

Healthcare: Biotechnology

Pharming Group NV (OTC: PHGUF) | PHARM.AS - €0.24 - AEX |

Buy

Analysis of Sales/Earnings

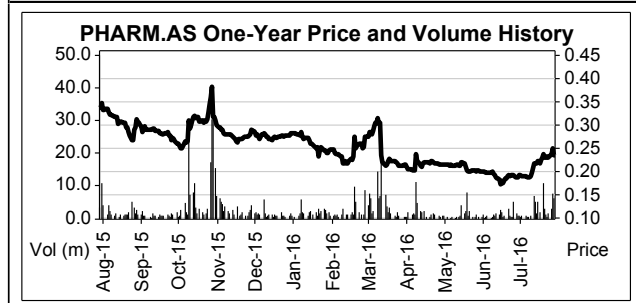
Stock Data	
52-Week Low - High	€0.15 - €0.40
Shares Out. (mil)	412.56
Mkt. Cap.(mil)	€97.4
3-Mo. Avg. Vol.	1,698,328
12-Mo.Price Target	\$1.84
Cash (mil)	€21.7
Tot. Debt (mil)	€14.9
Current Yield	NA

Pricing information reflects data from the securities primary listing, in this case the Amsterdam Exchange.

EPS €			
Yr Dec	—2015—	—2016E—	—2017E—
		Curr	Curr
1Q	0.00A	(0.01)A	-
2Q	(0.01)A	(0.01)A	-
3Q	(0.01)A	(0.01)E	-
4Q	(0.01)A	(0.01)E	-
YEAR	(0.02)A	(0.03)E	(0.04)E
P/E	NM	NM	NM

EPS may not add to full year due to rounding and increases in share count. EPS calculations based on fully diluted shares if profitable
 EPS reflects February 2013 1 for 10 reverse stock split

Revenue (€ millions)					
Yr Dec	—2015—	—2016E—		—2017E—	
		Curr	Prev	Curr	Prev
1Q	1.8A	2.2A	2.2A	-	-
2Q	3.5A	3.1E	2.5E	-	-
3Q	3.3A	3.1E	2.7E	-	-
4Q	2.3A	3.3E	3.9E	-	-
YEAR	10.8A	11.6E	11.3E	13.0E	12.9E



PHGUF: 2Q16 Results; Building Revenue and Thesis

Important positioning continues for Pharming, in our belief, with increasing Ruconest sales (beating our 2Q16 estimate), major Phase II prophylaxis data in hand, and pipeline visibility expected later this year. We maintain our Buy rating and \$1.84 target.

Event

Pharming announced 2Q16 results, posting EPS of (€0.01), in line with our estimate. Ruconest product revenue came in at €2.51 million, beating our estimate of €1.98 million. U.S Ruconest revenue under partner Valeant (VRX-NC) was up ~33% QoQ. Quarter end cash was €21.7 million with burn primarily associated with inventory costs for most recent batches of Ruconest.

Impact

We continue to have a positive view on Pharming and the Ruconest thesis. The company continues to take initiative to improve ex-U.S. sales and to also assist as much as the company can in driving revenue in the U.S. In the U.S., partner Valeant is driving marketing and this has led to a general negative perception based on the trials and tribulations at Valeant. To this end, the sales effort has been reorganized a couple of times (latest in 4Q15) and things appear to be moving in the right direction. What should represent a major driver, in our belief, in boosting future sales are the recent Phase II prophylaxis data for HAE, which was a major win for the company and differentiated from the competition (detailed below). A key differentiator continues to be the fact that Ruconest is recombinant vs. blood borne agents like Cinryze (thromboembolic and infectious risks). Later this year, we also expect to receive visibility on internal pipeline initiatives for Pompe and Fabry diseases.

Action

We maintain our Buy rating and \$1.84 price target. The company's strategy to expand geographies through collaborations and to develop therapies for rare diseases should bear fruit over the long term, in our opinion. Given the pricing power of orphan drugs and the expanding markets in these indications due to better diagnoses, we believe that Pharming is well-positioned for commercial success.

Intraday price \$0.28 as of 9:40am ET.

