Pharming Group NV

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

Update

RATING	**BUY**
PRICE TARGET	**€ 1.50**
Return Potential	33.6%
Risk Rating	High

JOENJA TO REVITALISE SALES AND PROFIT GROWTH

Pharming's orphan drug, Joenja, for the treatment of the rare disease, activated PI3K delta syndrome (APDS), was approved in the US at the end of March for patients 12 years and older and launched in early April. We expect Pharming's sales to more than double by 2026 following the drug's launch in the EU and UK by end 2023/early 2024 and subsequent launches in Australia, Canada and Japan. Pharming's sole revenue generating product prior to Q2/23 was Ruconest, which is indicated for acute hereditary angioedema (HAE) attacks. Ruconest was approved in the EU in 2010 and in the US in 2014. Due mainly to reference pricing and entrenched competition in Europe, US sales of Ruconest accounted for 99% of gross profit in 2022. We expect pricing of Joenja in Europe to be much more favourable than for Ruconest. We assume a 40% discount to the US price level, which is in line with the average for orphan drugs in the EU. Against this background, we expect gross profit growth to 2026 (+88%) to almost keep pace with revenue. PI3K delta is an important factor in a variety of diseases. Pharming is currently exploring further indications for Joenja and has stated that it will update the market on this topic later in 2023. We now see fair value for Pharming at €1.50. Our previous valuation of €1.80 included the now discontinued Pompe disease programme and higher growth projections for Ruconest. We maintain our Buy recommendation.

No. patients on paid Joenja therapy to move ahead briskly The annual wholesale acquisition cost of Joenja per patient is USD547,500. Based on available literature, Pharming estimates that over 1,500 patients are affected by APDS in the US, Europe, UK, Australia, Canada and Japan. Pharming has identified 150 APDS patients in the US as currently eligible for treatment with Joenja. At launch in April Joenja had 23 patients on paid therapy. Pharming has received enrollments from significantly more patients who are in the process of payor reimbursement authorisations. First sales of Joenja will be booked in Q2/23 (reporting date: 3 August). We assume an average of 26 patients on paid therapy in Q2/23, 47 in Q3/23 and 111 in Q4/23. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2021	2022	2023E	2024E	2025E	2026E
Revenue ($ m)	198.87	205.62	231.23	298.68	340.96	413.14
Y-o-y growth	7.1%	3.4%	12.5%	29.2%	14.2%	21.2%
EBIT ($ m)	13.56	18.23	-18.44	16.60	42.51	86.99
EBIT margin	6.8%	8.9%	-8.0%	5.6%	12.5%	21.1%
Net income ($ m)	16.00	13.67	-22.39	12.76	38.04	64.24
EPS (diluted) ($)	0.02	0.02	-0.03	0.02	0.05	0.09
DPS ($)	0.00	0.00	0.00	0.00	0.00	0.00
FCF ($m)	23.66	20.48	-27.58	7.89	34.10	56.96
Net gearing	-5.4%	-20.5%	-5.9%	-6.2%	-19.0%	-32.5%
Liquid assets ($ m)	191.92	207.34	179.76	187.64	88.36	145.32

RISKS

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

COMPANY PROFILE

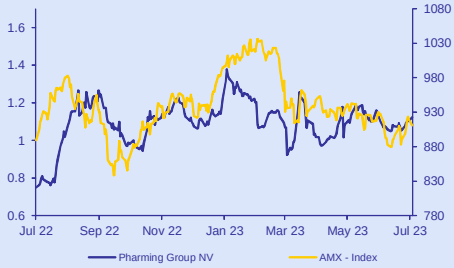
Lead drug Ruconest, indicated for acute hereditary angioedema attacks, received EMA approval in 2010 and FDA approval in July 2014. Joenja, indicated for APDS, was approved by the FDA in March 2023. Pharming has launched Joenja in the US and, subject to approval, plans launches of the drug in the EU, UK, Australia, Canada and Japan.

MARKET DATA

As of 17 Jul 2023	
Closing Price	€ 1.12
Shares outstanding	658.67m
Market Capitalisation	€ 739.69m
52-week Range	€ 0.75 / 1.38
Avg. Volume (12 Months)	8,007,975

Multiples	2022	2023E	2024E
P/E	58.1	n.a.	n.a.
EV/Sales	3.5	3.1	2.4
EV/EBIT	39.7	n.a.	43.6
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Mar 2023	
Liquid Assets	$ 184.78m
Current Assets	$ 266.06m
Intangible Assets	$ 75.61m
Total Assets	$ 423.00m
Current Liabilities	$ 59.00m
Shareholders' Equity	$ 199.34m

SHAREHOLDERS

RTW Investments LP	5.0%
Acadian Asset Management LLC	3.0%
BlackRock Inc.	2.4%
Sijmen de Vries	2.2%
Free float and other	87.4%

