Pharming Group NV

(NYSE Euronext: PHARM)

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HEALTH ■ SCIENCE ■ PRODUCTS

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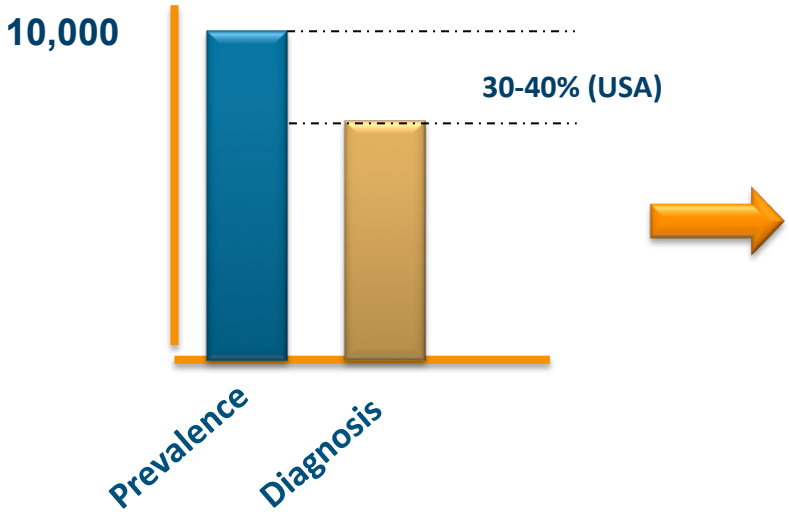
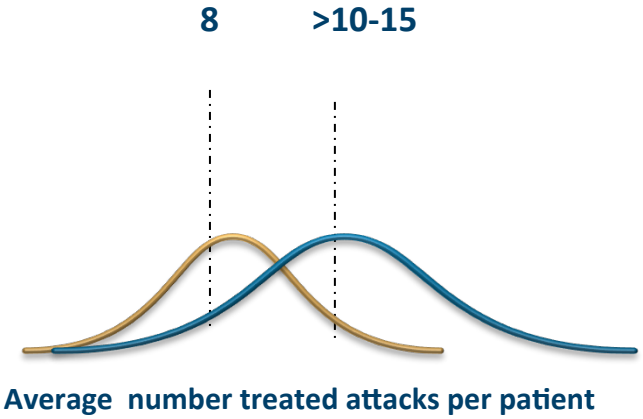
Highlights

- **PDUFA date for lead product Ruconest® (rhC1INH) in acute treatment of attacks of Hereditary Angio- Edema (HAE): 16 July 2014**
- **US partner: Santarus (SNTS)/ Salix Pharmaceuticals (SLXP)**
  - Differentiated competitive profile in US market **– potential to be best-in-class**
  - Preparations for US launch are ongoing (US$20M milestone at first commercial sale)
- **Significant potential from additional indications**
  - Prophylaxis of HAE: RCT to start 2H2014
  - Acute Pancreatitis: Seeking FDA guidance
- **Ruconest® rolling out in Europe for acute HAE (European partner: Sobi)**
  - In market sales increasing; positive feed- back patients and prescribers
- **Pipeline development: Strategic product development collaboration with Shanghai Institute for Pharmaceutical Industry (SIPI) a Sinopharm Company**
  - New product development up to IND and manufacturing at SIPI

Hereditary Angio-Edema (HAE)

- Rare genetic disorder caused by mutations in the gene encoding C1 esterase inhibitor (C1INH)
  - Patients present with swelling, severe abdominal pain, or acute airway obstruction





- Prevalence estimates range from 1 in 10K–50K
- 75% of patients present before age 15
- Misdiagnosis is common; rate of diagnosis varies widely (US is most developed market)

- Increase in attacks treated per patient per year
  - Still significant long term steroid prophylaxis
    - Ineffective and high liver toxicity risk
  - Laryngeal attacks are potentially lethal
  - More aggressive treatment of all type of attacks

Inhibition of C1 esterase is Gold Standard for HAE treatment (protein replacement)

Ruconest commercialisation 2013/2014

- **EU rollout continuing by partner Sobi**
  - Improving in- market sales under challenging EU market access conditions
    - FY2013 sales to Sobi at €0.9M
  - Significant market penetration in several Central/ Eastern European markets
  - Consistent and significant repeat use and high patient and physician satisfaction
- **Approved in Israel/ final stage of regulatory review in Turkey**
  - Partnered with Megapharm (Israel) and Eczasibasi (Turkey)
  - SE- Asian territories partnered with Transmedic Pte. and Hyupjin Corp.
  - China, Taiwan, Hong Kong and Macau partnered with SIPI
- **During 2014; (ex- US) sales to partners to increase by >€2 M to €3M**
- **Unlimited supply capabilities and significant economies of scale**
  - **Rapidly scale- able supply chain**
  - **Technology transfer to SIPI to set- up future second supply source in Shanghai**

