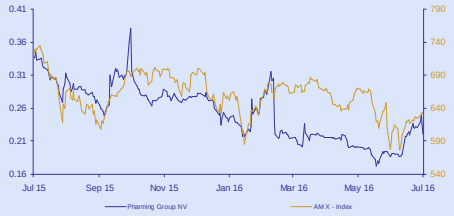
Pharming develops and produces therapeutic proteins from the milk of genetically modified rabbits. Pharming and Chinese SIPI signed a collaboration agreement in 2013, which will accelerate the addition of new projects to the firm's R&D pipeline. Lead drug Ruconest received EMA approval in 2010 and FDA approval in July 2014.

MARKET DATA

As of 28 Jul 2016	
Closing Price	€ 0.22
Shares outstanding	412.56m
Market Capitalisation	€ 90.76m
52-week Range	€ 0.17 / 0.38
Avg. Volume (12 Months)	2,845,087

Multiples	**2014**	**2015**	**2016E**
P/E	n.a.	n.a.	n.a.
EV/Sales	4.0	7.8	6.6
EV/EBIT	29.5	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Jun 2016	
Liquid Assets	€ 21.41m
Current Assets	€ 46.33m
Intangible Assets	€ 0.70m
Total Assets	€ 53.67m
Current Liabilities	€ 18.46m
Shareholders' Equity	€ 18.16m

SHAREHOLDERS

Kingdon Capital Management LLC	3.1%
Free Float	96.9%

Analyst: Simon Scholes, Tel. +49 (0)30 - 80 93 96 94

The US Q2/16 sales number was 16.7% below the prior year figure, which benefited from inventory building soon after the product's approval in November 2014. However, it was well above Q1/16 sales of €1.5m which suffered from the reorganisation of US partner Valeant's sales force. Sales of Ruconest outside the US were flat at €0.5m but above the €0.2m recorded during Q1/16 in which Pharming made no sales to its EMEA partner, Sobi. Overall revenues fell 11.4% to €3.1m (Q2/15: €3.5m) due to the lower US Ruconest sales figure.

Gross margin rises in Q2/16 due to a favourable shift in the sales mix Gross profit before inventory impairments was flat at €1.9m but the margin climbed from 55.2% to 62.8% due to a shift in the sales mix away from indirect sales by Sobi in EMEA towards US product sales and direct sales by Pharming in Germany, Austria and the Netherlands. Despite a negative €400k swing in inventory impairments, EBIT was also flat in Q2 at €-3.0m due to lower R&D costs (€3.3m vs. €3.9m). The six months numbers however showed a rise in R&D costs to €7.0m (H1/15: €6.6m) due to expansion of the R&D site in France and increased R&D activities in the Netherlands. Net profit fell by €1.1m to €-3.3m (Q2/15: €-2.2m) because of a €0.9m decline in gains on revaluation of warrants and a €0.2m fall in net interest.

Excellent preliminary results from phase II prophylaxis trial Preliminary results of the phase II clinical trial of Ruconest for prophylaxis of HAE published on 18 July were excellent. Ruconest showed a clinically and statistically significant reduction in attack frequency both in twice weekly and once weekly dosing. The primary efficacy endpoint was the number of HAE attacks per 28 day treatment period. Patients on placebo had a mean of 7.2 attacks per four week treatment period which was reduced to a mean of 2.7 attacks on Ruconest twice weekly and a mean of 4.4 attacks on Ruconest once weekly. The secondary endpoint was clinical response, defined as a ≥ 50% reduction in the number of attacks from treatment with placebo to treatment with Ruconest. In the per-protocol population of patients, which included patients who completed the study without any major deviations (n=23), 96% of patients on twice weekly Ruconest and 57% of patients on once weekly Ruconest had at least a 50% reduction in their attack frequency.

Value of US HAE prophylaxis market projected to reach USD700m in 2017 Management tell us that the final report on the phase II prophylaxis trial will be available during the next few weeks and that discussions with the FDA and EMA on further steps towards approval of Ruconest for prophylaxis of HAE will then begin. We expect Pharming to announce next steps later in H2. In our view, first revenues from Ruconest in the indication HAE prophylaxis are realistic well before the end of this decade. The US market for prophylaxis of HAE is expected to be worth USD700m in 2017 (up from USD500m in 2014). The only product currently approved for HAE prophylaxis in the US is Shire's Cinryze. If Ruconest is approved for HAE prophylaxis in the US, it will be the only product approved for both acute attacks and prophylaxis. The availability of one product for both indications has the potential to simplify management of the disease.

Progress in pipeline development Pharming continues to develop its pipeline to produce the next generation of therapies from its platform. In the Q2 report, management stated that the first program lead for Pompe disease has now reached the second stage of preclinical testing and that the second preclinical stage for Fabry disease is likely to start in around six months.

