

# Press Release

**ProStrakan Group plc**

**ProStrakan announces positive results from pivotal US “Fortify” study on Fortigel™ (testosterone 2% gel)**

***NDA filing expected in Q3 2008***

**Galashiels, Scotland - 8 May 2008** – ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company, today announces positive results from the pivotal US clinical program on Fortigel™ for testosterone replacement therapy in hypogonadal men. Based on these results, ProStrakan expects to re-file Fortigel with the FDA in Q3 2008.

Fortigel is a patented 2% testosterone transdermal gel, which utilises a proprietary metered dose delivery system that permits dose adjustment to individual patient requirements. Male hypogonadism is frequently characterised by reduced libido, loss of muscle mass, bone density and diminished energy levels. Estimates show that around 6%-12% of men over the age of 40 have clinically low testosterone (source: Araujo). These symptoms can be alleviated through testosterone replacement therapy. Fortigel is branded as Tostran, Itnogen or Tostrex in the EU.

The “Fortify” study met all primary and secondary endpoints, demonstrating that the product was able to maintain adequate testosterone levels within all of the pharmacokinetic parameters agreed with the FDA under Special Protocol Assessment (SPA). The study involved 149 men aged 29-77 and was conducted between August 2007 and March 2008.

In 2007 the total US testosterone market was \$660m. This represented an increase of 17% compared to one year earlier (source: IMS Health). US sales of testosterone gels in 2007 were \$545m, an increase of 18% compared to 2006 (source: IMS Health).

ProStrakan owns the global intellectual property rights to Fortigel and the product forms an important part of the Company’s commercial strategy in Europe and the US. It contains a higher concentration of testosterone than other gel formulations, allowing patients to apply a smaller volume. This patient benefit is thought to contribute to the market share levels achieved in some European countries, for example in Sweden where Tostran (Fortigel) has a 37% share of the testosterone gel market.

Commenting on these results Dr Wilson Totten, Chief Executive of ProStrakan, said:

“The US market for testosterone products is the most developed in the world and Fortigel has the potential to become a major product for ProStrakan in the US, with NDA filing later this year and, subject to approval, launch in the US mid 2009.

“Fortigel would be the second US product for ProStrakan, following the planned launch of Sancuso later this year, subject to regulatory approval. We are now well on track with our strategy to grow a significant US specialty pharmaceutical business, in addition to our European infrastructure, through which we can market our range of new medicines designed for easier patient use. ”

Ends

### **Notes to Editors**

#### **About the “Fortify” Study:**

- Following discussion with the FDA, the study was designed as an open label study in hypogonadal males.
- The primary endpoint was set at  $\geq 75\%$  of patients within the time-averaged plasma testosterone reference range of 300 – 1140 ng/dL at Day 90 and with the lower bound of the 95% confidence interval in  $\geq 65\%$  of patients.
- The secondary endpoints included:
  - Day 90 maximum plasma testosterone concentration
    - $\leq 1500$  ng/dL in  $\geq 85\%$  of patients
    - $\geq 1800 - \leq 2500$  ng/dL in  $\leq 5\%$  of patients
    - $> 2500$  ng/dL in 0 patients.
  - Safety of 2% testosterone gel in hypogonadal males

#### **About ProStrakan**

ProStrakan Group plc is a rapidly growing international specialty pharmaceutical company engaged in the development and commercialisation of prescription medicines for the treatment of unmet therapeutic needs in major markets. Headquartered in Scotland, the Company’s development facilities are situated in Galashiels in Scotland and Bedminster, NJ in the US. [www.prostrakan.com](http://www.prostrakan.com)

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