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

Joenja supports proper immune function by facilitating balanced signalling in the PI3K delta pathway Joenja, a small molecule phosphoinositide 3-kinase delta (PI3K delta) inhibitor, is the first and only treatment approved by the FDA for the indication activated PI3K delta syndrome or APDS. APDS is a rare primary immunodeficiency that affects approximately 1 to 2 people per million. By comparison, the estimated prevalence of HAE is 1 in every 50,000 people. APDS is caused by variants in either of two genes, PIK3CD or PIK3R1, that regulate maturation of white blood cells. Variants of these genes lead to hyperactivity of the PI3K delta (phosphoinositide 3-kinase delta) pathway. Balanced signalling in the PI3K delta pathway is essential for physiological immune function. When this pathway is hyperactive, immune cells fail to mature and function properly, leading to immunodeficiency and dysregulation.

APDS is characterized by severe, recurrent sinopulmonary infections, lymphoproliferation, autoimmunity, and enteropathy. Because these symptoms can be associated with a variety of conditions, including other primary immunodeficiencies, people with APDS are frequently misdiagnosed and suffer a median 7-year diagnostic delay.

As APDS is a progressive disease, this delay may lead to an accumulation of damage over time, including permanent lung damage and lymphoma. A definitive diagnosis can be made through genetic testing. Joenja facilitates balanced signalling in the PI3K delta pathway thereby supporting proper immune function.

Measures in place to expedite identification of APDS patients in both the US and Europe In March 2021, Pharming in collaboration with the US medical genetics company, Invitae, launched a genetic testing programme, NavigateAPDS, to speed the identification of APDS patients in the US and Canada. Pharming's support of the programme has facilitated genetic testing and counselling for eligible individuals in the US and Canada at no charge. The navigateAPDS programme offers testing with a choice of either the Invitae Primary Immunodeficiency Panel or the Invitae Inborn Errors of Immunity and Cytopenias Panel, which respectively analyzes 429 and 574 genes associated with inherited disorders of the immune system. In Europe, Pharming has intensified patient identification efforts together with leading immunology centres of excellence which treat patients with APDS and other rare immune deficiencies.

Pharming entered into a development collaboration and license agreement with Novartis to develop and commercialize Joenja in August 2019. Positive results of the registration-enabling phase 2/3 trial carried out by Novartis were published in early February 2022.

Pharming's Q2/23 results will include a USD10m milestone payment from Pharming to Novartis marking the first commercial sales of Joenja in the US. We expect a further USD10m milestone payment to Novartis to become due later this year following approval of leonilisib in Europe.

Pharming has received USD21.1m for priority review voucher Under the agreement with Novartis, the Swiss company also had the right to buy the priority review voucher issued to Pharming in connection with the development of Joenja for a small minority share of its value. On 1 June Pharming announced that it had received USD21.1m from Novartis for the priority review voucher.

Milestones to Novartis to reach USD180m if Joenja sales reach USD500m Pharming is obligated to make further milestone payments to Novartis based on worldwide annual sales of Joenja. The first milestone equals USD5m when annual net sales reach USD50m. The total commitment equals USD180 million when annual net sales reach USD500m.

Royalty rate starts at 12%, rises to 18% In addition, Pharming has agreed to pay royalties to Novartis on Joenja. These royalties are calculated as a fixed percentage of net sales and have a term of 10 years. The minimum royalty rate of 12% is applicable for annual sales up to USD150m. The royalty rate grows to a maximum of 18% when net sales exceed USD300m.

Joenja approve in EU and UK likely in late 2023/early 2024 Pharming submitted a marketing authorisation application for Joenja to the EMA in October last year. Management expects the CHMP (Committee for Medicinal Products for Human Use) to give an opinion during H2/23. Providing that the opinion is positive, approval is expected two months later. Filing with the MHRA in the UK is also scheduled for H2/23 with approval expected two months later under the ECDRP (European Commission Decision Reliance Procedure).

Pivotal trial/regulatory submissions in the works in Japan, Australia and Canada Pharming plans to begin a clinical trial with Joenja in APDS patients 12 years and older in Japan later this quarter. We have assumed first revenue in Japan from the drug in 2026. Pharming has also indicated that regulatory submissions in Australia and Canada are planned for the near term.

Pediatric trials with Joenja also moving ahead In February 2023 Pharming announced that the first patient had been enrolled in its Phase III clinical trial evaluating Joenja in children aged 4 to 11 years with APDS, at sites in the US, Europe, and Japan. A further trial, for children ages 1 to 6 is scheduled to begin later this quarter.

Our forecasts for Joenja sales (see figure 1 below) are based on enrollment of an increasing proportion of currently identified patients in reimbursed therapy, the identification of new patients and from 2025 a rising number of pediatric patients (who we assume account for 25% of total patients).

