Pharming Group NV

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

comparative study of acute HAE therapies

RATING	**BUY**
PRICE TARGET	**€ 2.00**
Return Potential	153.5%
Risk Rating	High

HEAD-TO-HEAD STUDY GIVES PHARMING NEW WEAPON AGAINST FIRAZYR

Results of an investigator-initiated comparative real-world study of therapies for acute attacks of hereditary angioedema (HAE) published on Friday show a significantly lower re-dosing rate for Pharming's Ruconest than for the bestselling therapy for HAE - Shire's Firazyr. 18 (90%) of 20 attacks treated with Ruconest were resolved after the first dose. Pharming say that this number would probably have been 100% had two patients not underdosed themselves by using only 1 vial of 2,100 IU compared with the 50 IU/kg dose recommended on the label. By contrast 11 (44%) of the 25 patients who took Firazyr required a second dose. Of these 11 patients, eight took a second dose of Firazyr. Five (62.5%) of these doses failed. Two of these five patients took a third dose of Firazyr. One of these doses failed. Firazyr is the bestselling product for treatment of HAE in either the acute or the prophylactic setting. Worldwide 9M/18 sales amounted to USD557m compared to USD117m for Ruconest. Past non-comparative studies have shown lower relapse rates for Ruconest than Firazyr but Pharming's marketing personnel have been prevented from referencing these data because of differences between the Ruconest and Firazyr study designs. They can now reference this comparative study. The study also strengthens the case for the use of a C1-inhibitor such as Ruconest as a rescue therapy in place of Firazyr within the context of a prophylaxis regime. We maintain our Buy recommendation and price target of €2.00.

Study based on seven patients and 69 HAE attacks On Friday Pharming published results of an investigator-initiated comparative study of therapies in acute attacks of HAE. The study was carried out at the Charité - Universitätsmedizin in Berlin and examined re-dosing rates for Ruconest (Pharming), Berinert (CSL Behring), Firazyr (Shire) and Cinryze (Shire) in seven patients who suffered a total of 69 attacks. As figure 1 overleaf shows, 18 (90%) of 20 attacks treated with Ruconest were resolved after the first dose. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2015	2016	2017	2018E	2019E	2020E
Revenue (€ m)	10.83	15.87	89.62	136.28	164.73	202.86
Y-o-y growth	-48.9%	46.6%	464.6%	52.1%	20.9%	23.1%
EBIT (€ m)	-12.83	-11.54	21.91	44.09	56.54	73.51
EBIT margin	-118.5%	-72.7%	24.4%	32.3%	34.3%	36.2%
Net income (€ m)	-9.96	-17.54	-79.96	22.26	45.00	68.32
EPS (diluted) (€)	-0.02	-0.04	-0.16	0.04	0.07	0.11
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-18.14	-67.48	32.17	41.03	45.05	74.78
Net gearing	-67.0%	128.4%	116.5%	-45.3%	-65.8%	-81.6%
Liquid assets (€ m)	31.64	31.89	58.66	91.99	105.05	147.82

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 through a bioreactor recombinant technology platform. Lead drug Ruconest received EMA approval in 2010 and FDA approval in July 2014.

MARKET DATA

	As of 11 Dec 2018
Closing Price	€ 0.79
Shares outstanding	617.36m
Market Capitalisation	€ 487.10m
52-week Range	€ 0.76 / 1.57
Avg. Volume (12 Months)	17,447,215

Multiples	2017	2018E	2019E
P/E	n.a.	21.6	10.8
EV/Sales	5.5	3.6	3.0
EV/EBIT	22.5	11.2	8.7
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW

COMPANY DATA

	As of 30 Sep 2018
Liquid Assets	€ 71.03m
Current Assets	€ 115.55m
Intangible Assets	€ 56.32m
Total Assets	€ 192.72m
Current Liabilities	€ 86.29m
Shareholders' Equity	€ 48.17m

SHAREHOLDERS

Goldman Sachs Group Inc.	3.2%
FMR LLC	3.1%
Polar Capital Partners Ltd.	3.0%
Hagemann G.J.	2.4%
Free float and other	88.4%

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If two patients had not underdosed themselves, as described above, the success rate would probably have been 100%. Meanwhile 11 (44%) of the 25 patients who took Firazyr required a second dose. Eight of these 11 patients took a second dose of Firazyr of which 5 (62.5%) failed. Two of these five patients took a third dose of Firazyr of which one failed.

