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# FLASH NOTE | EQUITY RESEARCH | October 13, 2014

# Healthcare: Biotechnology

# Pharming Group NV (OTC: PHGUF) | PHARM.AS - €0.38 - AEX | Buy

### **Company Update**

Stock Data							
52-Week	Low - High	€0.11 - €0.73					
Shares O	ut. (mil)	407.69					
Mkt. Cap.	· · ·	€156.1					
3-Mo. Avg	g. Vol.	10,580,930					
12-Mo.Price Target		\$3.00					
Cash (mil	)	€26.4					
Tot. Debt	(mil)	€0.0					
	ormation reflects data	from the securities pr	rimary listing, in this				
case the A	case the Amsterdam Exchange.						
EPS€							
Yr Dec	—2013—		—2015E—				
		Curr	Curr				
1Q	(0.05)A	(0.04)A	-				
2Q	(0.01)A	(0.02)A	-				
3Q	(0.02)A	0.04E	-				
4Q	(0.02)A	0.00E	-				
YEAR	(0.07)A	(0.01)E	0.04E				
P/E	NM	NM	0.1x				
EPS may not add to full year due to rounding and increases in share count EPS reflect February 2013 1 for 10 reverse stock split							
Revenue (€ millions)							

Yr Dec	—2013—			
		Curr	Curr	
1Q	0.5A	1.5A	-	
2Q	4.4A	1.2A	-	
3Q	1.1A	21.7E	-	
4Q	0.9A	4.3E	-	
YEAR	7.0A	28.6E	35.8E	
14.				



# PHARM: Optimizing Ruconest Distribution Should Support Growth

Pharming announced that it is amending and extending its distribution agreement with Swedish Orphan Biovitrum AB (SOBI-NC). Pharming will take over direct distribution of Ruconest in Germany, Austria and Netherlands. SOBI will in turn continue distribution in the rest of the E.U. and extend its distribution to new territories. This new agreement should translate to revenue growth due to direct sales and increased Ruconest sales due to added markets. Reiterate Buy.

#### Event

Pharming announced that it is amending and extending its distribution agreement with Swedish Orphan Biovitrum AB (SOBI-NC). Pharming will take over direct distribution of Ruconest in Germany, Austria and Netherlands. SOBI will in turn continue distribution in the rest of the EU and certain countries in the Middle East and North Africa and extend its distribution to Azerbaijan, Belarus, Georgia, Russia, Serbia and Ukraine. There will be a transition period, lasting to the end of 2014 in which SOBI will continue distributing Ruconest in Germany, Austria and Netherlands to ensure continuous supply.

#### Impact

This new agreement should translate to revenue growth due to direct sales and increased Ruconest sales due to the added markets. Pharming is able to take over distribution in these three countries due to its recent efforts in building a HAE commercialization and medical affairs team dedicated to Ruconest sales and distribution. We believe that through taking charge of direct distribution of Ruconest, Pharming will be able to improve its margin as well as establish itself as a distributor for its future pipeline products. Additionally, this agreement could help increase Ruconest overall sales with the addition of new territories by SOBI with its established expertise and presence in these countries. On the U.S. front, recall that Pharming and Salix (SLXP, Buy) recently announced the initiation of a Phase II HAE prophylaxis study with Ruconest. We believe that positive prophylaxis data could spur Salix to consider a PHARM buy-out in order to increase margins in what would be a larger prophylaxis market. Importantly, we now await the first sale in the U.S. for the recently approved acute HAE indication, which will trigger a \$20 million milestone payment to Pharming from Salix.

#### Action

Reiterate Buy rating and target of \$3. PHARM's strategy to expand geographies through collaborations and develop therapies for rare diseases should bear fruit over the long term, in our view. Given the pricing power of orphan drugs and the expanding markets in these indications due to better diagnoses, we believe that PHARM is well-positioned for commercial success.

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# VALUATION

We reiterate our Buy rating and \$3 price target. 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 will be marketed by U.S. partner Salix. 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 Salix 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 Salix 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 Rhucin, 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 collaborating with Santarus for the development and commercialization of Rhucin in the U.S.

Regulation Analyst Certification ("Reg AC"): The research analyst primarily responsible for the content of this report certifies the following under Reg AC: I hereby certify that all views expressed in this report accurately reflect my personal views about the subject company or companies and its or their securities. I also certify that no part of my compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

#### **Disclosures:**

Within the last twelve months, ROTH has received compensation for investment banking services from Pharming Group NV (OTC: PHGUF).

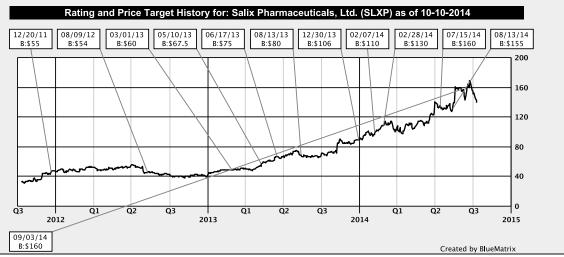
ROTH makes a market in shares of Salix Pharmaceuticals, Ltd. and as such, buys and sells from customers on a principal basis.

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.

Shares of Pharming Group NV (OTC: PHGUF) may not be eligible for sale in one or more states.

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

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		_	IB Serv./Past 12 Mos. as of 10/13/14	
Rating	Count	Percent	Count	Percent
Buy [B]	195	81.25	116	59.49
Neutral [N]	27	11.25	11	40.74
Sell [S]	1	0.42	0	0
Under Review [UR]	16	6.67	8	50.00

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.

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

**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.

**Under Review [UR]:** A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

Not Covered [NC]: ROTH does not publish research or have an opinion about this security.

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