Figure 1: Forecast Joenja sales 2023-2026

USD 000s	2023E	2024E	2025E	2026E
Sales	22,193	83,364	119,193	184,718
change (%)				
of which:				
US	22,193	66,412	82,370	106,477
change (%)	n.a.	199.2%	24.0%	29.3%
YE no. revenue generating patients	111	138	171	229
change (%)	n.a.	23.7%	24.0%	33.8%
Europe + ROW	0	16,951	36,823	78,241
change (%)	n.a.	n.a.	117.2%	112.5%
YE no. revenue generating patients	0	59	127	280
change (%)	n.a.	n.a.	117.2%	120.0%
Gross profit	16,651	65,007	94,692	151,276
margin	75.0%	78.0%	79.4%	81.9%
of which:				
US	16,651	55,092	68,330	91,445
margin	75.0%	83.0%	83.0%	85.9%
Europe + ROW	0	9,915	26,362	59,832
margin	n.a.	58.5%	71.6%	76.5%

Source: First Berlin Equity Research estimates

Intensifying competition has slowed Ruconest sales growth in recent years Figure 2 shows the development of Ruconest sales for the period 2016-2022 and our forecasts for 2023-2026. US sales of Ruconest multiplied over six fold in 2017 following Pharming's acquisition of the commercialisation rights to the drug from Bausch Health at the end of 2016. Ruconest's superior efficacy to established acute therapies such as Firazyr and shortages of plasma-based therapies kept sales moving ahead strongly in 2018. But sales growth slowed markedly from 2019 onward. The slowdown was attributable to a market shift from acute to prophylactic treatments, new more convenient methods of administration and the availability from 2019 of generic versions of Firazyr, which remains the leading treatment for acute HAE attacks.

Figure 2: Historic and forecast Ruconest sales 2016-2026

USD 000s	2016A	2017A	2018A	2019A	2020A	2021A	2022A	2023E	2024E	2025E	2026E
Sales	17,573	101,271	159,453	189,203	212,174	198,871	205,622	209,041	215,312	221,772	228,425
change	n.a.	476.3%	57.5%	18.7%	12.1%	-6.3%	3.4%	1.7%	3.0%	3.0%	3.0%
of which:											
US	14,242	94,598	149,430	182,115	202,684	193,419	200,082	203,409	209,511	215,796	222,270
change	n.a.	564.2%	58.0%	21.9%	11.3%	-4.6%	3.4%	1.7%	3.0%	3.0%	3.0%
Europe	2,508	5,755	8,456	5,643	8,232	4,933	4,924				
change	n.a.	129.5%	46.9%	-33.3%	45.9%	-40.1%	-0.2%				
ROW	824	918	1,567	1,445	1,258	519	616				
change	n.a.	11.4%	70.8%	-7.8%	-12.9%	-58.7%	18.7%				
Europe + ROW	3,331	6,673	10,023	7,088	9,490	5,452	5,540	5,632	5,801	5,975	6,154
change	n.a.	100.3%	50.2%	-29.3%	33.9%	-42.6%	1.6%	1.7%	3.0%	3.0%	3.0%
Gross profit	12,388	87,208	133,281	165,298	188,635	177,729	188,060	184,870	190,416	196,129	202,013
margin	70.5%	86.1%	83.6%	87.4%	88.9%	89.4%	91.5%	88.4%	88.4%	88.4%	88.4%
of which:											
US	11,069	85,260	131,666	162,067	184,024	176,266	186,263	183,068	188,560	194,217	200,043
margin	77.7%	90.1%	88.1%	89.0%	90.8%	91.1%	93.1%	90.0%	90.0%	90.0%	90.0%
Europe	706	1,206	342	2,139	3,534	1,049	1,378				
margin	28.2%	21.0%	4.0%	37.9%	42.9%	21.3%	28.0%				
ROW	613	742	1,273	1,093	1,077	414	419				
margin	74.5%	80.9%	81.3%	75.6%	85.6%	79.8%	68.0%				
Europe + ROW	1,320	1,948	1,615	3,232	4,611	1,463	1,797	1,802	1,856	1,912	1,969
margin	39.6%	29.2%	16.1%	45.6%	48.6%	26.8%	32.4%	32.0%	32.0%	32.0%	32.0%

Source: Pharming Group NV, First Berlin Equity Research estimates

Ca. 75% of US HAE patients currently use prophylactic therapy, up from 30% in 2018. The leading prophylactic therapy is Takhzyro, which was approved by the FDA in August 2018 and generated sales in the US of ca. USD1,120m during the twelve months to end March 2023. December 2020 saw the FDA approval of BioCryst's oral prophylactic therapy, Orladeyo. 2022 sales, over 80% of which were generated in the US, amounted to USD250m.

