Pharming Group NV

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

Update

RATING	**BUY**
PRICE TARGET	**€ 1.60**
Return Potential	119.9%
Risk Rating	High

TEMPORARY DIP IN LENIOLISIB NEW PATIENT GROWTH IS BUYING OPPORTUNITY

Q2/24 was a strong quarter for Pharming. Group revenue climbed 35% yoy and 33% sequentially to USD74.1m (Q2/23: USD54.9m; Q1/24; USD55.6m). Recent operating losses have been primarily a consequence of higher marketing costs following the Q2/23 launch of leniolisib in the US for APDS (activated PI3K delta syndrome) in patients 12 years and older. A higher revenue base meant that the operating loss narrowed to USD3.1m in Q2/24 from USD16.3m in Q1/24. Despite the good numbers, the share fell 8% on the day of the results. We think the main reason for the decline was slowing growth in new leniolisib patient enrolment. Pharming has identified ca. 150 patients in the US who are eligible for treatment with leniolisib. Between end June 2023 (2 months after the US launch) and YE 23 the number of US patients on paid therapy with the drug rose from 43 to 81. By end June this year, Pharming had added only 10 more patients (2 in Q1 and 8 in Q2) for a total of 91. The good news is that growth in patients on paid leniolisib therapy is likely to pick up strongly in 2025 and remain robust into the 2030s. APDS is caused by variants in either of two genes, PIK3CD or PIK3R1. By end Q4 Pharming expects to have completed screening of 1,200 patients in the US with a VUS (Variant of Uncertain Significance) in the PIK3CD or PIK3R1 genes. The literature suggests that 20% of these patients will be found to be pathogenic/likely pathogenic. We expect VUS screening to boost US leniolisib patients on paid therapy from 101 at YE 2024 to 149 at YE 2025. We model the number of patients on leniolisib to exceed 600 by end 2028 following approvals in the EU, Japan and for under 12 year-olds (all 2026). Leniolisib patient growth should gain substantial further impetus from ca. 2029 following its approval for certain non-APDS PIDs (primary immunodeficiencies) whose prevalence is 3.3x higher than APDS. We expect revenues from non-APDS PIDs to make leniolisib a bigger product than Ruconest. We believe the dip in leniolisib new patient growth is temporary and an opportunity to purchase the Pharming share cheaply. We maintain our Buy recommendation and price target of €1.60.

FINANCIAL HISTORY & PROJECTIONS

	2022	2023	2024E	2025E	2026E	2027E
Revenue ($ m)	205.62	245.32	288.70	297.70	326.85	400.25
Y-o-y growth	3.4%	19.3%	17.7%	3.1%	9.8%	22.5%
EBIT ($ m)	18.23	-5.39	-20.37	-17.79	-10.80	37.38
EBIT margin	8.9%	-2.2%	-7.1%	-6.0%	-3.3%	9.3%
Net income ($ m)	13.67	-10.55	-16.06	-17.55	-9.93	25.75
EPS (diluted) (USc)	1.93	-1.60	-2.19	-2.39	-1.35	3.51
DPS ($)	0.00	0.00	0.00	0.00	0.00	0.00
FCF ($m)	20.48	-18.77	-2.21	-12.80	-7.33	23.89
Net gearing	-20.5%	-19.8%	-21.1%	-8.9%	-5.1%	-12.3%
Liquid assets ($ m)	207.34	213.42	163.26	150.47	143.14	167.03

RISKS

The main risks to our price target include slower sales growth for Ruconest and Joenja than we currently model.

COMPANY PROFILE

Lead drug Ruconest, indicated for acute hereditary angioedema attacks, received EMA approval in 2010 and FDA approval in July 2014. Leniolisib, indicated for APDS, was approved by the FDA in March 2023. Pharming has launched leniolisib in the US and plans to expand the commercial availability of the drug for APDS patients to key markets in the EU, UK, Japan, Asia Pacific, Middle East, Latin America and Canada.

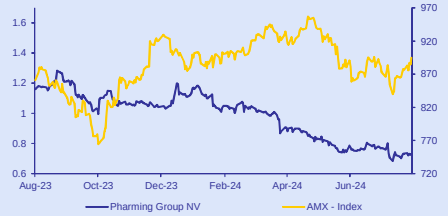
MARKET DATA

As of 23 Aug 2024

Closing Price	€ 0.73
Shares outstanding	678.35m
Market Capitalisation	€ 493.50m
52-week Range	€ 0.68 / 1.28
Avg. Volume (12 Months)	5,425,142

Multiples	2023	2024E	2025E
P/E	n.a.	n.a.	n.a.
EV/Sales	2.1	1.8	1.7
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Jun 2024

