

Pharming Group NV (PHARM.AS)
Rating: Buy

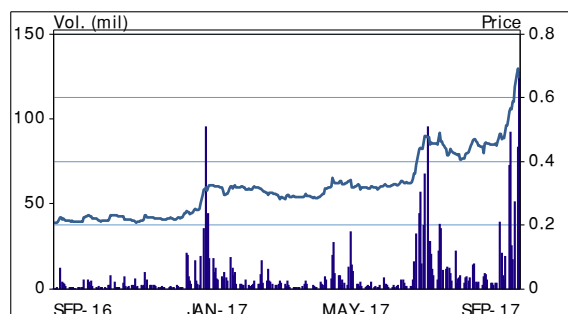
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Expanding Access and FDA Listens to Patients' Needs; We Project Continued Improvement in Positioning for Ruconest

Stock Data		09/25/2017	
Price		€0.69	
Exchange		AEX	
Price Target		€1.50	
52-Week High		€0.72	
52-Week Low		€0.20	
Enterprise Value (M)		€434.3	
Market Cap (M)		€356	
Public Market Float (M)		475.3	
Shares Outstanding (M)		514.4	
3 Month Avg Volume		18,264,800	
Short Interest (M)		NA	
Balance Sheet Metrics			
Cash (M)		€25.20	
Total Debt (M)		€103.50	
Total Cash/Share		€0.05	
EPS (€) Diluted			
Full Year - Dec	2016A	2017E	2018E
1Q	€(0.01)	€(0.01)A	--
2Q	€(0.01)	€(0.05)A	--
3Q	€(0.01)	€(0.02)	--
4Q	€(0.02)	€(0.02)	--
FY	€(0.04)	€(0.09)	€0.02
Revenue (M)			
Full Year - Dec	2016A	2017E	2018E
1Q	€2.2	€15.5A	--
2Q	€3.1	€15.1A	--
3Q	€3.4	€15.7	--
4Q	€7.2	€16.0	--
FY	€15.9	€62.3	€94.4

Negative EPS is calculated off of basic share count, and positive EPS off of diluted share count.
 Quarterly EPS may not add to full year due to increases in share count and rounding.



Pharming's Medicines Access Program links up with HAEi; only known program like this to be initiated through a patient group.

This morning Pharming announced a partnership between the company and the the HAEi International Patient Organization to have Inceptua Medicines Access be the new distribution partner as part of the HAEi Global Access Program (HAEi GAP). The scope of this program is to allow patients in all countries, including where not commercially available, access to Ruconest (under proper ethical and regulatory mechanisms). We believe this is a positive step for the company to make more Ruconest available (zero supply issues, unlike Cinryze) to patients as the clinical database continues to grow in strength. For 3Q17, we project Ruconest revenue of €15.4 million and 2017 revenue of €61.2 million.

FDA meeting points to improving Ruconest positioning. Yesterday, the FDA held a patient-focused public meeting to discuss the challenges faced by HAE patients and caregivers from a historical perspective of currently available drugs (meeting details published earlier today by Andrew Fein). In the U.S. alone, there are approximately 30,000 ER visits per year. While HAE has been a diagnosed disease for quite some time, a key takeaway from the meeting was that a significant increase in physician education is needed (recognizing and treating the disease). Further, the Holy Grail for HAE treatment is making it a chronic predictable condition, and this is lacking right now. With current therapies and looking to the future, we believe that Ruconest could provide an avenue to achieving this (discussed below). Our treatment related takeaways from the event include: 1) patient commentary about the lack of compelling efficacy of Firazyr (and side effect comments like "it burns"); 2) patient feedback of achieving good results on Ruconest after switching from Cinryze; 3) it was mentioned several times that the unavailability of Cinryze (shortage) has had a significant impact on patients' lives (further entry point for Ruconest projected); 4) the patients' stories of rebound and incomplete responses to Firazyr appeared to be the most public, to date; 5) initial commentary on Ruconest appeared to be positive as patient and physician experience grows; and 6) patient and physician feedback was clear; treatment should be initiated quickly at the start of symptoms (before fluid can travel to the tissues).

