Pharming Group NV

Netherlands / Biotechnology
Primary exchange: Euronext Amsterdam / Secondary exchange: Frankfurt
Bloomberg: PHARM NA
ISIN: NL0000377018

9M 2014 Results
&
US Product Launch

RATING	**BUY**
PRICE TARGET	**€1.50**
Return Potential	278.8%
Risk Rating	High

PRODUCT LAUNCH IN THE US AND RECEIPT OF USD20M MILESTONE PAYMENT

Pharming published its 9M 2014 results on 30 October, announced the launch of Ruconest on the US market on 3 November and confirmed the receipt of the anticipated USD20m milestone payment on 4 November. As anticipated, 9M European Ruconest sales grew y/y and operating expenditures were slightly higher due to increased activities such as the beginning of the phase II clinical trial of Ruconest for HAE (hereditary angioedema) prophylaxis. Pharming's operating cash flow during 9M 2014 was characterised by increased manufacturing activity ahead of the Ruconest launch in the US. During the reporting period, Pharming acquired the assets of Transgenic Rabbit Models SASU and thus gained access to potential new products. The firm and its European partner Swedish Orphan Biovitrum (SOBI) have also extended and amended their existing distribution agreement. Pharming will now focus on direct commercialisation in Austria, Germany and the Netherlands. Our updated pipeline valuation model yields a new price target of EUR1.50 (previously: EUR1.10). We reiterate our Buy recommendation.

9M generally in line expectations In 9M 2014, product sales in Europe increased to EUR2.19m (FBe: EUR2.41m; 9M/13: EUR0.61m). Due to a licensing payment of USD5m from US partner Santarus (now Salix Pharmaceuticals) during 9M 2013, license fees declined y/y to EUR1.65m (FBe: EUR1.46m; 9M/13: EUR5.35m). Total revenues thus came in at EUR3.84m (FBe: EUR3.87m; 9M/13: EUR5.97m). COGS including inventory impairments amounted to EUR2.66m (FBe: EUR2.83m; 9M/13: EUR0.42m). Following the increase in operating activities during the reporting period (such as the beginning of a phase II clinical trial with Ruconest for HAE prophylaxis), 9M OPEX was higher at EUR10.94m (FBe: EUR11.20m; 9M/13: EUR9.31m). Pharming's EBIT loss thus widened to EUR-9.66m (FBe: EUR-10.16m; 9M/13: EUR3.68m). Due to a EUR5.2m gain booked under financial income and expenses associated with the revaluation of outstanding warrants in Q3 … (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2011	2012	2013	2014E	2015E	2016E
Revenue (€m)	3.20	10.86	6.95	21.37	15.55	32.33
Y-o-y growth	n.a.	240.0%	-36.0%	207.4%	-27.2%	107.8%
EBIT (€m)	-18.50	-17.46	-6.91	1.97	-2.22	12.97
EBIT margin	-5.8%	-160.7%	-99.5%	9.2%	-14.3%	40.1%
Net income (€m)	-17.10	-24.09	-14.84	-11.78	-1.97	11.21
EPS (diluted) (€)	-0.04	-0.02	-0.04	-0.03	0.00	0.03
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-17.99	-10.88	-8.31	1.07	-4.93	5.22
Net gearing	-2178.6%	-320.1%	526.5%	220.0%	323.3%	58.0%
Liquid assets (€m)	3.78	5.27	16.97	32.24	27.30	32.53

RISKS

The main risks to our price target include delays in the commercialisation of Ruconest in the EU and the US.

COMPANY PROFILE

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

MARKET DATA

As of 04 Nov 2014	
Closing Price	€ 0.40
Shares outstanding	407.69m
Market Capitalisation	€ 161.44m
52-week Range	€ 0.12 / 0.67
Avg. Volume (12 Months)	23,581,877

Multiples	2013	2014E	2015E
P/E	n.a.	n.a.	n.a.
EV/Sales	23.4	7.6	10.4
EV/EBIT	n.a.	82.5	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW

COMPANY DATA

As of 30 Sep 2014	
Liquid Assets	€ 23.81m
Current Assets	€ 34.49m
Intangible Assets	€ 0.32m
Total Assets	€ 40.76m
Current Liabilities	€ 13.21m
Shareholders' Equity	€ 15.88m

SHAREHOLDERS

Kingdon Capital Management LLC	2.6%
Deerfield Management Company L.P.	2.5%
Broadfin Healthcare Master Fund	2.2%
Free Float	92.7%

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… (EUR2.4m related to a correction in the fair value of warrants at the end June 2014 and EUR2.8m related to the decrease in the fair value of the warrants in Q3 2014), Pharming's 9M net financial result amounted to EUR-9.21m (FBe: EUR-12.71; 9M/13: EUR-7.41m). Net income for the period was EUR-18.87m (FBe: EUR-22.87m; 9M/13: EUR-11.10m) or EUR-0.05 (FBe: EUR-0.06; 9M/13: EUR-0.06) per share.
In Q3 2014, Pharming reported positive net income of EUR1.3m due to the above mentioned gain in financial income and expenses. The company's Q3 EBIT loss was EUR-4.2m.

