



# Press Release

**ProStrakan Group plc**

## **Interim Management Statement**

**Galashiels, Scotland, 17 November 2008:** ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company, today issues its Interim Management Statement (IMS) for the period 1 July - 17 November 2008.

### **Trading**

Trading in the first 10 months of 2008 (1 January - 31 October) has been strong, and total product revenues increased by 33% over the corresponding period in 2007, with the stronger Euro accounting for 8% of that growth. Sales of the Group's pan-European products: Tostran, Rectogesic and Xomolix, grew by 72%, with the strength of the Euro accounting for 22% of this uplift. Sales of ProStrakan's best-selling product, Adcal-D3, which is marketed only in the UK, increased by 17%. The Board anticipates the Group's results for the year as a whole to be in line with its expectations.

### **Funding**

ProStrakan remains well financed through to breakeven, expected in late 2009, and had £26.1m cash at the bank at 31 October. In early November the Group further strengthened its cash position by making a precautionary drawdown of an additional £5m of its debt facility. As a result, the Company has now drawn down a total of £35m of this £50m facility.

### **US Development**

The period since the half-year has been both significant and eventful as the Company's focus continues to move towards higher value medicines. In addition to recently launched Sancuso, the Company plans to launch a number of additional products into the US over the next two years.

### **Sancuso**

In September the US Food & Drug Administration (FDA) granted approval for Sancuso, ProStrakan's novel, patent protected transdermal patch for the prevention of chemotherapy-induced nausea and vomiting. As ProStrakan's first US product, this was a pivotal event in the development of the Group. Sancuso was launched in the US market earlier this month and ProStrakan has shipped \$1.7m worth of stock into the US distribution network. The Company's dedicated sales force is now actively promoting this product to oncologists and oncology nurses across the US.

### Abstral (Rapinyl)

During the period, the Company announced that it has inlicensed, from Orexo AB, the North American rights to Abstral. This product – for breakthrough cancer pain – is another potentially high value medicine and Phase III US trials have recently completed enrolment. Highly positive results have previously been announced from an interim analysis and the Company expects to file the New Drug Application (NDA) for this product in 2009.

### Fortigel

Fortigel (2% testosterone gel used for testosterone replacement in hypogonadal men) is currently marketed in Europe under a number of brand names including Tostran. Following the successful completion of the FORTIFY clinical programme, which was conducted under Special Protocol Assessment, the Fortigel NDA re-submission remains on track for the year-end.

### Cellegesic

Cellegesic (GTN 0.4% ointment for the relief of pain associated with chronic anal fissure) is currently marketed in Europe under the brand name Rectogesic and has previously received “approvable” status from the FDA in the US. The APT (Anal Pain Trial) was conducted with FDA agreement as a confirmatory study and is the fourth Phase III study with Cellegesic in the US. The study has now completed and key planned sub-analyses of the primary variable showed statistical significance for reduction in the pain associated with chronic anal fissure following use of Cellegesic.

The study also showed that the safety profile of Cellegesic was acceptable and the treatment was well tolerated. As a result, ProStrakan intends to re-file the NDA for Cellegesic with the FDA in H1 2009.

## **EU Development**

### Abstral

Abstral received EU approval in June 2008 and ProStrakan expects to launch this product in the UK and Germany early in 2009 and in France and Spain in H2 2009. It was launched in Sweden in August 2008.

### Sancuso

Sancuso is currently undergoing the EU approval process and further updates will be provided as and when this process reaches a conclusion.

## **Outlicensing**

Earlier this month ProStrakan announced that it has signed an exclusive licence and supply agreement for Sancuso in the Middle East and Africa with UAE-based NewBridge Pharmaceuticals. This is in line with the Company’s strategy of capitalising on the value of its assets in non-core territories.

The company is announcing today an exclusive distribution agreement in the Republic of Ireland for both Abstral and Xomolix with Dublin-based Fannin Limited, a subsidiary of DCC plc.

Commenting on today's IMS, Dr Wilson Totten, ProStrakan's Chief Executive, said:

"This has been a transforming period for ProStrakan as we move to become a fully international specialty pharmaceutical company focused on higher value medicines that will drive us to near term breakeven. With further approvals in the pipeline, we will continue to focus on maintaining this momentum as we implement the Group's growth strategy."

The Company expects to announce its Preliminary Results for the 12 months ending 31 December 2008 on Thursday 19 March 2009.

***There will be a conference call for analysts today (Monday 17 November) at 9.30am. Contact Mo Noonan, Financial Dynamics (+44 (0)20 7269 7116), for details.***

**For more information on this announcement, please contact:**

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**About ProStrakan**

ProStrakan Group plc is a rapidly growing specialty pharmaceutical company engaged in the development and commercialisation of prescription medicines for the treatment of unmet therapeutic needs in major markets.

ProStrakan's head office is situated in Galashiels in Scotland. The company's development capabilities are centred on Galashiels and Bedminster, New Jersey, USA. Sales and marketing of ProStrakan's portfolio of products are handled by commercial subsidiaries in the UK, US, France, Germany, Spain and other EU countries.

**[www.prostrakan.com](http://www.prostrakan.com)**