Liquid Assets	$ 161.80m
Current Assets	$ 270.63m
Intangible Assets	$ 66.57m
Total Assets	$ 415.93m
Current Liabilities	$ 79.94m
Shareholders' Equity	$ 220.94m

SHAREHOLDERS

Acadian Asset Management LLC	3.0%
RTW Investments LP	3.0%
Sijmen de Vries	2.2%
FundLogic Alternatives PLC	1.7%
Free float and other	87.5%

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The Pharming share closed 2023 at €1.03. We think the decline to the current level of €0.73 has three main causes. First, as discussed on the first page of this note, new APDS patient adds have slowed markedly in 2024 compared with 2023. Second, the EU approval of leniolisib has been delayed by three years compared with the original schedule. Third, despite the resilience of Ruconest sales and margins in recent years in the face of intensifying competition, we think the market is concerned about the prospect of the H1/25 launch of an oral on demand competitor to Ruconest.

Figure 1: Recent and forecast leniolisib patient development

	H1/23	Q3/23	FY 23	Q1 24	H1 24	FY 24E	FY 25E	FY 26E	FY 27E	FY 28E
Estimated prevalence of APDS on key markets*	>1500	>1500	~2000	~2000	~2400	~2400	~2400	~2400	~2400	~2400
No patients identified by Pharming in key markets	>640	>640	>730	>730	>780	792	1,036	1,113	1,194	1,278
Identified patients as % of estimated prevalence	42.7%	42.7%	36.5%	36.5%	30.8%	33.0%	43.2%	46.4%	49.7%	53.3%
of which:										
US-based	>200	ca. 200	>200	>200	>230	260	460	490	520	550
of which ≥ 12 years old	>150	ca. 150	>150	>150	>150	225	345	368	390	413
of which < 12 years old	>50		>50	>50	>80	35	115	123	130	138
ROW-based	>440	>440	>530	>530	>550	532	576	623	674	728
of which ≥ 12 years old	>330	>330	>398	>398	>413	399	432	468	505	546
of which < 12 years old	>110	>110	>132	>132	>137	133	144	156	168	182
US patients aged ≥12 on paid therapy	43	63	81	83	91	101	149	169	193	214
% total patients ≥12 identified	28.7%	42.0%	54.0%	55.3%	52.6%	44.9%	43.3%	45.9%	49.4%	52.0%
US patients aged <12 on paid therapy	0	0	0	0	0	0	0	53	62	71
% total patients <12 identified	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	43.3%	47.6%	52.0%
ROW patients aged ≥12 on paid therapy	0	0	0	12	12	15	30	77	140	231
% total patients ≥12 identified	n.a.	n.a.	n.a.	2.6%	2.6%	3.2%	7.0%	16.4%	27.8%	42.3%
ROW patients aged <12 on paid therapy	0	0	0	0	0	0	0	19	71	122
% total patients <12 identified	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	12.0%	42.1%	67.3%
Total patients on paid therapy	**43**	**63**	**81**	**95**	**103**	**116**	**180**	**317**	**466**	**639**
Δ %	**n.a.**	**46.5%**	**28.6%**	**17.3%**	**8.4%**	**12.6%**	**54.9%**	**76.6%**	**46.9%**	**37.3%**
Total patients ≥12 on paid therapy	**43**	**63**	**81**	**95**	**103**	**116**	**180**	**245**	**333**	**445**
Δ %	**n.a.**	**46.5%**	**28.6%**	**17.3%**	**8.4%**	**12.6%**	**54.9%**	**36.6%**	**35.6%**	**33.8%**
Total patients <12 on paid therapy	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**72**	**133**	**194**
Δ %	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**85.2%**	**45.9%**

* at H1/23 these included the US, Europe, UK, Japan, Canada, Australia and Israel. Asia Pacific and Middle East added at FY/23 and Latin America at H1/24.

Source: Pharming NV, First Berlin Equity Research estimates

New APDS patient adds to pick up sharply from 2025 As figure 1 above shows, the number of new US APDS patients on paid therapy slowed from 38 in H2/23 to 10 in H1/24. We expect the growth rate in new patient adds to pick up sharply from 2025 onwards due to the impact of VUS screening in the US, the approval of leniolisib in Israel, UK, Australia, EU, Canada, Japan, and for under 12 year-olds, and from ca. 2029 its approval for certain non-APDS PIDs.

Pharming has identified approximately 1,200 patients in the US with a VUS in the PIK3CD or PIK3R1 genes. This figure will continue to grow over time, because any time that a patient gets a genetic test done, there is a possibility of a VUS result in either the PIK3CD gene or the PIK3R1 gene. Similar VUS frequencies are expected worldwide. Pharming is currently screening the US VUS patients to determine which of them are pathogenic for APDS.

