

# Press Release

## **ProStrakan Group plc**

### **Interim Management Statement**

**Galashiels, UK. 15<sup>th</sup> November 2010:** ProStrakan Group plc (LSE: PSK), the international specialty pharmaceutical company, today issues its Interim Management Statement for the period 1<sup>st</sup> January – 14th November, 2010, including a trading update for the period 1<sup>st</sup> January – 31<sup>st</sup> October, 2010.

#### **Trading**

Total revenues for the first 10 months of 2010 were £76.8m, an increase of 20% (22% at constant currency rates) over the corresponding period in 2009. Total product revenues increased by 24% to £74.1m (26% at constant currency rates) with growth in product sales coming from the EU, US and from our partners. Income from licensing was lower than for the same period in 2009, as 2009 saw certain one-off receipts being recognised, in relation to the out-licensing of Abstral in Central and Eastern Europe, which were not repeated in 2010.

#### **Product Sales**

Sales of the Group's pan-EU products – Rectogesic, Tostran and Xomolix – increased by 12% during the period. Adcal-D3, which is marketed only in the UK, recorded growth of 14%.

Abstral recorded sales of £14.1m in the first 10 months of the year, representing growth of 345% over the corresponding period in 2009. In September 2010, the Group launched Abstral in Italy which completes the roll-out of Abstral across the major European markets.

Sancuso recorded sales of £6.7m over the first 10 months of the year representing 10% growth over the corresponding period in 2009. This growth rate reflects the previously

announced manufacturing issues at Aveva Drug Delivery Systems in Florida. We plan to re-commence distribution of Sancuso early in the first quarter of 2011. As a consequence of this temporary stoppage there are not expected to be any material sales made during the remainder of 2010.

### **Business Development / Partnering**

**Fortesta (Tostran)** – Endo Pharmaceuticals Inc (“Endo”), our US partner for Fortesta (which is branded as Tostran in much of Europe and marketed and distributed there by ProStrakan), has now submitted a complete response to the US Food and Drug Administration (“FDA”) for this product. The FDA has set a PDUFA date of 30<sup>th</sup> December 2010. A further milestone payment will become payable by Endo to ProStrakan upon approval of the Fortesta NDA by the FDA.

### **Product Development**

**Abstral** – this product is completing registration in the US. The FDA has confirmed that the Risk Evaluation and Mitigation Strategy (“REMS”) is close to finalisation - final REMS comments have been provided to the FDA and labelling comments are expected imminently. Consequently, we now anticipate approval of Abstral by the FDA by the end of the year. Preparatory work for the US marketing launch of Abstral, planned for early in the first quarter of 2011, is also at an advanced stage.

### **Corporate**

Repayment instalments for the Group’s debt facility are due to commence in December 2010 at the rate of £1.0m per month with the outstanding balance becoming fully repayable at the end of February 2012. The Group is currently evaluating a range of options for the refinancing of this debt facility.

Peter Allen, Chairman & Acting Chief Executive of ProStrakan, said:

"The last few months have been interesting and challenging. We fully expect that the manufacturing issues with Sancuso and the approval of Abstral in the US will be concluded this year so that revenues from both products will start early in the New Year. Further we believe that Endo is confident of approval of Fortesta in the US for launch in the first quarter 2011. "

**Ends**

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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 located in Galashiels in Scotland. The company's development capabilities are centered in 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, Italy and other EU countries.

You can learn more about the business at: [www.prostrakan.com](http://www.prostrakan.com)