STIFEL

2 August 2016

Pharming Group N.V.

BUY

EU Pharmaceuticals

Company Update

Ruconest gathering momentum into 2H16

Pharming's 1H16 results demonstrated the steady growth of sales of Ruconest in the US (+33% Q/Q), and the benefits of selling the product direct in certain European territories (gross profit up 14% Y/Y). As the company increases direct commercialisation efforts in Europe we expect this improvement in profitability to continue. Furthermore, the recent successful Phase II trial results for the prophylactic treatment of HAE is a meaningful step towards expanding into this larger indication, dominated by Shire's Cinryze. We believe the current share price does not reflect the near-term potential of increasing Ruconest sales, and reiterate our Buy rating.

Increasing Ruconest sales. Pharming reported improved trends in Ruconest sales in the second quarter of 2016, which was boosted by modest expansion of its EU direct commercialisation efforts in Austria, Germany and the Netherlands. Following a renegotiation of the distribution agreement with SOBI, Pharming will directly commercialise Ruconest in a further 21 territories from October 2016, focusing initially on the key European markets of Spain, the UK and France. We would expect margins to improve as direct commercialisation efforts continue, which should have an increasingly meaningful impact on the company's profitability. We forecast €11.2m in revenues from sales of Ruconest for Pharming for FY16 and gross profit of €8.7m (+45% Y/Y). In the US, QoQ Ruconest sales growth of +33% for 2Q16 suggests improved sales efforts from Valeant following its restructuring in 4Q15, and US prescription data (overleaf) shows an encouraging upward trend.

Important milestone from Positive Phase II prophylaxis data. Pharming's recently announced Phase II data (included overleaf) using Ruconest as a prophylactic treatment for HAE demonstrated a significant reduction in attack frequency for both twice-weekly and once-weekly dosing. According to Pharming, the prophylactic market is expected to be around $800m in 2017 from sales of Shire's Cinryze; if approved, Ruconest would be the only product approved for acute and prophylactic use. Pharming may be able to apply for FDA and EU approval based on the Phase II data, but will meet with the regulators once the full data is available to discuss whether an additional Phase III trial is needed. We view the data as potentially strong enough to support an early filing, but for now still assume an additional trial will be required, and forecast sales of $85m of Ruconest for prophylactic use in 2020, with launch in 2018.

Reiterating Buy and €0.71 target price. Having had a slow start to 2016, we believe Pharming is on track to deliver a good year of growth from Ruconest. Sales in the US appear to be growing steadily since Valeant's reorganisation of its sales force in 4Q15; profitability in Europe is increasing as Pharming switches to a direct commercialisation model; and the success of the prophylaxis data is an important milestone in expanding Ruconest's label to include a large market in the US.

Price (1 August 2016)		€0.21
Changes	**Previous**	**Current**
Rating	-	BUY
Target Price	-	€0.71

Share price performance (indexed)

Key data

Stock code	PHARM NA
Market cap (€m)	87
Amsterdam Stock Exchange	628
Amsterdam Midkap Index	
1mth perf (%)	12.6
3mths perf (%)	(0.9)
12mths perf (%)	(35.7)
12mth high-low (€)	0 - 0
Free float (%)	100

Key financials

Year to Dec	2015A	2016E	2017E
Sales (€)	10.8	13.4	18.9
EBIT adj	(13.01)	(10.89)	(9.56)
EBIT margin (%)	(120.5)	(81.3)	(50.5)
EPS adj (c)	(2.4)	(2.9)	(2.6)
EV/EBITDA (x)	--	--	--
PE adj (x)	NA	NA	NA
DPS (c)	0	0	0
Div yield (%)	0	0	0
FCF yield (%)	0	0	0

Prices are as of close 1 August 2016.