Further strengthening of the equity position Due mainly to higher payments associated with third party manufacturing (EUR7.68m vs. EUR0.35m in 9M/13) ahead of the recently announced Ruconest launch in the US, Pharming's 9M operating cash outflow increased to EUR-13.68m (9M/13: EUR-7.12m). Proceeds from the capital increase earlier this year (see our comment of 20 May) and the issue of warrants meant that net cash flow was positive at EUR4.36m (9M/13: EUR7.30m). Cash (including restricted cash) by the end of September was EUR23.81m (end FY13: EUR19.15m). Deferred license fee income (current- and non-current) totalled EUR12.77m (end FY13: EUR14.42m). Due to Q3 2014's positive net income development, Pharming's equity position improved q/q. Equity at the end of September was EUR15.88m (end FY13: EUR5.01m), corresponding to an equity ratio of 39.0% (end FY13: 16.0%).

Slightly lowered EU product sales guidance, amended distribution agreement
Pharming has slightly lowered its 2014E product sales expectations for Europe and is now forecasting sales of EUR2.8m (previously: EUR3.0m).
The company's slightly lowered guidance is partly attributable to the amended and extended distribution agreement with SOBI. On 13 October, Pharming and SOBI announced that Pharming would focus with immediate effect on direct commercialisation of Ruconest in Austria, Germany and the Netherlands, and SOBI would extend Ruconest sales territory through the addition of Azerbaijan, Belarus, Georgia, Kazakhstan, Russia, Serbia and the Ukraine. Pharming has already begun hiring a small European team of experienced HAE commercialisation and medical affairs specialists to take over direct commercialization activities from SOBI for Ruconest in Austria, Germany and Netherlands. To guarantee a seamless handover of commercialisation activities in these three countries, SOBI will continue to deliver Ruconest (as before) and will also continue drug safety monitoring and reporting during the remainder of 2014.
By creating its own specialist commercial infrastructure, which in future can be leveraged through the marketing of other products, Pharming has the opportunity to increase revenues and margins. Over and above this, the extension of commercialisation territories through the partnership with SOBI creates additional sales potential for Pharming.

Ruconest launch in the US On 3 November Pharming and its US partner Salix Pharmaceuticals announced the launch of Ruconest in the US for the treatment of acute angioedema attacks in adult and adolescent patients with HAE (see our comment of 21 July). Ruconest is available (also for home use) by prescription across the whole country and comes with comprehensive patient support services (RUCONEST SOLUTIONS). Patients joining RUCONEST SOLUTIONS have the opportunity of a free trial of Ruconest. Ruconest's Orphan Drug designation by the FDA for the treatment of acute HAE attacks should provide seven years of marketing exclusivity in the US.

Receipt of USD20m milestone payment On 4 November Pharming announced the receipt of the USD20m (FBe: EUR15.4m) milestone payment from its US partner Salix Pharmaceuticals. The cash inflow further strenghtens Pharming's balance sheet and liquidity position. With a cash position to date of more than EUR38m, the company is sufficiently funded. (p.t.o.)

In our view, the milestone payment marks a turning point in the history of the company. The milestone payment associated with successful US market approval and future payments related to the distribution of Ruconest in the US create a cash cushion that will allow the company to fund its other R&D projects without issuing additional equity or debt financing instruments.

Potential new products added to the pipeline On 19 August, Pharming announced that it had acquired the assets of French company Transgenic Rabbit Models SASU (TRM) for EUR0.5m in cash. By acquiring these assets, Pharming has gained access to five potential new products: recombinant-human (rh)-α-glucosidase for the treatment of Pompe's disease, rh-α-galactosidase for the treatment of Fabry's disease, rh-β-cerebrosidase for the treatment of Gaucher's disease, rh-Factor VIII for the treatment of Haemophilia-A and rh-Factor IX for the treatment of Haemophilia-B. Pharming has also gained access to transgenic rabbit founder technology and know-how developed by TRM.
Pharming will set up a small research group in France to facilitate further optimisation of the product candidates, further enhancement of the rabbit founder technology and know-how as well as generation of additional potential future products.
The acquisition will enable Pharming to extend its EMA and FDA validated technology platform and also adds new products to the pipeline. The acquisition will also strengthen the company's own factor VIII project with SIPI and accelerate development timelines of new products for the treatment of rare genetic and life-threatening diseases.

