ROTH Capital Partners

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Healthcare: Biotechnology

Pharming Group NV (OTC: PHGUF) | PHARM.AS - €0.16 - AEX |

Buy

Company Update

Stock Data	
52-Week Low - High	€0.06 - €0.44
Shares Out. (mil)	209.18
Mkt. Cap.(mil)	€33.1
3-Mo. Avg. Vol.	8,824,602
12-Mo.Price Target	$2.00
Cash (mil)	$22.6
Tot. Debt (mil)	$0.0

Cash (mil): Proforma cash based on January 2013, Euro 16.35 million convertible debt financing

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

EPS €

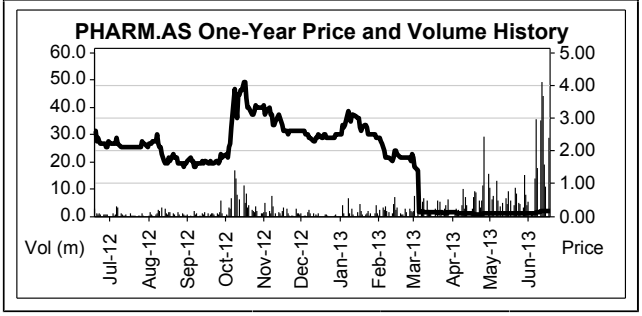
Yr Dec	—2012—	—2013E—	—2014E—
		Curr	Curr
1Q	(0.12)A	(0.04)E	-
2Q	(0.20)A	0.00E	-
3Q	(0.07)A	(0.02)E	-
4Q	0.00A	(0.02)E	-
YEAR	(0.33)A	(0.05)E	0.01E

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	—2012—	—2013E—	—2014E—
		Curr	Curr
1Q	1.0A	0.6E	-
2Q	0.9A	5.8E	-
3Q	0.5A	0.8E	-
4Q	8.5A	1.0E	-
YEAR	10.9A	8.1E	27.2E



PHGUF: BLA? Accepted. $5 Million In? Yup. Approval? We Think So; Reiterate Buy

The BLA filing for Ruconest in acute HEA has been accepted by the FDA triggering a $5 million milestone payment to Pharming. Recall that upon the first commercial sale in the U.S. by Santarus Pharming is also entitled to a $20 million milestone payment. An April 2014 PDUFA date has been set and an Advisory Committee is expected. We reiterate our Buy rating.

Event

The FDA has accepted the BLA filing for Ruconest triggering a $5 million milestone payment to Pharming from Santarus (SNTS-Buy). An April 16, 2014 PDUFA date has been set. The FDA is expected to present the BLA to the Blood Product Advisory Committee. Recall the BLA is based on 1) a positive Phase III study under SPA, and 2) 10 clinical studies encompassing 940 administrations of the drug with a benign safety profile. Pharming is entitled to a $20 million milestone payment for the first U.S. commercial sale of Ruconest.

Impact

We believe that the commercial opportunity for Ruconest is significant in the U.S., with continued strong commitment from Santarus. Recall that Pharming is eligible for sales-based milestones as well as tiered supply pricing, starting at 30% for net sales under $100 million. We believe that the drug is poised to take over a significant share of the HAE market, given its low COGS allowing for competitive pricing, its safety, convenience, and potentially higher efficacy. Based on dose response seen to date with C1INH replacement therapy and absence of relapse or worsening of attacks seen with Ruconest, we believe that the drug's shorter half life compared to Cinryze or Berinert does not impact its clinical profile in acute HAE. Furthermore, Ruconest benefits from a benign safety profile, with no thromboembolic events seen to date (940 administrations), compared to plasma derived Cinryze and Berinert with an incidence of ~3.4% rate of thrombosis events. The differential safety profile may be attributable to the purity of Ruconest versus plasma derived Cinryze and Berinert with ~20-25% impurities in their formulations. Upside for Ruconest may be represented by HAE attack prophylaxis with initial signs of efficacy in an open label study.