All sources unless otherwise stated: Company data, FactSet, Stifel estimates

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Key data[1]

Key valuation ratios (x)

	2015A	2016E	2017E	2018E
PE adj (x)	NA	NA	NA	NA
ROCE (% incl. gross goodwill)	(0.4)	(1.0)	(9.3)	1.3
Div yield (%)	0	0	0	0

Key profit and loss data (€)

	2015A	2016E	2017E	2018E
Sales (€)	10.8	13.4	18.9	27.1
EBITDA adj	(13.0)	(10.9)	(9.6)	(4.2)
EBIT adj	(13.01)	(10.89)	(9.56)	(4.22)
EBIT adj margin (%)	(120.5)	(81.3)	(50.5)	(15.6)
Net income	(10.2)	(12.0)	(10.7)	(5.3)
EPS adj (c)	(2.4)	(2.9)	(2.6)	(1.3)
DPS (c)	0	0	0	0

Key cash flow data (€)

	2015A	2016E	2017E	2018E
Operating profit	(13.0)	(10.9)	(9.6)	(4.2)
Depreciation	0	0	0	0
Other	0	0	0	0
Operating cash flow	(16.4)	(10.8)	(8.7)	(5.3)
Taxes paid	0	0	0	0
Net interest	0.1	0	0	0
Capex	(0.9)	0	0	0
Free cash flow	(17.2)	(10.8)	(8.7)	(5.3)
Dividends	0	0	0	0
Change in cash	(16)	(11)	(9)	(5)
Net debt	(16.8)	(6.0)	2.6	7.9

Key balance sheet (€)

	2015A	2016E	2017E	2018E
Intangible assets	1	1	1	1
PPE	6	6	6	6
Cash	32	18	6	(3)

Key information

Target price methodology/risks

Target price is based on our risk-adjusted product-based NPV valuation.

Risks to the investment include Pharming's reliance on distribution partners to execute commercialisation strategy for Ruconest, along with the risk that market acceptance is lower than expected or unforeseen safety and efficacy issues affect the global growth. Competition may also increase from 2018 onwards, and the increasing tendency of health insurers to reduce costs and reimbursement may provide additional headwind to Ruconest commercialisation.

Business description

Pharming is a Dutch biotechnology company with a platform technology for producing recombinant proteins in rabbit milk. The company's lead product, Ruconest, is approved in Europe and the US for the treatment of hereditary angioedema.

Senior management

Chairman - Jaap Blaak

Chief Executive Officer - Sijmen de Vries

Chief Operating Officer - Bruno Giannetti

Chief Financial Officer- Robin Wright

Key dates

27 October 2016 - 3Q16 results

4Q16 - Phase II data from paediatric study

2H16 - Pipeline update

Major shareholders

Kingdon Capital Management - 2.1%

Website

http://www.pharming.com/

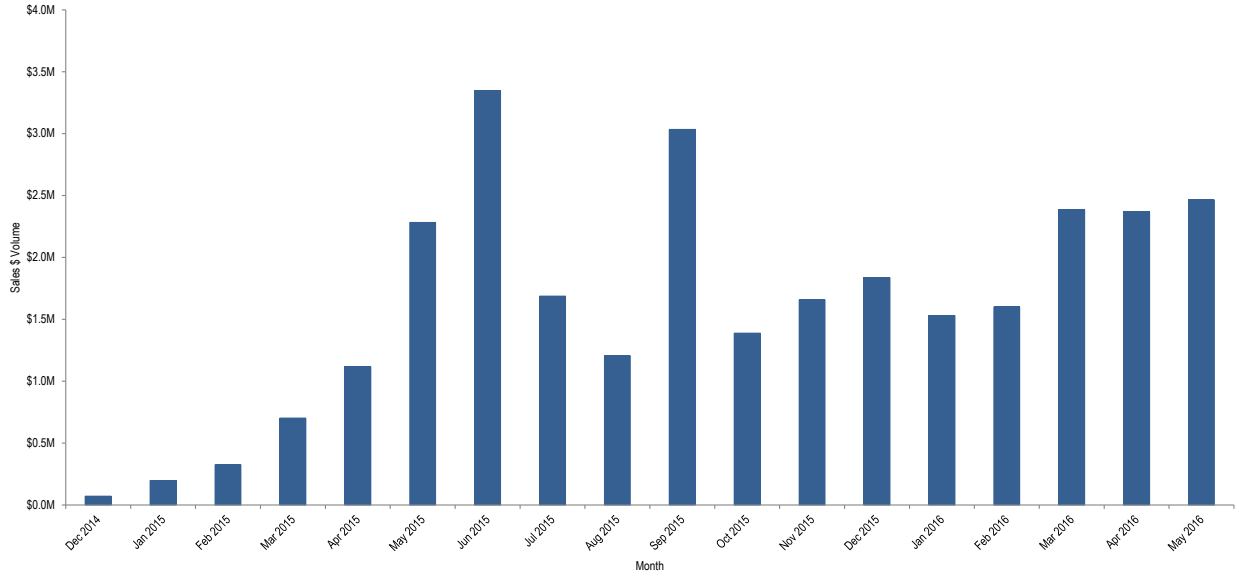
[1] *Year end December*
Data in millions, except per share and percentages
Source: Company data, FactSet, Stifel estimates