Resilience of Ruconest sales based on efficacy, breakthrough attacks suffered by users of competing products Despite intensifying competition (see figure 3), Pharming has succeeded in keeping sales of Ruconest broadly stable since 2020. Temporary disruptions in reimbursement for some patients on government insurance programmes pushed sales of Ruconest 8.7% lower to USD42.5m in Q1/23 (Q1/22: USD46.6m). However the market has since returned to normal and management reported that underlying demand for Ruconest continued to be strong in the first quarter, which saw a high number of new patient enrollments. In the 2022 annual report published in March, Pharming guided towards low single digit sales growth for Ruconest in 2023. This guidance was maintained in May's Q1 report.

Figure 3: Current HAE therapy competitive landscape

Company	Product	HAE Indication	Administration method	Mode of action	FDA approval date	EMA approval date	Worldwide sales, most recent fin. year (USDm)	Patent duration US	Patent duration EU
CSL Behring	Berinert	Acute	IV injection	plasma-derived C1 inhibitor	10/2009	12/2008	n.a.	n.a.	n.a.
Takeda	Cinryze	Prophylaxis	IV injection	plasma-derived C1 inhibitor	08/2008	06/2011	136	-	-
Takeda	Firazyr	Acute	Subcut. injection	bradykinin B2 receptor antagonist	08/2011	07/2008	182	-	-
CSL Behring	Haegarda	Prophylaxis	Subcut. injection	plasma-derived C1 inhibitor	06/2017	2017	n.a.	n.a.	n.a.
BioCryst	Orladeyo	Prophylaxis	Oral	serine protease kallikrein inhibitor	12/2020	04/2021	250	31 expiring 2023-39	n.a
Pharming	Ruconest	Acute	IV injection	recombinant C1 inhibitor	07/2014	10/2010	206	10/2026	10/2026
Takeda	Takhzyro	Prophylaxis	Subcut. injection	plasma kallikrein inhibitor (mAb)	08/2018	11/2018	1,120	08/2032	01/2031 - 11/2033

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 (CSL Behring; FDA approval: June 2017) and Takhzyro (Takeda; FDA approval: August 2018) suffer breakthrough attacks. For Orladeyo (BioCryst; FDA approval: December 2020) this figure is 90%. HAE patients using prophylactic therapies typically use acute treatments such as Ruconest to halt breakthrough attacks.

Figure 4 shows HAE therapies in clinical development. We view the most significant development in the HAE pipeline as the application of gene therapy to the disease as this technology holds out the prospect of a one-time curative treatment.

Figure 4: HAE therapies in clinical development

Company	Asset	Mode of Action	Route of Administration	Trial Phase	Role in Therapy
KalVista	Sebetralstat	Kallikrein inhibitor	Oral	III	Acute treatment
Pharvaris	PHA121 (PHVS416/PHVS719)	B2 receptor antagonist	Oral	II/III	Acute 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
BioMarin	BMN-331	Gene therapy	IV	I/II	Functional cure

Source: companies

Pharming cooperating with Orchard Pharmaceuticals to develop a gene therapy for HAE In 2021 Pharming signed a license agreement with UK-based Orchard Pharmaceuticals for OTL-105, a gene therapy for HAE patients. Pharming stated in its Q1/23 report that providing the data from pre-clinical animal studies meet scientific requirements, Investigational New Drug (IND) application-enabling pre-clinical studies of OTL-105 will start later this year.

OTL-105 utilises Orchard Therapeutics' ex vivo autologous hematopoietic stem cell (HSC) platform. Based on this platform, Orchard uses the HAE patients' own blood stem cells and inserts those cells into a working copy of the gene that is reduced in HAE. Specifically, CD34+ stem cells are isolated from the patients' blood and transduced with a lentiviral vector encoding the human SERPING1 gene. Once these gene-corrected stem cells are returned to the patient, the stemcell-derived leukocytes start producing the corrected gene product. In pre-clinical proof of concept studies, OTL-105 expressed the SERPING-1 gene and the gene-corrected stem cells produced a relevant quantity of active C1-esterase inhibitor.

Under the terms of the collaboration between Pharming and Orchard, Pharming has been granted worldwide rights to OTL-105 and will be responsible for clinical development, regulatory filings, and commercialisation, including associated costs. Orchard will lead the completion of IND-enabling activities and oversee manufacturing of OTL-105 during pre-clinical and clinical development, which will be funded by Pharming.