Pharming takes over distribution from Sobi in a further 21 countries In mid-July Pharming announced a further amendment to the distribution agreement concluded with Sobi in 2009. Pharming has been commercialising Ruconest directly in Germany, Austria and the Netherlands since the first quarter of 2015. From 1 October Pharming will market Ruconest directly to a further 21 countries in Europe, the Middle East and Africa including Belgium, France, Spain, Switzerland and the U.K.

We maintain Buy recommendation and price target of €1.00 Pharming has not given any financial guidance for 2016 but the company does confirm that it expects sales and gross profits to continue to improve during the remained of this year. We are leaving our forecasts unchanged and maintain our Buy recommendation and €1.00 price target.

Figure 1: Pipeline valuation model

Compound	Project[1)]	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Sales	PACME Margin[2)]	Discount Factor	Patent Life[3)]	Time to Market
Ruconest (EU)	HAE-AA	€77.2M	22K	€14,400	€318M	29%	€92M	17%	10%	12	-
Ruconest (US)	HAE-AA	€233.2M	10K	€52,364	€524M	25%	€148M	30%	10%	12	-
Ruconest (EU)	HAE-PR	€69.4M	7K	€78,998	€576M	32%	€212M	20%	15%	10	2 Years
Ruconest (US)	HAE-PR	€157.1M	3K	€319,091	€1,053M	25%	€303M	30%	15%	10	3 Years
rhC1INH	IRI*	€61.9M	-	-	-	-	-	-	-	-	> 5 Years
PACME PV		€598.8M			€2,471M		€754M				
Costs PV[4)]		€193.4M									
NPV		€405.4M									
Milestones PV		€1.1M									
Net Cash (pro-forma)		€19.3M									
Fair Value		€425.8M									
Share Count (fully diluted)		447,771K									
Price Target		€0.95									

1) A project typically refers to a specific indication or, where necessary or relevant, a combination between indication and geographic market

2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues. This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of partnership agreements)

3) Remaining patent life after the point of approval

4) Includes company-level R&D, G&A, Financing Costs and CapEx; COGS and S&M are factored into the PACME margin for each project

*) Combined PV of R&D projects DGF and AMI due to lower priority of the two projects

Source: First Berlin Equity Research

INCOME STATEMENT

All figures in EUR '000	2011A	2012A	2013A	2014A	2015A	2016E
Revenues	**2,999**	**10,613**	**6,844**	**21,186**	**10,828**	**12,864**
Costs of sales	-3,530	-4,267	-1,112	-3,427	-4,800	-3,613
Gross profit	**-531**	**6,346**	**5,732**	**17,759**	**6,028**	**9,251**
Other income	196	250	106	105	147	246
Research and development	-13,830	-19,350	-10,232	-11,663	-14,180	-16,595
General and administrative	-3,262	-3,080	-2,518	-3,324	-3,744	-4,066
Marketing and sales	0	0	0	0	-1,085	-1,082
Impairment charges	-35	-1,257	0	0	0	0
Share-based compensation	-1,039	-370	0	0	0	0
Operating income (EBIT)	**-18,501**	**-17,461**	**-6,912**	**2,877**	**-12,834**	**-12,246**
Net financial income	658	-6,632	-8,148	-8,644	2,877	-965
Pre-tax income (EBT)	**-17,843**	**-24,093**	**-15,060**	**-5,767**	**-9,957**	**-13,211**
Income taxes	0	0	0	0	0	0
Discontinued operations	643	0	0	0	0	0
Minority interests	0	0	0	0	0	0
Net income / loss	**-17,200**	**-24,093**	**-15,060**	**-5,767**	**-9,957**	**-13,211**
Diluted EPS	**-0.36**	**-0.33**	**-0.07**	**-0.02**	**-0.02**	**-0.03**
EBITDA	**-17,495**	**-15,366**	**-5,992**	**3,915**	**-12,023**	**-11,480**
Ratios						
EBIT margin on revenues	n.m.	n.m.	n.m.	13.6%	n.m.	n.m.
EBITDA margin on revenues	n.m.	n.m.	n.m.	18.5%	n.m.	n.m.
Net margin on revenues	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Expenses as % of revenues						
Cost of sales	117.7%	40.2%	16.2%	16.2%	44.3%	28.1%
Research and development	461.2%	182.3%	149.5%	55.1%	131.0%	129.0%
General and administrative	108.8%	29.0%	36.8%	15.7%	34.6%	31.6%
Marketing and sales	n.m.	n.m.	n.m.	n.m.	10.0%	8.4%
Y-Y Growth						
Revenues	423.4%	253.9%	-35.5%	209.6%	-48.9%	18.8%
Operating income	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Net income/ loss	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.

