

Healthcare: Biotechnology
Pharming Group NV (OTC: PHGUF) | PHARM.AS - €0.28 - AEX |
Buy
Company Update

Stock Data	
52-Week Low - High	€0.24 - €0.40
Shares Out. (mil)	408.27
Mkt. Cap.(mil)	€113.5
3-Mo. Avg. Vol.	4,173,431
12-Mo.Price Target	\$1.84
Cash (mil)	€34.9
Tot. Debt (mil)	€0.0
Pricing information reflects data from the securities primary listing, in this case the Amsterdam Exchange.	

EPS €			
Yr Dec	—2014—	—2015E—	—2016E—
		Curr	Curr
1Q	(0.04)A	0.00A	-
2Q	(0.02)A	(0.01)A	-
3Q	0.00A	(0.01)A	-
4Q	0.03A	(0.01)E	-
YEAR	(0.01)A	(0.02)E	0.00E
P/E	NM	NM	0.0x

*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	—2014—	—2015E—	—2016E—
		Curr	Curr
1Q	1.5A	1.8A	-
2Q	1.2A	3.5A	-
3Q	1.3A	3.3A	-
4Q	17.4A	3.6E	-
YEAR	21.3A	12.1E	20.6E

PHGUF: Prophylactic Data by End of 2Q16 to Help Drive Differentiation

Pharming and partner Valeant (VRX-NC) announced that the Phase II HAE prophylaxis study has been fully enrolled and data are expected by the end of 2Q16. We believe these data could be instrumental in driving Ruconest's market differentiation as Valeant continues its blocking and tackling in the acute setting, including its pure recombinant properties, and expect the likely initiation of a Phase III.

Event

Pharming announced that enrollment in the multi-national Phase II prophylaxis study with Ruconest is complete. Recall the study is being conducted with partner Valeant. The double-blind, randomized, placebo-controlled study targeted enrollment of 30 patients in three dosing regimens: 1) once weekly, 2) twice weekly and 3) placebo for four weeks each. Importantly, there is also a crossover design in the study where all patients in the study will ultimately receive each dosing regimen. The primary endpoint of the study will be the number of HAE attacks in a prophylactic setting. Data from this study are expected by the end of 2Q16. Following the data release, both companies will engage the FDA regarding next steps in the prophylactic setting where we anticipate a Phase III to support label expansion. With upcoming 4Q15 results, we project total revenue of €3.61 million growing from €3.25 million in 3Q15.

Impact

Looking toward prophylaxis data by the end of 2Q16, we believe it will represent a major step forward in defining Ruconest's potential differentiation. As Valeant continues its blocking and tackling in the U.S. in the acute setting, we believe its restructured marketing efforts will help expand the acute setting as well as significantly define the market for prophylaxis. Further, education and experience continues to grow in the clinical setting regarding the recombinant properties of Ruconest relative the plasma based products (especially Cinryze), which have inherent purity and thromboembolic risks.

Action

We maintain our Buy rating and \$1.84 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.

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 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.

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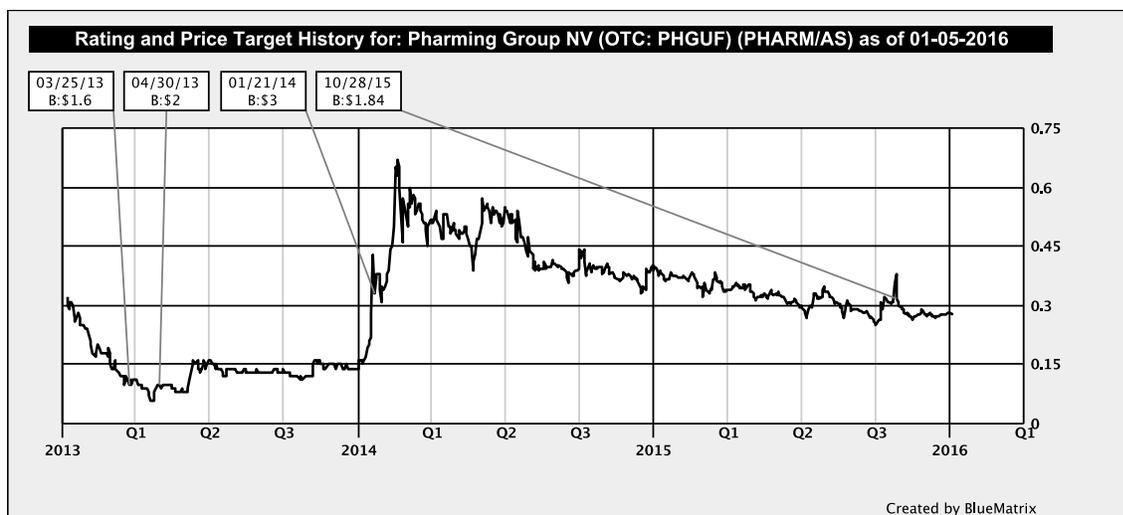
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Shares of Pharming Group NV (OTC: PHGUF) may not be eligible for sale in one or more states.

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 01/06/16	
			Count	Percent
Buy [B]	229	77.63	131	57.21
Neutral [N]	30	10.17	16	53.33
Sell [S]	5	1.69	0	0
Under Review [UR]	26	8.81	16	61.54

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.

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