(continued on next page)



Re-launch is still in early stages, but moons aligned, in our belief. Core to our thesis is the potential for Ruconest to reduce the number of infusions required by patients. This is supported in our belief, by both the approved acute setting data, as well as the recently published prophylaxis data. Further, the company is also working on a subcutaneous formulation of Ruconest, which could address one of the underlying concerns of patients discussed at yesterday's FDA meeting, namely the negative feelings around chronic IV infusions. Recall, that the drug is currently in a proverbial re-launch following Pharming's acquisition of North American rights to Ruconest from former partner Valeant (VRX; Neutral rated; Selvaraju). We believe the U.S. franchise is continuing its positive marketing realignment and now look toward a potentially major tipping for the point for the drug, potential entry into the prophylactic setting (discussed below).

Recent FDA interaction, or lack thereof, presents best scenario possible, in our belief. On September 11, Pharming announced that it would file a supplementary BLA (sBLA) in 4Q17 to potentially expand the Ruconest label into the prophylaxis setting. This was based in large part on feedback from the FDA and the publication of the Phase 2 prophylaxis data. Further, the end-of-Phase 2 meeting, which had been previously scheduled, was cancelled by the FDA and not required. We interpret this as a further positive signal for the path forward in the prophylactic setting. Recall, that we believe moving directly to a sBLA filing was the best possible outcome, as one of the potential options was to conduct an additional randomized Phase 3 study (additional time and expense). We also believe that this outcome continues to highlight the overall quality of both efficacy and safety of the Ruconest franchise. We also believe that Ruconest could be positively positioned further with competitor issues: 1) shortages of Cinryze; and 2) production scale issues of Haegarda continuing. To provide a comparison for the Haegarda scaling problem, approximately 1,500 humans worth of plasma is required to treat one HAE patient prescribed Haegarda. This is in stark contrast to needing only 30-40 rabbits (highly scalable) for Ruconest.

Peer reviewed validation for prophylaxis data. A driver to the positive FDA interactions, in our belief, was the recent announcement that the positive Phase 2 prophylaxis data were published in The Lancet (data originally presented in November 2016). The randomized, placebo-controlled study showed significant reductions in the number of HAE attacks with 22 of 23 patients (95.7%) experiencing >50% reduction with twice weekly Ruconest. Additionally, while Ruconest is currently only approved for the acute HAE setting, we have discussed how treating physicians are increasingly looking to tailor treatment to the individual. To this end, while specifics are not available, when patients are not adequately controlled in the prophylaxis setting such as Cinryze, due to breakthrough attacks, physicians are free to use other options, and we believe Ruconest is one of these options (helping to broaden positive experience with the drug).

Valuation and potential impediments to achieving it. We reiterate our Buy rating and €1.50 price target. Our valuation is based on our clinical net present value (NPV) model, which derives value from the commercial opportunity for Ruconest. This model allows us to flex multiple assumptions affecting a drug's potential commercial profile. Factors which could impede reaching our price target include, lack of meaningful market penetration, failed or inconclusive clinical trials, or inability of the company to secure adequate funding to progress its drugs through the development pathway.

(€ in millions except per share data)	December Fiscal								
Profit & Loss	2012A	2013A	2014A	2015A	2016A	2017E	2018E	2019E	2020E
Grant and licensing	10.1	6.0	18.3	2.2	2.2	1.1	1.1	1.1	1.1
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	13.7	61.2	93.4	143.2	274.0
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	15.9	62.3	94.4	144.3	275.1
CoGS	1.1	0.5	2.9	4.8	4.7	7.0	10.5	16.0	30.7
Gross Profit	9.7	6.4	18.4	6.0	11.2	55.3	84.0	128.3	244.4
<i>Gross margin</i>	90%	92%	87%	56%	70%	89%	89%	89%	89%
G&A	3.1	2.5	3.3	4.8	7.7	25.0	31.3	39.1	46.1
R&D	19.4	10.2	11.7	14.2	15.4	24.6	30.3	36.3	42.9
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)	(11.9)	5.6	22.4	52.8	155.4
<i>EBIT margin</i>	<i>nm</i>	<i>nm</i>	14%	<i>nm</i>	<i>nm</i>	9%	24%	37%	56%
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)	(11.9)	5.6	22.4	52.8	155.4
<i>EBITDA margin</i>	<i>nm</i>	<i>nm</i>	14%	<i>nm</i>	<i>nm</i>	9%	24%	37%	56%
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	(5.7)	(41.0)	0.5	0.5	0.5
Interest expense	7.9	3.3	(0.0)	(0.0)	(0.0)	11.8	11.0	6.4	2.7
EBT	(24.1)	(15.1)	(5.8)	(10.0)	(17.5)	(47.2)	11.9	46.9	153.2
<i>EBT margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	13%	33%	56%
Provision for taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	8.5	42.9
Net Income	(24.1)	(15.1)	(5.8)	(10.0)	(17.5)	(47.2)	11.9	46.9	153.2
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)	(17.5)	(47.2)	11.9	38.5	110.3
<i>net margin</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	<i>nm</i>	13%	27%	40%
NoSH - basic	73.0	213.0	407.7	407.7	415.4	506.0	512.0	515.0	520.0
NoSH - diluted				475.6	603.2	682.1	687.0	691.0	695.0
EPS - basic	(0.33)	(0.07)	(0.01)	(0.02)	(0.04)	(0.09)	0.02	0.07	0.21
EPS - diluted	(0.33)	(0.07)	(0.01)	(0.02)	(0.04)	(0.07)	0.02	0.06	0.16