BALANCE SHEET

All figures in EUR '000	2011A	2012A	2013A	2014A	2015A	2016E
Assets						
Current assets, total	**13,161**	**8,449**	**24,599**	**49,143**	**51,092**	**33,376**
Cash and cash equivalents	3,777	5,273	16,968	34,185	31,643	13,645
Short-term investments	0	0	0	0	0	0
Receivables	2,495	524	860	1,554	3,220	6,187
Inventories	6,580	2,101	4,763	13,404	16,229	13,544
Other current assets	309	551	2,008	0	0	0
Non-current assets, total	**11,533**	**8,395**	**6,809**	**6,575**	**6,585**	**6,609**
Property, plant & equipment	9,567	7,128	6,228	5,598	5,661	5,685
Goodwill & other intangibles	987	535	405	777	724	724
Other assets	979	732	176	200	200	200
Total assets	**24,694**	**16,844**	**31,408**	**55,718**	**57,677**	**39,985**
Shareholders' equity & debt						
Current liabilities, total	**8,135**	**8,968**	**12,925**	**14,873**	**13,475**	**15,213**
Short term debt	0	0	0	0	3,047	5,000
Deferred license fee income	1,171	1,215	2,200	2,200	2,207	2,207
Derivative financial liabilities	3,810	3,690	4,147	4,266	953	953
Trade and other payables	0	1,232	5,812	7,781	7,005	6,688
Finance lease liabilities	3,154	2,831	766	626	263	365
Longterm liabilities, total	**17,747**	**15,528**	**13,473**	**11,002**	**20,363**	**14,144**
Long term debt	0	0	0	0	11,757	7,721
Deferred license fee income	0	0	12,222	10,022	7,808	5,622
Finance lease liabilities	15,431	13,495	1,207	965	798	801
Other liabilities	2,316	2,033	44	15	0	0
Minority interests	**0**	**0**	**0**	**0**	**0**	**0**
Shareholders equity	**-1,188**	**-7,652**	**5,010**	**29,843**	**23,839**	**10,628**
Total consolidated equity and debt	**24,694**	**16,844**	**31,408**	**55,718**	**57,677**	**39,985**

Ratios						
Current ratio (x)	1.62	0.94	1.90	3.30	3.79	2.19
Quick ratio (x)	0.81	0.71	1.53	2.40	2.59	1.30
Net gearing	n.a.	n.a.	-302.8%	-109.9%	-67.0%	0.4%
Book value per share (€)	n.m.	n.m.	0.01	0.07	0.06	0.03
Net cash	-1,323	-3,149	-15,171	-32,794	-15,978	42
Return on equity (ROE)	n.m.	n.m.	n.m.	-33.1%	-37.1%	-76.7%

CASH FLOW STATEMENT

All figures in EUR '000	2011A	2012A	2013A	2014A	2015A	2016E
EBIT	**-18,501**	**-17,461**	**-6,912**	**2,877**	**-12,834**	**-12,246**
Depreciation and amortization	1,006	2,095	920	1,038	811	766
EBITDA	**-17,495**	**-15,366**	**-5,992**	**3,915**	**-12,023**	**-11,480**
Other adjustments	565	5,096	-2,301	-6,488	-4,399	-3,749
Operating cash flow	**-16,930**	**-10,270**	**-8,293**	**-2,573**	**-16,422**	**-15,230**
CAPEX	-1,098	108	241	-654	-898	-790
Free cash flow	**-18,028**	**-10,162**	**-8,052**	**-3,227**	**-17,320**	**-16,020**
Debt financing, net	**-172**	**7,162**	**16,023**	**-682**	**15,524**	**0**
Equity financing, net	**13,198**	**5,340**	**12,178**	**19,375**	**483**	**0**
Other changes in cash	**-1,523**	**-844**	**-5,454**	**-1,249**	**-1,229**	**-1,978**
Net cash flows	**-6,525**	**1,496**	**14,695**	**14,217**	**-2,542**	**-17,998**
Cash, start of the year	10,302	3,777	5,273	19,968	34,185	31,643
Cash, end of the year	**3,777**	**5,273**	**19,968**	**34,185**	**31,643**	**13,645**
EBITDA/share	**-0.37**	**-0.21**	**-0.03**	**0.01**	**-0.03**	**-0.03**
Y-Y Growth						
Operating cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Free cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EBITDA/share	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.

FIRST BERLIN RECOMMENDATION & PRICE TARGET HISTORY

Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	10 November 2009	€0.52	Buy	€0.70
2...30	↓	↓	↓	↓
31	3 November 2015	€0.29	Buy	€1.50
32	11 March 2016	€0.24	Buy	€1.20
33	20 May 2016	€0.20	Buy	€1.00
34	Today	€0.22	Buy	€1.00

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BUY: An expected favourable price trend of more than 25% percent.

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- **key sources of information in the preparation of this research report**
- **valuation methods and principles**
- **sensitivity of valuation parameters**

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