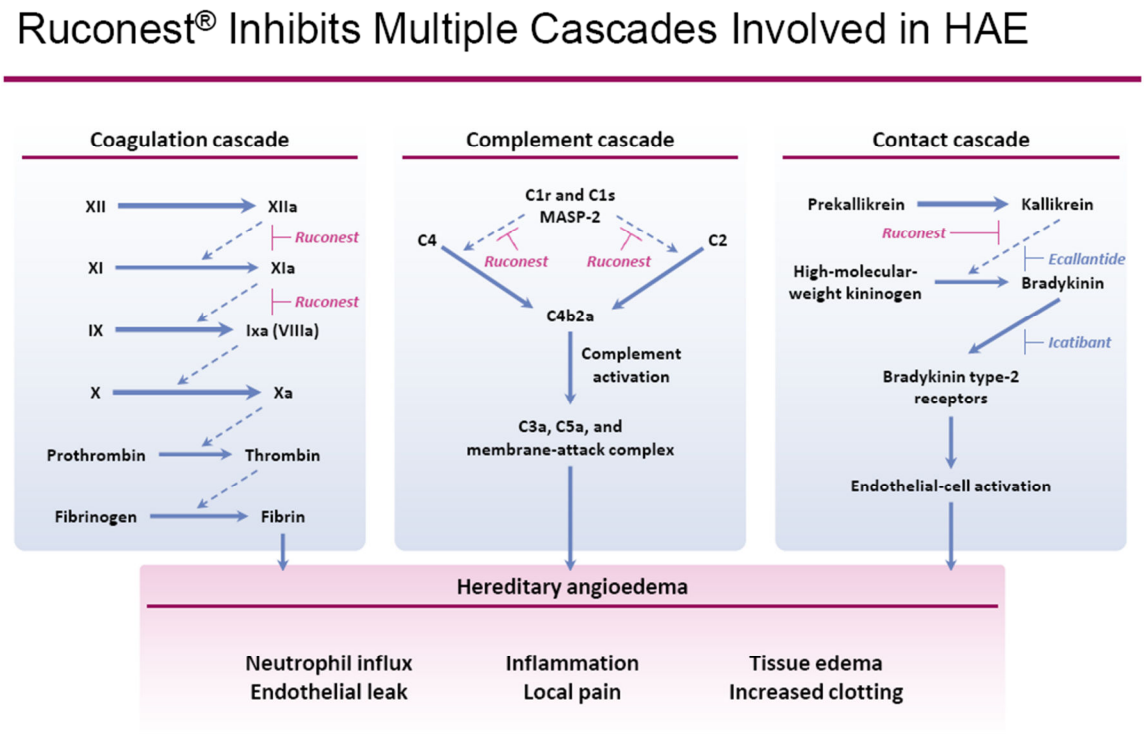
Action

We reiterate our Buy rating and $2.00 price target. The company's strategy to expand geographies through collaborations and to develop therapies for rare diseases will 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: $0.17 at 9:46am ET, 6/18/2013

We believe Ruconest benefits from key differentiating attributes compared to current treatment options

There are currently three approved products in the U.S. for acute HAE (plasma derived C1INH Berinert, the kallikrein inhibitor Kalbitor and the bradykinin B2 receptor inhibitor Firazyr). ViroPharma's Cinryze (plasma derived C1INH) is not approved in the acute setting (where it failed to show statistically significant responses) and is prescribed as a prophylactic. The figure below illustrates the three signaling cascades known to be modulated by C1INH:



Source: SNTS Analyst Day, April 2013

Physicians note that patient preference strongly influences the choice of treatment, as Firazyr is associated with injection site reactions, and Kalbitor has a black box warning for anaphylaxis (3.9% incidence in the registration study). Furthermore relapse or worsening of symptoms have been reported with Firazyr and Kalbitor (source: Cicardi et al, NEJM, 2010, Aberer et al, Ann Allergy Asthma Immunol 2010, Lumry et al, Ann Allergy Asthma Immunol, 2011).