We expect VUS screening will drive the addition of 48 new APDS patients in US by end 2025 A review of the literature, which includes more than 1.5 million patients, suggests that 20% of these VUS patients will be found to be pathogenic or likely pathogenic. We assume that 200 of the screened 1,200 patients will be found to be pathogenic or likely pathogenic and that VUS screening will drive the addition of 48 patients on paid APDS therapy by the end of 2025.

Leniolisib launches likely in Australia, Israel and UK in 2025 The Israeli Ministry of Health granted marketing authorisation for leniolisib for patients 12 years of age and older on 30 April, 2024. Launch is scheduled in 2025 following the completion of government payor negotiations which typically conclude in December. The UK's Medicines and Healthcare products Regulatory Agency (MHRA) validated Pharming's MAA for leniolisib on 17 April, 2024. The MHRA is expected to issue its decision in Q4 of this year. Pharming filed regulatory submissions in Canada and Australia in Q3/23. We expect approval in Australia in 2025 and in Canada in 2026. The 30 ROW patients ≥12 years old which we expect to be on paid therapy by end 2025 stem from the Israeli and UK launches of leniolisib and also include the 10-15 named patients who are currently on paid therapy ahead of launch in ROW countries. We do not expect any significant sales in Australia until 2026.

Leniolisib approval in Japan… A phase 3 study of leniolisib in 12 to 75 year-old patients is currently underway in Japan. Study completion is set for 31 March 2025. We expect regulatory approval in Japan in 2026. First sales could also occur in 2026.

…and for under 12 year-olds likely in 2026 Pharming is currently conducting two pediatric clinical trials with leniolisib, for children aged 4 to 11 and 1 to 6, at sites in the US, Japan, and the EU. Completion of the studies is scheduled for December and November 2025 respectively. We expect first regulatory approvals of leniolisib for patients under 12 years old from H2/26.

Pharming currently developing leniolisib for non-APDS PIDs. We assume approval and launch in 2029 APDS is a PID with immune dysregulation linked to PI3K signalling. This immune dysregulation causes lymphoproliferation, autoimmunity and other auto-inflammatory conditions. Pharming is currently developing leniolisib for other PIDs characterised by immune dysregulation linked to PI3K signalling. The genes involved include ALPS FAS, CTLA4 and PTEN. A phase 2 proof of concept clinical trial in 12 patients is due to start later this year. Study completion is expected in late 2025. One of the aims of the trial is to pick the best dose regimen for a phase 3 trial. Assuming the start of a phase 3 trial in 2026, we tentatively pencil in approval and launch in 2029. In terms of market potential, we note that the estimated combined prevalence of these PIDs at 5 per million is 3.3x that of the 1.5 per million for APDS.

Additional leniolisib indication under development Pharming is also developing leniolisib for an additional PID indication. Further details will be provided following regulatory feedback on the proposed clinical development plan.

Figure 2: Exchanges between Pharming and the CHMP on leniolisib

01/08/2022	EMA's Committee for Medicinal Products for Human Use (CHMP) grants accelerated assessment for marketing authorisation application (MAA) of leniolisib (150 instead of 210 days).
11/10/2022	Pharming submits MAA for leniolisib to EMA
28/10/2022	EMA validates leniolisib MAA for accelerated assessment Pharming expects marketing authorisation for leniolisib in EU in H1/23
16/02/2023	Pharming receives list of questions from the CHMP on leniolisib. The assessment timetable is shifted to standard from accelerated (210 instead of 150 days) Pharmng now expects a CHMP opinion on its MAA in H2 23
10/11/2023	Pharming receives a second list of questions from the CHMP on leniolisib. Pharmng now expects a CHMP opinion on its MAA in Q1 24
30/05/2024	CHMP affirms positive clinical benefit and safety of leniolisib but List of Outstanding Issues includes one remaining chemistry manufacturing and controls request. Pharming has until January 2026 to submit a response.

Source: Pharming NV

CHMP has affirmed positive clinical benefit and safety of leniolisib As figure 2 shows, Pharming originally expected leniolisib to be approved in the EU in H1/23. Two lists of questions and a list of outstanding issues have pushed this schedule back to mid-2026. The good news is that the CHMP has affirmed the positive clinical benefit and safety of leniolisib.

The CHMP has given Pharming until January 2026 to submit its response. Pharming now expects positive marketing authorisation for leniolisib in the EU in Spring 2026 and the first EU country launch in mid-2026.