SUMMARY

Phase II HAE Prophylaxis Data

The Ruconest Phase II prophylaxis study met its primary endpoint in significantly reducing HAE attacks. This study was a randomized, double-blind, placebo-controlled study, which enrolled 32 patients with HAE with at least four attacks per month. The primary endpoint was met in statistically significant fashion ($p < 0.0001$) and was a $>50\%$ reduction in the number of attacks compared to placebo over 28 days (details below). Twice weekly and once weekly dosing were compared to placebo. Recall that Ruconest is partnered 50/50 with U.S. partner Valeant (VRX-NC).

Intent-to-treat analysis - Number of attacks over 28-day treatment period

- Placebo - 7.2 attacks
- Twice-weekly Ruconest - 2.7 attacks ($p < 0.0001$)
- Once-weekly Ruconest - 4.4 attacks ($p = 0.0004$)
- 74% of patients on twice-weekly regimen had at least a 50% reduction in attack frequency

Per protocol reductions in attack frequency (n=23) of at least 50%

- Twice-weekly - 96%
- Once-weekly - 57%

Safety, Safety, Safety

- Generally safe and well tolerated
- No patients withdrew from study due to adverse events
- No related serious adverse events
- No thrombotic or thromboembolic events
- No hypersensitivity or anaphylactic reactions
- No neutralizing antibodies detected

The clinical data are strong and we believe that the data point to potential superiority over Shire's (SHPG-NC) Cinryze on two fronts: 1) the patient population in the Ruconest study appeared more severe with at least four attacks per month at baseline compared with Cinryze's two (we note though that the Cinryze study was a 12-week study) and 2) safety should represent the key differentiator as a recombinant protein compared to plasma based Cinryze. The risks around plasma based products continue, including thromboembolic events and bloodborne infections. Pharming and Valeant will now engage the FDA and EMA to discuss the path forward for Ruconest in the prophylaxis setting as the company continues to "block and tackle" in building its revenue and geographies in the acute setting. From a perception standpoint, we believe investors still have some trepidations, not on the strength of the data/product, but rather on the ongoing trials and tribulations at Valeant.

VALUATION

Our valuation of Pharming is based on our probability-weighted clinical net present value (NPV) valuation model. We believe this method is appropriate in capturing the value of the clinical stage pipeline. Factors that could impede the shares of Pharming reaching our price target are negative data readouts from ongoing clinical studies, any perceived or real delays in the commercial uptake of Rhucin/Ruconest as well as Pharming's ability to continue to fund its operations.

RISKS

- **Commercial and Regulatory Risk.** Ruconest was approved in the U.S. in July 2014 and is marketed by U.S. partner Valeant. As with all drug launches and subsequent commercial activities, there is no guarantee that Ruconest may meet revenue and market penetration expectations going forward. Pharming and Valeant also continue to develop Ruconest for additional indications, and such, is faced with continued developmental and regulatory risk as to whether these additional indications will be added to the drug's label.
- **Financial Risk.** Pharming is currently a non-profitable biotechnology company, and funding is continuously necessary to support operations and ongoing clinical studies. Should Pharming encounter problems in raising sufficient funds to continue its operations, the company's valuation may be greatly impacted.
- **Partnering Risk.** Pharming has attracted partnerships from SOBI and Valeant for Ruconest. Should it become unable to meet its agreement obligations or if clinical data fails to show safety and meaningful efficacy, the partnerships could be terminated. The company's progress with the development of its candidate products may be delayed, and future commercial activity negatively impacted.
- **Demand and reimbursement risk.** Ruconest is currently approved in Europe and developed in the U.S. for the treatment of HAE, a rare disease for which prevalence estimates vary greatly due to misdiagnosis and underdiagnosis. Failure to properly estimate market size may negatively impact Pharming's valuation. In addition, Ruconest faces competition from other drugs in the acute HAE setting. Pharming and its collaborators may have to undertake extensive efforts to educate physicians of the advantages of Ruconest over competitor products. Finally, given increased austerity measures imposed in Europe and pressure to reduce medical spending, Ruconest may see reimbursement pushback. However, we believe that Pharming is attempting to mitigate this risk having priced Ruconest in Europe at a competitive level, compared to alternative treatments.

