# PHARMING PROVIDES BUSINESS UPDATE

**Leiden, The Netherlands, January 12, 2010.** Biotech company Pharming Group NV ("Pharming" or "the Company") (NYSE Euronext: PHARM) today provided a business update. The Company has made substantial progress on corporate and development targets previously stated in 2009 and is now at a transformational stage with the anticipated approval of its lead product, Rhucin and commercialization partnerships for Rhucin in major territories expected during 2010.

### **Developments in 2009:**

- Submission of Marketing Authorization Application (MAA) for Rhucin with the European Medicines Agency (EMA, formerly EMEA) in September as planned
- Initiation of pre-BLA process (Biologics License Application) for Rhucin with US FDA in December as planned
- Orphan Drug Designation (ODD) and IND (Investigational New Drug) granted for Prodarsan and clinical program for Cockayne Syndrome (CS) indication initiated
- Partnering discussions for Rhucin and Lactoferrin ongoing
- No milestones received to date from lactoferrin collaboration with Aslan Group AS (Aslan)
- Convertible debt reduced from originally €70.0 million to €10.9 million
- Standby Equity Distribution Agreement (SEDA) with YA Global for a total of up to €30.0 million in a three year period.

Dr. Sijmen de Vries, Chief Executive Officer of Pharming, said: "This first full year as CEO of Pharming has been a challenging year, however as result of the hard work during this year, 2010 now has the potential to begin to reveal the true value of Pharming's impressive achievements. We have great confidence on the outcome of our European filing and remain on track for BLA filing. In the meantime, we are in advanced discussions with a number of parties for the marketing and sales of Rhucin in major world markets and we expect to secure commercial partnerships and additional financing in the not too distant future. All together, I am looking forward to 2010 with great confidence."

### Rhucin progression for HAE and other indications

As planned, Pharming submitted the MAA for Rhucin to EMEA early September 2009. The Day 120 List of Questions (LoQ) is expected end of January 2010. Pharming intends to respond within 3 months (as determined by the standard timetable), after which the review procedure will be continued (Day 121). Pharming may expect the adoption of the final opinion 90 days later (on Day 210). The Company also initiated the pre-BLA process with the US FDA with a pre-BLA meeting held early December as planned. Pharming will provide further updates with respect to progress on the US filing and review process for Rhucin during the first half of 2010.

The development and filing of Rhucin for the treatment of acute HAE attacks has continued to be the key focus. Preparations for development of Rhucin in other indications have progressed with limited resources. Pharming expects to initiate the clinical phase of development of its C1 inhibitor product for applications in the field of transplant indications in 2010.

### **Prodarsan and DNage**

In 2009, Pharming's wholly owned subsidiary DNage BV (DNage) made significant progress with its product Prodarsan for Cockayne Syndrome. In 2009, the FDA granted Prodarsan ODD designation and accepted the IND for Prodarsan to allow the initiation of a clinical study in children suffering from Cockayne Syndrome. Under the IND, DNage initiated an observational study in CS patients. Further clinical Phase II/III studies are expected to commence later in 2010.

### **Commercial agreements**

Rhucin

During the second half of 2009, Pharming has progressed discussions with several international pharma companies with a view to engage partners for the commercialization of Rhucin for major markets, such as the European area (excluding those covered by contracts with Esteve and Eczashibashi) and North America. Pharming expects to be able to conclude one or more commercial deals in the first half of 2010.

#### Lactoferrin

Due to various regulatory, logistical and legal issues, Aslan Group has not yet started operations in Turkey. As a result, Pharming has not yet received any of the milestones originally planned for 2009. It therefore has decided to identify other parties interested in setting up lactoferrin operations. Discussions with interested parties in Europe and Asia are currently ongoing and are expected to conclude during the first half of 2010. With respect to the lactoferrin GRAS filing in the USA no progress in reviewing the dossier could be reported in 2009. The Company has requested the authorities to stop the review of the file and may re-submit the file with additional data depending on progress in commercial partnerships.

# **Financial developments**

In 2009, Pharming has made considerable progress in its continuing efforts to strengthen its equity position while at the same time decreasing its liabilities and future interest payments. In December 2008 and during 2009, Pharming entered into various agreements with several holders of bonds to reduce the original convertible debt of €70.0 million to €10.9 million in exchange for €8.6 million in cash and a total of 45.1 million newly issued shares.

In April 2009, Pharming signed a €20.0 million Standby Equity Distribution Agreement with YA Global with an extension of €10.0 million in October 2009. In 2009, the Company started using the SEDA and called a total amount of €6.6 million in cash in exchange for the issuance of approximately 11.9 million Pharming shares. As per today, €23.4 million of the total €30.0 million facility is available. In addition, Pharming secured a short-term convertible debt financing of €7.5 million in early January 2010.

The financial results for the full year 2009 will be published on February 18, 2010.

# **About Pharming Group NV**

Pharming Group NV is developing innovative products for the treatment of genetic disorders, ageing diseases, specialty products for surgical indications, and nutritional products. Pharming's lead product Rhucin® for acute attacks of Hereditary Angioedema has passed clinical development stage and the Market Authorization Application is under review with EMEA. Prodarsan® is in early stage clinical development for Cockayne Syndrome and lactoferrin for use in food products The advanced technologies of the Company include innovative platforms for the production of protein therapeutics, technology and processes for the purification and formulation of these products, as well as technology in the field of DNA repair (via DNage). Additional information is available on the Pharming website, http://www.pharming.com.

### List of used abbreviations

Aslan Aslan Group AS from Istanbul, Turkey

BLA Biological License Application

CHMP Committee for Medicinal Products for Human Use

CS Cockayne Syndrome

DNage Pharming's wholly owned subsidiary DNage

EMEA European Medicines Agency
Esteve Laboratorios del Dr. Esteve, SA
FDA US Food and Drug Administration

HAE Hereditary Angioedema
IND Investigational New Drug
GRAS Generally Recognized As Safe

LoQ List of Questions as part of the European evaluation procedure

MAA Market Authorization Application
SEDA Standby Equity Distribution Agreement
YA Global Yorkville Advisors Global Master SPV LTD

This press release contains forward looking statements that involve known and unknown risks, uncertainties and other factors, which may cause the actual results, performance or achievements of the Company to be materially different from the results, performance or achievements expressed or implied by these forward looking statements.

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