Due to reference pricing and entrenched competition, pricing of Ruconest is much lower in Europe than in the US. During H1/24 the gross margin on Ruconest was 88.0% in the US and 33.0% in Europe/ROW. This means that Ruconest is hardly profitable in Europe/ROW after sales & marketing and general & administrative costs. The gross margin on leniolisib in H1/24 was 86.8% in the US and 87.8% in Europe/ROW. Leniolisib is not yet approved outside the US and so H1/24 sales in EU/ROW were low at USD2.0m and made from product provided on a named-patient basis. Given that leniolisib is the only available treatment for APDS, we expect pricing in Europe to be much better than for Ruconest. We model annual treatment costs for over 12 year-olds of USD340k in Europe – a 40% discount to the US figure of USD567k. We estimate that subject to approval, pricing at this level will allow Pharming to generate gross margins of >80% on leniolisib in Europe in the medium term. Given the positive profit potential for leniolisib in Europe, the delay in the approval process is significant.

We think leniolisib will need additional indications beyond APDS to overhaul Ruconest The annual wholesale acquisition cost of leniolisib for a year's course of treatment in the US is USD567k. We understand that the net price received by Pharming after discounts is 15% below this figure. We further estimate that revenue generated per patient in ROW is ca. 40% below the US figure. Assuming an approximate geographic patient split between the US and ROW of 50:50 by 2028, the blended net leniolisib price would be USD383k per patient per year. We expect an average number of patients in 2028 of 553 (there were 91 at end H1/24). Multiplying this figure by USD383k gets us close to our 2028 revenue forecast for leniolisib of USD212m. These numbers suggest that approval of leniolisib for additional PIDs will be necessary if the drug is to outstrip sales of Ruconest, which we expect to generate sales of USD237m in the US this year.

Figure 3: Current HAE therapy competitive landscape

Company	Product	HAE Indication	Administration method	Mode of action	FDA approval date	EMA approval date
CSL Behring	Berinert	On demand	IV injection	plasma-derived C1 inhibitor	10/2009	12/2008
Takeda	Cinryze	Prophylaxis	IV injection	plasma-derived C1 inhibitor	08/2008	06/2011
Takeda	Firazyr	On demand	Subcut. injection	bradykinin B2 receptor antagonist	08/2011	07/2008
CSL Behring	Haegarda	Prophylaxis	Subcut. injection	plasma-derived C1 inhibitor	06/2017	2017
BioCryst	Orladeyo	Prophylaxis	Oral	serine protease kallikrein inhibitor	12/2020	04/2021
Pharming	Ruconest	On demand	IV injection	recombinant C1 inhibitor	07/2014	10/2010
Takeda	Takhzyro	Prophylaxis	Subcut. injection	plasma kallikrein inhibitor (mAb)	08/2018	11/2018

Source: companies

The competitive landscape for HAE therapies has been very dynamic in recent years. The two main trends have been market share gains by prophylactic and/or orally administered products such as Takhzyro and Orladeyo from on demand products, such as Ruconest, which are used to stop attacks once they have already started. However, Ruconest sales have had only one down year (2021) since the product's launch in the EU and US in 2010 and 2014 respectively.

Figure 4: Recent sales development of Ruconest and competitors (USDm)

	2018	2019	2020	2021	2022	2023
Berinert	n.a.	n.a.	n.a.	n.a.	288	n.a.
	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Cinryze	28	224	213	172	147	118
	n.a.	701.0%	-4.9%	-19.3%	-14.4%	-19.5%
Firazyr	58	300	261	238	189	147
	n.a.	420.5%	-13.1%	-9.0%	-20.4%	-22.4%
Generic Icatibant	n.a.	n.a.	n.a.	n.a.	185	n.a.
	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Haegarda	n.a.	n.a.	n.a.	n.a.	436	n.a.
	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Kalbitor	11	42	38	40	30	n.a.
	n.a.	286.2%	-8.8%	5.9%	-25.7%	n.a.
Orladeyo	0	0	0	123	252	326
	n.a.	n.a.	n.a.	n.a.	105.3%	29.6%
Ruconest	160	189	212	199	206	227
	n.a.	18.5%	12.2%	-6.3%	3.4%	10.5%
Takhzyro	87	628	844	919	1,144	1,236
	n.a.	617.9%	34.5%	8.8%	24.5%	8.0%

Source: companies

Resilience of Ruconest sales based on efficacy…. In our view there are two reasons for the resilience of Ruconest's sales. Firstly, the drug has a high level of efficacy. In its most common forms, HAE is caused by a functional deficiency of a plasma protein called C1-inhibitor. Ruconest is a recombinant C1 inhibitor protein replacement therapy and so tackles the root cause of HAE. As it is intravenously delivered, it is immediately and completely bioavailable to stop the progression of HAE attacks. Results of an investigator-initiated comparative real-world study of therapies for acute attacks of hereditary angioedema (HAE) published by Pharming in December 2018 showed a significantly lower re-dosing rate for Ruconest than for Firazyr. 18 (90%) of 20 attacks treated with Ruconest were resolved after the first dose. According to Pharming 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.