Adjustments to our forecasts While Pharming's operating development during 9M 2014 was in line with our expectations, we have adjusted our forecasts for the announced acquisition of TRM assets (EUR0.5m), the amended SOBI distribution agreement (increased PACME margin and higher patient population for Ruconest EU projects), and the Ruconest product launch in the US. We have also lowered the discount rates for already approved projects and slightly lowered our time to market assumption for the US prophylaxis project. As mentioned above, the USD20m milestone payment marks a turning point in Pharming's history in our view. The milestone payment further strengthens the firm's liquidity position and we believe that it will allow the company to fund its other R&D projects without issuing additional equity or debt financing instruments. Changes to our financial forecasts are shown in table 2 below.
Even though Pharming has successfully increased its R&D pipeline by acquiring assets from TRM, we continue to base our valuation on the company's Ruconest projects. Our updated pipeline valuation yields a new price target of EUR1.50 (previously: EUR1.10). We reiterate our Buy recommendation.

Table 1: Estimates vs. reported figures

All figures in €m	9M-14A	9M-14E	Delta	9M-13A	Delta
Sales*	3.84	3.87	-0.6%	5.97	-35.6%
EBIT	-9.66	-10.16	-	-3.68	-
margin	*neg.*	*neg.*	-	*neg.*	-
Net income	-18.87	-22.87	-	-11.10	-
margin	*neg.*	*neg.*	-	*neg.*	-
EPS (in €)	-0.05	-0.06	-	-0.06	-

* Total sales including other operating income like milestone payments

Source: First Berlin Equity Research, Pharming Group NV

Table 2: Changes to forecasts

	2014E			2015E			2016E		
All figures in €m	**Old**	**New**	**Delta**	**Old**	**New**	**Delta**	**Old**	**New**	**Delta**
Sales*	25.29	21.37	-15.5%	20.50	15.55	-24.1%	62.18	32.33	-48.0%
EBIT	5.89	1.97	-66.6%	3.12	-2.22	-	43.27	12.97	-70.0%
margin	*23.3%*	*9.2%*	-	*15.2%*	*-14.3%*	-	*69.6%*	*40.1%*	-
Net income	-11.45	-11.78	-	2.76	-1.97	-	37.40	11.21	-70.0%
margin	*-45.3%*	*-55.1%*	-	*13.5%*	*-12.6%*	-	*60.1%*	*34.7%*	-
EPS (in €)	-0.03	-0.03	-	0.01	0.00	-	0.09	0.03	-69.8%

* Total sales including other operating income like milestone payments

Source: First Berlin Equity Research

Table 3: Pipeline valuation model

Compound	Project[1)]	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Sales	PACME Margin[2)]	Discount Factor	Patent Life[3)]	Time to Market
Ruconest (EU)	HAE-AA	€101.2M	22K	€14,400	€318M	35%	€124M	18%	10%	12	-
Ruconest (US)	HAE-AA	€259.4M	10K	€44,308	€443M	35%	€170M	30%	10%	12	-
Ruconest (EU)	HAE-PR	€103.9M	7K	€78,998	€576M	35%	€230M	18%	15%	10	4 Years
Ruconest (US)	HAE-PR	€223.3M	3K	€270,000	€891M	35%	€355M	30%	15%	10	3 Years
rhC1INH	IRI*	€51.8M	-	-	-	-	-	-	-	-	> 5 Years
PACME PV		€739.7M			€2,228M		€878M				
Costs PV[4)]		€137.1M									
NPV		€602.6M									
Milestones PV		€1.1M									
Net Cash (pro-forma)		€51.6M									
Fair Value		€655.3M									
Share Count (fully diluted)		449,635K									
Price Target		€1.46									

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

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

3) Remaining patent life after the point of approval

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

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

Source: First Berlin Equity Research

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...26	↓	↓	↓	↓
27	20 May 2014	€0.45	Buy	€0.95
28	21 July 2014	€0.51	Buy	€1.05
29	4 August 2014	€0.44	Buy	€1.10
30	Today	€0.40	Buy	€1.50

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SELL: Expected negative return greater than -15%

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