Figure1: Data from comparative study of HAE therapies

Initial Treatment	Resolved on 1st dose	%	Failed (required 2nd treatment)	%	Failed (required 3rd treatment)	%	Failed (required 4th treatment)	%
Berinert (6)	6	100.0	-	-			-	
Cinryze (18)	17	94.4	1	11.1			-	
Firazyr (25)	14	56.0	11	44.0	5 (of 8)	62.5	1 (of 2)	50.0
Ruconest (20)	18	90.0	2*	10.0*			-	
Total	**55**		**14**		**5**		**1**	

*Underdosed: only one vial administered and not the prescribed dose of 50 IU/Kg.
Note: The percentages show the failure rate within the drug noted, so that for example 5 out of 8 patients who sought to resolve their attacks with a second dose of Firazyr need a third treatment.

Source: Charité – Universitätsmedizin, Pharming

Data showing lower relapse rates for Ruconest vs. Firazyr have long been available… Firazyr and Ruconest were approved by the FDA for HAE in August 2011 and July 2014 respectively. Peer-reviewed articles on Ruconest and Firazyr indicate Ruconest's superior performance with regard to relapse rates. As Riedl et al. wrote in their 2013 review* of the pivotal Ruconest (rhC1-INH) phase III trial for acute HAE: "Of the rhC1-INH-treated patients who achieved beginning of persistent relief from symptoms within 4 hours of rhC1-INH treatment, one patient (3%) had a recurrence of symptoms within 24 hours. This was the only case of recurrence of symptoms after initial improvement within 24 hours after dosing across the entire rhC1-INH clinical development program. By comparison, relapse rates of 10% to 31% have been reported for other acute treatments for angioedema attacks in patients with HAE."

Specifically, in the FAST1, FAST2 and FAST3 clinical trials of Firazyr, 22%, 17% and 11% of patients respectively required rescue medication within 48 hours of the first administration of the drug.

…but Pharming's marketing team has been unable to tell this story until now Pharming's marketing personnel have so far been prevented from referencing these performance data because of differences between the Ruconest and Firazyr study designs. They can reference the data in the comparative study.

Firazyr sales up for grabs Firazyr is due to go off-patent in mid-2019. Fresenius Kabi USA LLC is planning to launch a generic of Firazyr next summer. We expect Friday's study data to limit the loss of Ruconest patients to Firazyr. Meanwhile, Shire is currently attempting to move patients from Firazyr to its recently launched prophylactic product, Takhzyro. Takhzyro has faster and more comfortable administration than Ruconest (injection time 10 to 60 seconds vs. 5 minutes for Ruconest; subcutaneous injection for Takhzyro vs. intraveneous injection for Ruconest). However, assuming twice monthly dosage, annual treatment cost at nearly USD600,000 is twice as high as for Firazyr and Ruconest (both USD290-300,000). We expect this to make some payers reluctant to finance patient transfer from Firazyr to Takhzyro given the existence of a cheaper but efficacious acute treatment. In addition the study also strengthens the case for the use of a C1-inhibitor such as Ruconest as a rescue therapy in place of Firazyr within the context of a prophylaxis regime. Two arguments are relevant here: first the reduction in attacks experienced by the patient and second the money saved because of a lower number of doses taken.