Orchard's ex vivo HSC gene therapy has so far generated one approved therapy, Libmeldy (OTL-200), for metachromatic leukodystrophy (MLD). The start of a pivotal trial of a second therapy (OTL-203) for Hurler Syndrome a.k.a. mucopolysaccharidisosis type IH (MPS-IH) is scheduled for later this year. A third therapy (OTL-201) for sanfilippo syndrome, a.k.a. mucopolysaccharidisosis type III, is the subject of a clinical proof of concept trial. Libmeldy is a one-time therapy that aims to correct the underlying genetic cause of MLD. It was approved by the EMA in December 2020. Orchard has initiated submission of a Biologics License Application (BLA) for OTL-200 to the FDA with potential for US approval in H1/24.
The EMA's publicly available overview of Libmeldy attests:

"The benefits of Libmeldy in treating MLD were shown in a main study involving 20 children with late infantile or early juvenile MLD…After 2 years, the overall Gross Motor Function Measure score (a value between 0 and 100 measuring a developing child's ability to make normal movements such as crawling, standing and walking) was 72.5 in the group with late infantile MLD, compared to 7.4 in records of similar untreated children. Similarly, in children with early juvenile MLD, the average score 2 years after treatment with Libmeldy was 76.5, whereas that in previous untreated cases was 36.3. Benefit was greatest in children who had not yet developed symptoms and seemed to be lost, in those who could no longer walk independently, or had developed mental deterioration. There was evidence of continuing benefit on follow-up for up to 8 years."

Durability of effect, safety are key drivers of Pharming's cooperation with Orchard
Pharming's CEO, Sijmen de Vries, observed at the time of the announcement of the Orchard deal in 2021, that the main reasons for Pharming's decision to enter the collaboration were "the durability of effect and safety observed in approved treatments from Orchard's HSC gene therapy portfolio and positive clinical data in several other programmes."

OTL-105 looks promising, but given the ten year gap between the start of the pivotal trial of Libmeldy in 2010 and approval by the EMA in 2020, we think it unlikely that it will reach the market before the end of this decade. As figure 4 shows, competitors' HAE gene therapy programmes are further advanced. According to clinical trials.gov the estimated primary completion dates for the ongoing BioMarin and Intellia phase I/II trials are November 2028 and April 2024 and respectively.

Approval of most advanced HAE gene therapy unlikely before the final years of this decade Last month Intellia announced interim results from the phase I portion of an ongoing phase 1/2 study of NTLA-2002, its in vivo CRISPR genome treatment for HAE.

Across all patients (n=10), a single dose of NTLA-2002 led to a 95% mean reduction in monthly HAE attack during the follow-up period (median duration: 9 months; range of 5.6 to 14.1 months). The previous month, Intellia announced that the first patient has been dosed in the phase 2 portion of its phase 1/2 clinical trial of NTLA-2002. Enrollment (n=25) is expected to complete later this year. The phase 1/2 study will identify the dose of NTLA-2002 for use in future studies. Intellia has indicated that it is planning a phase 3 trial of NTLA-2002; so approval of this drug is unlikely before 2028/29.

BioMarin continues to dose participants in the phase 1/2 HAERMONY study to evaluate BMN 331, an adeno-associated virus type 5-mediated gene therapy for HAE patients.

Figure 5: Historic and Forecast Group P&L 2021-2026

USD 000s	2021A	2022A	Q1/23A	Q2/23E	Q3/23E	Q4/23E	2023E	2024E	2025E	2026E
Sales	**198,871**	**205,622**	**42,541**	**56,133**	**61,639**	**70,921**	**231,234**	**298,676**	**340,965**	**413,143**
change	***-6.3%***	***3.4%***	***-8.7%***	***11.9%***	***13.6%***	***29.8%***	***12.5%***	***29.2%***	***14.2%***	***21.2%***
of which:										
Ruconest	198,871	205,622	42,541	53,000	56,000	57,500	209,041	215,312	221,772	228,425
change	-1.9%	3.4%	-8.7%	5.7%	3.2%	5.3%	1.7%	3.0%	3.0%	3.0%
Joenja	0	0	0	3,133	5,639	13,421	22,193	83,364	119,193	184,718
change	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	275.6%	43.0%	55.0%
Gross profit	**177,729**	**188,060**	**38,466**	**49,115**	**53,562**	**60,379**	**201,521**	**255,423**	**290,821**	**353,289**
margin	***89.4%***	***91.5%***	***90.4%***	***87.5%***	***86.9%***	***85.1%***	***87.2%***	***85.5%***	***85.3%***	***85.5%***
of which:										
Ruconest	177,729	188,060	38,466	46,872	49,525	50,008	184,870	190,416	196,129	202,013
margin	89.4%	91.5%	90.4%	88.4%	88.4%	87.0%	88.4%	88.4%	88.4%	88.4%
Joenja	0	0	0	2,243	4,037	10,371	16,651	65,007	94,692	151,276
margin	n.a.	n.a.	n.a.	71.6%	71.6%	77.3%	75.0%	78.0%	79.4%	81.9%
Other income	2,620	14,523	579	500	500	500	2,079	2,131	2,184	2,239
R&D	-70,369	-52,531	-15,620	-15,156	-16,643	-17,730	-65,149	-68,695	-71,603	-74,366
% sales	35.4%	25.5%	36.7%	27.0%	27.0%	25.0%	28.2%	23.0%	21.0%	18.0%
G&A	-36,974	-46,016	-9,981	-11,227	-11,711	-12,057	-44,976	-50,775	-54,554	-61,971
% sales	18.6%	22.4%	23.5%	20.0%	19.0%	17.0%	19.5%	17.0%	16.0%	15.0%
Sales & marketing	-59,445	-85,803	-27,107	-29,189	-28,354	-28,369	-113,019	-116,484	-119,338	-132,206
% sales	29.9%	41.7%	63.7%	52.0%	46.0%	40.0%	48.9%	39.0%	35.0%	32.0%
Milestones	0	0	0	-10,000	0	-10,000	-20,000	-5,000	-5,000	0
Sale of priority review voucher	0	0	0	21,100	0	0	21,100	0	0	0
Operating income (EBIT)	**13,561**	**18,233**	**-13,663**	**5,143**	**-2,646**	**-7,277**	**-18,443**	**16,600**	**42,510**	**86,985**
margin (%)	***6.8%***	***8.9%***	***-32.1%***	***9.2%***	***-4.3%***	***-10.3%***	***-8.0%***	***5.6%***	***12.5%***	***21.1%***
Net financial result	8,823	-2,163	-2,672	-1,500	-1,500	-1,500	-7,172	-3,342	714	-408
Associates	694	-1,083	-339	-300	-300	-300	-1,239	-500	0	0
Pre-tax income (EBT)	23,078	16,070	-16,674	3,343	-4,446	-9,077	-26,854	12,758	43,225	86,578
Income taxes	-7,082	-1,313	4,466	0	0	0	4,466	0	-5,187	-22,337
Net income / loss	**15,996**	**13,674**	**-12,208**	**3,343**	**-4,446**	**-9,077**	**-22,388**	**12,758**	**38,038**	**64,241**
Diluted EPS (USD)	**0.023**	**0.019**	**-0.017**	**0.005**	**-0.006**	**-0.013**	**-0.031**	**0.018**	**0.052**	**0.088**
Diluted EPS (EUR)	**0.019**	**0.018**	**-0.016**	**0.004**	**-0.006**	**-0.011**	**-0.028**	**0.016**	**0.047**	**0.079**