…and treatment of breakthrough attacks suffered by patients using prophylactic therapies Secondly, studies indicate that 50% of HAE patients using leading prophylactic therapies Haegarda and Takhzyro suffer breakthrough attacks. For Orladeyo this figure is 90%. HAE patients using prophylactic therapies typically use on demand treatments such as Ruconest to halt breakthrough attacks.

Figure 5: HAE therapies in clinical development

Company	Asset	Mode of Action	Route of Administration	Status	Role in Therapy
KalVista	Sebetralstat	Kallikrein inhibitor	Oral	NDA	On demand
Pharvaris	PHA121 (PHVS416/PHVS719)	B2 receptor antagonist	Oral	II/III	On demand and prophylaxis
Attune	ATN-249	Kallikrein inhibitor	Oral	I	Prophylaxis
CSL Behring	Garadacimab	Anti-factor XII mAb	IV/Subcutaneous	III	Prophylaxis
Ionis	Donidalorsen	Prekallikrein inhibitor	Subcutaneous	III	Prophylaxis
Astria	STAR-0215	Kallikrein inhibitor	Subcutaneous	Ia	Prophylaxis
ADARx	ADX-324	siRNA	Subcutaneous	I	Prophylaxis
Intellia	NTLA-2002	Gene therapy	IV	I/II	Functional cure

Source: companies

We view the threats to Ruconest from Kalvista's sebetralstat, loss of exclusivity in 2026 as limited The latest threat to Ruconest's position emanates from Kalvista's sebetralstat, which is the first oral on demand therapy candidate for HAE. Subject to FDA approval, sebetralstat could be launched in the US in H1/25. However, sebetralstat was tested in a patient population that is generally responsive to firazyr (icatibant) and its generic counterpart. A key part of the client base for Ruconest is comprised of patients who have failed on icatibant, which only serves the bradykinin/kallikrein pathway rather than addressing the root cause of HAE. We model modest declines of 5.0% in Ruconest sales in both 2025 and 2026 as patients try sebetralstat. However, we expect a substantial number of these patients to return to Ruconest as they discover that their needs are better served by the Pharming drug. We therefore expect Ruconest sales to exceed their 2024 level by 2028.

Exclusivity for Ruconest expires in 2026, but as far as we can ascertain, no biosimilars are under development. The absence of an emerging Ruconest biosimilar is not surprising given that its development would be costly and risky for a product that generates relatively modest revenues of USD200m-USD300m annually.