1H16 update

Ruconest sales: US

Figure 1 shows the monthly sales of Ruconest in the US since launch. Although monthly sales in the first year were variable (as patients and wholesalers determined ordering and stocking levels), we believe there is an overall increasing trend. If the increasing prescription trends from June and July continue (see Figure 2), Ruconest looks on track to reach our forecast of sales of $32m for 2016. Valeant's reorganisation of its sales team in 4Q15 impacted Ruconest sales in 1Q16, but was showing signs of improvement by 2Q16 (with +33% QoQ growth). Pharming recorded total income from sales of €3.5m in 1H16, slightly up on 1H15, when wholesalers had been ramping up stocking levels to meet increasing demand.

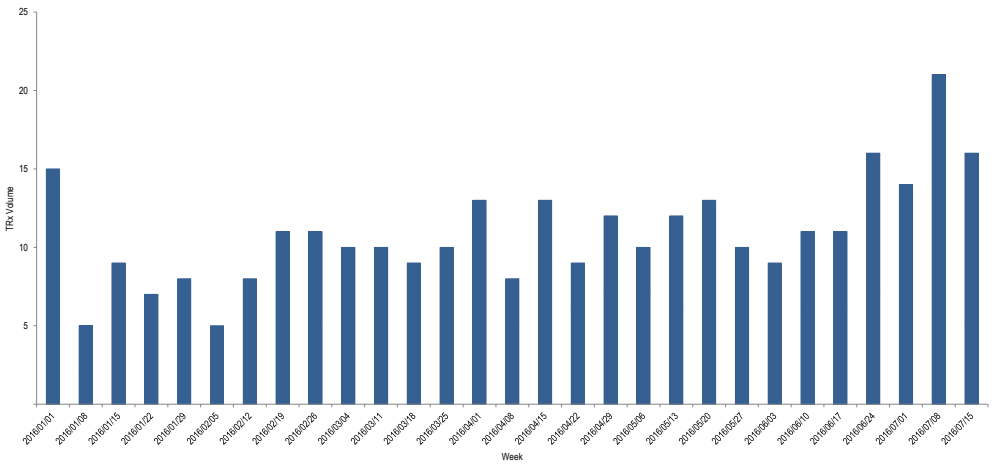
Figure 1: Ruconest US sales since launch



Source: IMS data

Figure 2 shows the prescriptions per week of Ruconest in the US. Notably, prescriptions in June and July look encouraging, and have not been captured in Pharming's 1H16 results.

Figure 2: Ruconest 2016 weekly prescription data



Source: IMS data

Ruconest sales: Europe & ROW

After the end of the period, Pharming updated its distribution agreement with SOBI, such that Pharming will commercialise Ruconest directly in a further 21 countries from October 2016. SOBI had not begun sales efforts in the majority of these countries, which include major EU markets like Spain, the UK and France.

Ruconest will consequently increase its direct commercialisation efforts in Europe in particular, having already commercialised the product itself in Austria, Germany and the Netherlands. Although the majority of vials of Ruconest are still sold through SOBI, Pharming is making good progress marketing the product direct, with a positive impact on margins. Sales have been aided by the European Commission's decision to allow Ruconest to be used in adolescents in Europe, and to remove the requirements for rabbit IgE testing that also formed part of the EU label. The company is working on securing European approval for home administration, which should be the final catalyst to boost sales in Europe.

Ongoing development for Ruconest

Prophylaxis: Pharming's key news in July was the positive data from its Phase II trial using Ruconest in the prophylactic treatment of HAE attacks. In the study, Ruconest showed a clinically meaningful and statistically significant reduction in HAE attacks with both twice-weekly and once-weekly treatment regimens compared with placebo.