Source: SEC filings and H.C. Wainwright estimates

February 2013 1 for 10 reverse split

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Quarterly P&L

December Fiscal (€ millions)	Q1'16A	Q2'16A	H1'16A	Q3'16A	9M'16A	Q4'16A	FY'16A	Q1'17A	Q2'17A	H1'17A	Q3'17E	9M'17E	Q4'17E	FY'17E
Grant and licensing	0.55	0.55	1.10	0.55	1.66	0.53	2.2	0.27	0.27	0.54	0.27	0.81	0.27	1.1
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	1.66	2.51	4.17	2.86	7.03	6.66	13.7	15.19	14.92	30.11	15.37	45.48	15.69	61.2
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	2.21	3.06	5.27	3.42	8.69	7.18	15.9	15.46	15.19	30.65	15.65	46.29	15.96	62.3
		38%							-2%					
CoGS	0.66	1.35	2.00	1.23	3.23	1.45	4.7	1.70	1.96	3.66	1.53	5.19	1.81	7.0
Gross Profit	1.56	1.71	3.27	2.19	5.46	5.73	11.2	13.76	13.23	26.99	14.11	41.10	14.15	55.3
Gross margin	70%	56%	62%	64%	63%	80%	70%	89%	87%	88%	90%	89%	89%	89%
G&A	1.16	1.49	2.65	1.38	4.03	3.65	7.7	5.29	6.50	11.78	6.59	18.37	6.66	25.0
R&D	3.70	3.33	7.03	4.05	11.08	4.31	15.4	4.69	6.45	11.14	6.64	17.78	6.84	24.6
Other op ex	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
EBITDA	(3.3)	(3.1)	(6.4)	(3.2)	(9.7)	(2.2)	(11.9)	3.8	0.3	4.1	0.9	5.0	0.7	5.6
EBITDA margin							nm							9%
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	(0.09)	(0.24)	(0.33)	(0.46)	(0.79)	(4.87)	(5.7)	(9.54)	(24.75)	(34.28)	(2.72)	(37.00)	(4.00)	(41.0)
Interest expense	0.00	0.00	0.00	0.00	0.00	(0.01)	(0.0)	0.00	0.00	0.00	6.00	6.00	5.80	11.8
EBT	(3.4)	(3.3)	(6.7)	(3.7)	(10.4)	(7.1)	(17.5)	(5.7)	(24.5)	(30.2)	(7.8)	(38.1)	(9.1)	(47.2)
EBT margin							nm							nm
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 of preferred stock														
Net Income to common	(3.4)	(3.3)	(6.7)	(3.7)	(10.4)	(7.1)	(17.5)	(5.7)	(24.5)	(30.2)	(7.8)	(38.1)	(9.1)	(47.2)
net margin							nm							nm
NoSH - basic	412.5	412.6	412.56	412.6	412.61	413.00	415.38	460.0	483.9	483.00	506.0	483.31	511.00	506.00
NoSH - diluted	465.0	465.0	465.20	485.0	412.61	525.00	603.21	460.0	483.9	483.00	506.0	483.31	511.00	682.10
EPS - basic	(0.008)	(0.008)	(0.016)	(0.009)	(0.025)	(0.017)	(0.042)	(0.012)	(0.051)	(0.063)	(0.015)	(0.079)	(0.018)	(0.093)
EPS - diluted	(0.007)	(0.007)	(0.014)	(0.008)	(0.025)	(0.014)	(0.042)	(0.012)	(0.051)	(0.063)	(0.015)	(0.079)	(0.018)	(0.069)