Figure 6: Historic and Forecast Group P&L 2021-2028

USD 000s	2022A	H1/23	H2/23	2023	H1/24A	H2/24E	2024E	2025E	2026E	2027E	2028E
Sales	**205,622**	**97,438**	**147,878**	**245,316**	**129,679**	**159,017**	**288,696**	**297,697**	**326,854**	**400,255**	**465,041**
change	***3.4%***	***0.7%***	***35.8%***	***62.5%***	***33.1%***	***7.5%***	***17.7%***	***3.1%***	***9.8%***	***22.5%***	***16.2%***
of which:											
Ruconest	205,622	93,646	133,488	227,134	108,973	134,038	243,011	230,860	219,317	241,249	253,311
change	3.4%	-3.2%	22.6%	10.5%	16.4%	0.4%	7.0%	-5.0%	-5.0%	10.0%	5.0%
Leniolisib	0	3,792	14,390	18,182	20,706	24,979	45,685	66,837	107,537	159,006	211,729
change	n.a.	n.a.	n.a.	n.a.	446.0%	73.6%	151.3%	46.3%	60.9%	47.9%	33.2%
Gross profit	**188,060**	**87,639**	**132,465**	**220,104**	**113,312**	**138,750**	**252,062**	**264,591**	**288,661**	**346,992**	**400,490**
margin	***91.5%***	***89.9%***	***89.6%***	***89.7%***	***87.4%***	***87.3%***	***87.3%***	***88.9%***	***88.3%***	***86.7%***	***86.1%***
of which:											
Ruconest	188,060	84,322	120,145	204,467	95,310	117,232	212,542	207,767	197,379	217,117	227,973
margin	91.5%	90.0%	90.0%	90.0%	87.5%	87.5%	87.5%	90.0%	90.0%	90.0%	90.0%
Leniolisib	0	3,317	12,320	15,637	18,002	21,518	39,520	56,823	91,282	129,875	172,518
margin	n.a.	87.5%	85.6%	86.0%	86.9%	86.1%	86.5%	85.0%	84.9%	81.7%	81.5%
Other income	14,523	22,507	842	23,349	1,257	1,000	2,257	-3,500	1,538	1,576	1,616
R&D	-52,531	-36,534	-32,380	-68,914	-40,118	-46,879	-86,997	-83,355	-84,982	-84,054	-88,358
% sales	25.5%	37.5%	21.9%	28.1%	30.9%	29.5%	30.1%	28.0%	26.0%	21.0%	19.0%
G&A	-46,016	-20,963	-34,914	-55,877	-30,707	-30,200	-60,907	-62,516	-63,737	-72,046	-79,057
% sales	22.4%	21.5%	23.6%	22.8%	23.7%	19.0%	21.1%	21.0%	19.5%	18.0%	17.0%
Sales & marketing	-85,803	-61,013	-63,036	-124,049	-63,177	-63,607	-126,784	-133,010	-152,279	-155,089	-148,813
% sales	41.7%	62.6%	42.6%	50.6%	48.7%	40.0%	43.9%	44.7%	46.6%	38.7%	32.0%
Operating income (EBIT)	**18,233**	**-8,364**	**2,977**	**-5,387**	**-19,433**	**-936**	**-20,369**	**-17,791**	**-10,798**	**37,380**	**85,879**
margin (%)	***8.9%***	***-8.6%***	***2.0%***	***-2.2%***	***-15.0%***	***-0.6%***	***-7.1%***	***-6.0%***	***-3.3%***	***9.3%***	***18.5%***
Net financial result	-2,163	-4,455	-1,881	-6,336	3,583	-160	3,423	-2,157	-2,591	-2,678	-2,609
Associates	-1,083	-469	180	-289	-834	-600	-1,434	0	0	0	0
Pre-tax income (EBT)	14,987	-13,288	1,276	-12,012	-16,684	-1,696	-18,380	-19,948	-13,389	34,703	83,269
Income taxes	-1,313	2,399	-935	1,464	3,018	-700	2,318	2,394	3,454	-8,953	-21,484
Net income / loss	**13,674**	**-10,889**	**341**	**-10,548**	**-13,666**	**-2,396**	**-16,062**	**-17,554**	**-9,934**	**25,749**	**61,786**
Diluted EPS (USD)	**0.019**	**-0.017**	**0.001**	**-0.016**	**-0.020**	**-0.002**	**-0.022**	**-0.024**	**-0.014**	**0.035**	**0.084**
Diluted EPS (EUR)	**0.018**	**-0.016**	**0.001**	**-0.015**	**-0.018**	**-0.002**	**-0.020**	**-0.022**	**-0.012**	**0.032**	**0.077**

Source: Pharming Group NV, First Berlin Equity Research estimates

Figure 7: Valuation model

Compound	Indication	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Sales	Gross margin	Discount Factor	Patent Life[2)]	Time to Market
Ruconest (US)	HAE-AA	€1,109.9M	4,000	€ 454,545	€1,818M	10%	€371M	91%	12%	12	-
Ruconest (ROW)	HAE-AA	€0.6M	8,000	€ 90,909	€727M	1%	€9M	33%	12%	16	-
Leniolisib (US)	APDS	€500.8M	500	€ 515,127	€258M	100%	€153M	85%	10%	14	-
Leniolisib (ROW)	APDS	€315.4M	1,900	€ 309,076	€587M	100%	€142M	83%	10%	11	2 years
PI3Kδ platform (US)	non-APDS PIDs	€670.1M	1,665	€ 515,127	€858M	100%	€508M	82%	10%	8	5 years
PI3Kδ platform (ROW)	non-APDS PIDs	€364.4M	6,327	€ 309,076	€1,956M	100%	€337M	80%	10%	8	5 years
PV of gross profits		€2,961.3M									
Costs PV		€1,746.3M									
PV after costs		€1,215.1M									
Leniolisib milestones		€93.1M									
Net cash (pro-forma)		€103.2M									
Fair Value		€1,225.2M									
Share Count (fully diluted, PV)		766,509K									
Fair value per share		**€ 1.60**									

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

Buy recommendation maintained at price target of €1.60 We expect VUS screening to boost US leniolisib patients on paid therapy from 101 at YE 2024 to 149 at YE 2025. We further model the number of patients on leniolisib to exceed 600 by end 2028 as the drug is approved, in the EU, Japan and for under 12 year-olds (all 2026). Leniolisib patient growth should gain substantial further impetus from ca. 2029 following its approval for certain non-APDS PIDs (primary immunodeficiencies) whose prevalence is 3.3x higher than APDS. We expect revenues from non-APDS PIDs to make leniolisib a bigger product than Ruconest. We believe the dip in leniolisib new patient growth is temporary and represents an opportunity to purchase the Pharming share cheaply. We maintain our Buy recommendation and price target of €1.60.