* Riedel et al, Annals of Allergy, Asthma & Immunology 112 (2014) 163-169

We are leaving our forecasts unchanged and maintain our Buy recommendation and price target of €2.00

Figure 2: Valuation model

Compound	Project[1)]	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Sales	Gross margin	Discount Factor	Patent Life2[)]	Time to Market
Ruconest (EU)	HAE-AA	€115.4M	4K	€ 43,478	€174M	20%	€40M	60%	10%	16	-
Ruconest (US)	HAE-AA	€1,481.0M	4K	€ 205,950	€824M	25%	€308M	87%	10%	12	-
Ruconest (EU)	HAE-PR	€9.7M	1K	€ 86,957	€87M	10%	€8M	60%	12%	4	4 Years
Ruconest (US)	HAE-PR	€332.2M	2K	€ 463,768	€723M	15%	€164M	87%	12%	5	3 Years
rhαGLU (EU+US)	Pompe	€466.2M	3K	€ 260,870	€826M	30%	€734M	85%	12%	18	5 Years
PV of gross profits		€2,404.5M			€2,634M		€1,254M				
Costs PV		€1,078.5M									
PV after costs		€1,326.0M									
Contingent consideration		€34.1M									
Net cash (pro-forma)		€12.5M									
Fair Value		€1,304.4M									
Share Count (fully diluted, PV)		652,843K									
Fair value per share		€ 2.00									

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

2) Remaining patent life in years after point of approval

Source: First Berlin Equity Research estimates

INCOME STATEMENT

All figures in EUR '000	2015A	2016A	2017A	2018E	2019E	2020E
Revenues	**10,828**	**15,873**	**89,620**	**136,280**	**164,730**	**202,863**
Costs of sales	-4,800	-4,683	-12,445	-21,924	-25,002	-31,980
Gross profit	**6,028**	**11,190**	**77,175**	**114,356**	**139,728**	**170,883**
Other income	147	335	790	623	0	0
Research and development	-14,180	-15,388	-18,657	-23,568	-26,357	-32,458
General and administrative	-3,744	-4,642	-5,974	-11,521	-12,355	-13,186
Marketing and sales	-1,085	-3,035	-31,422	-35,805	-44,477	-51,730
Operating income (EBIT)	**-12,834**	**-11,540**	**21,912**	**44,085**	**56,540**	**73,509**
Net financial result	2,877	-5,996	-111,311	-21,823	-11,542	-5,188
Pre-tax income (EBT)	**-9,957**	**-17,536**	**-89,399**	**22,262**	**44,998**	**68,321**
Income taxes	0	0	9,442	0	0	0
Minority interests	0	0	0	0	0	0
Net income / loss	**-9,957**	**-17,536**	**-79,957**	**22,262**	**44,998**	**68,321**
Diluted EPS	**-0.02**	**-0.04**	**-0.16**	**0.04**	**0.07**	**0.11**
EBITDA	**-11,871**	**-10,784**	**25,327**	**46,455**	**58,560**	**75,184**
Ratios						
Gross margin on revenues	55.7%	70.5%	86.1%	83.9%	84.8%	84.2%
EBITDA margin on revenues	n.m.	n.m.	28.3%	34.1%	35.5%	37.1%
EBIT margin on revenues	n.m.	n.m.	24.4%	32.3%	34.3%	36.2%
Net margin on revenues	n.m.	n.m.	n.m.	16.3%	27.3%	33.7%
Expenses as % of revenues						
Cost of sales	44.3%	29.5%	13.9%	16.1%	15.2%	15.8%
Research and development	131.0%	96.9%	20.8%	17.3%	16.0%	16.0%
General and administrative	34.6%	29.2%	6.7%	8.5%	7.5%	6.5%
Marketing and sales	10.0%	19.1%	35.1%	26.3%	27.0%	25.5%
Y-Y Growth						
Revenues	-48.9%	46.6%	464.6%	52.1%	20.9%	23.1%
Operating income	n.m.	n.m.	n.m.	101.2%	28.3%	30.0%
Net income/ loss	n.m.	n.m.	n.m.	n.m.	102.1%	51.8%