Furthermore, a Citizen Petition (linked here) was filed with the FDA based on third party, peer reviewed evidence of thromboembolic events associated with plasma-derived Berinert and Cinryze. The petition requests addition of a Black Box Warning on the label of these two products and require a REMS program. While the FDA may regard the risk of thombosis as a class effect for C1INH replacement therapy, we note the absence of any thromboembolic events with >1,000 administrations of Ruconest, in contrast to ~3.4% incidence of these events for plasma derived C1INH. We believe that these safety differences may be attributable to the fact that Ruconest is a purified recombinant C1 inhibitor, whereas Cinryze and Berinert are plasma derived proteins whose formulations contain 20-25% "impurities" many of which are unknown (beyond infectious disease testing that is part of purification process).

We believe that Ruconest could position itself as a differentiated product, with a benign safety profile, to provide rapid relief to acute HAE attack symptoms.

The incidence of HAE is estimated to be 1 in 30,000 individuals (1:10,000 – 1:50,000). According to physicians surveyed by Pharming, HAE patients experience an average of approximately eight acute attacks per year. Santarus is anticipating that a salesforce of 25 reps should be sufficient to target the allergy/immunology practices where the estimated ~6,000-8,000 U.S. HAE patients likely seek treatment. Based on market research performed by Santarus, ~60-70% of the HAE patients seeking treatment are taking "as needed" medication for acute attacks, including

Berinert, Kalbitor and Firazyr. With response rates of 80-100% for Ruconest compared to 70%, 58-74, and 73% for Berinert, Firazyr, and Kalbitor respectively, with the ease of use of a ~2 minute i.v. push injection (less painful than SubQ Firazyr) and with durable responses (compared to 11-31% and 21% relapse/worsening rate for Firazyr and Kalbitor, respectively), we believe that Ruconest may represent an attractive option for HAE patients.

Importantly, we note that Ruconest may benefit from significant pricing flexibility, given its low COGS compared to plasma derived compounds.

According to its collaboration with Santarus, Pharming is entitled to the following sales-based milestones:

- a $20 million milestone for calendar net sales >$300 million
- a $25 million milestone for calendar net sales >$500 million

SNTS pays Pharming a tiered supply price, based on % of net sales:

- 30% of net sales <$100 million
- 32% of net sales between $100 million and $250 million
- 34% of net sales between $250 million and $500 million
- 37% of net sales between $500 million and $750 million
- 40% of net sales >$750 million

Under the supply agreement, Pharming manufactures and supplies exclusively Ruconest to Santarus at the above mentioned supply prices.

HAE prophylaxis

An open label Ruconest study was published in the peer reviewed journal *Allergy*. The trial was conducted in 25 patients was suggestive of efficacy for weekly dosing at 50U/kg (source: Reshef et al, Allergy 2013). Participants in the study had a history of mean of 0.9 and median of 0.6 attacks per week. The mean breakthrough attack rate was reduced to 0.4 attacks per week (95% CI, 0.28 to 0.56 attacks per week) and the median to 0.25 attacks per week.

Santarus and Pharming are expected to meet with the FDA in 4Q13, to discuss the design of a proposed pivotal study in the HAE prophylactic setting. The sponsoring companies are likely to seek an SPA. The study design is likely to emulate regulatory requirements for Cinryze:

- Crossover study placebo controlled study (each patient serves as his/her own placebo)
- Endpoints to assess the number of events, such as breakthrough attack rate, over a set period of time (versus event driven Study 1310).

A potential sBLA filing for the prophylactic setting could occur by 2014 year end/early 2015.

VALUATION

We reiterate our Buy rating and $2.00 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 impact 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

· **Regulatory Risk.** FDA had issued a Refuse to File (RTF) letter to Pharming/Santarus' BLA submitted in December 2010, outlining concerns that efficacy data for the proposed Rhucin dose of 50 U/kg relied on a small number of patients, and that the method used to assess the primary endpoint had not been prospectively defined. The companies engaged in discussions with the agency and are sponsoring an additional Phase III trial (conducted under SPA) to address the issues raised by the FDA. In November 2012 this Phase III study met its primary endpoint. While we believe risk was reduced for the program, there is still no guarantee that the FDA will approve the product or issue a Complete Response letter.