COMPANY DESCRIPTION

Pharming focuses on developing pharmaceutical grade recombinant proteins for therapeutic use, based on its transgenic animal platform. The company produces high yield human-like recombinant proteins from the milk of transgenic rabbits, using its scalable platform. Pharming's pipeline is led by Ruconest, recombinant human C1 esterase inhibitor (rhC1INH), which was approved by the EMA in 2010 for the treatment of an orphan disease, hereditary angioedema (HAE). The drug is commercialized in the E.U. under the name Ruconest in collaboration with Swedish Orphan Biovitrum (SOBI). Pharming is also partnered with Valeant for the U.S.

(€ in millions except per share data)	December Fiscal								
Profit & Loss	2012A	2013A	2014A	2015A	2016E	2017E	2018E	2019E	2020E
Grant and licensing	10.1	6.0	18.3	2.2	2.0	2.0	2.0	2.0	2.0
R&D collaborations	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Product and Royalties	0.8	0.9	3.0	8.6	9.6	11.0	14.4	16.0	18.9
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Revenues	10.9	7.0	21.3	10.8	11.6	13.0	16.4	18.0	20.9
CoGS	1.1	0.5	2.9	4.8	5.0	6.0	7.2	7.6	8.6
Gross Profit	9.7	6.4	18.4	6.0	6.6	7.0	9.2	10.4	12.3
<i>Gross margin</i>	90%	92%	87%	56%	57%	54%	56%	58%	59%
G&A	3.1	2.5	3.3	4.8	5.7	6.2	6.7	7.3	8.4
R&D	19.4	10.2	11.7	14.2	14.3	16.5	19.8	22.7	26.1
Other op ex	4.8	0.6	0.6	0.0	0.0	0.0	0.0	0.0	0.0
EBIT	(17.5)	(6.9)	2.9	(13.0)	(13.4)	(15.7)	(17.3)	(19.6)	(22.2)
<i>EBIT margin</i>	<i>nm</i>	<i>nm</i>	14%	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>
Depreciation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Amortisation Intangibles	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA	(17.5)	(6.9)	2.9	(13.0)	(13.4)	(15.7)	(17.3)	(19.6)	(22.2)
<i>EBITDA margin</i>	<i>nm</i>	<i>nm</i>	14%	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>
Non operating expenses	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Interest Income/Other	1.3	(4.9)	(8.6)	3.0	0.3	0.5	0.5	0.5	0.5
Interest expense	7.9	3.3	(0.0)	(0.0)	0.0	1.0	1.0	1.0	0.0
EBT	(24.1)	(15.1)	(5.8)	(10.0)	(13.1)	(16.2)	(17.8)	(20.1)	(21.7)
<i>EBT margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>
Provision for taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income	(24.1)	(15.1)	(5.8)	(10.0)	(13.1)	(16.2)	(17.8)	(20.1)	(21.7)
Participation of preferred stock	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income to common	(24.1)	(15.1)	(5.8)	(10.0)	(13.1)	(16.2)	(17.8)	(20.1)	(21.7)
<i>net margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>
NoSH - basic	73.0	213.0	407.7	407.7	413.0	415.0	417.0	417.5	419.0
NoSH - diluted				475.6	465.5	467.0	469.0	472.0	480.0
EPS - basic	(0.33)	(0.07)	(0.01)	(0.02)	(0.03)	(0.04)	(0.04)	(0.05)	(0.05)
EPS - diluted	(0.33)	(0.07)	(0.01)	(0.02)	(0.03)	(0.03)	(0.04)	(0.04)	(0.05)