INCOME STATEMENT

All figures in USD '000	2022A	2023A	2024E	2025E	2026E	2027E
Revenues	**205,622**	**245,316**	**288,696**	**297,697**	**326,854**	**400,255**
Costs of sales	-17,562	-25,212	-36,634	-33,107	-38,193	-53,263
Gross profit	**188,060**	**220,104**	**252,062**	**264,591**	**288,661**	**346,992**
Other income	14,523	23,349	2,257	-3,500	1,538	1,576
Research and development	-52,531	-68,914	-86,997	-83,355	-84,982	-84,054
General and administrative	-46,016	-55,877	-60,907	-62,516	-63,737	-72,046
Marketing and sales	-85,803	-124,049	-126,784	-128,010	-137,279	-140,089
Milestones/PRV sales	0	0	0	-5,000	-15,000	-15,000
Operating income (EBIT)	**18,233**	**-5,387**	**-20,369**	**-17,791**	**-10,798**	**37,380**
Net financial result	-2,163	-6,336	3,423	-2,157	-2,591	-2,678
Associates	-1,083	-289	-1,434	0	0	0
Pre-tax income (EBT)	**14,987**	**-12,012**	**-18,380**	**-19,948**	**-13,389**	**34,703**
Income taxes	-1,313	1,464	2,318	2,394	3,454	-8,953
Net income / loss	**13,674**	**-10,548**	**-16,062**	**-17,554**	**-9,934**	**25,750**
Diluted EPS (US cents)	**1.934**	**-1.600**	**-2.186**	**-2.392**	**-1.354**	**3.509**
EBITDA	**26,753**	**2,708**	**-12,575**	**-8,860**	**-992**	**49,388**
Ratios						
Gross margin on revenues	91.5%	89.7%	87.3%	88.9%	88.3%	86.7%
EBITDA margin on revenues	13.0%	1.1%	n.m.	n.m.	n.m.	12.3%
EBIT margin on revenues	8.9%	n.m.	n.m.	n.m.	n.m.	9.3%
Net margin on revenues	6.7%	n.m.	n.m.	n.m.	n.m.	6.4%
Expenses as % of revenues						
Cost of sales	8.5%	10.3%	12.7%	11.1%	11.7%	13.3%
Research and development	25.5%	28.1%	30.1%	28.0%	26.0%	21.0%
General and administrative	22.4%	22.8%	21.1%	21.0%	19.5%	18.0%
Marketing and sales	41.7%	50.6%	43.9%	43.0%	42.0%	35.0%
Y-Y Growth						
Revenues	3.4%	19.3%	17.7%	3.1%	9.8%	22.5%
Operating income	34.5%	n.m.	n.m.	n.m.	n.m.	n.m.
Net income/ loss	-14.5%	n.m.	n.m.	n.m.	n.m.	n.m.

BALANCE SHEET

All figures in USD '000	2022A	2023A	2024E	2025E	2026E	2027E
Assets						
Current assets, total	**277,500**	**316,342**	**261,467**	**251,733**	**254,325**	**303,184**
Cash and cash equivalents	207,342	213,424	163,264	150,467	143,141	167,032
Restricted cash	213	0	0	0	0	0
Receivables	27,619	46,158	38,777	39,986	43,903	53,762
Inventories	42,326	56,760	59,426	61,279	67,281	82,390
Non-current assets, total	**148,297**	**146,512**	**139,745**	**147,825**	**143,252**	**147,658**
Property, plant & equipment	10,392	9,689	9,816	8,931	9,152	11,207
Right of use assets	28,753	23,777	22,208	35,724	35,954	44,028
Long term prepayments	228	92	320	330	362	444
Deferred tax assets	22,973	29,761	29,761	29,761	29,761	29,761
Investments accounted for using the equity method	2,501	2,285	851	851	851	851
Investments in FVTOCI equity instruments	403	2,020	2,020	2,020	2,020	2,020
Investments in FVTPL debt instruments	6,827	6,093	6,093	6,093	6,093	6,093
Goodwill & other intangibles	75,121	71,267	67,148	62,587	57,530	51,726
Restricted cash	1,099	1,528	1,528	1,528	1,528	1,528
Total assets	**425,797**	**462,854**	**401,212**	**399,558**	**397,577**	**450,842**
Shareholders' equity & debt						
Current liabilities, total	**59,698**	**77,968**	**83,061**	**86,921**	**94,669**	**114,993**
Debt	1,768	1,824	3,147	3,147	3,147	3,147
Trade and other payables	54,465	72,528	76,470	78,854	86,577	106,019
Finance lease liabilities	3,465	3,616	3,445	4,920	4,945	5,827
Longterm liabilities, total	**161,461**	**166,105**	**115,432**	**127,472**	**127,678**	**134,870**
Debt	131,618	136,598	87,323	87,323	87,323	87,323
Finance lease liabilities	29,843	29,507	28,109	40,149	40,355	47,547
Other financial liabilities	0	0	0	0	0	0
Shareholders' equity	**204,638**	**218,781**	**202,719**	**185,164**	**175,230**	**200,979**
Total consolidated equity and debt	**425,797**	**462,854**	**401,212**	**399,558**	**397,577**	**450,842**
Ratios						
Current ratio (x)	4.65	4.06	3.15	2.90	2.69	2.64
Quick ratio (x)	3.94	3.33	2.43	2.19	1.98	1.92
Net gearing	-20.5%	-19.8%	-21.1%	-8.9%	-5.1%	-12.3%
Book value per share (€)	0.29	0.30	0.28	0.25	0.24	0.27
Net debt	-41,960	-43,407	-42,768	-16,456	-8,899	-24,716
Return on equity (ROE)	6.9%	-5.0%	-7.6%	-9.1%	-5.5%	13.7%