Figure 3: Phase II prophylaxis trial data

		Placebo	Ruconest Once/week	Ruconest Twice/week
Intent-to-treat analysis				
(n=32)	**Mean number of attacks**	7.2	4.4 (p=0.0004)	2.7 (p<0.0001)
(n=31)	**% patients with more than 50% reduction in attack frequency**		42%	74%
Per protocol analysis				
(n=23)	**Mean number of attacks**	7.5	3.8 (p<0.0001)	2 (p<0.0001)
(n=23)	**% patients with more than 50% reduction in attack frequency**		57%	96%

Source: Company data

Cinryze is currently the only product approved for the prophylactic treatment on the US market. It was approved based on pivotal data in 24 patients, who were treated for 12 weeks every three-to-four days with Cinryze (or placebo). The study demonstrated that 50% of patients dosed with Cinryze had a >50% reduction in HAE attack frequency (96% of per protocol patients had a >50% reduction in HAE attacks with Ruconest). Although the two trials cannot be compared, it is interesting to note that the patients in Shire's trial may be less severe than the Ruconest trial, with a mean number of attacks of 12.7 in 12 weeks in the placebo group (n=22), versus Pharming's mean number of attacks of 7.2 in four weeks in the placebo group (n=32) (see Figure 4).

Figure 4: Cinryze pivotal trial summary statistics

		Cinryze (n=22)	Placebo (n=22)
Number of Attacks	**Mean**	6.1	12.7
	SD	5.4	4.8
	Median	6	13.5
	Min	0	6
	Max	17	22

Source: Cinryze FDA label

Once the full dataset has been evaluated and collated, Pharming and Valeant will meet with the US and EU regulatory authorities to determine the steps required for approval. It is feasible the FDA may allow the product to be approved on the basis of this Phase II trial, given that it was a controlled study with reasonable patient numbers, and that the safety of Ruconest has been confirmed since the product has been on the market. The treatment duration of four weeks, however, was shorter than Shire's 12-week treatment regimen with Cinryze. We have conservatively assumed a Phase III trial will be required, however, and that launch is therefore possible in 2018. The prophylaxis opportunity is large, with Shire's Cinryze the only approved treatment in the US, which achieved sales of $618m in 2015. We forecast $85m sales of Ruconest in prophylactic use in 2020, assuming launch in 2018.

Paediatric: Pharming's Phase II study on the use of Ruconest to treat HAE patients under the age of 12 is ongoing. Data is expected to be announced by the end of 2016, although paediatric trials are hard to recruit, and we believe this may be delayed until 1H17. Separately, CSL Behring's product Berinert (a plasma-derived C1 esterase inhibitor approved for acute use) was recently approved by the FDA for paediatric use, making it the only product approved in patients under 12.

Subcutaneous: Pharming alluded to the development of a subcutaneous version of Ruconest using higher concentrations of the product to suit the convenience needs of patients. Shire is in the process of developing a subcutaneous version of Cinryze - it is currently recruiting a 66-patient Phase III trial that is due to complete in September 2017. CSL Behring is also expected to submit to the FDA for approval of its subcutaneous version in mid-2016, although this is yet to happen.

Pipeline update

Pharming continues to develop its pipeline of next-generation recombinant therapies. Its lead pipeline programme for Pompe disease is now entering its next stage of pre-clinical testing and process development, with the second programme for Fabry disease approximately six months behind. The company expects to announce further detail on these programmes later in the year.

Forecasts

Figure 5: Pharming P&L forecasts (€m)