Source: SEC filings and ROTH Capital Partners estimates

February 2013 1 for 10 reverse split

Joseph Pantginis, Ph.D. jpantginis@roth.com

Quarterly P&L

December Fiscal (€ millions)	Q1'15A	Q2'15A	H1'15A	Q3'15A	9M'15A	Q4'15A	FY'15A	Q1'16A	Q2'16A	H1'16A	Q3'16E	9M'16E	Q4'16E	FY'16E
Grant and licensing	0.55	0.55	1.10	0.55	1.66	0.55	2.2	0.55	0.55	1.10	0.50	1.60	0.40	2.0
R&D collaborations	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Product and Royalties	1.23	2.90	4.13	2.70	6.83	1.79	8.6	1.66	2.51	4.17	2.58	6.75	2.87	9.6
Other	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Revenues	1.78	3.46	5.24	3.25	8.48	2.34	10.8	2.21	3.06	5.27	3.08	8.35	3.27	11.6
		94%							38%					
CoGS	1.00	1.35	2.35	1.38	3.73	1.07	4.8	0.66	1.35	2.00	0.97	3.73	1.27	5.0
Gross Profit	0.78	2.11	2.88	1.87	4.75	1.28	6.0	1.56	1.71	3.27	2.11	4.62	2.00	6.6
<i>Gross margin</i>	44%	61%	55%	57%	56%	54%	56%	70%	56%	62%	69%	55%	61%	57%
G&A	0.88	0.91	1.79	0.95	2.75	2.08	4.8	1.16	1.49	2.65	1.50	4.15	1.53	5.7
R&D	2.71	3.85	6.57	3.75	10.32	3.87	14.2	3.70	3.33	7.03	3.53	10.56	3.76	14.3
Other op ex	0.23	0.39	0.62	0.14	0.76	-0.76	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
EBITDA	(3.0)	(3.1)	(6.1)	(3.0)	(9.1)	(3.9)	(13.0)	(3.3)	(3.1)	(6.4)	(2.9)	(10.1)	(3.3)	(13.4)
<i>EBITDA margin</i>							<i>nm</i>							<i>nm</i>
Non operating expenses	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Net Interest Income/Other	1.72	0.89	2.61	0.56	3.17	(0.15)	3.0	(0.09)	(0.24)	(0.33)	0.38	0.05	0.25	0.3
Interest expense	0.00	0.00	0.00	0.00	0.00	(0.01)	(0.0)	0.00	0.00	0.00	0.00	0.00	0.00	0.0
EBT	(1.3)	(2.2)	(3.5)	(2.4)	(5.9)	(4.1)	(10.0)	(3.4)	(3.3)	(6.7)	(2.5)	(10.0)	(3.0)	(13.1)
<i>EBT margin</i>							<i>nm</i>							<i>nm</i>
Provision for taxes	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Participation o fpreferred stock														
Net income to common	(1.3)	(2.2)	(3.5)	(2.4)	(5.9)	(4.1)	0.0	(3.4)	(3.3)	(6.7)	(2.5)	(10.0)	(3.0)	(13.1)
<i>net margin</i>							0%							0%
NoSH - basic	408.1	408.2	408.16	410.0	408.77	410.00	407.70	412.5	412.6	412.56	413.0	412.69	413.00	413.00
NoSH - diluted	477.2	477.8	477.50	481.9	478.97	481.90	475.60	465.0	465.0	465.20	485.0	471.67	485.00	465.50
EPS - basic	(0.003)	(0.005)	(0.009)	(0.006)	(0.014)	(0.010)	(0.024)	(0.008)	(0.008)	(0.016)	(0.006)	(0.024)	(0.007)	(0.032)
EPS - diluted	(0.003)	(0.005)	(0.007)	(0.005)	(0.012)	(0.008)	(0.024)	(0.007)	(0.007)	(0.014)	(0.005)	(0.021)	(0.006)	(0.028)

Source: SEC filings and ROTH Capital Partners estimates

February 2013 1 for 10 reverse split

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Shares of Pharming Group NV (OTC: PHGUF) may be subject to the Securities and Exchange Commission's Penny Stock Rules, which may set forth sales practice requirements for certain low-priced securities.

On September 28, 2010, ROTH changed its rating system in order to replace the Hold rating with Neutral.

On May 26, 2011, ROTH changed its rating system in order to incorporate coverage that is Under Review.



Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

Distribution of IB Services Firmwide

Rating	Count	Percent	IB Serv./Past 12 Mos. as of 07/28/16	
			Count	Percent
Buy [B]	231	75.00	130	56.28
Neutral [N]	41	13.31	22	53.66
Sell [S]	5	1.62	1	20.00
Under Review [UR]	30	9.74	19	63.33

Our rating system attempts to incorporate industry, company and/or overall market risk and volatility. Consequently, at any given point in time, our investment rating on a stock and its implied price movement may not correspond to the stated 12-month price target.

Ratings System Definitions - ROTH employs a rating system based on the following:

Buy: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return of at least 10% over the next 12 months.

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Sell: A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

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