CASH FLOW STATEMENT

All figures in USD '000	2022A	2023A	2024E	2025E	2026E	2027E
Profit before tax	**14,987**	**-12,012**	**-18,380**	**-19,948**	**-13,389**	**34,703**
Depreciation, amortization, impairment	13,188	15,925	7,795	8,931	9,806	12,008
Gain on disposal of associate	-12,242	0	0	0	0	0
Equity-settled share-based payments	6,392	9,251	0	0	0	0
Fair value gain (loss) on revaluation	1,185	930	0	0	0	0
Gain on disposal from PRV sale	0	-21,279	0	0	0	0
Other finance income	-4,485	-3,663	0	0	0	0
Other finance expenses	5,463	9,069	0	0	0	0
Share of net profits in associates	1,083	289	1,434	0	0	0
Other	-1,576	-1,079	0	0	0	0
Changes in w orking capital	-387	-16,961	8,428	-688	-2,227	-5,607
Interest received, taxes paid	-1,150	2,228	2,318	2,394	3,454	-8,953
Operating cash flow	**22,458**	**-17,302**	**1,594**	**-9,311**	**-2,356**	**32,150**
Investment in tangible/intangible assets	-1,977	-1,464	-3,802	-3,485	-4,970	-8,259
Free cash flow	**20,481**	**-18,766**	**-2,208**	**-12,796**	**-7,326**	**23,891**
Proceeds from sale of associates	7,300	0	0	0	0	0
Proceeds on PRV sale	0	21,279	0	0	0	0
Investing cashflow	**5,323**	**19,815**	**-3,802**	**-3,485**	**-4,970**	**-8,259**
Debt financing, net	0	0	-47,952	0	0	0
Proceeds of equity and w arrants	2,281	8,133	0	0	0	0
Payment on contingent consideration	0	0	0	0	0	0
Paymnet of lease liabilities	-3,311	-5,126	0	0	0	0
Interest on loans	-3,952	-4,046	0	0	0	0
Financing cash flow	**-4,982**	**-1,039**	**-47,952**	**0**	**0**	**0**
Net cash flows	**22,799**	**1,474**	**-50,160**	**-12,796**	**-7,326**	**23,891**
Exchange rate effects, other	-7,381	4,608	0	0	0	0
Cash, start of the year	**191,924**	**207,342**	**213,424**	**163,264**	**150,467**	**143,141**
Cash, end of the year	**207,342**	**213,424**	**163,264**	**150,467**	**143,141**	**167,032**
EBITDA/share	**0.04**	**0.00**	**-0.02**	**-0.01**	**0.00**	**0.07**
Y-Y Growth						
Operating cash flow	-40.7%	n.m.	n.m.	n.m.	n.m.	n.m.
Free cash flow	-13.4%	n.m.	n.m.	n.m.	n.m.	n.m.
EBITDA/share	2.0%	-90.1%	n.m.	n.m.	n.m.	n.m.

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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.

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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...46	↓	↓	↓	↓
47	29 October 2019	€1.25	Buy	€1.90
48	16 January 2020	€1.48	Buy	€2.00
49	9 March 2020	€1.11	Buy	€2.00
50	23 April 2020	€1.34	Buy	€2.00
51	19 May 2020	€1.34	Buy	€2.10
52	4 August 2020	€1.01	Buy	€1.80
53	18 July 2023	€1.12	Buy	€1.50
54	9 August 2023	€1.13	Buy	€1.60
55	Today	€0.73	Buy	€1.60

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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**

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