Source: Pharming Group NV, Frist Berlin Equity Research estimates

We expect Pharming to return to the black in 2024 Figure 5 above illustrates how we expect the ramp-up of Joenja sales to accelerate overall group sales growth. We project that Pharming will record negative EBIT and net profit this year due to the impact of higher R&D and sales & marketing expense ahead of the launch of Joenja. However, we expect the company to return to the black next year as Joenja sales nearly quadruple due to growing patient numbers, a first full-year contribution from the US and first revenues in Europe.

Pharming should be comfortably able to repay €125m convertible maturing in January 2025 Pharming had net cash of USD15.8m at the end of Q1/23. We expect this figure to have shrunk to USD10.8m by the end of 2023 but to reach USD12.2m by the end of next year (unrestricted cash of USD187.6m, restricted cash of USD1.3m and debt of USD176.8m). The biggest component of Pharming's debt position is the €125m 3% coupon convertible bond placed in January 2020. The bond is convertible at €2.00 and matures in January 2025. On our forecasts Pharming will be able to repay this debt without recourse to refinancing.

Figure 6: 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	€1,029.9M	4K	€ 454,545	€1,818M	10%	€354M	90%	12%	3	-
Ruconest (ROW)	HAE-AA	€7.5M	8K	€ 90,909	€727M	1%	€10M	32%	12%	3	-
Joenja (US)	APDS	€595.9M	425	€ 497,727	€212M	100%	€212M	83%	10%	13	-
Joenja (ROW)	APDS	€454.3M	849	€ 298,636	€254M	100%	€238M	72%	10%	13	1 year
Joenja platform		€400.0M									
PV of gross profits		€2,487.6M									
Costs PV		€1,473.2M									
PV after costs		€1,014.4M									
Priority review voucher/Joenja milestones		€36.6M									
Net cash (pro-forma)		€46.9M									
Fair Value		€1,024.7M									
Share Count (fully diluted, PV)		700,234K									
Fair value per share		**€ 1.46**									

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 €1.50 (previously: €1.80) Pharming expects to have patent protection for Joenja in APDS under the Novartis composition of matter patent and applicable patent term adjustments, extensions, and pediatric extension through early 2037 in the US and EU. Ruconest has patent protection in the US and EU until 7 October 2026, as well as biologics reference product exclusivity in the United States expiring 16 July 2026. As far as we can ascertain, no Ruconest biosimilars are currently under development. However, the development of gene therapies for HAE is a threat in the medium term. As we pointed out above, if it successfully negotiates phases 2 and 3 and the approval process, Intellia's NTLA-2002 could reach the market in the latter years of this decade. The central role of PI3K delta in regulating numerous cellular functions of the adaptive immune system (B-cells and to a lesser extent T cells) as well as the innate immune system (neutrophil, mast cells, and macrophages) strongly indicates that PI3K delta is a valid and potentially effective therapeutic target for several immune diseases in addition to APDS. Pharming is currently exploring further indications for its PI3K delta inhibitor, Joenja, and has stated that it will update the market on this topic later in 2023. The combined potential market value of these indications is likely larger than for APDS. Against this background, we have included €400m in our valuation model, or ca. 40% of the value we accord Joenja for the APDS indication, to reflect the drug's platform value. We now see fair value for the Pharming share at €1.46 and set a price target of €1.50. Our previous valuation of €1.80 (August 2020) included the now discontinued Pompe disease programme as well as higher growth projections for Ruconest. We maintain our Buy recommendation.

