Pharming Group NV

Transgenic Platform for Production of Recombinant Proteins

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HEALTH ■ SCIENCE ■ PRODUCTS

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Pharming has successfully industrialised the transgenic animal production platform

Publicly listed biotech company, founded in 1988

- *NYSE Euronext: PHARM*

Headquartered in Leiden, the Netherlands

- R&D and production sites in NL and USA
- No of employees: ~75

Proprietary transgenic technology platform for recombinant protein production

- Significant experience in producing recombinant proteins
- C1 inhibitor, fibrinogen, lactoferrin (collagen and bile salt stimulated lipase)

First product to obtain approval was Ruconest®, a recombinant human C1 inhibitor

- Achieved EMA approval in October 2010
- Marketed as Ruconest® in all countries of the EU for acute attacks of Hereditary Angioedema (HAE)

Applying platform now for new products; recombinant blood clotting factors

- e.g. Factor VIII

Pharming's Pipeline

	Indication	R&D	Pre Clinical	Phase I	Phase II	Phase III	Registration	Market
Ruconest® / Rhucin®								
Ruconest® (rhC1INH) (Europe)	Hereditary Angioedema							
Rhucin® (rhC1INH) (US)	Hereditary Angioedema							
rhC1INH Ischemia Reperfusion Injury (IRI) indications								
rhC1INH	Delayed Graft Function (Kidney)							
rhC1INH	Other IRI indications							
New Projects								
rhFactor VIII	Haemophilia A							
Legacy pipeline								
hLactoferrin	Nutritional applications							

Core focus products/indications

Partnerships + risk sharing models for further development

Pharming has strong partners for Ruconest®/ Rhucin® (rhC1INH)

SANTARUS, INC.

sobi
SWEDISH ORPHAN BIOVITRUM

MegaPharm
We Know The Way

Eczacıbaşı

Transmedic

HYUPJIN
Corporation

Validated transgenic expression platform

Our engine of value creation

Seeking collaborations

Strong IP

- Granting of US patent (2027) further extends protection on core technology platform

Relevant for most therapeutic proteins

Complex proteins of high quality with relatively high yields

Initial focus on blood clotting factors & metabolic enzymes

Expression and high yields

Often achieving significantly higher expression (1-15 g/L) of recombinant human proteins in milk of transgenic animals

Recombinant product has several advantages over plasma derived products

No supply limitations

Safety and purity

- Highly purified protein, clean immunogenicity profile
- No risk of blood/plasma borne disease/ side effects from impurities

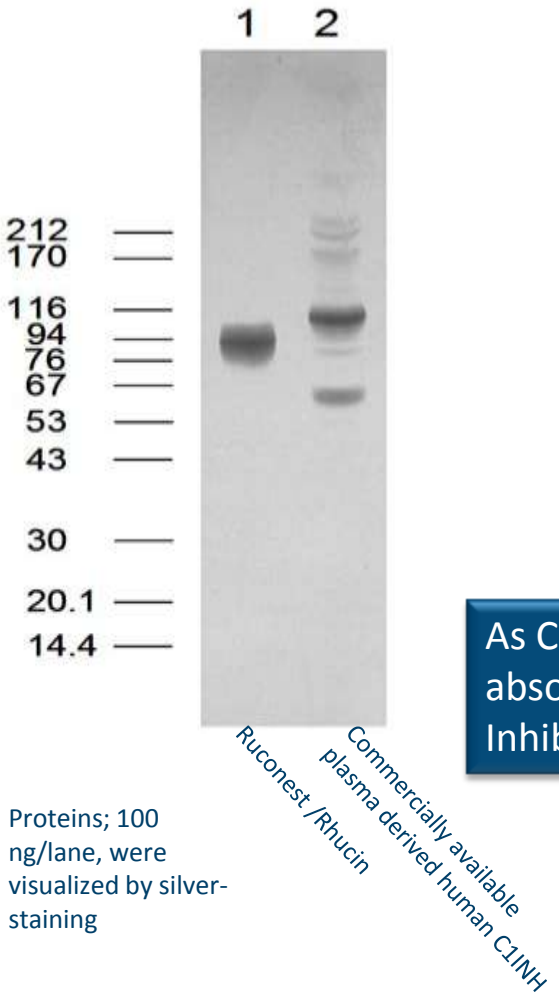
Allows high dose per vial and exploration of different dosing regimens

- Rhucin 2100 units vs Berinert 500 units
- Contributes to improved efficacy

Competitive cost of goods with significant potential for economies of scale

Ruconest®/ Rhucin® is highly purified

Non-reduced SDS-PAGE analysis of rhC1INH and commercially available plasma derived C1INH



Proteins; 100 ng/lane, were visualized by silver-staining

Ruconest®/ Rhucin®	Commercially available plasma derived human C1INH
• < 20 ppm non-product related impurities	• ~ 250,000 ppm non-product related impurities

As C1 Inhibitors may have to be dosed relatively high, (~200mg/ day+) the absolute amounts of impurities dosed/day with plasma derived C1 Inhibitors can become significant

Data on FIle

Technical aspects and advantages compared to cell cultures

GMP conform, validated production process

- Like cell cultures

Stable genetic information

- No risk of losses of expression

No need for sterile (up- stream manufacturing) environment

- ‘Self protecting/ immune competent’ bioreactors

Generally higher yields

- Up to more than 10 g/l

Glycosylation pattern generally more similar to human

- Low immunogenicity potential

Ideally suited for complex and/or highly glycosylated proteins that are poorly expressed in cell cultures

Successful expression of many recombinant human proteins in milk of transgenic animals achieved by Pharming and others

Plasma Proteins	• Serpins: C1 Inhibitor, α1-antitrypsin and Antithrombin-III • Clotting Factors VII, VIII, IX and von Willebrand Factor • Albumin and Fibrinogen
Metabolic enzymes	• α–Glucosidase
Monoclonal antibodies	• High expression levels in various species: up to 30 g/L reported
Hormones	• Human Growth Hormone • Follicle Stimulating Hormone
Structural proteins	• Collagen
Others	• Protein vaccines • Lactoferrin and Lysozyme • Bile-salt stimulated lipase

Producing FVIII in milk of transgenic rabbits will have lower cost of goods

Formulated and put into an injectable dosage form.

Purify FVIII from concentrated milk using lower-cost purification processes

Breed transgenic rabbits that produce FVIII in milk in higher concentrations than cell cultures

Pharming's summary and partnering strategy

- Pharming has proven experience in successfully developing and bringing a therapeutic protein to market using its transgenic technology
- Validated transgenic platform for production of a wide range of recombinant proteins
- Attractive cost of goods compared with mammalian cell culture systems for even the most complex proteins
- Specific interests in "biosimilar" blood clotting factors and metabolic enzymes
- Ongoing programme to produce Recombinant Factor VIII available for partnering
- Pharming wishes to explore co-development relationships with companies operating in the biosimilars and fast- followers area

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