· **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 Santarus for Rhucin. 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.** Rhucin 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, Rhucin faces competition from 3 other drugs in the acute HAE setting. Pharming and its collaborators may have to undertake extensive efforts to educate physicians of the advantages of Rhucin over competitor products. Finally, given increased austerity measures imposed in Europe and pressure to reduce medical spending, Rhucin 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.

(€ in millions except per share data) December Fiscal

Profit & Loss	2009A	2010A	2011A	2012A	2013E	2014E	2015E	2016E
Grant and licensing	1.1	1.7	2.1	10.1	1.5	1.0	1.0	1.0
R&D collaborations	0.0	0.0	0.0	0.0	5.0	20.0	10.0	10.0
Product and Royalties	0.0	0.1	1.1	0.8	1.6	6.2	24.8	54.0
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Revenues	**1.1**	**1.8**	**3.2**	**10.9**	**8.1**	**27.2**	**35.8**	**65.0**
CoGS	0.0	0.1	1.8	1.1	0.1	0.6	2.2	4.9
Gross Profit	**1.1**	**1.7**	**1.4**	**9.7**	**8.0**	**26.6**	**33.6**	**60.1**
Gross margin	*100%*	*95%*	*43%*	*90%*	*98%*	*98%*	*94%*	*93%*
G&A	3.6	3.3	3.3	3.1	3.3	3.3	3.4	3.6
R&D	24.6	21.2	13.8	19.4	20.9	21.5	22.0	23.7
Other op ex	0.8	21.3	2.8	4.8	0.3	0.3	0.0	0.0
EBIT	**(27.8)**	**(44.1)**	**(18.5)**	**(17.5)**	**(16.5)**	**1.5**	**8.2**	**32.8**
EBIT margin	*nm*	*nm*	*nm*	*nm*	*nm*	*5%*	*23%*	*51%*
Non operating expenses	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Interest Income/Other	4.4	0.0	1.8	1.3	0.1	0.1	0.2	0.2
Interest expense	8.3	16.5	0.4	7.9	0.1	0.0	0.0	0.0
EBT	**(31.7)**	**(60.6)**	**(17.1)**	**(24.1)**	**(16.5)**	**1.6**	**8.3**	**33.0**
EBT margin	*nm*	*nm*	*nm*	*nm*	*nm*	*6%*	*23%*	*51%*
Provision for taxes	0.3	(4.3)	0.0	0.0	0.0	0.0	0.0	0.0
Net Income	**(31.7)**	**(60.6)**	**(17.1)**	**(24.1)**	**(16.5)**	**1.6**	**8.3**	**33.0**
Participation of preferred stock	(0.0)	6.2	0.0	0.0	0.0	0.0	0.0	0.0
Net Income to common	**(32.1)**	**(50.2)**	**(17.1)**	**(24.1)**	**(16.5)**	**1.6**	**8.3**	**33.0**
net margin	*nm*	*nm*	*nm*	*nm*	*nm*	*6%*	*23%*	*51%*
NoSH	11.6	26.6	47.0	73.0	300.0	301.0	302.5	304.0
EPS - basic	**(2.76)**	**(1.89)**	**(0.36)**	**(0.33)**	**(0.05)**	**0.01**	**0.03**	**0.11**
EPS - diluted			**(0.36)**	**(0.33)**	**(0.05)**	**0.01**	**0.03**	**0.11**

Source: Company documents and ROTH Capital Partners estimates

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February 2013 1 for 10 reverse split