INCOME STATEMENT

All figures in USD '000	2021A	2022A	2023E	2024E	2025E	2026E
Revenues	**198,871**	**205,622**	**231,234**	**298,676**	**340,965**	**413,143**
Costs of sales	-21,142	-17,562	-29,713	-43,253	-50,144	-59,854
Gross profit	**177,729**	**188,060**	**201,521**	**255,423**	**290,821**	**353,289**
Other income	2,620	14,523	2,079	2,131	2,184	2,239
Research and development	-70,369	-52,531	-65,149	-68,695	-71,603	-74,366
General and administrative	-36,974	-46,016	-44,976	-50,775	-54,554	-61,971
Marketing and sales	-59,445	-85,803	-113,019	-116,484	-119,338	-132,206
Milestones/PRV sales	0	0	1,100	-5,000	-5,000	0
Operating income (EBIT)	**13,561**	**18,233**	**-18,443**	**16,600**	**42,510**	**86,985**
Net financial result	8,823	-2,163	-7,172	-3,342	714	-408
Associates	694	-1,083	-1,239	-500	0	0
Pre-tax income (EBT)	**23,078**	**14,987**	**-26,854**	**12,758**	**43,225**	**86,578**
Income taxes	-7,082	-1,313	4,466	0	-5,187	-22,337
Minority interests	0	0	0	0	0	0
Net income / loss	**15,996**	**13,674**	**-22,388**	**12,758**	**38,038**	**64,241**
Diluted EPS	**0.023**	**0.019**	**-0.031**	**0.018**	**0.052**	**0.088**
EBITDA	**26,009**	**25,185**	**-10,812**	**24,664**	**52,739**	**99,379**
Ratios						
Gross margin on revenues	89.4%	91.5%	87.2%	85.5%	85.3%	85.5%
EBITDA margin on revenues	13.1%	12.2%	n.m.	8.3%	15.5%	24.1%
EBIT margin on revenues	6.8%	8.9%	n.m.	5.6%	12.5%	21.1%
Net margin on revenues	8.0%	6.7%	n.m.	4.3%	11.2%	15.5%
Expenses as % of revenues						
Cost of sales	10.6%	8.5%	12.8%	14.5%	14.7%	14.5%
Research and development	35.4%	25.5%	28.2%	23.0%	21.0%	18.0%
General and administrative	18.6%	22.4%	19.5%	17.0%	16.0%	15.0%
Marketing and sales	29.9%	41.7%	48.9%	39.0%	35.0%	32.0%
Y-Y Growth						
Revenues	24.6%	3.4%	12.5%	29.2%	14.2%	21.2%
Operating income	-69.8%	34.5%	n.m.	n.m.	156.1%	104.6%
Net income/ loss	-45.8%	-14.5%	n.m.	n.m.	198.1%	68.9%