Year to 31 December	2015A	2016E	2017E	2018E	2019E	2020E
License fees	2.2	2.2	2.2	2.2	2.2	2.2
Milestones	0.0	0.0	0.0	0.0	0.0	0.0
Product sales and royalties	8.6	11.2	16.7	24.9	53.3	102.0
Total sales	**10.8**	**13.4**	**18.9**	**27.1**	**55.5**	**104.2**
%ch	*-49%*	*24%*	*41%*	*43%*	*105%*	*88%*
COGS %	*44.5%*	*35.0%*	*29.0%*	*28.0%*	*27.0%*	*26.0%*
COGS	(4.8)	(4.7)	(5.5)	(7.6)	(15.0)	(27.1)
Gross profit	**6.0**	**8.7**	**13.4**	**19.5**	**40.5**	**77.1**
SG&A	(4.8)	(5.1)	(5.6)	(6.2)	(6.8)	(7.5)
R&D	(14.2)	(14.5)	(17.4)	(17.6)	(17.7)	(17.9)
Other	0.2	0.0	0.0	0.0	0.0	0.0
Operating profit	**(12.8)**	**(10.9)**	**-9.6**	**-4.2**	**16.0**	**51.7**
Operating margins	*-118.7%*	*-81.3%*	*-50.5%*	*-15.6%*	*28.8%*	*49.6%*
Net interest	2.8	(1.1)	(1.1)	(1.1)	(1.1)	(1.1)
Exceptionals						
PBT	**(10.0)**	**(12.0)**	**(10.7)**	**(5.3)**	**14.9**	**50.6**
Tax rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Taxation	0	0	0	0	0	0
Profit after tax	**(10.0)**	**(12.0)**	**(10.7)**	**(5.3)**	**14.9**	**50.6**
Ratios						
Adjusted Pretax profit	(10.0)	(12.0)	(10.7)	(5.3)	14.9	50.6
GP	55.5%	65.0%	71.0%	72.0%	73.0%	74.0%
SG&A	44.5%	38.1%	29.6%	22.8%	12.2%	7.2%
R&D	131.6%	108.2%	91.9%	64.8%	32.0%	17.2%
Operating Profit	-118.7%	-81.3%	-50.5%	-15.6%	28.8%	49.6%
Shares	408	413	413	413	413	413
eps (cents)	-2.4	-2.9	-2.6	-1.3	3.6	12.3
adj. eps (pre-amortisation)	-2.4	-2.9	-2.6	-1.3	3.6	12.3
dps (cents)	0.0	0.0	0.0	0.0	0.0	0.0

Source: Company data, Stifel estimates

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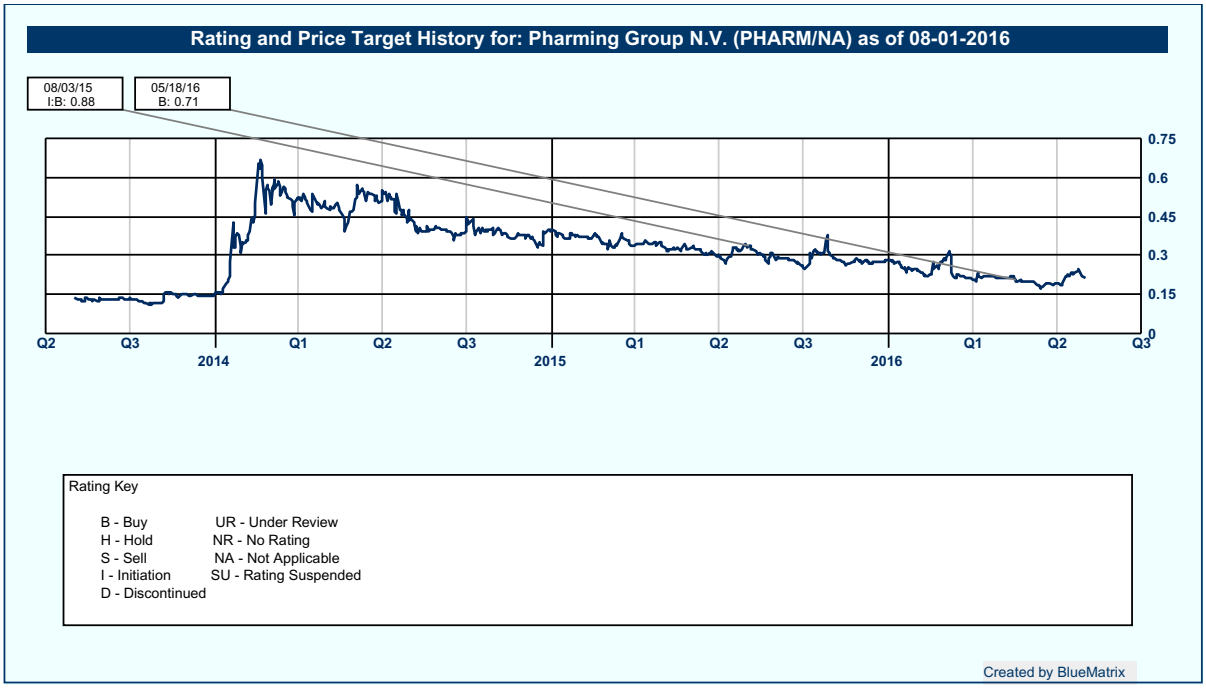

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