Quarterly P&L

December Fiscal (€ millions)	Q1'12A	Q2'12A	H1'12A	Q3'12A	9M'12A	Q4'12E	FY'12A	Q1'13E	Q2'13E	H1'13E	Q3'13E	9M'13E	Q4'13E	FY'13E
Grant and licensing	0.59	0.51	1.10	0.50	1.60	8.46	10.1	0.38	0.38	0.75	0.38	1.13	0.38	1.5
R&D collaborations	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	5.00	5.00	0.00	5.00	0.00	5.0
Product and Royalties	0.39	0.40	0.79	0.00	0.79	0.00	0.8	0.20	0.38	0.58	0.42	1.00	0.60	1.6
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	**0.99**	**0.91**	**1.90**	**0.50**	**2.40**	**8.47**	**10.9**	**0.58**	**5.76**	**6.33**	**0.80**	**7.13**	**0.98**	**8.1**
CoGS	0.39	0.44	0.84	0.00	0.84	0.29	1.1	0.09	0.17	0.26	0.19	0.45	-0.31	0.1
Gross Profit	**0.59**	**0.47**	**1.06**	**0.50**	**1.56**	**8.18**	**9.7**	**0.49**	**5.58**	**6.07**	**0.61**	**6.68**	**1.28**	**8.0**
Gross margin	*60%*	*51%*	*56%*	*100%*	*65%*	*97%*	*90%*	*84%*	*97%*	*96%*	*76%*	*94%*	*131%*	*98%*
G&A	0.88	0.79	1.67	0.65	2.32	0.76	3.1	0.79	0.81	1.60	0.83	2.43	0.84	3.3
R&D	4.24	5.01	9.25	4.83	14.09	5.26	19.4	5.10	5.20	10.30	5.25	15.55	5.35	20.9
Other op ex	0.07	3.47	3.54	0.32	3.87	0.90	4.8	0.08	0.08	0.15	0.08	0.23	0.08	0.30
EBITDA	**(4.6)**	**(8.8)**	**(13.4)**	**(5.3)**	**(18.7)**	**1.3**	**(17.5)**	**(5.5)**	**(0.5)**	**(6.0)**	**(5.5)**	**(11.5)**	**(5.0)**	**(16.5)**
EBITDA margin							*nm*							*nm*
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	0.30	1.66	1.96	(0.20)	1.76	(0.48)	1.3	0.03	0.03	0.05	0.03	0.08	0.03	0.1
Interest expense	2.18	5.11	7.29	0.00	7.29	0.63	7.9	0.01	0.01	0.03	0.01	0.04	0.01	0.050
EBT	**(6.5)**	**(12.3)**	**(18.7)**	**(5.5)**	**(24.2)**	**0.1**	**(24.1)**	**(5.5)**	**(0.5)**	**(6.0)**	**(5.5)**	**(11.5)**	**(5.0)**	**(16.5)**
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 o fpreferred stock														
Net Income to common	**(6.5)**	**(12.3)**	**(18.7)**	**(5.5)**	**(24.2)**	**0.1**	**(24.1)**	**(5.5)**	**(0.5)**	**(6.0)**	**(5.5)**	**(11.5)**	**(5.0)**	**(16.5)**
net margin							*nm*							*nm*
NoSH	53.8	61.6	57.67	76.0	63.73	72.98	72.98	133.0	245.0	189.00	300.0	226.00	300.00	300.00
EPS - basic	**(0.12)**	**(0.20)**	**(0.32)**	**(0.07)**	**(0.38)**	**0.00**	**(0.33)**	**(0.04)**	**(0.00)**	**(0.03)**	**(0.02)**	**(0.05)**	**(0.02)**	**(0.05)**

Source: Company documents and ROTH Capital Partners estimates

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February 2013 1 for 10 reverse split

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ROTH makes a market in shares of Santarus, Inc. 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

Rating	Count	Percent	IB Serv./Past 12 Mos. as of 06/18/13 Count	Percent
Buy [B]	177	73.75	87	49.15
Neutral [N]	40	16.67	6	15.00
Sell [S]	3	1.25	2	66.67
Under Review [UR]	20	8.33	9	45.00

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.

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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