US market: Rapid growth, significant potential

- **HAE disease awareness in the US continues to improve, leading to more patient identification***
- **FY 2013 sales for acute treatment increased to approx. US$ 275M from US$ 156M for FY2012 (50% growth) excluding Berinert® sales (not disclosed***)**
  - US$ 235M Firazyr®of which US$ 81M in Q4 2013 (US$ 116M; 2012)**
  - US$ 40.5M Kalbitor® (US$ 39.8M;2012)**
  - Treatment costs estimated at US$70k/ annum***
- **FY 2013 sales for prophylaxis (Cinryze®) increased to approx. US$395M from US$327M for FY 2012****
- **More patients seeking treatment for moderate symptoms***
  - Guidelines recommend treating all attacks since any one could become severe
  - Many patients use multiple products, patient driven therapies
  - Significant steroid usage remains to date

* Leerink Swann, competitor interviews, 13 Sept13, 2012,

** **Quarterly results 2013** , analyst estimates and FY 2013 results10-Q filings VPHM DYAX, SHPG

*** Seeking alpha an overview of HAE 18 Sep 2012

HAE treatment options (published data)

		recombinant C1 Inhibitor	plasma derived C1 Inhibitor		bradykinin receptor antagonist	kallikrein inhibitor
		Ruconest^	**Cinryze^^**	**Berinert**	**Firazyr****	**Kalbitor^^^**
Efficacy		**Excellent**	**Good**	**Good**	**Good**	**Good**
	Dosing (C1INH)	**50 U/kg***	**~ 12 U/kg**	**20 U/kg**		
	Treatment type	**Any acute**	**Prophylaxis**	**Limited******	**Any acute**	**Any acute**
	Response < 4h	**80-100%**	**~ 60%**	**70%**	**58-74%**	**73%**
Safety concerns		**Very low risk of allergic reaction**	**Warning: Risk of blood clots**	**Warning: Risk of blood clots**	**97% injection site reactions**	**Black box warning 3.9% anaphylaxis**
	Plasma risk	**NO**	**YES**	**YES**	**No**	**No**
Purity (C1INH)		**>99.9%**	**±80%**	**±95%**		
Relapse / worsening		Uncommon	Uncommon	Uncommon	**11-31%*****	**21%**
Administration		IV	IV	IV	SQ	SQ (no self-administration)

***Optimal efficacy of C1INH therapy is achieved at doses ≥50 U/kg (**"Target levels of functional C1-inhibitor in hereditary Angioedema". Allergy, C. E. Hack, A. Relan, E. S. van Amersfoort & M. Cicardi**)**

**Icatibant Clinical Briefing Document, CDER, FDA, 2011./ Aberer, et al. Ann Allergy Asthma Immunol 2010; 105(5):P238

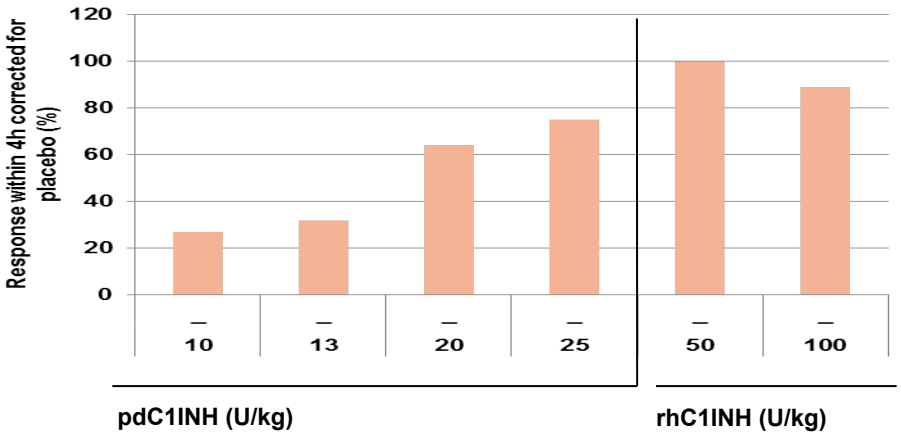
** *Cicardi et al, N Engl J Med 2010;363:532-41.; Aberer, et al. Ann Allergy Asthma Immunol 2010; 105(5):P238; Lumry, et al. Ann Allergy Asthma Immunol. 2011;107:529 –537.

****Berinert not licensed for peripheral attacks in the US,
^Ruconest approved in EU and Israel, ^^Cinryze not licensed for acute therapy in US. ^^^Kalbitor not approved in EU.