BALANCE SHEET

All figures in EUR '000	2015A	2016A	2017A	2018E	2019E	2020E
Assets						
Current assets, total	**51,092**	**62,190**	**88,251**	**133,285**	**154,717**	**203,206**
Cash and cash equivalents	31,643	31,889	58,657	91,993	105,047	147,825
Receivables	3,220	12,360	11,260	19,079	22,950	22,315
Inventories	16,229	17,941	18,334	22,214	26,720	33,067
Other current assets	0	0	0	0	0	0
Non-current assets, total	**6,585**	**64,593**	**77,339**	**77,296**	**78,539**	**79,793**
Property, plant & equipment	5,661	6,043	8,234	9,540	9,836	10,143
Long term prepayments	0	1,622	2,296	0	0	0
Deferrred tax assets	0	0	9,442	9,442	9,442	9,442
Goodwill & other intangibles	724	56,680	56,631	57,578	58,525	59,472
Restricted cash	200	248	736	736	736	736
Total assets	**57,677**	**126,783**	**165,590**	**210,581**	**233,255**	**283,000**
Shareholders' equity & debt						
Current liabilities, total	**13,475**	**51,378**	**57,928**	**75,510**	**77,550**	**54,051**
Debt	3,047	26,136	21,962	32,000	32,000	1,000
Deferred license fee income	2,207	943	204	204	204	0
Derivative financial liabilities	953	9,982	8,301	8,973	4,102	2,072
Trade and other payables	7,005	14,054	27,198	34,070	40,982	50,716
Finance lease liabilities	263	263	263	263	263	263
Longterm liabilities, total	**20,363**	**47,938**	**88,860**	**75,337**	**46,102**	**48,995**
Debt	11,757	40,395	58,684	33,000	1,000	0
Deferred license fee income	7,808	2,270	1,467	13,628	16,393	20,286
Finance lease liabilities	798	599	390	390	390	390
Other liabilities	0	4,674	28,319	28,319	28,319	28,319
Minority interests	**0**	**0**	**0**	**0**	**0**	**0**
Shareholders equity	**23,839**	**27,467**	**18,802**	**59,734**	**109,603**	**179,954**
Total consolidated equity and debt	**57,677**	**126,783**	**165,590**	**210,581**	**233,255**	**283,000**

Ratios						
Current ratio (x)	3.79	1.21	1.52	1.77	2.00	3.76
Quick ratio (x)	2.59	0.86	1.21	1.47	1.65	3.15
Net gearing	-67.0%	128.4%	116.5%	-45.3%	-65.8%	-81.6%
Book value per share (€)	0.06	0.06	0.03	0.10	0.18	0.29
Net debt	-15,978	35,256	21,906	-27,076	-72,130	-146,908
Return on equity (ROE)	-37.1%	-68.4%	-345.6%	56.7%	53.1%	47.2%