BALANCE SHEET

All figures in USD '000	2021A	2022A	2023E	2024E	2025E	2026E
Assets						
Current assets, total	**249,444**	**277,500**	**258,627**	**289,455**	**204,556**	**286,073**
Cash and cash equivalents	191,924	207,342	179,757	187,643	88,360	145,324
Restricted cash	227	213	213	213	213	213
Receivables	29,983	27,619	31,059	40,118	45,798	55,493
Inventories	27,310	42,326	47,598	61,481	70,185	85,043
Non-current assets, total	**147,871**	**148,297**	**155,147**	**161,435**	**164,275**	**170,647**
Property, plant & equipment	13,222	10,392	10,174	10,155	10,570	11,981
Right of use assets	19,943	28,753	32,335	38,828	40,916	45,446
Long term prepayments	194	228	256	331	378	458
Deferred tax assets	21,216	22,973	27,439	27,439	27,439	27,439
Investments accounted for using the equity method	7,201	2,501	1,262	762	762	762
Investments in FVTOCI equity instruments	1,449	403	403	403	403	403
Investments in FVTPL debt instruments	0	6,827	6,827	6,827	6,827	6,827
Goodwill & other intangibles	83,834	75,121	75,352	75,591	75,881	76,232
Restricted cash	812	1,099	1,099	1,099	1,099	1,099
Total assets	**397,315**	**425,797**	**413,775**	**450,890**	**368,831**	**456,720**
Shareholders' equity & debt						
Current liabilities, total	**46,771**	**59,698**	**66,855**	**217,012**	**95,045**	**114,634**
Debt	1,879	1,768	1,768	133,386	0	0
Trade and other payables	42,473	54,465	61,249	79,113	90,315	109,433
Finance lease liabilities	2,419	3,465	3,838	4,513	4,730	5,202
Longterm liabilities, total	**157,628**	**161,461**	**164,670**	**38,870**	**40,741**	**44,799**
Debt	139,007	131,618	131,618	0	0	0
Finance lease liabilities	18,456	29,843	33,052	38,870	40,741	44,799
Other financial liabilities	165	0	0	0	0	0
Shareholders' equity	**192,916**	**204,638**	**182,250**	**195,008**	**233,046**	**297,286**
Total consolidated equity and debt	**397,315**	**425,797**	**413,775**	**450,890**	**368,831**	**456,720**
Ratios						
Current ratio (x)	5.33	4.65	3.87	1.33	2.15	2.50
Quick ratio (x)	4.75	3.94	3.16	1.05	1.41	1.75
Net gearing	-16.2%	-20.5%	-5.9%	-6.2%	-19.0%	-32.5%
Book value per share (€)	0.30	0.32	0.29	0.31	0.37	0.47
Net debt	-31,202	-41,960	-10,794	-12,186	-44,201	-96,635
Return on equity (ROE)	8.6%	6.9%	-11.6%	6.8%	17.8%	24.2%

CASH FLOW STATEMENT

All figures in USD '000	2021A	2022A	2023E	2024E	2025E	2026E
Profit before tax	**23,078**	**14,987**	**-26,854**	**12,758**	**43,225**	**86,578**
Depreciation, amortization, impairment	19,610	13,188	7,631	8,064	10,229	12,394
Gain on disposal of associate	0	-12,242	0	0	0	0
Equity-settled share-based payments	9,056	6,392	0	0	0	0
Fair value gain (loss) on revaluation	-114	1,185	0	0	0	0
Other finance income	-14,906	-4,485	0	0	0	0
Other finance expenses	6,196	5,463	0	0	0	0
Share of net profits in associates	-694	1,083	1,239	500	0	0
Other	524	-1,576	0	0	0	0
Changes in w orking capital	-4,961	-387	-1,957	-5,152	-3,231	-5,514
Interest received, taxes paid	53	-1,150	0	0	-5,187	-22,337
Operating cash flow	**37,842**	**22,458**	**-19,941**	**16,170**	**45,036**	**71,121**
Investment in tangible/intanbigle assets	-14,186	-1,977	-7,644	-8,284	-10,934	-14,157
Free cash flow	**23,656**	**20,481**	**-27,585**	**7,886**	**34,102**	**56,964**
Proceeds from sale of associates	0	7,300	0	0	0	0
Investment in FVTOCI	-4,589	0	0	0	0	0
Acquisition of license	-2,530	0	0	0	0	0
Investing cashflow	**-21,305**	**5,323**	**-7,644**	**-8,284**	**-10,934**	**-14,157**
Debt financing, net	0	0	0	0	-133,386	0
Proceeds of equity and w arrants	4,718	2,281	0	0	0	0
Payment on contingent consideration	-25,000	0	0	0	0	0
Paymnet of lease liabilities	-3,217	-3,311	0	0	0	0
Interest on loans	-4,448	-3,952	0	0	0	0
Financing cash flow	**-27,947**	**-4,982**	**0**	**0**	**-133,386**	**0**
Net cash flows	**-11,410**	**22,799**	**-27,585**	**7,886**	**-99,284**	**56,964**
Exchange rate effects	-1,825	-7,381	0	0	0	0
Cash, start of the year	**205,159**	**191,924**	**207,342**	**179,757**	**187,643**	**88,360**
Cash, end of the year	**191,924**	**207,342**	**179,757**	**187,643**	**88,360**	**145,324**
EBITDA/share	**0.04**	**0.04**	**-0.01**	**0.03**	**0.07**	**0.14**
Y-Y Growth						
Operating cash flow	n.a.	-40.7%	n.m.	n.m.	178.5%	57.9%
Free cash flow	n.a.	-13.4%	n.m.	n.m.	332.4%	67.0%
EBITDA/share	n..a	-4.0%	n.m.	n.m.	113.8%	88.4%

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AGREEMENT WITH THE ANALYSED COMPANY AND MAINTENANCE OF OBJECTIVITY

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.

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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...45	↓	↓	↓	↓
46	29 July 2019	€0.94	Buy	€1.90
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
54	Today	€1.12	Buy	€1.50

INVESTMENT HORIZON

Unless otherwise stated in the financial analysis, the ratings refer to an investment period of twelve months.

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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: https://firstberlin.com/disclaimer-english-link/

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