Ruconest: potential to be best in class

Ruconest

- Inhibition of C1 esterase is Gold Standard for HAE treatment (protein replacement)
- Ruconest features best-in-class efficacy and cleanest safety profile (confirmed in Study 1310)
  - Absence of thrombo- embolic complications, no anaphylactic reactions
- Ability to administer higher dosing and clean safety profile provides significant efficacy and safety advantages over plasma derived C1 Inhibitor
  - Optimal efficacy of C1INH therapy is achieved at doses ≥50 U/kg*



- Once approved in the US, Ruconest profile could provide some (US) patients with the first dependable option to dose “acutely” for all types of attacks instead of having to rely on (expensive) and only partly efficacious** (plasma derived) prophylactic therapy

*Allergy, 2011 C. E. Hack, A. Relan, E. S. van Amersfoort & M. Cicardi)
** N Engl J Med 2010;363:513-22, Zuraw et al

Technology (protein expression and production) Platform

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Pharming protein expression and production platform (rabbit milk)

- Low set- up costs compared to cell based systems
- No changes in yield/ protein structure from up- scaling
- Capable of yielding high concentrations of complex (highly glycosylated) proteins (expression of rhC1INH at ≅12 grams/ liter) in combination with significant volumes (150-200 ml/day)
- Minimal differences with human glycosylation pattern
- Flexible supply chain and reduced financial risk/ exposure: Low cost intermediate holding stage (frozen milk) and rapid scale-ability
- Wide applicability, significant experience
  - Plasma proteins (C1INH/ F VII/ F VIII/ F IX
  - Metabolic enzymes (α- glucosidase)
  - Monoclonal antibodies
  - Hormones

Strategic product development collaboration

SIPI (Shanghai Institute for Pharmaceutical Industry: A Sinopharm company)

- Leveraging of the potential of the Pharming platform by combining SIPI's product development resources and capabilities and SIPI's favourable cost structures for development and manufacturing with the competitive features of the platform

- Technology transfer of Pharming platform to SIPI facilities in Shanghai
  - Initial projects C-1 Inhibitor and Factor VIII
  - Includes manufacturing of (future) finished products

- Product development at SIPI
  - Under Pharming's fully ICH compliant QA systems
  - Compliant with CFDA, FDA and EMA standards
  - Funded by SIPI up to IND
  - Aligned clinical development (SIPI funds China/ Pharming funds ROW)

SIPI collaboration

- **Commercialisation rights: SIPI China/ Pharming ROW**
  - Reciprocal royalties at 4%: SIPI (China)/ Pharming (ROW)
  - SIPI to pay product related milestones for all future products developed
  - SIPI to supply Pharming on “cost plus” basis for ROW

- SIPI pays €1.26 million upfront and € 0.84 million technology transfer fees and all Pharming technology transfer related expenses

- SIPI pays €0.3 million at receipt of Ruconest drug importation license
  - Until completion of technology transfer, Pharming to supply SIPI with Ruconest as imported product (“cost plus” basis and 4% royalties)

Financial and investment highlights

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FY2013 Financials highlights

- **Revenues decreased to €7.0M (2012: €10.9M)**
  - Included US$10M (2012) and US$5M (2013) milestones from SNTS
- **Operating costs decreased to €12.8M (2012: €24.1M)**
  - Decreased R&D costs (2012:Phase III study) and restructuring/ downsizing of organisation and reduction in inventory impairments
- **Cash outflows from operating activities decreased to €8.3M (2012: €10.3M)**
  - Net cash inflows from financing €21.1M
  - Clean balance sheet: Convertible Bond fully redeemed per 01 October 2013
- **YE cash balance €19.2M (2012: €6.3M)**
  - **Pro- forma: €23.4M, following receipt of €4.2M, 2014 YTD as result of exercises of warrants**

Outlook 2014

- **Ruconest PDUFA date 16 July 2014**
  - First US commercial sale triggers US$20M milestone
  - Proceeds from supply of Ruconest to SLXP
    - 30%- 40% of SLXP Ruconest net sales
    - Up to US$45 million in sales related milestones
- **Increasing revenues from sales (ex- US) by >€2M to €3M**
- **Expansion of rhC1INH franchise**
  - Prophylaxis of HAE: RCT to start 2H2014
  - Acute pancreatitis FDA guidance
- **Leverage potential of the platform**
  - C1 inhibitor technology transfer to SIPI
  - Factor VIII development at SIPI

Investment Highlights

- **PDUFA date Ruconest® for acute HAE 16 July 2014.**
  - Differentiated competitive profile/ Rapidly expanding US acute market segment estimated at >US$ 400M + per annum
  - Significant potential near term milestone US$ 20M (first US commercial sale)
  - Revenues from US net sales between 30-40%
- **Significant up- side potential from additional indications**
  - Prophylaxis of HAE and Acute Pancreatitis
- **Ruconest® sales increasing in Europe and ROW**
- **Pipeline development**
  - New product development at SIPI and supply by SIPI
- **Stabilised balance sheet + low operating costs: Basis for future profitability**
  - Increasing ROW sales and US market entry to drive economies of scale/ reduction of COGS
  - Significant value inflexion points ahead

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