CASH FLOW STATEMENT

All figures in EUR '000	2015A	2016A	2017A	2018E	2019E	2020E
EBIT	**-12,834**	**-11,540**	**21,912**	**44,085**	**56,540**	**73,509**
Depreciation and amortization	963	756	3,415	2,370	2,020	1,676
EBITDA	**-11,871**	**-10,784**	**25,327**	**46,455**	**58,560**	**75,184**
Changes in working capital	-5,267	642	11,099	9,630	1,299	7,712
Net interest, other	-103	138	1,787	-10,430	-11,542	-5,188
Operating cash flow	**-17,241**	**-10,004**	**38,213**	**45,655**	**48,317**	**77,708**
CAPEX	-898	-57,474	-6,045	-4,622	-3,263	-2,930
Free cash flow	**-18,139**	**-67,478**	**32,168**	**41,033**	**45,054**	**74,778**
Debt financing, net	**15,524**	**63,635**	**-10,088**	**-15,646**	**-32,000**	**-32,000**
Equity financing, net	**483**	**8,825**	**6,833**	**7,949**	**0**	**0**
Other changes in cash	**-210**	**-4,688**	**-1,057**	**-1,336**	**0**	**0**
Net cash flows	**-2,342**	**294**	**27,856**	**32,000**	**13,054**	**42,778**
Cash, start of the year	34,185	31,843	32,137	59,993	91,993	105,047
Cash, end of the year	**31,843**	**32,137**	**59,993**	**91,993**	**105,047**	**147,825**
EBITDA/share	**-0.03**	**-0.03**	**0.05**	**0.08**	**0.09**	**0.12**
Y-Y Growth						
Operating cash flow	n.m.	n.m.	n.m.	19.5%	5.8%	60.8%
Free cash flow	n.m.	n.m.	n.m.	27.6%	9.8%	66.0%
EBITDA/share	n.m.	n.m.	n.m.	51.4%	24.6%	28.4%

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...39	↓	↓	↓	↓
40	8 May 2018	€1.37	Buy	€2.00
41	18 May 2018	€1.33	Buy	€2.00
42	30 October 2018	€0.95	Buy	€2.00
43	Today	€0.79	Buy	€2.00

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PRICE TARGET DATES

Unless otherwise indicated, current prices refer to the closing prices of the previous trading day.

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The present financial analysis is based on the author's own knowledge and research. The author prepared this study without any direct or indirect influence exerted on the part of the analysed company. Parts of the financial analysis were possibly provided to the analysed company prior to publication in order to avoid inaccuracies in the representation of facts. However, no substantial changes were made at the request of the analysed company following any such provision.

ASSET VALUATION SYSTEM

First Berlin's system for asset valuation is divided into an asset recommendation and a risk assessment.

ASSET RECOMMENDATION

The recommendations determined in accordance with the share price trend anticipated by First Berlin in the respectively indicated investment period are as follows:

Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy[1]	An expected favourable price trend of:	> 50%	> 30%
Buy	An expected favourable price trend of:	> 25%	> 15%
Add	An expected favourable price trend of:	0% to 25%	0% to 15%
Reduce	An expected negative price trend of:	0% to -15%	0% to -10%
Sell	An expected negative price trend of:	< -15%	< -10%

[1] The expected price trend is in combination with sizable confidence in the quality and forecast security of management.

Our recommendation system places each company into one of two market capitalisation categories. Category 1 companies have a market capitalisation of €0 – €2 billion, and Category 2 companies have a market capitalisation of > €2 billion. The expected return thresholds underlying our recommendation system are lower for Category 2 companies than for Category 1 companies. This reflects the generally lower level of risk associated with higher market capitalisation companies.

RISK ASSESSMENT

The First Berlin categories for risk assessment are low, average, high and speculative. They are determined by ten factors: Corporate governance, quality of earnings, management strength, balance sheet and financial risk, competitive position, standard of financial disclosure, regulatory and political uncertainty, strength of brandname, market capitalisation and free float. These risk factors are incorporated into the First Berlin valuation models and are thus included in the target prices. First Berlin customers may request the models.

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At the time of publication of this financial analysis it is not certain whether, when and on what occasion an update will be provided. In general First Berlin strives to review the financial analysis for its topicality and, if required, to update it in a very timely manner in connection with the reporting obligations of the analysed company or on the occasion of ad hoc notifications.

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Legally required information regarding

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

can be accessed through the following internet link: http://firstberlin.com/disclaimer-english-link/

SUPERVISORY AUTHORITY: Bundesanstalt für Finanzdienstleistungsaufsicht (German Federal Financial Supervisory Authority) [BaFin], Graurheindorferstraße 108, 53117 Bonn and Lurgiallee 12, 60439 Frankfurt

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