Source: SEC filings and H.C. Wainwright estimates

February 2013 1 for 10 reverse split

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Important Disclaimers

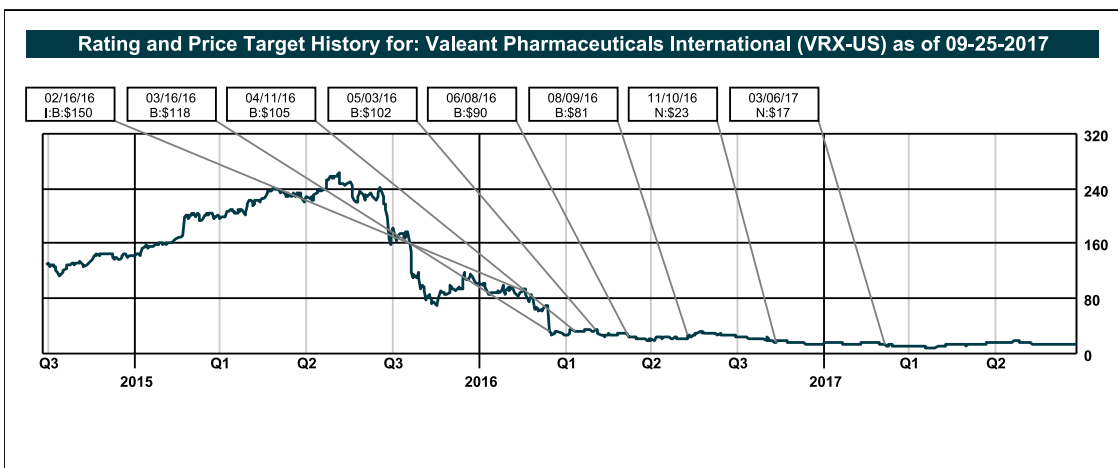
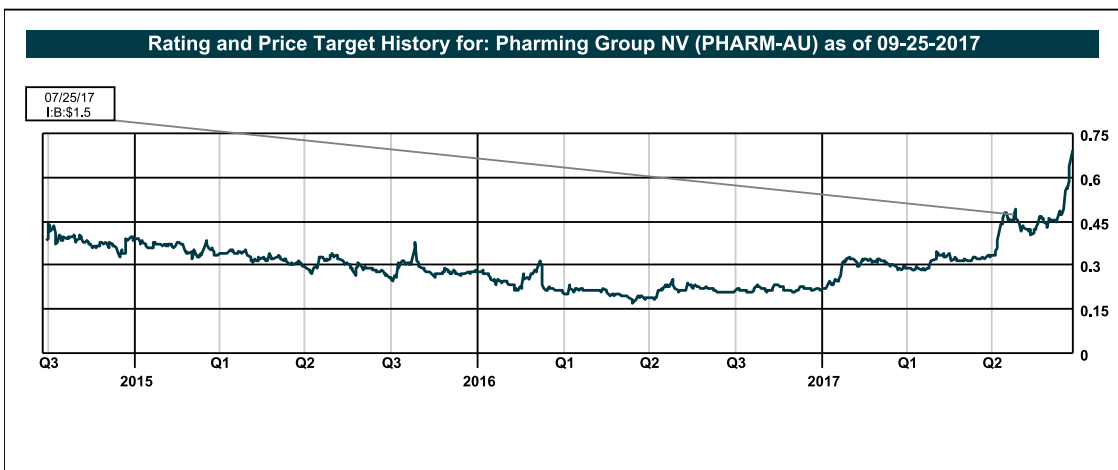
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RETURN ASSESSMENT

Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

Market Perform (Neutral): The common stock of the company is expected to mimic the performance of a passive index comprised of all the common stock of companies within the same sector.

Market Underperform (Sell): The common stock of the company is expected to underperform a passive index comprised of all the common stock of companies within the same sector.



Related Companies Mentioned in this Report as of Sep/25/2017					
Company	Ticker	H.C. Wainwright Rating	12 Month Price Target	Price	Market Cap
Valeant Pharmaceuticals International	VRX	Neutral	\$17.00	\$14.10	\$4905

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Distribution of Ratings Table as of September 25, 2017				
Ratings	Count	Percent	IB Service/Past 12 Months	
			Count	Percent
Buy	222	88.80%	73	32.88%
Neutral	10	4.00%	0	0.00%
Sell	0	0.00%	0	0.00%
Under Review	18	7.20%	3	16.67%
Total	250	100%	76	30.40%

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